AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 79 Monday,

No. 188 September 29, 2014

Pages 58241–58654

OFFICE OF THE FEDERAL REGISTER

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.ofr.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 at *www.fdsys.gov*, a service of the U.S. Government Printing Office.

The online edition of the **Federal Register** 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 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 59, 1 (January 2, 1994) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Printing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

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: U.S. Government Printing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; 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: 77 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.

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:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

Printed on recycled paper.

Contents

Federal Register

Vol. 79, No. 188

Monday, September 29, 2014

Agency for Healthcare Research and Quality
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58346–58352

Agriculture Department
See Farm Service Agency
See Rural Business-Cooperative Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58313

Antitrust Division
NOTICES
Changes under the National Cooperative Research and Production Act:
The Open Group, LLC, 58383

Antitrust
See Antitrust Division

Army Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58337

Centers for Disease Control and Prevention
NOTICES
Issuance of 10 Final Skin Notation Profile Publications, 58352–58353
Meetings:
Advisory Committee to the Director, 58353
Requests for Nominations:
Board of Scientific Counselors, Office of Infectious Diseases, 58353–58354

Centers for Medicare & Medicaid Services
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58354–58355

Coast Guard
RULES
Shipping and Transportation:
Technical, Organizational, and Conforming Amendments, 58270–58289
PROPOSED RULES
Security Zones:
Dignitary Arrival/Departure and United Nations Meetings, New York, NY, 58298–58301

Commerce Department
See Economic Development Administration
See Foreign-Trade Zones Board
See International Trade Administration
See National Oceanic and Atmospheric Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58316–58317

Corporation for National and Community Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58331

Defense Department
See Army Department
PROPOSED RULES
Limitations on Terms of Consumer Credit Extended to Service Members and Dependents, 58602–58641
NOTICES
Arms Sales, 58331–58337

Economic Development Administration
NOTICES
Trade Adjustment Assistance Eligibility; Petitions, 58317–58318

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Grants Under the Student Support Services Program (1894–0001), 58338

Employment and Training Administration
NOTICES
Worker Adjustment Assistance Eligibility; Investigations; Corrections, 58383–58384

Energy Department
PROPOSED RULES
Energy Efficiency Program for Consumer Products:
Energy Conservation Standards for Ceiling Fans; Meeting and Preliminary Technical Support Document, 58290–58293
NOTICES
Meetings:
Fusion Energy Sciences Advisory Committee; Open Teleconference, 58339
State Energy Advisory Board; Open Teleconference, 58338–58339

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
California; Placer County Air Pollution Control District; Stationary Source Permits, 58263–58266
Manufacturing (Import) Exemptions:
Defense Logistics Agency; Polychlorinated Biphenyls (PCBs), 58266–58270
PROPOSED RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
California; Placer County Air Pollution Control District; Stationary Source Permits, 58301–58302
California; Regional Haze Progress Report, 58302–58309
Montana; Prevention of Significant Deterioration, 58309–58312

NOTICES
Meetings:
Proposed List of Potential Peer Reviewers, Estimating Exposures and Incremental Health Effects in Public and Commercial Buildings, 58339–58341

Executive Office of the President
See Presidential Documents

Export-Import Bank
NOTICES
Applications for Final Commitments for Long-Term Loans or Financial Guarantee in Excess of 100 Million Dollars, 58341

Farm Service Agency
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
United States Warehouse Act, 58313–58314

Federal Aviation Administration
RULES
Special Conditions:
Boeing, Model 767–200/–300 Series Airplane, as Modified by Avionics Support Group; Installed Rechargeable Lithium Batteries and Battery Systems, 58243–58245
PROPOSED RULES
Airworthiness Directives:
The Boeing Company Airplanes, 58294–58298

Federal Communications Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58341–58343
Meetings; Sunshine Act, 58343–58344
Termination of Dormant Proceedings, 58344–58345

Federal Maritime Commission
NOTICES
Ocean Transportation Intermediary License Applicants, 58345–58346

Federal Reserve System
NOTICES
Changes in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 58346

Federal Trade Commission
RULES
Advertising Allowances and Other Merchandising Payments and Services, 58245–58256

Fish and Wildlife Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Coastal Impact Assistance Program, 58374–58375

Food and Drug Administration
PROPOSED RULES
Food for Animals:
Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls, 58476–58521
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 58574–58599
Human Foods:
Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls, 58524–58572
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 58434–58473
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Records and Reports Concerning Experiences with Approved New Animal Drugs: Adverse Event Reports, 58355–58357
Voluntary Cosmetic Registration Program, 58357
Guidance:
Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007; Availability, 58358
Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices, 58357–58358
Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, 58359

Foreign-Trade Zones Board
NOTICES
Reorganizations under Alternative Site Frameworks:
Foreign-Trade Zone 58, Bangor, ME; Application, 58318
Foreign-Trade Zone 93, Raleigh–Durham, NC, 58318

Health and Human Services Department
See Agency for Healthcare Research and Quality
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See Indian Health Service
See National Institutes of Health

Healthcare Research and Quality Agency
See Agency for Healthcare Research and Quality

Homeland Security Department
See Coast Guard
RULES
Commonwealth of the Northern Mariana Islands-Only Transitional Worker Numerical Limitation for Fiscal Year 2015, 58241–58242

Housing and Urban Development Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Closeout Instructions for Community Development Block Grant Programs Grants, 58369–58370
Housing Opportunities for Persons with AIDS Program, Annual Grantee Performance Reporting Requirements, etc., 58370–58371
Planning Phase Evaluation of the LGBTQ Youth Homelessness Prevention Initiative, 58368–58369
Request for Prepayment of Section 202 or 202/8 Direct Loan Project, 58367–58368
Survey Questions for Small Contractor Marketplace, 58371–58372
Privacy Act; Systems of Records, 58372–58374

Indian Health Service
See Indian Health Service

NOTICES
Final Policy on Conferring with Urban Indian Organizations, 58359–58363

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See National Park Service
See Surface Mining Reclamation and Enforcement Office
NOTICES
Charter Renewals:
Exxon Valdez Oil Spill Public Advisory Committee, 58374

Internal Revenue Service
RULES
Employee Retirement Benefit Plan Returns Required on Magnetic Media, 58256–58261
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58430–58431

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
53-Foot Domestic Dry Containers from the People's Republic of China, 58320–58322
Certain Pasta from Italy, 58319–58320
Low-Enriched Uranium from France, 58322–58324
Determinations of Sales at Less Than Fair Value:
Grain-Oriented Electrical Steel from the Czech Republic, 58324–58326
Monosodium Glutamate from the People's Republic of China, 58326–58329
Monosodium Glutamate from the Republic of Indonesia, 58329–58330

International Trade Commission
NOTICES
Investigations; Determinations, Modifications, and Rulings, etc.:
Certain Formatted Magnetic Data Storage Tapes and Cartridges Containing the Same, 58382–58383

Justice Department
See Antitrust Division

Labor Department
See Employment and Training Administration

Land Management Bureau
NOTICES
Plats of Surveys:
Montana, 58376
Public Lands; Temporary Closures:
Dona Ana County, NM, 58376
Realty Actions:
Proposed Non-Competitive Direct Sale of Public Lands, Washington County, UT, 58376–58377

Legal Services Corporation
NOTICES
Meetings; Sunshine Act, 58384

National Highway Traffic Safety Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58402–58403

National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI, 58363–58364
Meetings:
Center for Scientific Review, 58364–58367
National Center for Advancing Translational Sciences, 58366–58367
National Institute of Allergy and Infectious Diseases, 58364
National Institute of Arthritis and Musculoskeletal and Skin Diseases, 58364
National Institute on Aging, 58366

National Oceanic and Atmospheric Administration
NOTICES
Meetings:
Pacific Fishery Management Council, 58330–58331

National Park Service
RULES
Concession Contracts, 58261–58263
NOTICES
Environmental Impact Statements; Availability, etc.:
Big Thicket National Preserve, TX; General Management Plan, 58378
Lake Meredith National Recreation Area, Alibates Flint Quarries National Monument, TX; General Management Plan, 58377–58378
National Register of Historic Places:
Pending Nominations and Related Actions, 58378–58380
Repatriations of Cultural Items:
U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC, 58380–58381

Nuclear Regulatory Commission
NOTICES
Meetings:
Advisory Committee on Reactor Safeguards, 58384–58385
Meetings; Sunshine Act, 58385–58386

Postal Regulatory Commission
NOTICES
New Postal Products, 58386

Postal Service
NOTICES
Product Changes:
Priority Mail Negotiated Service Agreements, 58386–58387

Presidential Documents
PROCLAMATIONS
Pacific Remote Islands Marine National Monument; Expansion (Proc. 9173), 58643–58653

Rural Business-Cooperative Service
NOTICES
Applications:
Advanced Biofuels Payment Program, 58314–58316

Securities and Exchange Commission
NOTICES
Self-Regulatory Organizations; Proposed Rule Changes:
Financial Industry Regulatory Authority, Inc., 58390–58393

ISE Gemini Exchange, LLC, 58387–58388
NASDAQ OMX BX, Inc., 58397–58399
NASDAQ OMX PHLX LLC, 58393–58395
NASDAQ Stock Market LLC, 58388–58390
OneChicago, LLC, 58395–58397
Trading Suspension Orders:
All Grade Mining, Inc., et al., 58399

Small Business Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58399–58400

State Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Training/Internship Placement Plan, 58400–58401
Certifications:
Foreign Military Financing for Colombia, 58401
Culturally Significant Objects Imported for Exhibition:
Madame Cezanne, 58401–58402
Vodou — Sacred Powers of Haiti, 58401

Surface Mining Reclamation and Enforcement Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58381–58382

Transportation Department
See Federal Aviation Administration
See National Highway Traffic Safety Administration

Treasury Department
See Internal Revenue Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 58403–58404
Funding Availability:
Community Development Financial Institutions Fund, 58404–58430

Veterans Affairs Department
NOTICES
Meetings:
Biomedical Laboratory Research and Development Service, Special Emphasis Panel—Gulf War Veterans' Illnesses Biorepository, 58431–58432

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 58434–58473

Part III
Health and Human Services Department, Food and Drug Administration, 58476–58521

Part IV
Health and Human Services Department, Food and Drug Administration, 58524–58572

Part V
Health and Human Services Department, Food and Drug Administration, 58574–58599

Part VI
Defense Department, 58602–58641

Part VII
Presidential Documents, 58643–58653

Reader Aids

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR
Proclamations:
9173 58645

8 CFR
214 58241

10 CFR
Proposed Rules:
430 58290

14 CFR
25 58243
Proposed Rules:
39 58294

16 CFR
240 58245

21 CFR
Proposed Rules:
1 (2 documents) 58524, 58574
16 (2 documents) 58476, 58524
112 58434
117 (2 documents) 58476, 58524
507 58476

26 CFR
301 58256

32 CFR
Proposed Rules:
232 58602

33 CFR
Proposed Rules:
165 58298

36 CFR
51 58261

40 CFR
52 58263
761 58266
Proposed Rules:
52 (3 documents) 58301, 58302, 58309

46 CFR
1 58270
4 58270
6 58270
10 58270
11 58270
12 58270
13 58270
14 58270
15 58270
24 58270
27 58270
28 58270
30 58270
35 58270
38 58270
42 58270
44 58270
45 58270
52 58270
62 58270
67 58270
69 58270
70 58270
71 58270
72 58270
76 58270
77 58270
78 58270
90 58270
92 58270
95 58270
97 58270
105 58270
109 58270
111 58270
114 58270
115 58270
117 58270
119 58270
121 58270
122 58270
131 58270
150 58270
151 58270
153 58270
154 58270
159 58270
160 58270
161 58270
162 58270
163 58270
164 58270
167 58270
169 58270
171 58270
172 58270
174 58270
175 58270
176 58270
180 58270
181 58270
182 58270
185 58270
188 58270
189 58270
190 58270
194 58270
196 58270
197 58270
199 58270

Rules and Regulations

Federal Register
Vol. 79, No. 188
Monday, September 29, 2014

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 214

[CIS No. 2545–14; DHS Docket No. USCIS–2012–0010]

RIN 1615–ZB30

Commonwealth of the Northern Mariana Islands (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2015

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Notification of numerical limitation.

SUMMARY: The Secretary of Homeland Security announces that the annual fiscal year numerical limitation for the Commonwealth of the Northern Mariana Islands (CNMI)-only Transitional Worker (CW–1) nonimmigrant classification for fiscal year (FY) 2015 is set at 13,999. In accordance with Title VII of the Consolidated Natural Resources Act of 2008 (CNRA) (codified, in relevant part, at 48 U.S.C. 1806(d)) and 8 CFR 214.2(w)(1)(viii)(C), this document announces the mandated annual reduction of the CW–1 numerical limit and provides the public with additional information regarding the new CW–1 numerical limit. This document is intended to ensure that CNMI employers and employees have sufficient notice regarding the maximum number of CW–1 transitional workers who may be granted status during FY 2015.

DATES: Effective Date: September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Paola Rodriguez Hale, Adjudications Officer (Policy), Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529–2060. Contact telephone (202) 272–1470.

SUPPLEMENTARY INFORMATION:

I. Background

Title VII of the CNRA extended U.S. immigration law to the CNMI and provides CNMI-specific provisions affecting foreign workers. *See* Public Law 110–229, 122 Stat. 754, 853. The CNRA included provisions for a ''transition period'' to phase-out the CNMI's nonresident contract worker program and phase-in the U.S. federal immigration system in a manner that minimizes the adverse economic and fiscal effects and maximizes the CNMI's potential for future economic and business growth. *See* sec. 701(b) of the CNRA. The CNRA authorized the Department of Homeland Security (DHS) to create a nonimmigrant classification that would ensure adequate employment in the CNMI during the transition period. *See id.;* 48 U.S.C. 1806(d)(2). The CNRA also mandated an annual reduction in the allocation of the number of permits issued per year and the total elimination of the CW nonimmigrant classification by December 31, 2014, or by the end of any extension of the transition period for the CW program. *See* 48 U.S.C. 1806(d)(2).

Consistent with this mandate under the CNRA, DHS published a final rule on September 7, 2011 amending the regulations at 8 CFR 214.2(w) to implement a temporary, CNMI-only transitional worker nonimmigrant classification (CW classification, which includes CW–1 for principal workers and CW–2 for spouses and minor children). *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification, 76 FR 55502 (Sept. 7, 2011). DHS established the CW–1 numerical limitation for FY 2011 at 22,417 and for FY 2012 at 22,416. *See* 8 CFR 214.2(w)(1)(viii)(A) and (B). DHS opted to publish any future annual numerical limitations by **Federal Register** notice. *See* 8 CFR 214.2(w)(1)(viii)(C). Instead of developing a numerical limit reduction plan, DHS determined that it would be best to instead assess the CNMI's workforce needs on a yearly basis. *Id.* This initial approach to the allocation system ensured that employers had an adequate supply of workers to provide a smooth transition into the federal immigration system. It also provided DHS with the flexibility to adjust to the future needs of the CNMI economy and to assess the total foreign workforce needs based on the number of requests for transitional worker nonimmigrant classification received following implementation of the CW–1 program.

DHS followed this same rationale for the FY 2013 and FY 2014 annual fiscal year numerical limitations. After assessing all workforce needs, including the opportunity for economic growth, DHS set the CW–1 numerical limitation at 15,000 and 14,000, respectively. *CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2013,* 77 FR 71287 (Nov. 30, 2012); *CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2014,* 78 FR 58867 (Sept. 25, 2013). The FY 2013 and FY 2014 numerical limitations were based on the actual demonstrated need for foreign workers within the CNMI during FY 2012. *See id.*

The CNRA directed the U.S. Secretary of Labor to determine, not later than 180 days before the end of the transition period, whether an extension of the CW program for an additional period of up to five years is necessary to ensure an adequate number of workers will be available for legitimate businesses in the CNMI, and further provided the Secretary of Labor with the authority to provide for such an extension through notice in the **Federal Register**. *See* 48 U.S.C. 1806(d)(5). On June 3, 2014, the Secretary of Labor exercised this statutory responsibility and authority by extending the CW program for an additional five years, through December 31, 2019. *See Secretary of Labor Extends the Transition Period of the Commonwealth of the Northern Mariana Islands-Only Transitional Worker Program,* 79 FR 31988 (June 3, 2014).

II. Maximum Number of CW–1 Nonimmigrant Workers for Fiscal Year 2015

The CNRA requires an annual reduction in the number of transitional workers but does not mandate a specific reduction. *See* 48 U.S.C. 1806(d)(2). In addition, 8 CFR 214.2(w)(1)(viii)(C) provides that the numerical limitation for any fiscal year will be less than the number established for the previous fiscal year, and it will be reasonably

calculated to reduce the number of CW–1 nonimmigrant workers to zero by the end of the program. DHS may adjust the numerical limitation at any time via notice in the **Federal Register**, but may only reduce the figure, not raise it. *See* 8 CFR 214.2(w)(viii)(D).

To comply with these requirements, meet the CNMI's labor market's needs, provide opportunity for growth, and preserve access to foreign labor, DHS has set the numerical limitation for FY 2015 at 13,999. DHS arrived at this figure by taking the number of CW–1 nonimmigrant workers needed based on the FY 2014 limitation of 14,000, and then nominally reducing it by one.

In setting this new numerical limitation for FY 2015, DHS considered its effect in conjunction with the Secretary of Labor's five-year extension of the transitional worker program. The Department of Labor's (DOL's) **Federal Register** notice indicated that DOL examined a number of factors, including but not limited to, studies on the need for foreign workers, unemployment rates, and prior use of foreign workers in certain industries, in reaching its decision to extend the program.[1] *See* 79 FR at 31989. In reviewing workforce studies that examined the economic impact of alien workers on the CNMI economy and on the labor market, DOL found that the majority of the CNMI's current labor supply is provided by foreign workers. *Id.* DOL indicated that the studies unanimously concluded that restrictions on the foreign labor supply will exacerbate the CNMI's current economic problems and restrain current economic growth. *Id.* In examining the unemployment rate, the labor force, and the number of jobs available in the CNMI, DOL also determined that even if all the U.S. workers in the labor force were employed, a significant number of jobs would still need to be filled by foreign workers. *Id.* On the need for foreign workers to fill specific industry jobs, CNMI government officials reported to DOL that legitimate businesses in the CNMI have difficulty finding qualified applicants for skilled jobs who are U.S. citizens and lawful permanent residents. *Id.* DOL thus concluded that there are an insufficient number of U.S. workers available to meet CNMI's businesses' current needs, and that a five-year extension of the CW–1 program is warranted. *Id.*

For the aforementioned reasons, DHS recognizes that any numerical limitation must account for the fact that the CNMI economy continues to be based on a workforce comprised primarily of foreign workers. Therefore, any new fiscal year numerical limit must allow for economic growth until the end of the transitional worker program, which is now December 31, 2019. DHS must reduce the annual numerical limitation as statutorily mandated, but also must ensure that there are enough CW–1 workers for future fiscal years until the end of the program. DHS believes that a conservative reduction of only one worker is appropriate for FY 2015 because the new baseline must preserve access to foreign labor, as well as accommodate future reductions to the numerical limitation until the end of the transitional worker program. Accordingly, DHS is reducing the number of transitional workers from the current fiscal year numerical limitation of 14,000, and establishing the maximum number of CW–1 nonimmigrant visas available for FY 2015 at 13,999. Given the significantly extended time horizon for the CW program until December 31, 2019, DHS believes that the prudent approach to the numerical limit for the next fiscal year is to essentially preserve the status quo rather than implement a more aggressive reduction of CW–1 numbers at this time.

This number of CW–1 nonimmigrant workers will be available beginning on October 1, 2014. DHS may adjust the numerical limitation for a fiscal year or other period, in its discretion, at any time via notice in the **Federal Register**. *See* 8 CFR 214.2(w)(1)(viii)(D). Consistent with the rules applicable to other nonimmigrant worker visa classifications, if the numerical limitation for the fiscal year is not reached, the unused numbers do not carry over to the next fiscal year. *See* 8 CFR 214.2(w)(1)(viii)(E).

Each CW–1 nonimmigrant worker with an approved employment start date that falls within FY 2015 will be counted against the new numerical limitation of 13,999. Counting each CW–1 nonimmigrant worker in this manner will help ensure that USCIS does not approve requests for more than 13,999 CW–1 nonimmigrant workers. If USCIS determines that sufficient petitions have been filed to reach the 13,999 limit for CW–1 nonimmigrant workers, USCIS will hold any subsequently-received petitions until a final determination is made on the petitions already pending before USCIS. Any approved CW–1 workers from those pending petitions will be counted against the new numerical limitation of 13,999. Subsequently-received petitions on hold will be accepted for processing and forwarded for adjudication in the order in which they were received until USCIS has approved petitions for the maximum number of CW–1 nonimmigrant workers. Any remaining petitions that were held or that are newly received will be rejected once the numerical limitation for CW–1 nonimmigrant workers has been reached.

This document does not affect the immigration status of foreign workers who already have CW–1 nonimmigrant status. Foreign workers currently holding such status, however, will be affected by this document when their CNMI employers file for an extension of their CW–1 nonimmigrant classification, or a change of status from another nonimmigrant status to that of CW–1 nonimmigrant status.

This document does not affect the status of any individual currently holding CW–2 nonimmigrant status as the spouse or minor child of a CW–1 nonimmigrant worker. This document also does not directly affect the ability of any individual to extend or otherwise obtain CW–2 status, as the numerical limitation applies to CW–1 principals only. Individuals seeking CW–2 status may, however, be indirectly affected by the applicability of the cap to the CW–1 principals from whom their status is derived.

Jeh Charles Johnson,

Secretary.

[FR Doc. 2014–23024 Filed 9–26–14; 8:45 am]

BILLING CODE 9110–97–P

[1] The CNRA stipulates that in making the determination of whether foreign workers are necessary to ensure an adequate number of workers in the CNMI, the Secretary of Labor may consider eight factors: (1) Government, industry, or independent workforce studies reporting on the need, or lack thereof, for alien workers in the Commonwealth's businesses; (2) the unemployment rate of U.S. citizen workers residing in the Commonwealth; (3) the unemployment rate of aliens in the Commonwealth who have been lawfully admitted for permanent residence; (4) the number of unemployed alien workers in the Commonwealth; (5) any good faith efforts to locate, educate, train, or otherwise prepare U.S. citizen residents, lawful permanent residents, and unemployed alien workers already within the Commonwealth, to assume those jobs; (6) any available evidence tending to show that U.S. citizen residents, lawful permanent residents, and unemployed alien workers already in the Commonwealth are not willing to accept jobs of the type offered; (7) the extent to which admittance of alien workers will affect the compensation, benefits, and living standards of existing workers within those industries and other industries authorized to employ alien workers; and, (8) the prior use, if any, of alien workers to fill those jobs, and whether the industry requires alien workers to fill those jobs. 48 U.S.C. 1806(d)(5)(C).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2014–0737; Special Conditions No. 25–570–SC]

Special Conditions: Boeing, Model 767–200/–300 Series Airplane, as Modified by Avionics Support Group; Installed Rechargeable Lithium Batteries and Battery Systems

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Boeing, Model 767–200/–300 series airplanes. These airplanes, as modified by Avionics Support Group, will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is an ePhone handset for use with the ICS SATCOM System that will use rechargeable lithium batteries and battery systems. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. 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 29, 2014. We must receive your comments by November 13, 2014.

ADDRESSES: Send comments identified by docket number FAA–2014–0737 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov/.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Nazih Khaouly, FAA, Airplane and Flight Crew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2432; facsimile 425–227–1149.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval 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 publication in the **Federal Register**.

Comments Invited

We invite interested people to take part in this rulemaking by sending 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 will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On March 3, 2014, Avionics Support Group applied for a supplemental type certificate (STC) for the installation of an ePhone handset for use with the ICG ICS–120A/220A SATCOM System that will use rechargeable lithium batteries and battery systems. The Model 767–200/–300 series airplanes are transport category airplanes powered by two turbo-fan engines.

Rechargeable lithium batteries are a novel or unusual design feature in transport category airplanes. This type of battery has certain failure, operational, and maintenance characteristics that differ significantly from those of the nickel-cadmium and lead-acid rechargeable batteries currently approved for installation on transport category airplanes.

Type Certification Basis

Under the provisions of 14 CFR 21.101, Avionics Support Group must show that the Model 767–200/–300, as changed, continues to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A1NM 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.''

In addition, if the regulations incorporated by reference do not provide adequate standards regarding the change, the applicant must comply with certain regulations in effect on the date of application for the change.

If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model 767–200/–300 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of 14 CFR 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for an STC to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model.

In addition to the applicable airworthiness regulations and special conditions, the Model 767–200/–300 series 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.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under 14 CFR 21.101.

Novel or Unusual Design Features

The Model 767–200/–300 series airplanes will incorporate the following novel or unusual design feature: The installation of an ePhone handset for use with the ICG ICS–120A/220A SATCOM System that will use rechargeable lithium batteries and battery system.

Discussion

The current regulations governing installation of batteries in large transport-category airplanes were derived from Civil Air Regulations (CAR) part 4b.625(d) as part of the re-codification of CAR 4b that established 14 CFR part 25 in February 1965. The new battery requirements, § 25.1353(c)(1) through (c)(4), basically reworded the CAR requirements.

Increased use of nickel-cadmium batteries in small airplanes resulted in increased incidents of battery fires and failures that led to additional rulemaking affecting large transport category airplanes as well as small airplanes. On September 1, 1977, and March 1, 1978, the FAA issued § 25.1353(c)(5) and (c)(6), respectively, governing nickel-cadmium battery installations on large transport-category airplanes.

The proposed use of rechargeable lithium batteries for equipment and systems on the Model 767–200/–300 series airplanes prompted the FAA to review the adequacy of these existing regulations. Our review indicates that the existing regulations do not adequately address several failure, operational, and maintenance characteristics of rechargeable lithium batteries that could affect the safety and reliability of the lithium battery installations.

At present, there is limited experience with the use of rechargeable lithium batteries and battery systems in applications involving commercial aviation. However, other users of this technology, ranging from wireless telephone manufacturers to the electric-vehicle industry, have noted safety problems with rechargeable lithium batteries. These problems include overcharging, over-discharging, and flammability of cell components.

1. Overcharging

In general, lithium batteries are significantly more susceptible to internal failures that can result in self-sustaining increases in temperature and pressure (i.e., thermal runaway) than their nickel-cadmium or lead-acid counterparts. This condition is especially true for overcharging, which causes heating and destabilization of the components of the cell, leading to the formation (by plating) of highly unstable metallic lithium. The metallic lithium can ignite, resulting in a self-sustaining fire or explosion. Finally, the severity of thermal runaway, due to overcharging, increases with increasing battery capacity due to the higher amount of electrolyte in large batteries.

2. Over-Discharging

Discharge of some types of lithium battery cells beyond a certain voltage (typically 2.4 volts), can cause corrosion of the electrodes of the cell, resulting in loss of battery capacity that cannot be reversed by recharging. This loss of capacity may not be detected by the simple voltage measurements commonly available to flightcrews as a means of checking battery status—a problem shared with nickel-cadmium batteries.

3. Flammability of Cell Components

Unlike nickel-cadmium and lead-acid batteries, some types of lithium batteries use liquid electrolytes that are flammable. The electrolyte can serve as a source of fuel for an external fire, if there is a breach of the battery container.

These problems experienced by users of lithium batteries raise concern about the use of these batteries in commercial aviation. The intent of the special conditions are to establish appropriate airworthiness standards for lithium battery installations in the Model 767–200/–300 series airplanes and to ensure, as required by §§ 25.1309 and 25.601, that these batteries are not hazardous or unreliable.

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.

Applicability

As discussed above, these special conditions are applicable to Boeing Model 767–200/–300 series airplanes. Should Avionics Support Group apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A1NM to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on two airplane model series. 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. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, 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 publication in the **Federal Register**. 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 recordkeeping 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 type certification basis for Boeing Model 767–200/–300 series airplanes modified by Avionics Support Group.

Installed Rechargeable Lithium Batteries and Battery Systems.

These special conditions require that (1) all characteristics of the rechargeable lithium batteries and battery installation that could affect safe operation of the Model 767–200/–300 series airplanes are addressed; and (2) appropriate instructions for continued airworthiness, which include maintenance requirements, are established to ensure the availability of electrical power, when needed, from the batteries.

In lieu of the requirements of Title 14, Code of Federal Regulations (14 CFR) 25.1353(b)(1) through (b)(4) at Amendment 25–123, all rechargeable lithium batteries and battery systems on Model 767–200/–300 series airplanes, modified by Avionics Support Group, must be designed and installed as follows:

1. Safe cell temperatures and pressures must be maintained during any foreseeable charging or discharging

condition and during any failure of the charging or battery monitoring system not shown to be extremely remote. The rechargeable lithium battery installation must preclude explosion in the event of those failures.

2. Design of the rechargeable lithium batteries must preclude the occurrence of self-sustaining, uncontrolled increases in temperature or pressure.

3. No explosive or toxic gases emitted by any rechargeable lithium battery in normal operation, or as the result of any failure of the battery charging system, monitoring system, or battery installation which is not shown to be extremely remote, may accumulate in hazardous quantities within the airplane.

4. Installations of rechargeable lithium batteries must meet the requirements of § 25.863(a) through (d).

5. No corrosive fluids or gases that may escape from any rechargeable lithium battery may damage surrounding structure or any adjacent systems, equipment, or electrical wiring of the airplane in such a way as to cause a major or more severe failure condition, in accordance with § 25.1309(b) and applicable regulatory guidance.

6. Each rechargeable lithium battery installation must have provisions to prevent any hazardous effect on structure or essential systems caused by the maximum amount of heat the battery can generate during a short circuit of the battery or of its individual cells.

7. Rechargeable lithium battery installations must have a system to control the charging rate of the battery automatically, so as to prevent battery overheating or overcharging, and,

a. A battery temperature sensing and over-temperature warning system with a means for automatically disconnecting the battery from its charging source in the event of an over-temperature condition, or,

b. A battery failure sensing and warning system with a means for automatically disconnecting the battery from its charging source in the event of battery failure.

8. Any rechargeable lithium battery installation, the function of which is required for safe operation of the airplane, must incorporate a monitoring and warning feature that will provide an indication to the appropriate flight crewmembers whenever the state-of-charge of the batteries has fallen below levels considered acceptable for dispatch of the airplane.

9. The instructions for continued airworthiness required by § 25.1529 must contain maintenance requirements to assure that the battery is sufficiently charged at appropriate intervals specified by the battery manufacturer and the equipment manufacturer that contain the rechargeable lithium battery or rechargeable lithium battery system. This is required to ensure that lithium rechargeable batteries and lithium rechargeable battery systems will not degrade below specified ampere-hour levels sufficient to power the airplane systems for intended applications. The instructions for continued airworthiness must also contain procedures for the maintenance of batteries in spares storage to prevent the replacement of batteries with batteries that have experienced degraded charge retention ability or other damage due to prolonged storage at a low state of charge. Replacement batteries must be of the same manufacturer and part number as approved by the FAA. Precautions should be included in the instructions for continued airworthiness maintenance instructions to prevent mishandling of the rechargeable lithium battery and rechargeable lithium battery systems, which could result in short-circuit or other unintentional impact damage caused by dropping or other destructive means that could result in personal injury or property damage.

Note 1: The term ''sufficiently charged'' means that the battery will retain enough of a charge, expressed in ampere-hours, to ensure that the battery cells will not be damaged. A battery cell may be damaged by lowering the charge below a point where the battery experiences a reduction in the ability to charge and retain a full charge. This reduction would be greater than the reduction that may result from normal operational degradation.

Note 2: These special conditions are not intended to replace § 25.1353(b) in the certification basis of airplane Model 767–200/–300 series airplanes. These special conditions apply only to rechargeable lithium batteries and lithium battery systems and their installations. The requirements of § 25.1353(b) remain in effect for batteries and battery installations on Model 767–200/–300 series airplanes that do not use lithium batteries.

Issued in Renton, Washington, on September 19, 2014.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–23042 Filed 9–26–14; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 240

Guides for Advertising Allowances and Other Merchandising Payments and Services

AGENCY: Federal Trade Commission.

ACTION: Final changes to guides.

SUMMARY: The Federal Trade Commission (''the Commission'') previously published in the **Federal Register** a request for public comments on the overall costs and benefits of and the continuing need for its Guides for Advertising Allowances and Other Merchandising Payments and Services (''the Guides''). The Commission issued this request as part of its program for periodic review of its rules and guides to ensure they are up-to-date, effective, and not overly burdensome.

DATES: This action is effective as of November 10, 2014.

FOR FURTHER INFORMATION CONTACT: Michael J. Bloom, 202–326–2475, or Julie A. Goshorn, 202–326–3033, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Background

The Commission originally issued the Guides in 1969 to help businesses comply with sections 2(d) and 2(e) of the Robinson-Patman Act (''R–P Act'' or ''the Act''). The Guides were last revised in 1990, to bring them into conformity with then-current legal developments and to eliminate nonessential requirements. *See* 55 FR 33651 (Aug. 17, 1990). The changes published in this document reflect more recent legal developments as well as changes in technology and methods of marketing that have occurred since the Guides were last reviewed, such as the emergence of the Internet and widespread online marketing.[1]

As the name suggests, the Guides are not binding regulations, but are advisory interpretations providing assistance to businesses seeking to comply with sections 2(d) and 2(e) of the R–P Act.[2]

[1] *See* 77 FR 71741 (Dec. 4, 2012) (request for public comments).

[2] 15 U.S.C. 13(d) (section 2(d) of the R–P Act) reads: ''[I]t shall be unlawful for any person engaged in commerce to pay or contract for the payment of anything of value to or for the benefit of a customer of such person in the course of such commerce as compensation or in consideration for any services or facilities furnished by or through such customer in connection with the processing, handling, sale, or offering for sale of any products or commodities manufactured, sold, or offered for sale by such person, unless such payment or consideration is available on proportionally equal

Continued

These sections generally prohibit a seller from paying allowances or furnishing services to promote the resale of its products unless the allowances or services are offered to all competing customers on proportionally equal terms. Sections 2(d) and 2(e) relate to the resale of a firm's products, as opposed to section 2(a) of the Act, which relates to the original or first sale.

The R–P Act is the principal federal statute directed at price discrimination. The principal provision of the Act is section 2(a), which bans direct or indirect discrimination in price when competitive injury might result. Certain defenses are allowed, notably that the difference in price is justified by cost differences or that the lower price is given to meet an offer of a seller's competitor.

Sections 2(d) and 2(e) are complements to section 2(a). Their purpose is to prohibit disguised price discriminations in the form of promotional payments or services. Sections 2(d) and 2(e) thus attempt to prevent evasions of section 2(a). In contrast to section 2(a), sections 2(d) and 2(e) do not require proof of likely adverse competitive effects, nor do they permit a cost-justification defense. They do, however, permit a meeting-competition defense. The Commission has observed that the *per se* unlawful characteristics of sections 2(d) and 2(e) impose an obligation on the FTC and the courts ''to ensure that the jurisdictional prerequisites of these sections are reasonably, and not expansively, construed.'' *Herbert R. Gibson, Sr.,* 95 F.T.C. 553, 726 (1980), *aff'd sub nom. Gibson* v. *F.T.C.,* 682 F.2d 554 (5th Cir. 1982), *cert. denied,* 460 U.S. 1068 (1983).

The Commission issued the Guides in 1969 at the invitation of the Supreme Court in *F.T.C.* v. *Fred Meyer, Inc.,* 390 U.S. 341 (1968). The Guides address the main issues of sections 2(d) and 2(e)—the measurement of proportionally equal treatment, the concept of availability of offers to competing customers, the notification of offers required to be given to customers, and other issues such as the interstate commerce requirements of section 2(d) and 2(e).

Developments in technology, methods of commerce, and the law since the last revision of the Guides suggest that certain provisions of the Guides might usefully be revised. As identified in the Commission's request for public comments, these developments include the emergence of the Internet as an important retail sales and communications channel. They also include a jurisprudential development: some courts have discussed the possibility that under some circumstances an apparent promotional allowance may constitute an indirect price discrimination, for which an action against the recipient for knowing inducement or receipt of a discrimination in price might lie under § 2(f) of the R–P Act. *See, e.g., American Booksellers Ass'n* v. *Barnes & Noble,* 135 F. Supp. 2d 1031 (N.D. Calif. 2001). These cases signal a heightened risk of liability in connection with promotional allowances and services of which businesses and their counselors may wish to take account. These developments in technology, methods of commerce, and the law have influenced the changes to the Guides set forth here. The legislative history of the Act and the case law pertinent to each issue also have been considered.

In response to the Commission's request for public comments, the Commission received and considered seven submissions. These were submitted by the American Antitrust Institute (''AAI''); the Section of Antitrust Law of the American Bar Association (''the Antitrust Section''); the Food Marketing Institute (''FMI''); the National Automobile Dealers Association (''NADA''); the National Community Pharmacists Association (''NCPA''); Richard Steuer, Esq.[3]; and the National Grocers Association (''NGA''). The Commission has considered each of these comments in its entirety. The following discussion summarizes comments relating to the continuing need for and cost-effectiveness of the Guides. It then addresses certain specific recommendations of commenters, as well as the Commission's actions with respect to those recommendations.

Continuing Need for the Guides

The Guides are intended to assist businesses seeking to comply with sections 2(d) and 2(e) of the R–P Act. To determine whether the Guides continue to do so, the Commission asked about the continuing need for the Guides. In addition, the Commission asked about the benefits and costs of the Guides, and changes, if any, that might increase the Guides' benefits or reduce their costs.

Every comment that addressed the question concluded that there is a continuing need for the Guides. The Antitrust Section noted that ''lawyers, industry, and the courts have generally relied on [the Guides] as accurate statements of the law.'' FMI stated that ''the Guides serve a useful purpose and should be retained.'' NADA concluded that the Guides ''provide a great deal of certainty for manufacturers and dealers alike.'' NGA reported that it ''has strongly supported the Fred Meyer Guides because of the assistance and guidance they provide to buyers, sellers, and their counsel in assuring voluntary compliance with Sections 2(d) and (e) of the Act.''

None of the comments identified a need for a major overhaul to the Guides to improve the balance between benefits and costs. Rather, some comments urged various changes to update the Guides in keeping with the commenters' view of legal, technological, and commercial developments. For example, the Antitrust Section recommended that ''the Commission should revise the Guides to bring them into conformity with current case law and technology.'' NADA agreed, noting that ''[s]ensible, limited changes to reflect modern market conditions'' should be made, while urging the Commission ''to reject calls to make significant changes to the Guides where there is no pressing need'' to do so. FMI suggested that the Guides should be revised ''to reflect developments in the law and changes in distribution and marketing practices.''

For these reasons, the Commission will retain the Guides in their current form, making specific changes as discussed below. (Section numbers below starting with 240 refer to sections of the Guides.)

Discussion of Public Comments and Changes to the Guides

Section 240.2—Applicability of the Law

Several comments are relevant to this section of the Guides, which identifies the essential elements of section 2(d) and 2(e) violations.

Three of the comments—those of the Antitrust Section, AAI, and FMI—urged the Commission to modify the 1990 Guides in ways that seemingly would add an ''injury to competition'' element to sections 2(d) and 2(e). For example, the Antitrust Section urged the

terms to all other customers competing in the distribution of such products or commodities.''

15 U.S.C. 13(e) (section 2(e) of the R–P Act) reads: ''[I]t shall be unlawful for any person to discriminate in favor of one purchaser against another purchaser or purchasers of a commodity bought for resale, with or without processing, by contracting to furnish or furnishing, or by contributing to the furnishing of, any services or facilities connected with the processing, handling, sale, or offering for sale of such commodity so purchased upon terms not accorded to all purchasers on proportionally equal terms.''

[3] Mr. Steuer's comment was in the form of an article published elsewhere and submitted for the Commission's consideration in connection with its review of the Guides.

Commission to ''ma[ke] clear at the outset of the Guides'' that sections 2(d) and 2(e) are ''aimed at significant harm to competition.'' An FMI comment was to similar effect. And AAI noted its continued adherence to the proposition that a plaintiff ''challenging favoritism in promotional allowances or services . . . should be required to prove that the discrimination is likely to cause competitive injury . . . '' One of the seven comments received, that of NGA, opposed any change that would, in effect, engraft an ''injury to competition'' element onto sections 2(d) and 2(e).

The Commission noted in its 1990 review of the Guides that sections 2(d) and 2(e) are complements to section 2(a), which bans certain discriminations in price ''when a specified competitive injury might result.'' Sections 2(d) and 2(e) are intended ''to prohibit disguised price discriminations in the form of promotional payments or services''; they ''attempt to prevent evasions of section 2(a).'' 55 FR 33651. And ''in contrast to section 2(a), they do not require proof of likely adverse competitive effects.* * *'' *Id.* No comment pointed to any court decision calling these principles into question. *Volvo Trucks North America* v. *Reeder-Simco GMC, Inc.,* 546 U.S. 164 (2006) (holding that a manufacturer may not be liable under the R–P Act without a showing that it discriminated between dealers competing to sell to the same customer), cited in the Antitrust Section comment and others, was decided under section 2(a) of the Act and did not address the standards for proving a violation of sections 2(d) or (e).

Revising the Guides to suggest that sections 2(d) and 2(e) plaintiffs must prove likely injury to competition therefore would not be supportable in the case law, even though requiring proof of likely injury to competition is sound enforcement policy. Accordingly, stating that sections 2(d) and 2(e) require such a showing might not provide accurate guidance to the business community about the risks of private litigation. Therefore, the Commission did not revise the Guides to suggest that a competitive injury element to section 2(d) or 2(e) of the Act can be fairly implied based on the current state of the law. However, consistent with the Supreme Court's expressed view in *Volvo Trucks,* 546 U.S. at 181, that the Robinson-Patman Act should be construed to be consistent with the antitrust laws generally, the Commission has modified section 240.13 of the Guides, which relates to Section 5 of the FTC Act, to reflect its own view that Section 5 should be used only in cases of likely harm to competition.

In another comment, Richard Steuer urged that the Act be interpreted such that it would be ''lawful to charge different prices and provide different promotional assistance, if the combined value of the discounts and promotional assistance to each retailer is of equal value.'' Mr. Steuer asserted that this would resolve a quandary created by the Act as conventionally interpreted, because ''[d]ealers more often treat money as fungible, whether it is in the form or a discount, a rebate, or a credit, and whether earmarked for advertising and promotion or not.'' The Commission is unaware of any court that has so-interpreted the R–P Act, however, and such an interpretation seemingly conflicts with the explicit terms of the Act, in which Congress separately, and differently, addressed discrimination in price (in section 2(a)) and discrimination in the provision of promotional allowances and services (in sections 2(d) and 2(e)). Revision of the 1990 Guides to reflect Mr. Steuer's premise would be inconsistent with the purpose of the Guides, which is to assist businesses in complying with the Act as it is currently understood.

Section 240.4—Definition of Customer

A Note appended to the definition of ''customer'' in the 1990 Guides provides that, ''a retailer or [*sic*] purchasing solely from other retailers . . . will not be considered a 'customer' of the seller unless the seller has been put on notice that such retailer is selling its product.'' The Antitrust Section urged the Commission to delete the limiting phrase, ''unless the seller has been put on notice that such retailer is selling its product.'' According to the Antitrust Section, that revision would better conform to the congressional intent underlying the Act as reflected in *Falls City Indus.* v. *Vanco Beverage, Inc.,* 460 U.S. 428 (1983) and reduce ''unnecessary'' compliance costs.

The Commission believes that the Note as currently written is consistent with the intent underlying the Act and does not impose unreasonable compliance costs. The Commission does not read *Falls City,* which pre-dated the 1990 review of the Guides, to the contrary. Sections 2(d) and 2(e) of the Act require that competing purchasers be treated similarly. The Note already recognizes an exception to this principle when the seller is unable to identify the purchaser to provide it with promotional allowances or services. Where, however, the seller does know the identity of a purchaser, there is no appropriate basis for denying similar treatment. Therefore, the Note appended to section 240.4 remains substantively unchanged.[4]

Section 240.5—Definition of Competing Customers

In its request for public comments on the Guides, the Commission asked whether and how the 1990 Guides should be revised to take into account new methods of commerce associated with the growth of the Internet since 1990. Every commenter that addressed this question agreed that the growth of Internet commerce is an important development, and that the Guides should be understood to apply to Internet commerce. In response, the Commission has added references to the Internet to the lists of promotional media dispersed throughout the Guides.

AAI noted that online retail sales in the United States are expected to reach $155 billion by 2014, and that, ''[f]or a particular brand, . . . Internet-based resellers may compete with their brick and mortar counterparts.'' AAI concluded that differences in reseller formats, consumer demand, and other things ''will affect this determination.'' Similarly, the Antitrust Section observed that ''Internet retailers . . . are potential competitors of every other retailer that sells the same or comparable products.'' More specifically, AAI observed that in the past two decades some reseller formats have increased in sophistication and others have newly emerged, including ''company-owned stores, interactive kiosks, vending machines, and home shopping networks.'' According to AAI, ''[d]epending on the circumstances, these new formats may compete with one another and more traditional reseller formats and accordingly be considered competing customers'' for purposes of the Robinson-Patman Act. These commenters requested that in reviewing and revising the 1990 Guides, the Commission consider the implications of retailers increasingly selling online and through these other formats.

The Commission agrees that retailers, whether operating through brick-and-mortar stores, online, or through other formats, may be competing customers of a seller under the Act, and might therefore be entitled to proportionally equal promotional allowances and services. Such retailers are more likely to be deemed competing customers to the extent that they: purchase goods of

[4] The Commission has corrected a nonsubstantive error in the text. In the phrase quoted at the beginning of this section, the word ''or'' appearing immediately before ''purchasing'' has been deleted.

like grade and quality from the same seller for resale; and contemporaneously market those goods to the same or similar prospective purchasers (among others). In determining whether retailers using different retail formats should be deemed ''competing customers in the distribution of such products or commodities,'' it will be relevant to consider the particular characteristics of the retailers' formats, the location and characteristics of the retailers' target and actual customers, and other factors.

To the extent that retailers are competing customers of a seller, they may be entitled to proportionally equal promotional allowances and services. Neither the developed law nor commenters on the Guides have provided any detailed guidance as to how sellers should, or currently do, make their promotional allowances and services available on proportionally equal terms across reseller formats, such as brick-and-mortar and online sales. No single means of doing so is required, and a seller's application of common sense and good faith will be relevant in assaying efforts to proportionalize promotional allowances and services across different sales formats.

Section 240.6—Interstate Commerce

The 1990 Guides suggest that the ''interstate commerce'' requirement for application of sections 2(d) and 2(e) ''may be'' satisfied ''if there is any part of a business which is not wholly within one state (for example, sales or deliveries of products, their subsequent distribution or purchase, or delivery of supplies or raw materials).'' The Antitrust Section commented that the greater weight of judicial authorities supports a narrower ''interstate commerce'' requirement, and urged that the Commission revise the 1990 Guides to apply only to promotional allowances and services ''relating to transactions as to which at least one of the sales crosses state lines.'' An FMI comment was to similar effect. The Commission considered and rejected similar suggestions in its 1990 review of the Guides, and none of the current commenters has provided new authority in support of a different conclusion now.

The Commission agrees that sections 2(d) and 2(e) may be interpreted to require sales that cross state lines, as described by the Antitrust Section and FMI. *See, e.g., Zoslaw* v. *MCA Distrib. Corp.,* 693 F.2d 870 (9th Cir. 1983), *cert. denied* 460 U.S. 1085 (1983). But the authorities are not of one mind. For example, in *Shreveport Macaroni Mfg. Co.* v. *FTC,* 321 F.2d 404, 408 (5th Cir. 1963), *cert denied,* 375 U.S. 971 (1964), the court held that the ''interstate commerce'' requirement of section 2(d) is satisfied where a promotional allowance moves in interstate commerce, even if no sale crossed state lines.[5] The Guides do not purport to settle the question. Rather, they purposefully note that sections 2(d) and 2(e) ''may be'' applicable in certain circumstances in addition to those in which one of the sales was itself in interstate commerce. That is appropriate given the uncertain law and the fact that the Guides seek to demarcate a safe path for businesses seeking to navigate the Act.

Section 240.7—Services or Facilities

Section 240.7 of the Guides identifies the types of services and facilities covered by sections 2(d) and 2(e) of the Act. As section 240.7 currently explains, only services and facilities ''used primarily to promote the resale of the seller's product by the customer'' are covered, whereas services and facilities used primarily to promote a product's initial sale are covered by section 2(a) of the Act. Some commenters suggested that differentiating between a product's initial sale and its resale has at times been difficult in practice, and that the Commission should try to provide additional guidance. In particular, AAI suggested that further guidance be provided with respect to the classification of the diverse fees and allowances that have come to be referred to as slotting allowances.[6] FMI similarly urged that the Commission clarify the applicability of the Act to ''shelf-space'' allowances.

The Commission agrees that additional guidance would be helpful.[7] To that end, the Commission has added an Example following the list of examples of promotional services and facilities at the end of section 240.7 of the Guides. It provides: ''*Example 1:* A seller offers a supermarket chain an allowance of $500 per store to stock a new packaged food product and find space for it on the supermarket's shelves and a further allowance of $300 per store for placement of the new product on prime display space, an aisle endcap. The $500 allowance relates primarily to the initial sale of the product to the supermarket chain, and therefore should be assessed under section 2(a) of the Act. In contrast, the $300 allowance for endcap display relates primarily to the resale of the product by the supermarket chain, and therefore should be assessed under section 2(d).''

Section 240.7 contains a list of ''some examples . . . of promotional services and facilities covered by sections 2(d) and 2(e), such as cooperative advertising, catalogues, displays, and special packaging or package sizes.'' The Antitrust Section urged that ''special packaging and package sizes'' be deleted from the list because ''the established law is now clear that partial refusals to deal with particular resellers, including refusals to sell them particular products in a product line, are not covered by the [R–P Act].'' NGA opposed that suggestion, stating that the discriminatory provision of special packaging and package sizes continues to be used to advantage ''power buyer[s]'' when they are given the option to purchase special packaging or package sizes and competing customers are not, thereby creating ''class of trade distinctions.''

All of the decisions cited by the Antitrust Section predate the Commission's 1990 revision of the Guides, and none of them squarely addressed the question of whether the provision of special packaging or package sizes to only some competing customers may violate section 2(e) of the Act. For example, *Purdy Mobile Homes* v. *Champion Home Builders,* 594 F.2d 1313 (9th Cir. 1979), cited by the Antitrust Section, held that the refusal of a mobile home manufacturer (Champion) to sell two additional lines of mobile homes to a retailer (Purdy) to which it had sold another line did not constitute discrimination in the provision of services or facilities

[5] There also are several decisions arising under section 2(c) of the Act finding the ''commerce'' requirement to be satisfied where both parties to an intrastate transaction are otherwise engaged in interstate commerce. *See, e.g., Fitch* v. *Kentucky-Tennessee Light & Power Co.,* 136 F.2d 12 (6th Cir. 1943).

[6] ''Slotting fees and allowances'' initially referred to one-time payments made by a supplier to a retailer as a condition for the initial placement of the supplier's product on the retailer's store shelves or for initial access to the retailer's warehouse space. *See, e.g.,* ''Slotting Allowances in the Retail Grocery Industry,'' FTC Staff Study (November 2003), *http://www.ftc.gov/os/2003/11/slottingallowancerpt031114.pdf.* The use of the term has since broadened to include a variety of product placement arrangements. *See, e.g.,* AAI comment at 8.

[7] The Commission briefly discussed discriminatory purchase-of-shelf-space requirements in the **Federal Register** notice publishing the 1990 Guides: ''Section 2(d) applies more readily'' to payments for ''a preferential position within the store that would enhance resale,'' than to ''payments for admittance to a store.'' 55 FR 33662 (Aug. 17, 1990). The only reference to this subject in the Guides themselves is in footnote 1 to Example 5 following section 240.9. That footnote provided minimal guidance, stating only that, ''[t]he discriminatory purchase of display or shelf space, whether directly or by means of allowances, may violate the Act . . . .'' With the addition of the new example described in the text, footnote 1 becomes superfluous, and the Commission has deleted it.

connected with the resale of the line of mobile homes that Champion did sell to Purdy. Champion's refusal to sell additional lines of products is quite different from a hypothetical seller's refusal to provide special packaging or package sizes of the same product. The other decisions cited by the Antitrust Section also are distinguishable.[8]

''Special packaging, or package sizes'' are retained in the Guides' list of covered promotional services or facilities. However, the Commission has concluded that additional guidance may be helpful to users of the Guides, to underscore that special packaging or package sizes are covered only insofar as they primarily promote a product's resale. Accordingly, the Commission has added two Examples following the list of examples of promotional services and facilities. The first new Example states: ''*Example 2:* During the Halloween season, a seller of multi-packs of individually wrapped candy bars offers to provide those multi-packs to retailers in Halloween-themed packaging. The primary purpose of the special packaging is to promote customers' resale of the candy bars. Therefore, the special packaging is a promotional service or facility covered by section 2(d) or 2(e) of the Act.'' The second new Example states: ''*Example 3:* A seller of liquid laundry detergent ordinarily packages its detergent in containers having a circular footprint. A customer asks the seller to furnish the detergent to it in special packaging having a square footprint, so that the customer can more efficiently warehouse and transship the detergent. Because the purpose of the special packaging is primarily to promote the original sale of the detergent to the customer and not its resale by the customer, the special packaging is not a promotional service or facility covered by section 2(d) or 2(e) of the Act.''

NADA suggested adding an example to the non-exhaustive list of covered promotional services or facilities in section 240.7 in recognition of the prevalence of Internet-based platforms in the advertising and sale of products. The Commission agrees that it may be useful to make explicit the application of the Guides to those platforms, and therefore has added ''online advertising'' to the list of examples in section 240.7.

Finally, the Commission declines to adopt the Antitrust Section's suggestion that section 240.7 be revised by deleting the word ''primarily'' from the definition of covered services or facilities, which states that a covered service or facility is one that is ''used primarily to promote the resale of the seller's product.'' Deletion of the word ''primarily'' would imply that services or facilities are covered under sections 2(d) and 2(e) of the Act only if they do not promote, in any measure, the initial sale of the product. But a service or facility provided by a seller to its customers may somewhat promote the initial sale of a product, while its predominant effect is to promote the product's resale. Neither of the two judicial decisions cited in the comment addresses such a situation.[9] The Commission does not think it appropriate to adopt so-limited a construction of the scope of sections 2(d) and 2(e) in the Guides.

Section 240.8—Need for a Plan

Section 240.8 states that ''[a]lternative terms and conditions should be made available to customers who cannot, in a practical sense, take advantage of some of the plan's offerings.'' The Antitrust Section and FMI asserted that this language is overly restrictive, and that a plan should suffice so long as a customer can take advantage of *any* of the offerings. The Commission agrees, and has revised the section as follows: ''Alternative terms and conditions should be made available to customers who cannot, in a practical sense, take advantage of any of the plan's offerings.''

Section 240.8 further states that ''[t]he seller should inform competing customers of the plans available to them, in time for them to decide whether to participate.'' The Antitrust Section proposed that ''it should be sufficient for the plan to contain a statement that a customer who cannot take advantage of any of the offerings should contact the seller so that something usable by the customer can be arranged.'' But, the Act requires the seller to take such actions as are necessary to provide proportional services and facilities to competing customers.[10] The Antitrust Section comment suggested, in effect, that the seller may shift a part of its statutory burden to the customer. The law does not permit such burden-shifting.[11]

Section 240.9—Proportionally Equal Terms

Section 240.9 states the core requirement of sections 2(d) and 2(e): that promotional services and allowances should be made available to competing customers on proportionally equal terms. It notes that ''[n]o single way to do this is prescribed by law,'' and that ''[a]ny method that treats competing customers on proportionally equal terms may be used.'' At the same time, the Guides explain, ''[g]enerally, this can be done most easily by basing the payments made or the services furnished on the dollar volume or on the quantity of the product purchased during a specified period.'' But again, the Guides note that ''other methods that result in proportionally equal allowances and services being offered to all competing customers are acceptable.''

The Antitrust Section and FMI both urged the Commission to adopt language in the Guides that would explicitly ''endorse proportionalization based on the value to the seller of the promotional services rendered.'' NGA opposed any such revision and stated that ''[t]he Commission is well aware of the numerous subjective factors that make a value standard a slippery slope to price discrimination by sellers for the advantage of power buyers.''

In preparing for its 1990 review of the Guides, the Commission expressly invited comment on alternative standards of proportional equality, including a standard ''based on the value to the seller of promotions in different media or by different groups of customers, called the 'seller's value standard,' or simply the value standard.'' *See* 55 FR 33655 (Aug. 17, 1990). In reply, the Commission received and carefully considered 210 comments on this issue. The ''overwhelming majority'' of comments

[8] *Black Gold, Ltd.* v. *Rockwool Indus. Inc.,* 729 F.2d 676 (10th Cir. 1984), *cert. denied* 469 U.S. 854 (1984), concluded that a refusal to deal in a different product line was not a discriminatory sale under section 2(a) of the R–P Act . *L&L Oil Co.* v. *Murphy Oil Corp.,* 674 F.2d 1113 (5th Cir. 1982), held that a fuel oil refiner's imposition on a customer of unfavorable allotments and delivery terms did not violate sections 2(a) and 2(e) of the R–P Act because delivery was neither a covered service nor one promoting the customer's resale of the fuel oil. Finally, *Mullis* v. *Arco Petroleum,* 502 F.2d 290 (7th Cir. 1974), addressed the question whether sections 2(a) and 2(d) of the R–P Act or the Sherman Act protected a local jobber from otherwise lawful termination, and concluded that neither did.

[9] *See Freightliner of Knoxville* v. *Daimler Chrysler Vans, LLC,* 484 F.3d 865 (6th Cir. 2007) (question of fact existed as to whether allegedly discriminatory promotion was paid for by seller or by customer); *Alan's of Atlanta, Inc.* v. *Minolta Corp.,* 903 F.2d 1414 (11th Cir. 1990), *reh'g denied,* 929 F.2d 704 (11th Cir. 1991) (''Generally, financing programs do not relate to the resale of the supplier's goods and therefore are not services and facilities within the meaning of sections 2(d) and (e).'').

[10] *See Alterman Foods, Inc.* v. *F.T.C.,* 497 F.2d 993, 1001 (5th Cir. 1974) (holding that to avoid unlawful discrimination, ''a supplier must not merely be willing, if asked, to make an equivalent deal with other customers, but must take affirmative action to inform them of the availability of the promotion programs'').

[11] The Commission has corrected a non-substantive error in the text of section 240.8. The word ''describe'' has been changed to ''described''.

opposed adoption of a seller's value standard, whereas they generally concluded that the cost-based standard identified in the Guides worked well. ''While some [felt] that the adoption of the seller's value standard might promote the efficient allocation of promotional resources, many considered it contrary to the Act's purpose of fairness and [thought] it would result in unjustified favorable treatment for large buyers.'' 55 FR 33654–33657 (Aug. 17, 1990). The Commission concluded then, as it does now, that ''[t]he law may also permit use of the value standard, at least so far as recognizing the varying value of different media for the seller's promotional efforts.'' But the Commission declined to incorporate the seller's value standard in the 1990 Guides because, ''unless carefully monitored, sellers may use elastic, expansive measurements of value which could help disguise persistent, systematic discrimination. . . . These concerns . . . counsel against including it in the Guides, which are intended to help businesses comply with the law.'' No subsequent changes in fact or law counsel differently now.

The Antitrust Section and FMI pointed to *Texaco Inc.* v. *Hasbrouck,* 496 U.S. 543 (1990), by way of suggesting that the Commission's concerns were unwarranted. In *Hasbrouck,* a majority of the Supreme Court opined that functional discounts ''that merely accord due recognition and reimbursement for actual marketing functions'' do not violate section 2(a) of the R–P Act, and that such reimbursement might be based on the actual value to the seller of those marketing functions. *Hasbrouck* does not clarify the circumstances under which use of a value standard would be lawful under sections 2(d) and 2(e). Particularly given the fact that sections 2(d) and 2(e) of the R–P Act were enacted to inhibit evasion of section 2(a) by disguising price discriminations as promotional allowances or services,[12] concern remains that explicit endorsement of the value standard in the Guides might promote imprecision, subjectivity, and ''elastic, expansive measurements of value'' which might facilitate the concealment of price discrimination, contrary to the intent underlying the Act. Accordingly, the current language of section 240.9 with regard to the standard of proportional treatment is retained.

The Antitrust Section and FMI also urged the Commission to delete Example 4 of section 240.9, which provides that ''[a] seller should not identify or feature one or a few customers in its own advertising without making the same service available on proportionally equal terms'' to competing customers. The Antitrust Section stated that alternative offers of ''useable and suitable'' promotional services should be acceptable. The Commission believes that Example 4 is useful because it addresses a commonly furnished promotional service. At the same time, Example 4 may be unduly rigid and confining, especially insofar as proportionally identifying or featuring all competing customers in a seller's advertising may be impracticable under some circumstances, as where the seller has a few relatively large customers and many relatively small ones. For these reasons, the Commission has revised Example 4 to provide that the seller should ''not identify or feature one or a few customers in its own advertising without making the same or if impracticable, alternative services available to competing customers on proportionally equal terms. . . .''[13]

Section 240.10—Availability to All Competing Customers

Section 240.10(a) of the Guides discusses the requirement that a seller take reasonable steps to ensure that offered promotional services and facilities are ''useable in a practical sense'' by competing customers; *i.e.,* functionally available. Example 1 following section 240.10(a) currently states: ''A manufacturer offers a plan for cooperative advertising on radio, TV, or in newspapers of general circulation. Because the purchases of some of the manufacturer's customers are too small, this offer is not useable in a practical sense by them. The manufacturer should offer them alternative(s) on proportionally equal terms that are useable in a practical sense by them.'' Given the rapid development of online retailing, the Commission has revised Example 1 to encourage the making of online promotional alternatives available to online customers (and others) as appropriate. The example is amended by adding to the current text the following: ''In addition, some competing customers are online retailers that cannot make practical use of radio, TV, or newspaper advertising. The manufacturer should offer them proportionally equal alternatives, such as online advertising, that are useable by them in a practical sense.''

Section 240.10(b) discusses the requirement that a seller take reasonable steps to provide competing customers with notice of available promotional services and facilities. The Antitrust Section suggested revisions pertaining to use of the Internet to provide customers with notice of the availability of promotional services or allowances. The Antitrust Section stated that the section should be revised ''to state that it is sufficient for the notice to direct customers to the seller's Web site for details of the offer,'' and that ''Web site postings'' should be added to section 240.10's non-exhaustive list of acceptable methods of notifying customers about the availability of promotional services and allowances. FMI made a similar suggestion. In addition, the Antitrust Section urged that a retailer be barred from claiming that it did not receive promotional services and allowances if it failed to look at the seller's Web site for posted promotional programs.

The R–P Act requires the seller to provide competing customers with proportionally equal promotional services and allowances. The dramatic increase in Internet use by sellers and customers does not justify shifting to customers the burden of learning about sellers' promotional programs in the first instance, which might require a merchant reselling the products of scores of manufacturers to regularly search scores of Web sites just to determine whether promotional services and allowances might be available. For that reason, the Guides will continue to provide that the seller must ''take steps reasonably designed to provide notice to competing customers of the availability of promotional services and allowances,'' as suggested by the non-exhaustive list of acceptable methods of notification contained in section 240.10(b). Acceptable methods listed include, for example, the provision of ''information on shipping containers or product packages of the availability and essential features of an offer, identifying a specific source for further information.'' This last clause ensures that once customers are put on notice of the availability and essential features of an offer, the details of that offer can be efficiently conveyed without sacrifice of effectiveness. Given the general availability of the Internet to sellers and customers, the ''specific source for further information'' can be a Web site posting to which the customer has been directed.

[12] *See, e.g., L & L Oil Co., Inc.* v. *Murphy Oil Corp.,* 674 F. 2d 1113 (5th Cir. 1982) (''[T]he intent of s 2(e) was to end disguised price discriminations in the form of advertising and promotional activities and cooperative merchandising.'') (citing Congressman Patman).

[13] The Commission has corrected a nonsubstantive error in the text of section 240.9. The word ''lterms'' has been replaced with ''terms''.

Section 240.11—Wholesaler or Third Party Performance of Seller's Obligations

Section 240.11 of the Guides provides that a seller may contract with intermediaries to perform some or all of its obligations under sections 2(d) and 2(e) of the R–P Act, but that use of intermediaries does not relieve the seller of its responsibility for compliance with the Act. The Antitrust Section suggested that although a seller may be obliged to monitor and supervise its intermediaries, ''it should not be held as a guarantor of its intermediaries' performance.''

Section 240.11 is retained without change. A seller may work through intermediaries to comply with the R–P Act, but the seller's obligation to comply with the Act is not itself delegable—the seller remains responsible for compliance in fact.

The Antitrust Section also urged that a new sentence be added to section 240.11, informing intermediaries that they ''may be held responsible under Section 5 of the FTC Act for failing to perform.'' The current regulatory review is not an appropriate vehicle for assessing or putting forward new theories of liability under section 5 of the FTC Act.

Section 240.13—Customer's and Third Party Liability

Current section 240.13 of the Guides notes that although sections 2(d) and 2(e) apply to a seller and not to its customer, a customer that knows or should know that it is receiving services or allowances not made proportionally available to competing customers may be liable under section 5 of the FTC Act.[14] FMI urged the Commission to modify section 240.13 ''to make it clear that the Commission would not proceed against a buyer [under Section 5] . . . absent evidence of likely injury to competition.''

Likely injury to competition is not an element of seller liability under section 2(d) or 2(e). Similarly, the Commission and some courts have held that a finding of likely injury to competition is not required to establish *buyer liability* under FTC Act section 5 for knowing inducement or receipt of promotional assistance prohibited by section 2(d) or 2(e).[15] FMI questions the soundness of those precedents and urges the Commission to ''make it clear'' that the Commission would not proceed against a buyer for knowing inducement or receipt ''absent evidence of likely injury to competition.''

The Supreme Court has instructed that the Robinson-Patman Act should be construed consistent with antitrust policy generally, which focuses on harm to competition.[16] Likewise, the Commission believes that a finding of an ''unfair method of competition'' under § 5 should be tethered to likely injury to competition. Accordingly, the Commission has revised section 240.13 of the Guides to state that ''where there is likely injury to competition,'' the Commission may proceed under § 5 against a customer who knows, or should know, that it is receiving services or allowances not made proportionally available to competing customers.

Section 240.13(a) contains several illustrative Examples pertaining to a customer's and third-party liability. Example 1 discourages inducement or receipt of advertising allowances for promotion of the seller's product in connection with a customer's new store opening or anniversary sale when the customer knows or should know that proportionally equal allowances, or suitable alternatives, are not available to competing customers. Example 2 discourages inducement or receipt of in-store services—stocking of shelves, building of displays, and rotating of inventory, for example—under similar circumstances. FMI argued that the ''suggestion[s] of liability'' contained in these examples are unwarranted and discourage efficient competitive conduct. FMI asserted: that Example 1 discourages companies ''from developing special or exclusive promotional programs . . ., where such promotions are part of the supplier's overall promotional program'', and that Example 2 similarly discourages companies from seeking to make best use of in-store services by '' 'fine-tuning' them to particular customers or channels,'' where alternative services are made available to competing customers as part of the supplier's overall promotional program. FMI's critique, however, does not recognize the fundamental requirement applicable both to sellers that grant and customers that knowingly induce or receive allowances, services, or facilities: as stated in the text of Guide 240.13(a), they must be ''made available on proportionally equal terms'' to ''competitors engaged in the resale of a seller's product.'' Examples 1 and 2 do not discourage the development of specialized promotions or the fine-tuning of in-store service programs, where those programs are part of the supplier's overall promotional program *and* that program makes available to competing customers proportionally equal allowances, services, and facilities that are useable as a practical matter. And FMI has not demonstrated relevant changed facts or law since the Commission last reviewed the Guides. These Examples to section 240.13 remain valid and useful, and the Guides retain them.

With respect to Example 2, FMI also noted ''the importance of in-store follow through,'' and then asserted that ''[f]ew, if any, suppliers have the resources to provide or pay for personnel for [in-store services for] every customers' stores,'' and that doing so would not ''be beneficial to retailers or ultimate consumers.'' This last point seems to be less directed at Example 2, which pertains to knowing inducement or receipt of prohibited services and facilities, as at the basic requirement of sections 2(d) and 2(e) that sellers provide services and facilities to competing customers proportionally.

As noted, section 240.13 of the Guides states that sections 2(d) and 2(e) are inapplicable to knowing inducement or receipt of greater-than-proportional promotional assistance, but that the Commission may, where there is likely injury to competition, challenge such conduct under section 5 of the FTC Act (which creates no private right of action). In so saying, section 240.13 may imply that there is no private right of action for knowing inducement or receipt of greater-than-proportional promotional assistance. Some judicial decisions published after the Commission's 1990 review of the Guides, however, have held that under some circumstances there may be a private right of action for knowing inducement or receipt of discriminatory pricing under § 2(f) of the R–P Act. *See, e.g., American Booksellers Ass'n, Inc.* v. *Barnes & Noble, Inc.,* 135 F. Supp. 2d 1031, 1068 (N.D. Cal. 2001) (to extent promotional allowances ''do not bear a reasonable relationship to [defendants'] actual advertising expenditures, . . .

[14] Section 2(f) of the R–P Act condemns knowing inducement or receipt of a price discrimination prohibited by section 2(a). The Act does not have a similar provision condemning knowing inducement or receipt of promotional assistance prohibited by sections 2(d) and 2(e). The absence of such a provision has been held to be ''more 'inadvertent' than 'studious,' . . . [t]he practices themselves [having been] declared contrary to the public interest and therefore unlawful.'' *Grand Union Co.* v. *F.T.C.,* 300 F.2d 92, 96–97 (2nd Cir. 1962).

[15] *See, e.g., Grand Union Co.* v. *F.T.C.,* 300 F.2d 92, 99 (2nd Cir. 1962), *aff'g In re Grand Union Co.,* 57 FTC 382 (August 12, 1960).

[16] *See, e.g., Volvo Trucks North America, Inc.* v. *Reeder-Simco GMC, Inc.,* 546 U.S. 164, 181 (2006) (''[W]e . . . resist interpretation [of the R–P Act] geared more to the protection of existing *competitors* than to the stimulation of *competition*.''); *Brown Shoe Co.* v. *U.S.,* 370 U.S. 294, 320 (1962).

they can be challenged as indirect price discriminations under § 2(a) and § 2(f)''). In its recent request for public comments, the Commission asked whether the Guides should be revised in light of these decisions.

FMI replied that ''the law on this subject is sufficiently clear that no additional discussion is needed in the Guides.'' But, FMI added, if the Commission were inclined to so-revise the Guides, it should explain that sections 2(a) and 2(f) of the R–P Act may apply to ostensible promotional allowances only where *no* services are performed in return, or where the payments are not reasonably related to the ''customer's cost of performance *or the value of the promotional service to the supplier*.'' (Emphasis in original.) The Antitrust Section appears to have derived a similar standard from its review of recent decisions, but did not comment on the utility of so-revising the Guides.

AAI did not specifically address this question, but stated that the Commission should take account of recent research findings in its review of the Guides. Specifically, AAI noted that researchers have documented that ''[r]etailer's [*sic*] buying power has significantly increased in recent years . . . , '' and that retailers ''reportedly 'exert [discriminatory] buying power over manufacturers. . . .'''' (Brackets in original; footnotes omitted.)

The Commission concludes that the Guides should be revised to acknowledge the possible applicability of sections 2(a) and 2(f) of the Act to promotional allowances, and the attendant risk of customer enforcement. Doing so is necessary to remedy the Guides' possible implication to the contrary, and to better assist businesses in complying with the Act, as interpreted by the courts. The Commission agrees with FMI and the Antitrust Section that sections 2(a) and 2(f) are applicable only in limited circumstances. Specifically, the Commission has revised the Guides by adding a new paragraph immediately prior to the Examples in section 240.13(a), as follows: ''In addition, the giving or knowing inducement or receipt of proportionally unequal promotional allowances may be challenged under sections 2(a) and 2(f) of the Act, respectively, where no promotional services are performed in return for the payments, or where the payments are not reasonably related to the customer's cost of providing the promotional services. *See, e.g., American Booksellers Ass'n* v. *Barnes & Noble,* 135 F. Supp. 2d 1031 (N.D. Cal. 2001); *but see United Magazine Co.* v. *Murdoch Magazines Distrib., Inc.* 2001 U.S. Dist. Lexis 20878 (S.D.N.Y. 2001). Sections 2(a) and 2(f) of the Act may be enforced by disfavored customers, among others.''

The Commission declines to add a statement that sections 2(a) and 2(f) are inapplicable to promotional allowances where the payments are reasonably related to the value of the promotional service to the initial seller. Neither *American Booksellers* nor other decisions cited by the commenters support adoption of a ''seller's value standard''. *See also* the discussion of the ''seller's value standard'' in connection with section 240.9 of the Guides.

240.14—Meeting Competition

Section 240.14 of the Guides states that a seller may defend against charges that it has violated section 2(d) or 2(e) by showing that the promotional allowances or services in question were provided ''in good faith to meet equally high payments or equivalent services offered or supplied by a competing seller. . . .'' The Antitrust Section stated that the Commission should modify section 240.14 to ''clarify that a supplier can meet the competition offered by a lower priced brand, including a private label brand, when the customer. . . informs the seller that unless the seller offers the allowance or service requested by the reseller, the customer will accept a competitive offer from the lower-priced brand . . . and either eliminate or reduce the promotional services provided to the seller refusing the request.'' The Commission does not believe that such a change is necessary or appropriate.

The Antitrust Section's comment does not indicate that the applicable law has changed since 1990 or that concrete difficulties have since arisen in the application of section 240.14. Nevertheless, the Antitrust Section asks the Commission to conclude that sellers of higher-priced brands always may discriminate in the provision of promotional allowances or services based only on representations and threats made by buyers of lower-priced alternative goods, including store-brands. Such a sweeping summary disposition would be inconsistent with section 2(b) of the R–P Act, which limits the ''meeting competition'' defense to instances in which a seller acts ''in good faith to meet . . . the services or facilities furnished by a competitor.'' [17] Furthermore, the R–P Act ''places the burden of establishing the defense on the [seller].'' [18] Whether that burden is met depends on ''the facts and circumstances of the particular case.'' [19] A seller must ''show the existence of facts which would lead a reasonable and prudent person to believe that the granting of [the discrimination] would in fact meet the equally [favorable terms] of a competitor.'' [20] Whether a seller has done so is a question best left for resolution on the totality of a developed record.[21] Further, because the question of the seller's good faith belief ''lies at the core of the defense,'' issues of credibility ''are inherently bound up'' with claims of meeting competition.[22] Again, those issues are best resolved on the totality of a developed record. Amending section 240.14 of the Guides as urged by the Antitrust Section unnecessarily and unwisely would cut short the development of the record in an entire category of proceedings. Thus, the Guides will retain section 240.14 without change.

Conclusion

The Commission has concluded its review of the Guides by retaining the Guides with some amendments. The revised Guides should increase the use and confidence of use by the public in seeking to conduct business in accordance with sections 2(d) and 2(e) of the R–P Act.

List of Subjects in 16 CFR Part 240

Advertising, Promotional allowances and services, Robinson-Patman Act, Trade practices.

For the reasons stated above, the Federal Trade Commission revises 16 CFR part 240 to read as follows:

[17] *See, e.g., Hoover Color Corp.* v. *Bayer Corp.,* 199 F.3d 160, 164 (4th Cir. 1999), in which the court noted that ''courts have rarely granted the seller judgment as a matter of law on the basis of the [meeting competition] defense,'' citing with approval *Alan's of Atlanta Inc.* v. *Minolta Corp.,* 903 F.2d 1414 (11th Cir. 1990).

[18] *Falls City Industries* v. *Vanco Beverage,* 460 U.S. 428, 451 (1983).

[19] *Id.* at 441, quoting *United States* v. *U.S. Gypsum Co.,* 438 U.S. 422 (1978).

[20] *Great Atl. & Pac. Tea Co.* v. *FTC,* 440 U.S. 69, 82 (1979), quoting *FTC* v. *A.E. Staley Mfg.,* 324 U.S. 746, 759–60 (1945) (discussing the applicability of section 2(b) to discrimination in price).

[21] *See Alan's of Atlanta, Inc.* v. *Minolta Corp.,* 903 F.2d 1414 (11th Cir. 1990). *Compare Reserve Supply Corp.* v. *Owens-Corning Fiberglas Corp.,* 971F.2d 37 (7th Cir. 1992), in which the court affirmed summary judgment based on the seller's meeting competition claim, which was supported by evidence of the seller's experience with and evaluation of the credibility of the buyer, the size and reputation of and the threats made by the buyer, pricing otherwise available in the market, etc. The evidence in *Reserve Supply* goes well beyond the predicate facts on which the Antitrust Section would have the Commission summarily authorize wholesale application of the defense.

[22] *Alan's of Atlanta, Inc.,* 903 F. 2d at 1425–26.

PART 240—GUIDES FOR ADVERTISING ALLOWANCES AND OTHER MERCHANDISING PAYMENTS AND SERVICES

Sec.
240.1 Purpose of the Guides.
240.2 Applicability of the law.
240.3 Definition of seller.
240.4 Definition of customer.
240.5 Definition of competing customers.
240.6 Interstate commerce.
240.7 Services or facilities.
240.8 Need for a plan.
240.9 Proportionally equal terms.
240.10 Availability to all competing customers.
240.11 Wholesaler or third party performance of seller's obligations.
240.12 Checking customer's use of payments.
240.13 Customer's and third party liability.
240.14 Meeting competition.
240.15 Cost justification.

Authority: Secs. 5, 6, 38 Stat. 719, as amended, 721; 15 U.S.C. 45, 46; 49 Stat. 1526; 15 U.S.C. 13, as amended.

§ 240.1 Purpose of the Guides.

The purpose of these Guides is to provide assistance to businesses seeking to comply with sections 2(d) and (e) of the Robinson-Patman Act (the ''Act''). The guides are based on the language of the statute, the legislative history, administrative and court decisions, and the purposes of the Act. Although the Guides are consistent with the case law, the Commission has sought to provide guidance in some areas where no definitive guidance is provided by the case law. The Guides are what their name implies—guidelines for compliance with the law. They do not have the force of law. They do not confer any rights on any person and do not operate to bind the FTC or the public.

§ 240.2 Applicability of the law.

(a) The substantive provisions of section 2(d) and (e) apply only under certain circumstances. Section 2(d) applies only to:

(1) A seller of products

(2) Engaged in interstate commerce

(3) That either directly or through an intermediary

(4) Pays a customer for promotional services or facilities provided by the customer

(5) In connection with the resale (not the initial sale between the seller and the customer) of the seller's products

(6) Where the customer is in competition with one or more of the seller's other customers also engaged in the resale of the seller's products of like grade and quality.

(b) Section 2(e) applies only to:

(1) A seller of products

(2) Engaged in interstate commerce

(3) That either directly or through an intermediary

(4) Furnishes promotional services or facilities to a customer

(5) In connection with the resale (not the initial sale between the seller and the customer) of the seller's products

(6) Where the customer is in competition with one or more of the seller's other customers also engaged in the resale of the seller's products of like grade and quality.

(c) Additionally, section 5 of the FTC Act may apply to buyers of products for resale or to third parties. See § 240.13 of these Guides.

§ 240.3 Definition of seller.

Seller includes any person (manufacturer, wholesaler, distributor, etc.) who sells products for resale, with or without further processing. For example, selling candy to a retailer is a sale for resale without processing. Selling corn syrup to a candy manufacturer is a sale for resale with processing.

§ 240.4 Definition of customer.

A *customer* is any person who buys for resale directly from the seller, or the seller's agent or broker. In addition, a ''customer'' is any buyer of the seller's product for resale who purchases from or through a wholesaler or other intermediate reseller. The word ''customer'' which is used in section 2(d) of the Act includes ''purchaser'' which is used in section 2(e).

Note: There may be some exceptions to this general definition of ''customer.'' For example, the purchaser of distress merchandise would not be considered a ''customer'' simply on the basis of such purchase. Similarly, a retailer purchasing solely from other retailers, or making sporadic purchases from the seller or one that does not regularly sell the seller's product, or that is a type of retail outlet not usually selling such products (e.g., a hardware store stocking a few isolated food items) will not be considered a ''customer'' of the seller unless the seller has been put on notice that such retailer is selling its product.

Example 1: A manufacturer sells to some retailers directly and to others through wholesalers. Retailer A purchases the manufacturer's product from a wholesaler and resells some of it to Retailer B. Retailer A is a customer of the manufacturer. Retailer B is not a customer unless the fact that it purchases the manufacturer's product is known to the manufacturer.

Example 2: A manufacturer sells directly to some independent retailers, to the headquarters of chains and of retailer-owned cooperatives, and to wholesalers. The manufacturer offers promotional services or allowances for promotional activity to be performed at the retail level. With respect to such services and allowances, the direct-buying independent retailers, the headquarters of the chains and retailer-owned cooperatives, and the wholesaler's independent retailer customers are customers of the manufacturer. Individual retail outlets of the chains and the members of the retailer-owned cooperatives are not customers of the manufacturer.

Example 3: A seller offers to pay wholesalers to advertise the seller's product in the wholesalers' order books or in the wholesalers' price lists directed to retailers purchasing from the wholesalers. The wholesalers and retailer-owned cooperative headquarters and headquarters of other bona-fide buying groups are customers. Retailers are not customers for purposes of this promotion.

§ 240.5 Definition of competing customers.

Competing customers are all businesses that compete in the resale of the seller's products of like grade and quality at the same functional level of distribution regardless of whether they purchase directly from the seller or through some intermediary.

Example 1: Manufacturer A, located in Wisconsin and distributing shoes nationally, sells shoes to three competing retailers that sell only in the Roanoke, Virginia area. Manufacturer A has no other customers selling in Roanoke or its vicinity. If Manufacturer A offers its promotion to one Roanoke customer, it should include all three, but it can limit the promotion to them. The trade area should be drawn to include retailers who compete.

Example 2: A national seller has direct-buying retailing customers reselling exclusively within the Baltimore area, and other customers within the area purchasing through wholesalers. The seller may lawfully engage in a promotional campaign confined to the Baltimore area, provided that it affords all of its retailing customers within the area the opportunity to participate, including those that purchase through wholesalers.

Example 3: B manufactures and sells a brand of laundry detergent for home use. In one metropolitan area, B's detergent is sold by a grocery store and a discount department store. If these stores compete with each other, any allowance, service or facility that B makes available to the grocery store should also be made available on proportionally equal terms to the discount department store.

§ 240.6 Interstate commerce.

The term ''interstate commerce'' has not been precisely defined in the statute. In general, if there is any part of a business which is not wholly within one state (for example, sales or deliveries of products, their subsequent distribution or purchase, or delivery of supplies or raw materials), the business may be subject to sections 2(d) and 2(e) of the Act. (The commerce standard for sections 2(d) and (e) is at least as inclusive as the commerce standard for

section 2(a).) Sales or promotional offers within the District of Columbia and most United States possessions are also covered by the Act.

§ 240.7 Services or facilities.

The terms ''services'' and ''facilities'' have not been exactly defined by the statute or in decisions. One requirement, however, is that the services or facilities be used primarily to promote the resale of the seller's product by the customer. Services or facilities that relate primarily to the original sale are covered by section 2(a). The following list provides some examples—the list is not exhaustive—of promotional services and facilities covered by sections 2(d) and (e):

Cooperative advertising;
Handbills;
Demonstrators and demonstrations;
Catalogues;
Cabinets;
Displays;
Prizes or merchandise for conducting promotional contests;
Special packaging, or package sizes; and
Online advertising.

Example 1: A seller offers a supermarket chain an allowance of $500 per store to stock a new packaged food product and find space for it on the supermarket's shelves and a further allowance of $300 per store for placement of the new product on prime display space, an aisle endcap. The $500 allowance relates primarily to the initial sale of the product to the supermarket chain, and therefore should be assessed under section 2(a) of the Act. In contrast, the $300 allowance for endcap display relates primarily to the resale of the product by the supermarket chain, and therefore should be assessed under section 2(d).

Example 2: During the Halloween season, a seller of multi-packs of individually wrapped candy bars offers to provide those multi-packs to retailers in Halloween-themed packaging. The primary purpose of the special packaging is to promote customers' resale of the candy bars. Therefore, the special packaging is a promotional service or facility covered by section 2(d) or 2(e) of the Act.

Example 3: A seller of liquid laundry detergent ordinarily packages its detergent in containers having a circular footprint. A customer asks the seller to furnish the detergent to it in special packaging having a square footprint, so that the customer can more efficiently warehouse and transship the detergent. Because the purpose of the special packaging is primarily to promote the original sale of the detergent to the customer and not its resale by the customer, the special packaging is not a promotional service or facility covered by section 2(d) or 2(e) of the Act.

§ 240.8 Need for a plan.

A seller who makes payments or furnishes services that come under the Act should do so according to a plan. If there are many competing customers to be considered or if the plan is complex, the seller would be well advised to put the plan in writing. What the plan should include is described in more detail in the remainder of these Guides. Briefly, the plan should make payments or services functionally available to all competing customers on proportionally equal terms. (See § 240.9 of this part.) Alternative terms and conditions should be made available to customers who cannot, in a practical sense, take advantage of any of the plan's offerings. The seller should inform competing customers of the plans available to them, in time for them to decide whether to participate. (See § 240.10 of this part.)

§ 240.9 Proportionally equal terms.

(a) Promotional services and allowances should be made available to all competing customers on proportionally equal terms. No single way to do this is prescribed by law. Any method that treats competing customers on proportionally equal terms may be used. Generally, this can be done most easily by basing the payments made or the services furnished on the dollar volume or on the quantity of the product purchased during a specified period. However, other methods that result in proportionally equal allowances and services being offered to all competing customers are acceptable.

(b) When a seller offers more than one type of service, or payments for more than one type of service, all the services or payments should be offered on proportionally equal terms. The seller may do this by offering all the payments or services at the same rate per unit or amount purchased. Thus, a seller might offer promotional allowances of up to 12 cents a case purchased for expenditures on either newspaper or Internet advertising or handbills.

Example 1: A seller may offer to pay a specified part (e.g., 50 percent) of the cost of local advertising up to an amount equal to a specified percentage (e.g., 5 percent) of the dollar volume of purchases during a specified period of time.

Example 2: A seller may place in reserve for each customer a specified amount of money for each unit purchased, and use it to reimburse these customers for the cost of advertising the seller's product.

Example 3: A seller should not provide an allowance or service on a basis that has rates graduated with the amount of goods purchased, as, for instance, 1 percent of the first $1,000 purchased per month, 2 percent of the second $1,000 per month, and 3 percent of all over that.

Example 4: A seller should not identify or feature one or a few customers in its own advertising without making the same, or if impracticable, alternative services available on proportionally equal terms to customers competing with the identified customer or customers.

Example 5: A seller who makes employees available or arranges with a third party to furnish personnel for purposes of performing work for a customer should make the same offer available on proportionally equal terms to all other competing customers or offer useable and suitable services or allowances on proportionally equal terms to competing customers for whom such services are not useable and suitable.

Example 6: A seller should not offer to pay a straight line rate for advertising if such payment results in a discrimination between competing customers; e.g., the offer of $1.00 per line for advertising in a newspaper that charges competing customers different amounts for the same advertising space. The straight line rate is an acceptable method for allocating advertising funds if the seller offers small retailers that pay more than the lowest newspaper rate an alternative that enables them to obtain the same percentage of their advertising cost as large retailers. If the $1.00 per line allowance is based on 50 percent of the newspaper's lowest contract rate of $2.00 per line, the seller should offer to pay 50 percent of the newspaper advertising cost of smaller retailers that establish, by invoice or otherwise, that they paid more than that contract rate.

Example 7: A seller offers each customer promotional allowances at the rate of one dollar for each unit of its product purchased during a defined promotional period. If Buyer A purchases 100 units, Buyer B 50 units, and Buyer C 25 units, the seller maintains proportional equality by allowing $100 to Buyer A, $50 to Buyer B, and $25 to Buyer C, to be used for the Buyers' expenditures on promotion.

§ 240.10 Availability to all competing customers.

(a) *Functional availability.* (1) The seller should take reasonable steps to ensure that services and facilities are useable in a practical sense by all competing customers. This may require offering alternative terms and conditions under which customers can participate. When a seller provides alternatives in order to meet the availability requirement, it should take reasonable steps to ensure that the alternatives are proportionally equal, and the seller should inform competing customers of the various alternative plans.

(2) The seller should insure that promotional plans or alternatives offered to retailers do not bar any competing retailers from participation, whether they purchase directly from the seller or through a wholesaler or other intermediary.

(3) When a seller offers to competing customers alternative services or allowances that are proportionally equal

and at least one such offer is useable in a practical sense by all competing customers, and refrains from taking steps to prevent customers from participating, it has satisfied its obligation to make services and allowances ''functionally available'' to all customers. Therefore, the failure of any customer to participate in the program does not place the seller in violation of the Act.

Example 1: A manufacturer offers a plan for cooperative advertising on radio, TV, or in newspapers of general circulation. Because the purchases of some of the manufacturer's customers are too small this offer is not useable in a practical sense by them. The manufacturer should offer them alternative(s) on proportionally equal terms that are useable in a practical sense by them. In addition, some competing customers are online retailers that cannot make practical use of radio, TV, or newspaper advertising. The manufacturer should offer them proportionally equal alternatives, such as online advertising, that are useable by them in a practical sense.

Example 2: A seller furnishes demonstrators to large department store customers. The seller should provide alternatives useable in a practical sense on proportionally equal terms to those competing customers who cannot use demonstrators. The alternatives may be services useable in a practical sense that are furnished by the seller, or payments by the seller to customers for their advertising or promotion of the seller's product.

Example 3: A seller offers to pay 75 percent of the cost of advertising in daily newspapers, which are the regular advertising media of the seller's large or chain store customers, but a lesser amount, such as only 50 percent of the cost, or even nothing at all, for advertising in semi-weekly, weekly, or other newspapers or media, such as the Internet, that may be used by small retail customers. Such a plan discriminates against particular customers or classes of customers. To avoid that discrimination, the seller in offering to pay allowances for newspaper advertising should offer to pay the same percent of the cost of newspaper advertising for all competing customers in a newspaper of the customer's choice, or at least in those newspapers that meet the requirements for second class mail privileges. While a small customer may be offered, as an alternative to advertising in daily newspapers, allowances for other media and services such as envelope stuffers, handbills, window banners, Web sites, and the like, the small customer should have the choice to use its promotional allowance for advertising similar to that available to the larger customers, if it can practicably do so.

Example 4: A seller offers short term displays of varying sizes, including some which are useable by each of its competing customers in a practical business sense. The seller requires uniform, reasonable certification of performance by each customer. Because they are reluctant to process the required paper work, some customers do not participate. This fact does not place the seller in violation of the functional availability requirement and it is under no obligation to provide additional alternatives.

(b) *Notice of available services and allowance.:* The seller has an obligation to take steps reasonably designed to provide notice to competing customers of the availability of promotional services and allowances. Such notification should include enough details of the offer in time to enable customers to make an informed judgment whether to participate. When some competing customers do not purchase directly from the seller, the seller must take steps reasonably designed to provide notice to such indirect customers. Acceptable notification may vary. The following is a non-exhaustive list of acceptable methods of notification:

(1) By providing direct notice to customers;

(2) When a promotion consists of providing retailers with display materials, by including the materials within the product shipping container;

(3) By including brochures describing the details of the offer in shipping containers;

(4) By providing information on shipping containers or product packages of the availability and essential features of an offer, identifying a specific source for further information;

(5) By placing at reasonable intervals in trade publications of general and widespread distribution announcements of the availability and essential features of promotional offers, identifying a specific source for further information; and

(6) If the competing customers belong to an identifiable group on a specific mailing list, by providing relevant information of promotional offers to customers on that list. For example, if a product is sold lawfully only under Government license (alcoholic beverages, etc.), the seller may inform only its customers holding licenses.

(c) A seller may contract with intermediaries or other third parties to provide notice. See § 240.11.

Example 1: A seller has a plan for the retail promotion of its product in Philadelphia. Some of its retailing customers purchase directly and it offers the plan to them. Other Philadelphia retailers purchase the seller's product through wholesalers. The seller may use the wholesalers to reach the retailing customers that buy through them, either by having the wholesalers notify these retailers, or by using the wholesalers' customer lists for direct notification by the seller.

Example 2: A seller that sells on a direct basis to some retailers in an area, and to other retailers in the area through wholesalers, has a plan for the promotion of its product at the retail level. If the seller directly notifies competing direct purchasing retailers, and competing retailers purchasing through the wholesalers, the seller is not required to notify its wholesalers.

Example 3: A seller regularly promotes its product at the retail level and during the year has various special promotional offers. The seller's competing customers include large direct-purchasing retailers and smaller retailers that purchase through wholesalers. The promotions offered can best be used by the smaller retailers if the funds to which they are entitled are pooled and used by the wholesalers on their behalf (newspaper advertisements, for example). If retailers purchasing through a wholesaler designate that wholesaler as their agent for receiving notice of, collecting, and using promotional allowances for them, the seller may assume that notice of, and payment under, a promotional plan to such wholesaler constitutes notice and payment to the retailer. The seller must have a reasonable basis for concluding that the retailers have designated the wholesaler as their agent.

§ 240.11 Wholesaler or third party performance of seller's obligations.

A seller may contract with intermediaries, such as wholesalers, distributors, or other third parties, to perform all or part of the seller's obligations under sections 2(d) and (e). The use of intermediaries does not relieve a seller of its responsibility to comply with the law. Therefore, in contracting with an intermediary, a seller should ensure that its obligations under the law are in fact fulfilled.

§ 240.12 Checking customer's use of payments.

The seller should take reasonable precautions to see that the services the seller is paying for are furnished and that the seller is not overpaying for them. The customer should expend the allowance solely for the purpose for which it was given. If the seller knows or should know that what the seller is paying for or furnishing is not being properly used by some customers, the improper payments or services should be discontinued.

§ 240.13 Customer's and third party liability.

(a) *Customer's liability.* Sections 2(d) and (e) apply to sellers and not to customers. However, where there is likely injury to competition, the Commission may proceed under section 5 of the Federal Trade Commission Act against a customer who knows, or should know, that it is receiving a discriminatory price through services or allowances not made available on proportionally equal terms to its competitors engaged in the resale of a seller's product. Liability for knowingly receiving such a discrimination may

result whether the discrimination takes place directly through payments or services, or indirectly through deductions from purchase invoices or other similar means. In addition, the giving or knowing inducement or receipt of proportionally unequal promotional allowances may be challenged under sections 2(a) and 2(f) of the Act, respectively, where no promotional services are performed in return for the payments, or where the payments are not reasonably related to the customer's cost of providing the promotional services. *See, e.g., American Booksellers Ass'n* v. *Barnes & Noble,* 135 F. Supp. 2d 1031 (N.D. Cal. 2001); *but see United Magazine Co.* v. *Murdoch Magazines Distrib., Inc.* 2001 U.S. Dist. Lexis 20878 (S.D.N.Y. 2001). Sections 2(a) and 2(f) of the Act may be enforced by disfavored customers, among others.

Example 1: A customer should not induce or receive advertising allowances for special promotion of the seller's product in connection with the customer's anniversary sale or new store opening when the customer knows or should know that such allowances, or suitable alternatives, are not available on proportionally equal terms to all other customers competing with it in the distribution of the seller's product.

Example 2: Frequently the employees of sellers or third parties, such as brokers, perform in-store services for their grocery retailer customers, such as stocking of shelves, building of displays and checking or rotating inventory, etc. A customer operating a retail grocery business should not induce or receive such services when the customer knows or should know that such services (or usable and suitable alternative services) are not available on proportionally equal terms to all other customers competing with it in the distribution of the seller's product.

Example 3: Where a customer has entered into a contract, understanding, or arrangement for the purchase of advertising with a newspaper or other advertising medium, such as the Internet, that provides for a deferred rebate or other reduction in the price of the advertising, the customer should advise any seller from whom reimbursement for the advertising is claimed that the claimed rate of reimbursement is subject to a deferred rebate or other reduction in price. In the event that any rebate or adjustment in the price is received, the customer should refund to the seller the amount of any excess payment or allowance.

Example 4: A customer should not induce or receive an allowance in excess of that offered in the seller's advertising plan by billing the seller at ''vendor rates'' or for any other amount in excess of that authorized in the seller's promotional program.

(b) *Third party liability.* Third parties, such as advertising media, may violate section 5 of the Federal Trade Commission Act through double or fictitious rates or billing. An advertising medium, such as the Internet, a newspaper, broadcast station, or printer of catalogues, that publishes a rate schedule containing fictitious rates (or rates that are not reasonably expected to be applicable to a representative number of advertisers), may violate section 5 if the customer uses such deceptive schedule or invoice for a claim for an advertising allowance, payment or credit greater than that to which it would be entitled under the seller's promotional offering. Similarly, an advertising medium that furnishes a customer with an invoice that does not reflect the customer's actual net advertising cost may violate section 5 if the customer uses the invoice to obtain larger payments than it is entitled to receive.

Example 1: A newspaper has a ''national'' rate and a lower ''local'' rate. A retailer places an advertisement with the newspaper at the local rate for a seller's product for which the retailer will seek reimbursement under the seller's cooperative advertising plan. The newspaper should not send the retailer two bills, one at the national rate and another at the local rate actually charged.

Example 2: A newspaper has several published rates. A large retailer has in the past earned the lowest rate available. The newspaper should not submit invoices to the retailer showing a high rate by agreement between them unless the invoice discloses that the retailer may receive a rebate and states the amount (or approximate amount) of the rebate, if known, and if not known, the amount of rebate the retailer could reasonably anticipate.

Example 3: A radio station has a flat rate for spot announcements, subject to volume discounts. A retailer buys enough spots to qualify for the discounts. The station should not submit an invoice to the retailer that does not show either the actual net cost or the discount rate.

Example 4: An advertising agent buys a large volume of newspaper advertising space at a low, unpublished negotiated rate. Retailers then buy the space from the agent at a rate lower than they could buy this space directly from the newspaper. The agent should not furnish the retailers invoices showing a rate higher than the retailers actually paid for the space.

§ 240.14 Meeting competition.

A seller charged with discrimination in violation of sections 2(d) and (e) may defend its actions by showing that particular payments were made or services furnished in good faith to meet equally high payments or equivalent services offered or supplied by a competing seller. This defense is available with respect to payments or services offered on an area-wide basis, to those offered to new as well as old customers, and regardless of whether the discrimination has been caused by a decrease or an increase in the payments or services offered. A seller must reasonably believe that its offers are necessary to meet a competitor's offer.

§ 240.15 Cost justification.

It is no defense to a charge of unlawful discrimination in the payment of an allowance or the furnishing of a service for a seller to show that such payment or service could be justified through savings in the cost of manufacture, sale or delivery.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2014–23137 Filed 9–26–14; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9695]

RIN 1545–BL54

Employee Retirement Benefit Plan Returns Required on Magnetic Media

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the requirements for filing certain employee retirement benefit plan statements, returns, and reports on magnetic media. The term magnetic media includes electronic filing, as well as other magnetic media specifically permitted under applicable regulations, revenue procedures, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. These regulations affect plan administrators and employers maintaining retirement plans that are subject to various employee benefit reporting requirements under the Internal Revenue Code (Code).

DATES: *Effective Date:* These regulations are effective September 29, 2014.

Applicability Date: For dates of applicability, see §§ 301.6057–3(f), 301.6058–2(f), and 301.6059–2(f).

FOR FURTHER INFORMATION CONTACT: William Gibbs or Pamela Kinard at (202) 317–6799 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 301. On August 30, 2013, a notice of proposed rulemaking (REG–111837–13) relating to the requirements

for filing certain employee retirement benefit plan statements, returns, and reports on magnetic media was published in the **Federal Register** (78 FR 53704). The proposed regulations provide that a plan administrator (or, in certain situations, an employer maintaining a plan) required by the Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year must use magnetic media to file certain statements, returns, and reports required under sections 6057, 6058, and 6059 of the Code. Comments responding to the notice of proposed rulemaking were received. No public hearing was requested or held. After consideration of all the comments, the proposed regulations are adopted as modified by this Treasury decision.

Summary of Comments and Explanation of Revisions

I. Use of FIRE System for Filing Form 8955–SSA

The proposed regulations under section 6057 provide that a registration statement required under section 6057(a) or a notification required under section 6057(b) must be filed on magnetic media if the filer is required by the Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year. Magnetic media is defined as electronic filing or other media specifically permitted under applicable regulations, revenue procedures, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. See § 601.601(d)(2)(ii)(*b*) of this chapter.

The form used to satisfy the requirement to file the registration statement under section 6057 is Form 8955–SSA, ''Annual Registration Statement Identifying Separated Participants with Deferred Vested Benefits.'' The preamble to the proposed regulations noted that many filers of the Form 8955–SSA already voluntarily file electronically with the IRS, but did not identify the system currently used to file electronically.

Commenters expressed concern that not identifying the ''Filing Information Returns Electronically'' (FIRE) system as the system currently used to file the Form 8955–SSA electronically could imply that the use of the FIRE system is not (or, in the near future, will not be) an acceptable system to file the Form 8955–SSA electronically. In response to this concern, the Department of the Treasury and the IRS confirm that the FIRE system is an acceptable electronic system to file the Form 8955–SSA. If, in the future, the IRS replaces the FIRE system with another electronic filing system, sufficient time will be provided to filers of the Form 8955–SSA to accommodate programming and other implementation needs.

Commenters also stated that certain aspects of the FIRE system need improvement, including the lack of an efficient batch processing system and costs associated with using the system. The specific requirements of the FIRE system are outside the scope of these regulations, but comments on possible FIRE system improvements have been forwarded to the staff at the IRS responsible for the FIRE system.

II. Application of the E-File Mandate to One-Participant Plans

The proposed regulations under section 6058 provide that a return required under section 6058 must be filed on magnetic media if the filer is required by the Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year. The preamble to the proposed regulations noted that filers of the Form 5500, ''Annual Return/Report of Employee Benefit Plan,'' and Form 5500–SF, ''Short Form Annual Return/Report of Small Employee Benefit Plan,'' are already required, pursuant to Department of Labor (DOL) rules, to file these returns electronically through the computerized ERISA Filing Acceptance System (EFAST2). The preamble to the proposed regulations also noted that, while electronic filing is not available for the Form 5500–EZ, ''Annual Return of One-Participant (Owners and their Spouses) Retirement Plan,'' certain filers that would otherwise file the Form 5500–EZ on paper may instead file the Form 5500–SF electronically through EFAST2.

One commenter asked whether the proposed regulations impose additional filing obligations, other than the requirement to file electronically, on one-participant plans that meet the 250-return threshold for mandatory electronic filing. In particular, the commenter asked whether a one-participant plan would now be required to file an actuarial report under section 6059 when filing the Form 5500–SF in lieu of a paper Form 5500–EZ.

In response to this comment, the Department of the Treasury and the IRS confirm that a one-participant plan (or a foreign plan) required to file electronically must use the Form 5500–SF to file the information required on the Form 5500–EZ, but will not be required to attach to the filing a Schedule SB, ''Single-Employer Defined Benefit Plan Actuarial Information,'' or Schedule MB, ''Multiemployer Defined Benefit Plan and Certain Money Purchase Plan Actuarial Information.''

III. Economic Hardship Waiver

As noted in the proposed regulations, the Commissioner may waive the requirement to file electronically in cases of undue economic hardship. Because the Department of the Treasury and the IRS believe that electronic filing will not impose significant burdens on the taxpayers covered by these regulations, the Commissioner anticipates granting waivers of the electronic filing requirement in only exceptional cases. The Department of the Treasury and the IRS anticipate issuing guidance that will set forth procedures whereby a taxpayer may request a hardship waiver for electronically filing the Form 8955–SSA and the Form 5500 series. The Department of the Treasury and the IRS anticipate that the guidance would not provide hardship waiver procedures for any electronic filing requirement for a form that a filer is already required to file electronically, such as Form 5500 and Form 5500–SF, which filers are already required to file electronically through EFAST2.

IV. Request To Extend Proposed Effective Date

Commenters requested that the effective date of these regulations be extended from the effective date set forth in the proposed regulations. The proposed regulations provided that they would be effective for plan years that begin on or after January 1, 2014, but only for filings with a filing deadline (not taking into account extensions) after December 31, 2014. With respect to the filing requirements under section 6057, commenters specifically requested that the IRS confirm that the use of the existing FIRE system will satisfy the electronic filing requirement for the Form 8955–SSA through 2016. Because there is no current plan to change the electronic system used to file the Form 8955–SSA prior to the end of calendar year 2016, and significant changes to the form itself are not anticipated, these regulations generally retain the proposed effective date for section 6057 filings. However, the regulations do provide an extended effective date for plans with short 2014 plan years by providing that these regulations only apply to filings with a filing deadline on or after July 31, 2015. For example, a plan with a short 2014 plan year ending November 30, 2014, would have a filing deadline of June 30, 2015, and thus would not be required to file electronically for that plan year.

With respect to the filing requirements under sections 6058 and 6059, these regulations extend the effective date by 12 months, so that the regulations generally apply to returns and actuarial reports required to be filed for plan years that begin on or after January 1, 2015, but only for filings with a filing deadline (not taking into account extensions) after December 31, 2015. As announced in the proposed regulations, the IRS anticipates adding items on the Form 5500 and Form 5500–SF relating solely to Code requirements and intends to provide an optional paper-only form containing those Code-related items for use by small filers. It is anticipated that the form will be available to satisfy the filing requirements with respect to the 2015 plan year.

V. Certain Delinquent Filers Required To File on Paper

Notice 2014–35 (2014–23 IRB 1072) provides administrative relief from IRS penalties under sections 6652(d), 6652(e), and 6692 for a failure to file timely in accordance with annual reporting requirements under sections 6047(e), 6057, 6058, and 6059. This administrative relief from IRS penalties applies to late filers that satisfy the requirements of the Delinquent Filer Voluntary Compliance Program (''DFVC Program'') administered by DOL. In order to be eligible for relief from the IRS penalties for a plan year, the late filer, within a certain time period after completing the filing under the DFVC Program, must file on paper with the IRS any delinquent Form 8955–SSA for the plan year.

Similarly, Revenue Procedure 2014–32 (2014–23 IRB 1073) establishes a pilot program providing administrative relief for late filers of the Form 5500–EZ. In general, in order to receive relief from IRS penalties, the late filer must submit a complete Form 5500–EZ, including all required schedules and attachments, for each plan year for which the late filer is seeking penalty relief. A complete return for a plan year consists of a signed, filled-out paper version of the Form 5500–EZ for that plan year.

Although the Department of the Treasury and IRS generally encourage filers to file electronically whenever possible, the IRS currently does not have the capability to accept electronic filing of a delinquent Form 8955–SSA or Form 5500–EZ. Thus, a delinquent filing of a Form 8955–SSA or Form 5500–EZ that complies with the paper filing requirements in Notice 2014–35 and Rev. Proc. 2014–32, is excluded from the electronic filing requirements under these regulations. The IRS will announce those statements and returns that are excluded from electronic filing under these regulations in its publications, forms, and instructions.

Effective Date

The regulations apply to employee retirement benefit plan statements and notifications required to be filed under section 6057 for plan years that begin on or after January 1, 2014, but only for filings with a filing deadline (not taking into account extensions) on or after July 31, 2015.

For employee retirement benefit plan returns and reports required to be filed under sections 6058 and 6059, the regulations apply for plan years that begin on or after January 1, 2015, but only for filings with a filing deadline (not taking into account extensions) after December 31, 2015.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that 5 U.S.C. 533(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. In addition, it is hereby certified that any collection of information contained in this regulation will not have a significant economic impact on a substantial number of small entities, and therefore no flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations have been submitted to the Office of Chief Counsel for Advocacy of the Small Business Administration for comments on its impact on small businesses.

The certification is based on the fact that §§ 301.6057–1, 301.6058–1, and 301.6059–1 currently require filing with the IRS of information under sections 6057, 6058, and 6059 in accordance with applicable forms, schedules, and accompanying instructions. The regulations merely require that this information be filed electronically by persons required to file at least 250 returns for the calendar year, consistent with section 6011(e)(2)(A), which provides that, in prescribing regulations providing standards for determining which returns must be filed on magnetic media or in other machine-readable form, the Secretary shall not require any person to file returns on magnetic media unless the person is required to file at least 250 returns during the calendar year. Many small entities are unlikely to file 250 returns or more during the calendar year. Filers of the Form 5500 and Form 5500–SF are already required to file the returns electronically through EFAST2 pursuant to DOL regulations. In addition, many filers of the Form 8955–SSA already voluntarily file electronically with the IRS through the use of the FIRE system.

Further, if a taxpayer's operations are computerized, reporting in accordance with the regulations should be less costly than filing on paper. The Department of the Treasury and the IRS have determined that taxpayers should be able to comply at a reasonable cost with the requirement in these regulations to file employee retirement statements, returns, and reports on magnetic media. In addition, the regulations provide that the IRS may waive the electronic filing requirements upon a showing of economic hardship.

Drafting Information

The principal authors of these regulations are William Gibbs and Pamela R. Kinard, Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and the Treasury Department participated in the development of these regulations.

List of Subjects in 26 CFR Part 301

Administrative practice and procedure, Alimony, Bankruptcy, Child support, Continental shelf, Courts, Crime, Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Investigations, Law enforcement, Oil pollution, Penalties, Pensions, Reporting and recordkeeping requirements, Seals and insignia, Statistics and Taxes.

Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 1.** The authority for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7508* * *

■ **Par. 2.** Section 301.6057–3 is added to read as follows:

§ 301.6057–3 Required use of magnetic media for filing requirements relating to deferred vested retirement benefit.

(a) *Magnetic media filing requirements under section 6057.* A registration statement required under section 6057(a) or a notification required under section 6057(b) with respect to an employee benefit plan

must be filed on magnetic media if the filer is required by the Internal Revenue Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year. Returns filed on magnetic media must be made in accordance with applicable revenue procedures, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. In prescribing revenue procedures, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site, the Commissioner may direct the type of magnetic media filing. See § 601.601(d)(2)(ii)(*b*) of this chapter.

(b) *Economic hardship waiver.* The Commissioner may waive the requirements of this section in cases of undue economic hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the registration statements or notifications on magnetic media in accordance with this section exceeds the cost of filing the registration statements or notifications on other media. A request for a waiver must be made in accordance with applicable published guidance, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. See § 601.601(d)(2)(ii)(*b*) of this chapter. The waiver will specify the type of filing (that is, a registration statement or notification under section 6057) and the period to which it applies. In addition, the waiver will be subject to such terms and conditions regarding the method of filing as may be prescribed by the Commissioner.

(c) *Failure to file.* If a filer required to file a registration statement or other notification under section 6057 fails to file the statement or other notification on magnetic media when required to do so by this section, the filer is deemed to have failed to file the statement or other notification. See section 6652(d) for the amount imposed for the failure to file a registration statement or other notification required under section 6057. In determining whether there is reasonable cause for the failure to file the registration statement or notification under section 6057, § 301.6652–3(b) and rules similar to the rules in § 301.6724–1(c)(3)(ii) (regarding undue economic hardship related to filing information returns on magnetic media) will apply.

(d) *Meaning of terms.* The following definitions apply for purposes of this section.

(1) *Magnetic media.* The term *magnetic media* means electronic filing, as well as other media specifically permitted under applicable regulations, revenue procedures, or publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. See § 601.601(d)(2)(ii)(*b*) of this chapter.

(2) *Registration statement required under section 6057(a).* The term *registration statement required under section 6057(a)* means a Form 8955–SSA (or its successor).

(3) *Notification required under section 6057(b).* The term *notification required under section 6057(b)* means either a Form 8955–SSA (or its successor) or a return in the Form 5500 series (or its successor).

(4) *Determination of 250 returns*—(i) *In general.* For purposes of this section, a filer is required to file at least 250 returns if, during the calendar year that includes the first day of the plan year, the filer is required to file at least 250 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(ii) *Definition of filer.* For purposes of this section, the term *filer* means the plan administrator within the meaning of section 414(g). If the plan administrator within the meaning of section 414(g) is the employer, the special rules in § 1.6058–2(d)(3)(iii) will apply.

(e) *Example.* The following example illustrates the provisions of paragraph (d)(4) of this section:

Example. In 2015, P, the plan administrator of Plan B, is required to file 252 returns (including Forms 1099–R, ''Distributions From Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, etc.;'' Form 8955–SSA, ''Annual Registration Statement Identifying Separated Participants with Deferred Vested Benefits;'' Form 5500, ''Annual Return/Report of Employee Benefit Plan;'' and Form 945, ''Annual Return of Withheld Federal Income Tax''). Plan B's plan year is the calendar year. Because P is required to file at least 250 returns during the 2015 calendar year, P must file the 2015 Form 8955–SSA for Plan B electronically.

(f) *Effective/applicability date.* This section is applicable for registration statements and other notifications required to be filed under section 6057 for plan years that begin on or after January 1, 2014, but only for filings with a filing deadline (not taking into account extensions) on or after July 31, 2015.

■ **Par. 3.** Section 301.6058–2 is added to read as follows:

§ 301.6058–2 Required use of magnetic media for filing requirements relating to information required in connection with certain plans of deferred compensation.

(a) *Magnetic media filing requirements under section 6058.* A return required under section 6058 with respect to an employee benefit plan must be filed on magnetic media if the filer is required by the Internal Revenue Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year. Returns filed on magnetic media must be made in accordance with applicable revenue procedures, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. In prescribing revenue procedures, publications, forms, and instructions, or other guidance on the IRS.gov Internet site, the Commissioner may direct the type of magnetic media filing. See § 601.601(d)(2)(ii)(*b*) of this chapter.

(b) *Economic hardship waiver.* The Commissioner may waive the requirements of this section in cases of undue economic hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return on magnetic media in accordance with this section exceeds the cost of filing the returns on other media. A request for a waiver must be made in accordance with applicable published guidance, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. See § 601.601(d)(2)(ii)(*b*) of this chapter. The waiver will specify the type of filing (that is, a return required under section 6058) and the period to which it applies. In addition, the waiver will be subject to such terms and conditions regarding the method of filing as may be prescribed by the Commissioner.

(c) *Failure to file.* If a filer required to file a return under section 6058 fails to file the return on magnetic media when required to do so by this section, the filer is deemed to have failed to file the return. See section 6652(e) for the amount imposed for the failure to file a return required under section 6058. In determining whether there is reasonable cause for failure to file the return, § 301.6652–3(b) and rules similar to the rules in § 301.6724–1(c)(3)(ii) (regarding undue economic hardship related to filing information returns on magnetic media) will apply.

(d) *Meaning of terms.* The following definitions apply for purposes of this section.

(1) *Magnetic media.* The term *magnetic media* means electronic filing, as well as other media specifically permitted under applicable regulations, revenue procedures, or publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. See § 601.601(d)(2)(ii)(*b*) of this chapter.

(2) *Return required under section 6058.* The term *return required under*

section 6058 means a return in the Form 5500 series (or its successor).

(3) *Determination of 250 returns*—(i) *In general.* For purposes of this section, a filer is required to file at least 250 returns if, during the calendar year that includes the first day of the plan year, the filer is required to file at least 250 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(ii) *Definition of filer.* For purposes of this section, the term *filer* means the employer or employers maintaining the plan and the plan administrator within the meaning of section 414(g).

(iii) *Special rules relating to determining 250 returns.* For purposes of applying paragraph (d)(3)(ii) of this section, the aggregation rules of section 414(b), (c), (m), and (o) will apply to a filer that is or includes an employer. Thus, for example, a filer that is a member of a controlled group of corporations within the meaning of section 414(b) must file the Form 5500 series on magnetic media if the aggregate number of returns required to be filed by all members of the controlled group of corporations is at least 250.

(e) *Example.* The following example illustrates the provisions of paragraph (d)(3) of this section:

Example. In 2016 Employer X (the plan sponsor of Plan A) and P (the plan administrator of Plan A) are required to file 267 returns. Employer X is required to file the following: one Form 1120, ''U.S. Corporation Income Tax Return;'' 195 Forms W–2, ''Wage and Tax Statement;'' 25 Forms 1099–DIV, ''Dividends and Distributions;'' one Form 940, ''Employer's Annual Federal Unemployment (FUTA) Tax Return;'' and four Forms 941, ''Employer's Quarterly Federal Tax Return.'' P is required to file 40 Forms 1099–R, ''Distributions From Pensions, Annuities, Retirement, Profit-Sharing Plans, IRAs, Insurance Contracts, etc.'' P and Employer X are jointly required to file one Form 5500 series return. Plan A's plan year is the calendar year. Because P and Employer X, in the aggregate, are required to file at least 250 returns during the calendar year, the 2016 Form 5500 for Plan A must be filed electronically.

(f) *Effective/applicability date.* This section is applicable for returns required to be filed under section 6058 for plan years that begin on or after January 1, 2015, but only for filings with a filing deadline (not taking into account extensions) after December 31, 2015.

Par. 4. Section 301.6059–2 is added to read as follows:

§ 301.6059–2 Required use of magnetic media for filing requirements relating to periodic report of actuary.

(a) *Magnetic media filing requirements under section 6059.* An actuarial report required under section 6059 with respect to an employee benefit plan must be filed on magnetic media if the filer is required by the Internal Revenue Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year. Actuarial reports filed on magnetic media must be made in accordance with applicable revenue procedures, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. In prescribing revenue procedures, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site, the Commissioner may direct the type of magnetic media filing. See § 601.601(d)(2)(ii)(*b*) of this chapter.

(b) *Economic hardship waiver.* The Commissioner may waive the requirements of this section in cases of undue economic hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the reports on magnetic media in accordance with this section exceeds the cost of filing the reports on other media. A request for a waiver must be made in accordance with applicable published guidance, publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. See § 601.601(d)(2)(ii)(*b*) of this chapter. The waiver will specify the type of filing (that is, an actuarial report required under section 6059) and the period to which it applies. In addition, the waiver will be subject to such terms and conditions regarding the method of filing as may be prescribed by the Commissioner.

(c) *Failure to file.* If a filer required to file an actuarial report under section 6059 fails to file the report on magnetic media when required to do so by this section, the filer is deemed to have failed to file the report. See section 6692 for the penalty for the failure to file an actuarial report. In determining whether there is reasonable cause for failure to file the report, § 301.6692–1(c) and rules similar to the rules in § 301.6724–1(c)(3)(ii) (regarding undue economic hardship related to filing information returns on magnetic media) will apply.

(d) *Meaning of terms.* The following definitions apply for purposes of this section.

(1) *Magnetic media.* The term *magnetic media* means electronic filing, as well as other media specifically permitted under applicable regulations, revenue procedures, or publications, forms, instructions, or other guidance on the IRS.gov Internet Web site. See § 601.601(d)(2)(ii)(*b*) of this chapter.

(2) *Actuarial report required under section 6059*—(i) *Single employer plans.* For a single employer plan, the term *actuarial report required under section 6059* means the Schedule SB, ''Single-Employer Defined Benefit Plan Actuarial Information,'' of the Form 5500 series (or its successor).

(ii) *Multiemployer and certain money purchase plans.* For multiemployer and certain money purchase plans, the term *actuarial report required under section 6059* means the Schedule MB, ''Multiemployer Defined Benefit Plan and Certain Money Purchase Plan Actuarial Information,'' of the Form 5500 series (or its successor).

(3) *Determination of 250 returns*—(i) *In general.* For purposes of this section, a filer is required to file at least 250 returns if, during the calendar year that includes the first day of the plan year, the filer is required to file at least 250 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(ii) *Definition of filer.* For purposes of this section, the term *filer* means the plan administrator within the meaning of section 414(g). If the plan administrator within the meaning of section 414(g) is the employer, the special rules in § 1.6058–2(d)(3)(iii) will apply.

(e) *Example.* The following example illustrates the provisions of paragraph (d)(3) of this section:

Example. In 2016, P, the plan administrator of Plan B (a single employer defined benefit plan), is required to file 266 returns (including Forms 1099–R ''Distributions From Pensions, Annuities, Retirement, Profit-Sharing Plans, IRAs, Insurance Contracts, etc.'' and one Form 5500 series). Plan B's plan year is the calendar year. Because P is required to file at least 250 returns during the calendar year, P must file the 2016 Schedule SB of the Form 5500 series return for Plan B electronically.

(f) *Effective/applicability date.* This section is applicable for actuarial reports required to be filed under section 6059 for plan years that begin on or after January 1, 2015, but only for filings with a filing deadline (not taking

into account extensions) after December 31, 2015.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: September 23, 2014.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2014–23161 Filed 9–26–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 51

[NPS–WASO–16649; PX.XVPAD0517.00.1]

RIN 1024–AE22

Concession Contracts

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: We are amending our concessions contracts regulations to clarify that the Director may amend or extend a prospectus soliciting proposals for a concession contract prior to and including the proposal due date and may award a temporary concession contract. We are also updating consolidated information collection requirements.

DATES: This rule is effective September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Jo Pendry, National Park Service Acting Chief of Commercial Services, by telephone: 202–513–7156 or email: *jo_pendry@nps.gov.*

SUPPLEMENTARY INFORMATION:

Background

The National Park Service (NPS) issues concession contracts to provide commercial visitor services in over 150 units of the National Park System under the authority of the NPS Concessions Management Improvement Act of 1998 (Pub. L. 105–391; 16 U.S.C. 5951–5966 (1998 Act). Title 36 CFR Part 51, adopted in 2000, implements the 1998 Act. This rule clarifies an ambiguity in 36 CFR 51.11, eliminates outdated procedural restrictions in 36 CFR 51.24, and updates 36 CFR 51.104. You may view information about the NPS Commercial Services Program at *http://concessions.nps.gov.*

Amending or Extending a Prospectus (36 CFR 51.11)

Title 36 CFR 51.11 describes when the NPS may amend or extend the solicitation period for a prospectus seeking proposals for a concession contract opportunity. As written, the regulation could be interpreted to limit the agency's needed ability to amend or extend a solicitation on the date the solicitation period expires. This rule clarifies that the NPS may amend a prospectus or extend the submission date prior to and on the proposal due date.

Awarding a Temporary Concession Contract (36 CFR 51.24)

Under the 1998 Act, the NPS may award temporary concession contracts for a term not to exceed three years in order to avoid an interruption of services to the public. (16 U.S.C. 5952(11)).

The current 36 CFR 51.24 describes the circumstances under which the NPS may award a temporary concession contract. When the NPS promulgated 36 CFR Part 51 in 2000, it provided in § 51.24 that, except in limited circumstances, the Director could not issue a temporary concession contract to continue visitor services provided under an extended contract. This regulatory restriction was the result of a policy decision of the NPS rather than a requirement of the 1998 Act. Although the NPS has successfully awarded replacement contracts within the term limits of contracts and authorized extension periods, the inventory of concession contracts currently includes several extended, complex contracts with respect to which the NPS may need the flexibility to award a temporary contract upon contract expiration in order to assure that visitor services continue uninterrupted. This rule amends § 51.24(a) to provide this flexibility. The NPS anticipates it will exercise this authority sparingly and only when the award of a temporary contract is the only practical alternative to an interruption of visitor services.

In addition, the NPS is deleting the text of 36 CFR 51.24(b) in its entirety except for the last sentence in the current subsection, which will be moved to become the last sentence in the amended § 51.24(a) for purposes of determining the existence of a preferred offeror when awarding a temporary concession contract to continue services under an extended concession contract. The current § 51.24(b) only applies to contracts that were in effect as of November 13, 1998, and that either had been extended as of that date or were due to expire by December 31, 1998, and were subsequently extended. There are no longer any existing NPS concession contracts that fall within these limitations, and this provision is no longer needed.

We are also making two conforming amendments. We are deleting the current reference to § 51.24(b) in § 51.22, and we are also revising the current reference to § 51.24(b) stated in § 51.24(c) and replacing it with a reference to § 51.24(a).

Update to OMB Approval of Information Collection (36 CFR 51.104)

In November 2013, the Office of Management and Budget (OMB) approved our request to consolidate the information collection requirements associated with applying for and operating NPS concessions (previously approved under four separate control numbers: 1024–0029, 1024–0125, 1024–0126, and 1024–0231) into one single control number, 1024–0029. Upon receiving OMB approval for the renewal and consolidation of 1024–0029, we discontinued OMB Control Numbers 1024–0125, 1024–0126, and 1024–0231. We are amending § 51.104 to reflect this change.

Summary of Public Comments

We published the proposed rule at 79 FR 45390 (August 5, 2014). We accepted comments through the mail, hand delivery, and through the Federal eRulemaking Portal at *http://www.regulations.gov.* Comments were accepted through September 4, 2014, and we received two timely comments. Both comments supported the proposed rule and did not request any change. After considering the public comments and after additional review, we did not make any changes in the final rule.

Compliance With Other Laws, Executive Orders, and Department Policy

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Executive Order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant,

feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (RFA)

This rule will not have a significant economic effect on a substantial number of small entities under the RFA (5 U.S.C. 601 *et seq.*). This certification is based on the cost-benefit and regulatory flexibility analyses found in the report entitled ''Economic Analysis of the Proposed Rulemaking to Amend the Concession Contract Regulations of the National Park Service'' which can be viewed online at *http://concessions.nps.gov/regulations.htm.*

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the SBREFA. This rule:

(a) Does not have an annual effect on the economy of $100 million or more;

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions;

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Administrative Procedure Act (Effective Date)

We recognize that under 5 U.S.C 553(d) new rules ordinarily go into effect thirty days after publication in the **Federal Register**. However, we have determined under 5 U.S.C. 553(d) and 318 DM HB 6.18 that good cause exists for this rule to become effective upon publication in the **Federal Register**, for the following reason. We are facing the possibility that, due to contracting delays, we may this year have expiring concession contracts that we have no authority to extend further. This situation could result in closure of visitor facilities at affected parks and thereby deprive park area visitors of needed concession services. Making this rule effective immediately upon publication could allow us to enter into temporary contracts for those expiring contracts without an interruption in visitor services this year. This will keep visitor services open, private sector businesses operating, and avoid employee layoffs.

Unfunded Mandates Reform Act (UMRA)

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. This rule clarifies NPS procedures and does not impose requirements on other agencies or governments. A statement containing the information required by the UMRA (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

This rule does not affect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

Federalism (Executive Order 13132)

Under the criteria in section 1 of Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism summary impact statement. A Federalism summary impact statement is not required.

Civil Justice Reform (Executive Order 12988)

This rule complies with the requirements of Executive Order 12988. This rule:

(a) Meets the criteria of section 3(a) requiring agencies to review all regulations to eliminate errors and ambiguity and write them to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring agencies to write all regulations in clear language and contain clear legal standards.

Consultation With Indian Tribes (Executive Order 13175 and Department Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined it has no substantial direct effects on federally recognized Indian tribes and consultation under the Department's tribal consultation policy is not required.

Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.)

This rule does not contain new collections of information that require approval by the Office of Management and Budget under the PRA. The rule does not impose new recordkeeping or reporting requirements on State, tribal, or local governments; individuals; businesses; or organizations. OMB has reviewed and approved the information collection requirements associated with concessions and assigned OMB Control No. 1024–0029, which expires November 30, 2016. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (NEPA)

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA of 1969 is not required. We have determined the rule is categorically excluded under 43 CFR 46.210(i) because it is administrative, legal, and technical in nature. We also have determined the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

Effects on the Energy Supply (Executive Order 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects in not required.

Drafting Information: The primary author of this regulation was Debra Hecox, National Park Service, Commercial Services Program, Washington, DC.

List of Subjects in 36 CFR Part 51

Concessions, Government contracts, National parks, Reporting and recordkeeping requirements.

In consideration of the foregoing, the National Park Service amends 36 CFR Part 51 as follows:

PART 51—CONCESSION CONTRACTS

■ 1. Revise the authority citation for Part 51 to read as follows:

Authority: 16 U.S.C. 1 *et seq.,* particularly, 16 U.S.C. 3 and Title IV of the National Parks Omnibus Management Act of 1998 (Pub. L. 105–391).

Subpart C—Solicitation, Selection, and Award Procedures

■ 2. Revise § 51.11 to read as follows:

§ 51.11 May the Director amend, extend, or cancel a prospectus of solicitation?

The Director may amend a prospectus or extend the submission date, or both, prior to and on the proposal due date. The Director may cancel a solicitation at any time prior to award of the concession contract if the Director determines in his discretion that this action is appropriate in the public interest. No offeror or other person will obtain compensable or other legal rights as a result of an amended, extended, canceled, or resolicited solicitation for a concession contract.

■ 3. In § 51.22, revise the first sentence to read as follows:

§ 51.22 When may the Director award the concession contract?

Before awarding a concession contract with anticipated annual gross receipts in excess of $5,000,000 or of more than 10 years in duration, the Director must submit the concession contract to the Committee on Natural Resources of the House of Representatives and the Committee on Energy and Natural Resources of the Senate. * * *

Subpart D—Non-Competitive Award of Concession Contracts

■ 4. Revise § 51.24 to read as follows:

§ 51.24 May the Director award a temporary concession contract without a public solicitation?

(a) Notwithstanding the public solicitation requirements of this part, the Director may non-competitively award a temporary concession contract or contracts for consecutive terms not to exceed three years in the aggregate—*e.g.,* the Director may award one temporary contract with a three year term; two consecutive temporary contracts, one with a two year term and one with a one year term; or three consecutive temporary contracts with a term of one year each—to any qualified person for the conduct of particular visitor services in a park area if the Director determines that the award is necessary to avoid interruption of visitor services. Before determining to award a temporary concession contract, the Director must take all reasonable and appropriate steps to consider alternatives to avoid an interruption of visitor services. Further, the Director must publish notice in the **Federal Register** of the proposed temporary concession contract at least 30 days in advance of its award (except in emergency situations). A temporary concession contract may not be extended. A temporary concession contract may be awarded to continue visitor services that were provided under an extended concession contract pursuant to the terms and conditions in this paragraph. A temporary concession contract awarded under the authority of the prior sentence will be considered as a contract extension for purposes of determining the existence of a preferred offeror under § 51.44.

(b) [Reserved]

(c) A concessioner holding a temporary concession contract will not be eligible for a right of preference to a qualified concession contract that replaces a temporary contract unless the concessioner holding the temporary concession contract was determined or was eligible to be determined a preferred offeror under an extended concession contract that was replaced by a temporary concession contract under paragraph (a) of this section.

Subpart M—Information Collection

■ 5. Revise § 51.104 to read as follows:

§ 51.104 Has OMB approved the collection of information?

The Office of Management and Budget (OMB) reviewed and approved the information collection requirements contained in this Part and assigned OMB Control No. 1024–0029. We use this information to administer the National Park Service concessions program, including solicitation, award, and administration of concession contracts. A Federal agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. You may send comments on the information collection requirements to the Information Collection Clearance Officer, National Park Service, 1849 C Street NW., (2601), Washington, DC 20240.

Dated: September 22, 2014.

Michael Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2014–23080 Filed 9–26–14; 8:45 am]

BILLING CODE 4310–EJ–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0538; FRL–9915–51–Region 9]

Revision of Air Quality Implementation Plan; California; Placer County Air Pollution Control District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to the Placer County Air Pollution Control District (PCAPCD) portion of the California State Implementation Plan (SIP). This revision concerns a permitting rule that regulates construction and modification of major stationary sources of air pollution. These revisions correct deficiencies in PCAPCD Rule 502, New Source Review, previously identified by EPA in a final rule dated September 24, 2013. We are approving revisions that correct the identified deficiencies.

DATES: This rule is effective on November 28, 2014 without further notice, unless EPA receives adverse comments by October 29, 2014. If we receive such comments, we will publish a timely withdrawal in the **Federal Register** to notify the public that this direct final rule will not take effect.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2014–0538, by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions.
2. *Email: R9airpermits@epa.gov.*
3. *Mail or deliver:* Gerardo Rios (Air-3), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or email. *http://www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of

your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: EPA has established a docket for this action under EPA–R09–OAR–2014–0538. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material, large maps, multi-volume reports), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: La weeda Ward, EPA Region IX, (213) 244–1812, *ward.laweeda@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA.

Table of Contents

I. The State's Submittal
A. What rule did the State submit?
B. Are there other versions of this rule?
C. What is the purpose of the submitted rule revision?
II. EPA's Evaluation and Action
A. How is EPA evaluating the rule?
B. Does the rule meet the evaluation criteria?
C. Public Comment and Final Action
III. Statutory and Executive Order Reviews

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule we are approving with the date it was adopted by the local air agency and submitted to EPA by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULE

Local agency	Rule #	Rule title	Amended	Submitted
PCAPCD	502	New Source Review	8/8/13	5/13/14

On July 18 2014, EPA determined that the submittal for PCAPCD Rule 502 met the completeness criteria in 40 CFR part 51, appendix V, including evidence of public adoption of this regulation, which must be met before formal EPA review.

B. Are there other versions of this rule?

EPA approved a previous version of Rule 502, into the SIP on September 24, 2013 (78 FR 58460).

C. What is the purpose of the submitted rule revision?

Section 110(a)(2) of the Clean Air Act (CAA) requires that each SIP include, among other things, a preconstruction permit program to provide for regulation of the construction and modification of stationary sources within the areas covered by the plan as necessary to assure that the National Ambient Air Quality Standards (NAAQS) are achieved, including a permit program as required in parts C and D of title I of the CAA. For areas designated as nonattainment for one or more NAAQS, the SIP must include preconstruction permit requirements for new or modified major stationary sources of such nonattainment pollutant(s), commonly referred to as ''Nonattainment New Source Review'' or ''NNSR.'' CAA 172(c)(5).

The portion of Placer County that lies within the Sacramento Metro air basin is currently designated severe nonattainment for both the 1997 and 2008 8-hour ozone NAAQS and moderate nonattainment for the 2006 24-hour $PM_{2.5}$ NAAQS. *See* 40 CFR 81.305. Therefore, California is required under part D of title I of the Act to adopt and implement a SIP-approved NNSR program for the nonattainment portions of Placer County that applies, at a minimum, to new or modified major stationary sources of the following pollutants: volatile organic compounds (VOCs), nitrogen oxides (NO_X), particular matter of 2.5 microns or less ($PM_{2.5}$) and sulfur oxides (SO_x).[1]

Rule 502, New Source Review, implements the NNSR requirements under part D of title I of the CAA for new or modified major stationary sources of nonattainment pollutants. The PCAPCD amended Rule 502 to correct minor program deficiencies identified by EPA on September 24, 2013 (78 FR 58460).

II. EPA's Evaluation and Action

A. How is EPA evaluating the rule?

EPA has reviewed the submitted permitting rule for compliance with the CAA's general requirements for SIPs in CAA section 110(a)(2), EPA's regulations for nonattainment stationary source permit programs in 40 CFR 51.165, and the CAA requirements for SIP revisions in CAA section 110(l).[2]

B. Does the rule meet the evaluation criteria?

With respect to procedures, CAA sections 110(a) and 110(l) require that revisions to a SIP be adopted by the State after reasonable notice and public hearing. EPA has promulgated specific procedural requirements for SIP revisions in 40 CFR part 51, subpart F. These requirements include publication of notices, by prominent advertisement in the relevant geographic area, a public comment period of at least 30 days, and an opportunity for a public hearing.

Based on our review of the public process documentation included in CARB's May 13, 2014 submittal, we find that the State has provided sufficient evidence of public notice and opportunity for comment and public hearing prior to adoption and submittal of this rule to EPA.

With respect to substantive requirements, EPA has reviewed the submitted rule in accordance with the CAA and regulatory requirements that apply to NNSR permit programs under part D of title I of the Act. Based on our evaluation of this rule, as summarized in the Public Comment and Final Action section of this document, we find that the rule meets the CAA and regulatory requirements for NNSR permit programs in part D of title I of the Act and EPA's NNSR implementing regulations in 40 CFR section 51.165 for new or modified major stationary sources proposing to locate within the District. Final

[1] VOCs and NO_X are subject to NNSR as ozone precursors, and NO_X and SO_x are subject to NNSR as $PM_{2.5}$ precursors. *See* 40 CFR 51.165(a)(1)(xxxvii)(C).

[2] Section 110(l) of the CAA require that SIP revisions undergo reasonable notice and public hearing prior to adoption and submittal by states to EPA and prohibits EPA from approving any SIP revision that would interfere with any applicable requirement concerning attainment and reasonable further progress or any other applicable requirement of the Act.

approval of Rule 502 would correct all deficiencies in PCAPCD's permit program identified in our September 24, 2013 final rule. 78 FR 58460.

C. Public Comment and Final Action.

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted rule because we believe it fulfills all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rule. If we receive adverse comments by October 29, 2014, we will publish a timely withdrawal in the **Federal Register** to notify the public that the direct final approval will not take effect and we will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on November 28, 2014. This will incorporate the rule into the federally enforceable SIP.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For the reasons given above, under CAA section 110(k)(3) and 301(a), we are approving Rule 502. In the State's May 13, 2014 submittal, PCAPCD corrected certain deficiencies noted in our September 24, 2013 rule (78 FR 58460) that prevented full approval at that time. The deficiencies for Rule 502 [3] were: (1) An inadequate definition of the term ''Regulated NSR Pollutant''; and (2) missing justification for the stated $PM_{2.5}$ interpollutant offset ratios. The first deficiency was corrected by adding the following sentences to the definitions of PM_{10} and $PM_{2.5}$: ''Gaseous emissions which condense to form PM_{10} shall also be counted as PM_{10}.'', and ''Gaseous emissions which condense to form $PM_{2.5}$ shall also be counted as $PM_{2.5}$.'' The second deficiency was corrected by deleting the following wording in section 303.6.4 of the rule: ''The interpollutant offset ratios for $PM_{2.5}$ shall be: NO_X to $PM_{2.5}$—100:1 and SO_X to $PM_{2.5}$—40:1; and adding the wording ''Interpollutant emission offsets between $PM_{2.5}$ and $PM_{2.5}$ precursors are not allowed unless modeling demonstrates that $PM_{2.5}$ interpollutant offset ratios are appropriate in an approved $PM_{2.5}$ attainment plan.'' This language resolves the deficiency by prohibiting the use of $PM_{2.5}$ interpollutant offsets until a justification for specified $PM_{2.5}$ interpollutant offset ratios is approved into the SIP.

[3] The submitted rule also corrects an issue with public notice requirements regarding lead emissions. For a full review of all revisions, please see the ''Placer County Air Pollution Control District Staff Report, Rule 502, New Source Review, August 8, 2013'', which can also be found in the docket for this final action.

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action 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).

List of Subjects in 40 CFR Part 52

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

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

Dated: July 31, 2014.

Jared Blumenfeld,

Regional Administrator, Region IX.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraph (c)(441) (i)(B) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(441) * * *

(i) * * *

(B) Placer County Air Pollution Control District.

(*1*) Rule 502, ''New Source Review,'' amended on August 8, 2013.

* * * * *

[FR Doc. 2014–23003 Filed 9–26–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 761

[EPA–HQ–RCRA–2013–0396; FRL–9917–21–OSWER]

RIN 2050–AG79

Polychlorinated Biphenyls (PCBs): Manufacturing (Import) Exemption for the Defense Logistics Agency (DLA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA or the Agency) is taking final action on a petition from the United States Defense Logistics Agency (DLA) to import foreign-manufactured polychlorinated biphenyls (PCBs). For purposes of the Toxic Substances Control Act (TSCA), ''manufacture'' is defined to include the import of chemical substances into the customs territory of the United States. With certain exceptions, section 6(e)(3) of TSCA bans the manufacture, processing, and distribution in commerce of PCBs. One of these exceptions is TSCA section 6(e)(3)(B), which gives the EPA authority to grant petitions to import PCBs into the customs territory of the United States for a period of up to 12 months, provided the EPA can make certain findings by rule. On April 23, 2013, the EPA received a petition from DLA, a component of the United States Department of Defense (DOD), to import PCBs that DOD currently owns in Japan for disposal in the United States. The EPA is granting DLA's petition as of October 1, 2014. This decision to grant the petition allows DLA to ''manufacture'' (i.e., import) certain PCBs for disposal. Without an exemption granted by the EPA, DLA would not be allowed to import the PCB waste to the U.S. for proper disposal.

DATES: This final rule is effective October 1, 2014.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–RCRA–2013–0396. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the RCRA Docket, EPA/DC, WJC West, Room 3334, 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 RCRA Docket is (202) 566–0270.

FOR FURTHER INFORMATION CONTACT: William Noggle, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5304P), 1200 Pennsylvania Avenue NW, Washington, DC 20460, Phone: 703–347–8769; or by email: *noggle.william@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action applies to the petitioner, the U.S. Defense Logistics Agency. However, you may be potentially affected by this action if you process, distribute in commerce, or dispose of the PCB waste imported by DLA, i.e., you are an EPA-permitted PCB waste handler. Potentially affected categories and entities include, but are not necessarily limited to:

- Waste treatment and disposal (North American Industrial Classification System (NAICS) code 5622), e.g., facilities that store or dispose of PCB waste.
- Materials recovery facilities (NAICS code 56292), e.g., facilities that process and/or recycle metals.
- Public administration (NAICS code 92), e.g., the petitioning agency (i.e., the DLA).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially affected by this action. Other types of entities not listed in this section could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 Code of Federal Regulations (CFR) part 761. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under the **FOR FURTHER INFORMATION CONTACT** section of this document.

II. Background

Section 6(e)(3)(A) of TSCA prohibits the manufacture, which includes the import of chemical substances into the customs territory of the United States, processing, and distribution in commerce of PCBs, except for the distribution in commerce of PCBs that were sold for purposes other than resale before April 1, 1979. Section 6(e)(1) of TSCA also authorizes the EPA to regulate the disposal of PCBs consistent with the provisions in section 6(e)(2) and (3) of TSCA.

Section 6(e)(3)(B) of TSCA, however, stipulates that any person may petition the EPA Administrator for an exemption from the prohibition on the manufacture, processing, and distribution in commerce of PCBs. The Administrator may by rule grant an exemption if the Administrator finds that:

(i) An unreasonable risk of injury to health or the environment would not result, and (ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl. (15 U.S.C. 2605(e)(3)(B)(i)–(ii)).

The Administrator may prescribe terms and conditions for an exemption and may grant an exemption for a period of not more than one year from the date the petition is granted. In addition, section 6(e)(4) of TSCA requires that a rule under section 6(e)(3)(B) of TSCA be promulgated in accordance with sections 6(c)(2), (3) and (4) of TSCA, which provide for publication of a proposed rule, the opportunity for written comments and an informal hearing, if requested, and publication of a final rule.

EPA's procedures for rulemaking under section 6 of TSCA are found under 40 CFR part 750. This part includes Subpart B—Interim Procedural Rules for Manufacturing Exemptions, which describes the required content for manufacturing exemption petitions and the procedures that the EPA follows in rulemaking regarding these petitions. These rules are codified at 40 CFR 750.10 through 750.21.

III. Findings Necessary to Grant Petitions

A. No Unreasonable Risk Finding

Before granting an exemption petition, section 6(e)(3)(B)(i) of TSCA requires the Administrator to find that granting an exemption would not result in an unreasonable risk of injury to health or to the environment. The EPA expects a petitioner to demonstrate in its petition that the activity will not pose an unreasonable risk. (See 40 CFR 750.11).

To determine whether a risk is unreasonable, the EPA balances the probability that harm will occur to health or to the environment against the benefits to society from granting or denying each petition. See generally, 15 U.S.C. 2605(c)(1). Specifically, the EPA considers the following factors:

1. *Effects of PCBs on human health and the environment.* In deciding whether to grant an exemption, the EPA considers the magnitude of exposure and the effects of PCBs on humans and the environment. The following discussion summarizes EPA's assessment of these factors. A more complete discussion of human health and environmental effects of PCBs is provided in the advance notice of proposed rulemaking for the reassessment of PCB use authorizations in the **Federal Register** of April 7, 2010 (75 FR 17645) (Ref. 5). The Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile for PCBs (2000) has also provided a recent review of PCB human health and environmental effects (Ref. 6).

a. Health effects. The EPA has determined that PCBs cause significant human health effects, including cancer (classified as a probable human carcinogen), immune system suppression, liver damage, skin irritation, and endocrine disruption. PCBs also exhibit neurotoxicity, as well as reproductive and developmental toxicity. PCBs are readily absorbed through the skin and are absorbed at even faster rates when inhaled. Because PCBs are stored in animal fatty tissue, humans are also exposed to PCBs through ingestion of animal products.

b. Environmental effects. Certain PCB congeners are among the most stable chemicals known, and decompose very slowly once they are released into the environment. PCBs are absorbed and stored in the fatty tissue of higher organisms as they bioaccumulate up the food chain through invertebrates, fish, and mammals. Significantly, bioaccumulated PCBs appear to be even more toxic than those found in the ambient environment, since the more toxic PCB congeners are more persistent and thus more likely to be retained. PCBs also have reproductive and other toxic effects in aquatic organisms, birds, and mammals.

c. Risks. Toxicity and exposure are the two basic components of risk. The EPA has concluded that exposure of humans or the environment to PCBs may be significant, depending on such factors as the quantity of PCBs involved in the exposure and the effect of exposure. Minimizing exposure to PCBs should minimize potential risk. As shown through the 40 CFR part 761 regulations that detail proper disposal and storage options, the EPA has previously determined that some activities, including the disposal of PCBs in accordance with those regulations, pose no unreasonable risks. Other activities, such as long-term storage of PCB waste, are generally considered by the EPA to pose unreasonable risks.

2. *Benefits and costs.* The benefits to society of granting an exemption vary, depending on the activity for which the exemption is requested. The reasonably ascertainable costs of denying an exemption also vary, depending on the individual petition. As discussed in Section IV of this preamble, the EPA has taken benefits and costs into consideration when evaluating this exemption petition.

B. Good Faith Efforts Finding

Section 6(e)(3)(B)(ii) of TSCA requires the Administrator to find that ''good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for [PCBs].'' The EPA expects a petitioner to demonstrate in its petition how this standard is met. (See 40 CFR 750.11.) The EPA considers several factors in determining whether good faith efforts have been made. For each petition, the EPA considers the kind of exemption the petitioner is requesting. In each case, the burden is on the petitioner to show specifically what was done to substitute non-PCB material for PCBs or to show why it was not feasible to substitute non-PCBs for PCBs.

To satisfy this finding for requests for an exemption to import PCBs for disposal, a petitioner must show why such activities should occur in the United States and what steps have been taken to develop a substitute. While requiring a petitioner to demonstrate that good faith efforts to develop a substitute for PCBs makes sense when dealing with exemption petitions for traditional manufacture and distribution in commerce, the issue of the development of substitute chemicals seems to have little bearing on whether to grant a petition for exemption that would allow the import into the United States for disposal of PCB waste. However, because section 6(e)(3)(B) allows a petitioner to request an exemption from any of the prohibitions listed in section 6(e)(3)(A), it is appropriate to apply the standard in a way that is relevant to the particular exemption requested. Therefore, the relevant ''good faith'' issue for an exemption request to import PCBs for disposal in the customs territory of the United States is whether the disposal of the waste could and/or should occur outside the United States.

IV. Final Disposition of This Exemption Petition

A. The Petition: April 23, 2013 Petition to Import PCBs Located in Japan

On April 23, 2013, DLA submitted a petition seeking a 1–year exemption to import PCBs and PCB Items currently in storage at U.S. military installations in Japan (Ref. 1). DLA estimates as much as 1,014,222 pounds of waste contaminated with PCBs could be generated in Japan through calendar year 2014. The material in Japan consists of transformers (drained and un-drained), large and small capacitors, voltage regulators, switches, electromagnets, circuit breakers, reclosers, electrical cable, electric light ballasts, used dielectric fluids containing PCBs, and PCB-contaminated soil and debris (*e.g.,* rags, small parts, packaging materials). Ninety four percent of the waste is at PCB concentrations below 50 ppm. Details of the particular amounts and concentrations DLA is petitioning to import can be found in Attachment 1 of the DLA petition, which can be found in the docket to this rulemaking. The EPA has concluded that import of the DLA PCBs will not cause a shortage of domestic PCB storage or disposal capacity. In addition, the EPA has concluded the amounts of PCBs available for import are small in comparison to domestic generation, and pose little threat of overwhelming domestic disposal capacity (Ref. 4).

1. Information Regarding No Unreasonable Risk Provided by the Petitioner

DLA will package, transport, treat, and dispose of these PCBs in the same manner as PCBs identified in its previous petitions, which the EPA granted in 2003 and 2007 to allow the import of up to 4,293,621 and 1,328,428

pounds of waste contaminated with PCBs, respectively (Ref. 2, 3). Specifically, DLA notes its adherence to applicable modal and inter-modal national and/or international packaging, marking, labeling and shipping paper regulations, such as the United Nations Performance Oriented Packaging (UNPOP) standards, the International Maritime Dangerous Goods (IMDG) Code/International Maritime Organization (IMO) requirements, the International Civil Aviation Organization (ICAO) Technical Instructions, requirements of the International Air Transport Association (IATA), United Nations (UN) Recommendations on the Transport of Dangerous Goods Code, and provisions of the Hazardous Materials Regulations at 49 CFR 100–199. DLA further notes that proper handling and shipping will include blocking, bracing, over packing, and inclusion of spill containment devices, as required by applicable transportation regulations.

DLA further indicates it will handle and dispose of all PCBs and PCB Items in conformance with the PCB regulations at 40 CFR part 761. DLA has considerable experience and expertise in awarding and administering disposal contracts for PCBs and PCB Items in the U.S. and will award contracts with commercial firms in accordance with all applicable Federal procurement statutes and the Federal Acquisition Regulations (FAR). DLA additionally notes only companies with the required Federal and/or state-permits for the transportation, storage, treatment and disposal of PCBs and PCB Items would be considered as eligible for award of such contracts. DLA's exemption petition does not request to limit the storage, treatment or disposal of PCBs and PCB Items imported from Japan to management at a particular facility; rather DLA requests any storage, treatment, or disposal facility that has the appropriate Federal and/or state permits for PCBs and PCB Items and for which DLA has entered a contract be allowed to manage these materials.

DLA notes that it and its contractors have extensive experience in safely returning PCBs and PCB Items to the United States for treatment and disposal, and that DLA has returned several million pounds of PCBs and PCB Items for compliant disposal in the United States, including 3.6 million pounds of foreign-manufactured PCBs and PCB Items imported under the two previously granted exemptions. As noted previously, DLA had authority to import up to 5.5 million pounds of PCBs and PCB Items under the previous two exemptions. Throughout the course of this experience, DLA has used the same standards and procedures discussed above without spills or safety problems affecting human health or the environment.

2. Information Regarding Good Faith Efforts Provided by the Petitioner

DLA states in its petition that disposal of its PCBs and PCB Items in Japan is not an available disposal option. Specifically, as DLA noted in its exemption request, there are significant impediments to disposal on DOD military installations in Japan. For example, while there may exist certain mobile technology capable of treating some of the PCBs and PCB Items generated by United States military forces in Japan, there are also significant impediments to obtaining the permits that would be required to have that technology approved for use on United States military installations, where residual wastes and metals would still need to be taken off-installation for disposal. Complicating the situation further is any transfer or sale of property from the U.S. military installations into Japanese commerce is considered an ''import'' of property. Japan has banned the importation of PCBs and PCB Items at any detectable concentration, including concentrations below the very stringent 0.5 ppm level at which Japan regulates domestic PCBs. DLA's market research suggested a potential option could exist for disposal of some limited waste streams in newly permitted Japanese facilities (i.e., ''off-installation'' disposal). However, DLA has not been able to identify any change in Japanese law that would allow off-installation disposal in Japan nor the existence of any properly permitted vendor or technology that would be currently available to properly treat the DOD generated PCBs and PCB Items within the confines of the United States installations in Japan. Accordingly, on-site treatment does not present a reasonable alternative to the import of these wastes for proper disposal in the United States in compliance with the TSCA Section 6(e)(3).

DLA further notes disposal of this waste in another country is not a viable option. DLA cites its 1999 Report to Congress as background on the difficulty it faces in finding suitable disposal alternatives for PCBs and PCB Items generated or owned by DOD overseas. In particular, DLA discusses the difficulty of shipping waste from Japan to other countries as a result of the Basel Convention. Prior to its previous petitions, DLA and its primary disposal contractor made extensive contacts over a period of several years with Japanese officials and disposal facilities in numerous locations outside the United States in an effort to identify firms who could dispose of such PCBs and PCB Items while satisfying the Basel Convention requirements. At that time, the DOD also consulted at length with State Department officials in Japan and in the United States whose responsibilities include international environmental matters. The variety of problems identified in these contacts regarding overseas disposal of certain PCB Items resulted in a consensus that use of existing facilities in other developed countries was not a reasonable alternative. Even if other countries had the physical capacity to accept these wastes, non-governmental organizations might be expected to oppose the DOD's disposal of its waste in third countries (that is, countries other than Japan and the United States) because the United States has the technical capability to properly dispose of the hazardous materials itself.

DLA concludes that its diligent but so far unsuccessful attempts to locate appropriate disposal sites outside the United States demonstrate its good faith efforts to pursue alternatives to disposal within the United States and fulfill the requirements of TSCA 6(e)(3)(B).

B. What comment did the EPA receive and how is it addressed?

On April 2, 2014, the EPA published a direct final rule with an accompanying proposed rule in the **Federal Register** (79 FR 18471). In that rule, we noted if adverse comments or a request for an informal hearing were received, then the EPA would publish a timely withdrawal in the **Federal Register** informing the public that this rule would not take effect based on the direct final rule. We also stated that we would then address all public comments in any subsequent final rule based on the proposed rule which accompanied the direct final rule.

During the public comment period, the EPA received one adverse comment and request for informal hearing. The comment received states in part, ''In brief, since the first two permissions were granted in 2003 and 2007, there have been alarming increases in previously rare malignancies such as melanoma and liver carcinoma. Additionally even common malignancies such as breast cancer have had substantial rises. PCBs have also been linked to endocrine disorders such as diabetes and obesity both of which have seen dramatic increasing trends'' (Docket Document ID EPA–HQ–RCRA–2013–0396–0004). The comment did not include specific information to support

the claim of increased numbers of cancers nor did the comment include any support for the claim that this increase is due to PCB exposures.

On June 13, 2014, the EPA published a withdrawal of the direct final rule and notice of informal hearing (79 FR 33867). During the informal hearing, held on July 8, 2014, the EPA received one presentation, which was submitted by the same person who submitted the adverse comment and request for an informal hearing. The presentation included a request for the EPA to update EPA's classification of PCBs from a probable human carcinogen to a known human carcinogen, as well as included citations to studies purportedly indicating a connection between certain types of cancers and PCBs (Docket Document ID EPA–HQ–RCRA–2013–0396–0011). In the direct final rule for this action, as well as re-stated in this final rule, the EPA recognizes cancer as a possible health effect from exposure to PCBs. Therefore, neither information in the comment nor in the presentation characterizes risks of PCBs that were not previously considered by the EPA, and the information does not change EPA's evaluation that granting this exemption will not result in an unreasonable risk of injury to health or the environment. Specifically, the additional research states cancer has been associated with PCB exposure, and argues PCBs are causal for a specific cancer (e.g., non-Hodgkin lymphoma), is insufficient to demonstrate that proper disposal in accordance with our regulations would result in an unreasonable risk. The PCB wastes under this exemption must be properly disposed of according to the regulations set forth in 40 CFR part 761.

C. EPA's Final Decision on the Petition: April 23, 2013 Petition; EPA is Granting This Petition

1. *No unreasonable risk determination.* The EPA finds generally that the disposal of imported PCBs and PCB Items at an EPA-approved PCB disposal facility poses no unreasonable risks as these facilities have been approved on the basis of that standard. In addition, as with the previous two petitions, the EPA concurs with DLA's assessment that transportation of this waste will pose no unreasonable risk if conducted in accordance with all applicable laws and regulations. Therefore, for the following reasons, the EPA finds there is no unreasonable risk from importing the PCBs and PCB Items by DLA from Japan to the United States for disposal, as outlined below.

i. PCBs are hazardous and pose a potential risk to health and the environment. Proper disposal in accordance with the 40 CFR part 761 regulations would reduce PCB-associated risks.

ii. Risk results from a combination of exposure (likelihood, magnitude and duration) and the probability of effects occurring under the conditions of exposure. Because the probability of a transport accident occurring is low (Ref. 4), the likelihood of exposure to PCBs is commensurately low. Consequently, the probability of adverse effects to human health or the environment is low.

iii. The PCB-containing materials will be packaged in a manner consistent with Federal, State, and local regulations addressing the risks associated with the storage and transportation of hazardous wastes. In addition, PCB waste will be continuously monitored during the ocean transport from Japan to the United States. Contingency plans are required by the International Maritime Dangerous Goods Code and U.S. Department of Transportation (DOT) to be in place before and after the import of PCB-containing items to the United States. Moreover, the PCB Items that will be transported to the United States generally have a low combustion likelihood, which will make the probability of fires low. Together, these contingency measures will minimize exposure to humans and the environment in the event of an accident or emergency during ocean transport.

iv. Given the aforementioned information, the exposure likelihood, frequency, and duration are so low that even though PCBs are considered to be highly hazardous, any risk resulting from the combined exposure and hazard potential would not be unreasonable to human health or the environment.

v. The potential for human health risks are further mitigated by the limited duration of potential exposure. Under the transport scenario proposed, any exposures to humans (i.e., accidental or emergency situation) would be of very short duration. Hence, the low probability of exposure occurring combined with the short-term duration of exposure, should one occur, further support a qualitative conclusion that there is no unreasonable risk to human health.

vi. The long-term concern is the potential for accumulation in the ecological environment. Under a worst case scenario where all of the PCBs were released due to an unforeseen and unlikely catastrophic event during transport, PCB-exposed biological receptors could be adversely affected. However, this scenario would require a failure of all safeguards that will be in place. Furthermore, the alternative of storing the PCBs indefinitely seems to pose more risk than transport. Moreover, should an accident occur, emergency response authorities would be invoked to mitigate and/or remediate exposures.

2. *Good faith efforts to find substitutes met.* Section 6(e)(3)(B)(ii) of TSCA requires the Administrator to make an additional finding, that ''good faith efforts have been made to develop a chemical substance that does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.'' The EPA has interpreted this provision to require that a petitioner has the burden of demonstrating that it has made the requisite good faith efforts to identify alternatives to management of the PCB waste in the United States. (See 40 CFR 750.11).

The EPA finds that DLA has demonstrated good faith efforts to find alternatives to disposal of this PCB waste in the United States. The EPA acknowledges the restrictions to disposing of this waste in Japan. DLA has also explored exporting this waste to other countries as an alternative. However, DLA has indicated, and the EPA acknowledges, the peculiar circumstances of DOD's PCBs and PCB Items, which, while present in one country (i.e., Japan), are generated by another country's government, leading to significant difficulty in providing Basel Convention notification to third countries. Given these difficulties, the EPA concurs with DLA's conclusion that disposal in a third country (that is, countries other than Japan and the United States) is not a viable alternative for this waste.

3. *Benefits of Granting the Petition*

i. *Avoiding the risks of long-term storage.* The EPA believes granting the petition to DLA to import 1,014,222 pounds of waste contaminated with PCBs (94% of which is less than 50 ppm) will benefit the United States and the environment in general. As DLA notes, the continued long-term storage of PCB waste on U.S. military facilities in Japan poses risks to U.S. personnel and the environment—risks that can be eliminated through the action finalized in the petition.

ii. *Ensuring proper and safe disposal.* Granting the petition allows the United States to accept responsibility for the PCBs and PCB Items it generates by assuring proper and safe disposal in domestic permitted disposal facilities.

iii. *Ensuring the safety of Japanese citizens.* The EPA considers the reduction of risk to Japanese citizens to

be advantageous, especially in light of the heightened concerns over PCBs in that country. Granting the petition is the only practical mechanism to remove this waste from Japan; otherwise, the U.S. military would be required to explain to its Japanese hosts that it cannot remove its own toxic waste from their country because U.S. law does not allow the waste to be sent to the United States.

For all these reasons, the EPA finds DLA has satisfied the exemption criteria of TSCA section 6(e)(3)(B) and is granting the petition.

V. References

1. DOD, DLA. Petition from David Rodriguez, Director to EPA. Subject: Petition to the United States Environmental Protection Agency For an Exemption Under the Toxic Substances Control Act to Import Polychlorinated Biphenyls (PCB) and PCB Items for Disposal. April 23, 2013. 19 pp.

2. EPA, OPPT. Polychlorinated Biphenyls; Manufacturing (Import) Exemption. Final Rule. **Federal Register** (72 FR 53152, September 18, 2007) (FRL–8143–4). Available on-line at *https://www.federalregister.gov/articles/2007/09/18/E7-18345/polychlorinated-biphenyls-manufacturing-import-exemption,* Document ID: EPA–HQ–OPPT–2005–0042–0008.

3. EPA, OPPT. Polychlorinated Biphenyls; Manufacturing (Import) Exemptions. Final Rule. **Federal Register** (68 FR 4934, January 31, 2003) (FRL–7288–6). Available on-line at *http://www.federalregister.com/Browse/Document/usa/na/fr/2003/1/31/03-2344,* Document ID: EPA–HQ–OPPT–2002–0013–0041.

4. EPA, OPPT. Disposal of Polychlorinated Biphenyls; Import for Disposal. Final Rule. **Federal Register** (61 FR 11095, March 18, 1996) (FRL–5354–8). Available on-line at *http://www.epa.gov/fedrgstr/EPA-TOX/1996/March/Day-18/pr-24122.txt.html.*

5. EPA, OPPT. Polychlorinated Biphenyls (PCBs); Reassessment of Use Authorizations. Advanced Notice of Proposed Rulemaking. **Federal Register** (75 FR 17645, April 7, 2010). (FRL–8811–7). Available on-line at *http://www.regulations.gov,* Document ID: EPA–HQ–OPPT–2009–0757–0001.

6. The U.S. Department of Agriculture, Public Health Service, Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile for Polychlorinated Biphenyls (PCBs) (November 2000). Available online at *http://www.atsdr.cdc.gov/toxprofiles/tp17.pdf.*

VI. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), this action is not a ''significant regulatory action'' and is therefore not subject to OMB review. Because this action is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) or Sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments. This action does not create new binding legal requirements that substantially and directly affect Tribes under Executive Order 13175 (65 FR 67249, November 9, 2000). This action does not have significant Federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). 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., 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). This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. Under the CRA, 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).

List of Subjects in 40 CFR Part 761

Environmental protection, Hazardous substances, and Polychlorinated biphenyls.

Dated: September 19, 2014.

Mathy Stanislaus,

Assistant Administrator, Office of Solid Waste and Emergency Response.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 761—POLYCHLORINATED BIPHENYLS (PCBs) MANUFACTURING, PROCESSING, DISTRIBUTION IN COMMERCE, AND USE PROHIBITIONS

■ 1. The authority citation for Part 761 continues to read as follows:

Authority: 15 U.S.C. 2605, 2607, 2611, 2614, and 2616.

Subpart E—[Amended]

■ 2. Section 761.80 is amended by revising paragraph (j) to read as follows:

§ 761.80 Manufacturing, processing and distribution in commerce exemptions.

* * * * *

(j) The Administrator grants the United States Defense Logistics Agency's April 23, 2013 petition for an exemption for 1 year beginning on October 1, 2014, to import up to 1,014,222 pounds of PCBs and PCB Items stored or in use in Japan as identified in its petition for disposal.

* * * * *

[FR Doc. 2014–23104 Filed 9–26–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 1, 4, 6, 10, 11, 12, 13, 14, 15, 24, 27, 28, 30, 35, 38, 42, 44, 45, 52, 62, 67, 69, 70, 71, 72, 76, 77, 78, 90, 92, 95, 97, 105, 109, 111, 114, 115, 117, 119, 121, 122, 131, 150, 151, 153, 154, 159, 160, 161, 162, 163, 164, 167, 169, 171, 172, 174, 175, 176, 180, 181, 182, 185, 188, 189, 190, 194, 196, 197, and 199

[Docket No. USCG–2014–0688]

RIN 1625–ZA33

Shipping and Transportation; Technical, Organizational, and Conforming Amendments

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is issuing a final rule that makes non-substantive changes throughout Title 46 of the Code of Federal Regulations. The purpose of this rule is to make conforming amendments and technical corrections to Coast Guard regulations. This rule will have no substantive effect on the regulated public. These changes are provided to coincide with the annual recodification of Titles 46 and 49 on October 1, 2014.

DATES: This final rule is effective September 29, 2014.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2014–0688 and are available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov* and following the instructions on that Web site.

FOR FURTHER INFORMATION CONTACT: If you have questions on this final rule, call or email Mr. Paul H. Crissy, Coast Guard; telephone 202–372–1093, email *Paul.H.Crissy@uscg.mil*. If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations
II. Regulatory History
III. Background and Purpose
IV. Discussion of the Rule
V. Regulatory Analyses
A. Regulatory Planning and Review
B. Small Entities
C. Assistance for Small Entities
D. Collection of Information
E. Federalism
F. Unfunded Mandates Reform Act
G. Taking of Private Property
H. Civil Justice Reform
I. Protection of Children
J. Indian Tribal Governments
K. Energy Effects
L. Technical Standards
M. Environment

I. Abbreviations

CFR Code of Federal Regulations
DDE Designated Duty Engineer
DHS Department of Homeland Security
E.O. Executive Order
FR Federal Register
MMC Merchant Mariner Credential
OMB Office of Management and Budget
§ Section symbol
TRE Type-rating Endorsement
U.S.C. United States Code

II. Regulatory History

We did not publish a notice of proposed rulemaking for this rule. Under 5 U.S.C. 553(b)(A), the Coast Guard finds that this rule is exempt from notice and comment rulemaking requirements, because these changes involve rules of agency organization, procedure, or practice. In addition, the Coast Guard finds that notice and comment procedures are unnecessary under 5 U.S.C. 553(b)(B), as this rule consists only of corrections and editorial, organizational, and conforming amendments, and that these changes will have no substantive effect on the public. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this final rule effective upon publication in the **Federal Register**. It is unnecessary to delay the effective date of this rule because the final rule consists only of corrections and editorial, organizational, and conforming amendments that have no substantive effect on the public.

III. Background and Purpose

On the 1st of October each year, the printed editions of Titles 46 and 49 of the Code of Federal Regulations (CFR) are re-codified. This rule, which becomes effective September 29, 2014 makes technical and editorial corrections throughout Title 46. There are no technical or editorial corrections for Title 49 this year. This rule does not create or change any substantive requirements. For a comprehensive list of each change in Title 46 in the CFR, see the Table of Changes available in the docket for this rulemaking.

IV. Discussion of the Rule

This rule corrects misspellings and punctuation in sections throughout Title 46 in the CFR. For a list of each correction, see the Table of Misspellings available in the docket for this rulemaking.

This rule amends 46 CFR 6.06(b)(2) to reflect a name change from ''Military Sea Transportation Service'' to ''Military Sealift Command.''

This rule amends 46 CFR 10.211(c) to strike the phrase ''Beginning April 15, 2009,'' as it is unnecessary. When originally drafted, this section was to become effective April 15, 2009. However, the rule containing this provision did not publish prior to that date, so the qualifying date was and is unnecessary.

This rule corrects a typographical error in 46 CFR 11.201(h) by removing an extra (1) before the sentence beginning with ''The firefighting course must have been completed. . . .'' The (1) is incorrectly included in a paragraph already labeled (1).

This rule amends 46 CFR 11.301(g)(3) and 12.601(c)(3) by correcting the phrase ''was completed before March 24, 2014 . . .'' to ''commenced before March 24, 2014.'' This change corrects a typo that is inconsistent with other provisions of 11.301. This change also reflects the intent of the Implementation of the Amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, and Changes to National Endorsements (STCW) final rule, and is supported by the final rule's preamble. 78 FR 77862. The STCW regulations were written with timing and implementation in mind. The training required by the STCW final rule will take some time to implement. To avoid a delay in the availability of qualified candidates, the existing training would need to be sufficient, in the interim, to qualify officers for the intended credential. Therefore, training that was ''commenced by March 24, 2014'' was the true intent of the STCW regulations, and therefore is corrected in this amendment.

This rule amends several sections of 46 CFR part 11 to align language in the regulations with what is actually written on Merchant Mariner Credential (MMC) endorsements. For a list of corrections, see Table 1.

TABLE 1—CORRECTIONS IN 46 CFR PART 11

CFR Parts	Old text/current CFR	New text/revision
11.305 (section heading)	Requirements to qualify for an STCW endorsement as master on vessels of 3,000 GT or more (management level).	Requirements to qualify for an STCW endorsement as master of vessels of 3,000 GT or more (management level).
Table 1 to 11.305(E)	STCW Endorsement as Master on Vessels of 3,000 GT or More.	STCW Endorsement as Master of Vessels of 3,000 GT or More.
11.307 (section heading)	Requirements to qualify for an STCW endorsement as chief mate on vessels of 3,000 GT or more (management level).	Requirements to qualify for an STCW endorsement as chief mate of vessels of 3,000 GT or more (management level).
Table 1 to 11.307(E)	STCW Endorsement as Chief Mate on Vessels of 3,000 GT or More.	STCW Endorsement as Chief Mate of Vessels of 3,000 GT or More.

TABLE 1—CORRECTIONS IN 46 CFR PART 11—Continued

CFR Parts	Old text/current CFR	New text/revision
Table 1 to 11.309(E)	STCW Endorsement as OICNW on Vessels of 500 GT or More.	STCW Endorsement as OICNW of Vessels of 500 GT or More.
Table 1 to 11.311(D)	STCW Endorsement as Master on Vessels of 500 GT or More and Less Than 3,000 GT.	STCW Endorsement as Master of Vessels of 500 GT or More and Less Than 3,000 GT.
Table 1 to 11.313(D)	STCW Endorsement as Chief Mate on Vessels of 500 GT or More and Less Than 3,000 GT.	STCW Endorsement as Chief Mate of Vessels of 500 GT or More and Less Than 3,000 GT.
11.459 (section heading)	Requirements for national endorsement as master or mate of rivers.	Requirements for national endorsement as master or mate on rivers.

This rule amends 46 CFR 11.309(a)(4)(v), 11.317(a)(3)(iii), 11.319(a)(4)(v), 11.321(a)(3)(iii), 11.329(a)(3)(iii), and 11.335(a)(3)(iii) to include proficiency in survival craft and rescue boats other than lifeboats and fast rescue boats (Personal Survival Craft-limited). This change clarifies the language in these sections to be consistent with 46 CFR 12.617(a)(2) and the intent of the STCW regulations, since an endorsement holder could be required to hold one of several Personal Survival Craft endorsements.

This rule amends 46 CFR 11.329(e) to replace an erroneously printed table. The current table is a repeat of Table 11.327(d), and the correct table was included in the final rule text submitted to the Office of the Federal Register. The correct table, which appears below in the regulatory text, was available for notice and comment in the STCW SNPRM, and there were no comments made regarding that table. [78 FR 77796].

This rule amends Table 1 to 11.331(e) to include a missing footnote. As in Tables 11.325(d) footnote 5, 11.327(d) footnote 4, and 11.329(e) footnote 1, the table should limit vessels less than 500 GRT for both Designated Duty Engineer (DDE) entries. This change is consistent with the limitations placed on DDEs in Part 11 and therefore the added footnote is a reminder of those limitations.

This rule amends 46 CFR 11.335(b) to remove a redundant phrase. The phrase that will be omitted from paragraph (b) is repeated in subparagraph (b)(2). Removal of this phrase brings clarity to the paragraph but does not change the requirements.

This rule amends 46 CFR 11.493(b) and (c) to correct misstated terminology. The words ''an endorsement as'' will be removed before ''master (OSV)'' as the master (OSV) of 1,600 GRT/3,000 GT or more is not the name of an endorsement.

This rule amends 46 CFR 11.495(b) and (c) to correct misstated terminology. The words ''for an endorsement as'' will be removed before ''chief mate (OSV)'', as chief mate (OSV) of 1,600 GRT/3,000 GT or more is not the name of an endorsement.

This rule amends 46 CFR 11.555(a)(2) to align the paragraph with the correct endorsement. We add the word ''assistant'' because this section applies to assistant engineers.

This rule amends paragraphs (b) through (e) in 46 CFR 11.821 to correct terminology relating to an endorsement. The high-speed craft type-rating endorsement (TRE) was erroneously referred to as a ''certificate;'' however, in 46 CFR 11.109(a)(44), it is identified as one of the national officer endorsements to an MMC. This was an oversight in drafting.

This rule amends 46 CFR 11.903(c)(1) to remove the phrase ''and STCW endorsement,'' as it is unnecessary. This paragraph speaks to national endorsements and does not require a discussion with regard to STCW endorsements. Therefore, the reference to an STCW endorsement is removed.

In Table 2 of 46 CFR 11.910, under the National Maritime Law heading, the title of ''Licensing and Certification of Seaman'' is changed to ''Credentialing of Seaman.'' This change reflects the movement from a license to a credential. The change does not alter the substance of the relevant course, but rather changes the title of the course to improve accuracy.

This rule amends the following sections to remove repetitive tables: 46 CFR 24.05–1(a), 70.05–1(a), 90.05–1(a), and 188.05–1(a). The repetitive tables are duplications of information contained in Table 2.01–7(A), and therefore we replace the tables with a reference back to the complete, original table published as Table 2.01–7(A) in 46 CFR 2.01–7(a). The removal of the duplicative tables will alleviate any errors in reproducing the tables and ensure that any changes to Table 2.01–7(A) will be consistent throughout Title 46.

This rule amends 46 CFR 28.50, 28.255(a)(1), 35.20–1(a), 78.05–1(a), 78.10–1, 97.05–1(a), 97.10–5, 131.910, 167.65–45(a), and 196.05–1(a), to reflect an agency name change from ''the Defense Mapping Agency Hydrographic/Topographic Center'' or ''the National Imagery and Mapping Agency'' to ''the National Geospatial-Intelligence Agency.'' Sections 35.20–1(c), 78.05–1(b), 97.05–1(b), 167.65–45(b), and 196.05–1(b) are amended to incorporate the same name change as well as to expand the weekly notices to national coverage of local notices to mariners instead of being geographically limited. A Web site is added where the notices are accessible to the public free of charge.

Further, these sections will incorporate the name change and also the new method of access for worldwide weekly notices. The former system in which worldwide information is accessed is no longer available. Therefore, we revise the sections to include a reference to a Web site where the notices are accessible to the public.

This rule amends 46 CFR 52.25–5 to correct a typographical error. The word ''of'' is repeated twice. This rule will remove that repetition.

This rule amends 46 CFR 76.10–10 to remove the ''-T/ALL'' designation from its section heading. This designation is not applicable to its subpart and was included erroneously.

This rule amends 46 CFR 153.1119(c)(1) to update the contact information for the Coast Guard's Office of Design and Engineering Standards (CG–ENG). This final rule updates the phone number to 202–372–1420, and adds the *HazmatStandards@uscg.mil* email address.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders (E.O.s) related to rulemaking. Below we summarize our analyses based on these statutes and E.O.s.

A. Regulatory Planning and Review

E.O.s 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This rule is not a significant regulatory action under section 3(f) of E.O. 12866 as supplemented by E.O. 13563, and does not require an assessment of potential costs and benefits under section 6(a)(3) of E.O. 12866. The Office of Management and Budget (OMB) has not reviewed it under E.O. 12866. Nonetheless, we assessed the costs and benefits of the rule to ascertain its probable impacts on industry. Because this rule involves non-substantive changes and internal agency practices and procedures, it will not impose any additional costs on the public.

B. Small Entities

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, rules exempt from the notice and comment requirements of the Administrative Procedure Act are not required to examine the impact of the rule on small entities. Nevertheless, 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.

There is no cost to this rule, and we do not expect it to have an impact on small entities, because the provisions of this rule are technical and non-substantive. This rule will have no substantive effect on the public and will impose no additional costs. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we offer to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If this rule would affect your small business, organization, or governmental jurisdiction, and you have questions concerning its provisions or options for compliance, please contact Mr. Paul Crissy by telephone at 202–372–1093, or via email at *Paul.H.Crissy@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. 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.

E. Federalism

A rule has implications for federalism under E.O. 13132 (''Federalism'') if it has 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. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

F. 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 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under E.O. 12630 (''Governmental Actions and Interference with Constitutionally Protected Property Rights'').

H. Civil Justice Reform

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

I. Protection of Children

We have analyzed this rule under E.O. 13045 (''Protection of Children from Environmental Health Risks and Safety Risks''). This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under E.O. 13175 (''Consultation and Coordination with Indian Tribal Governments''), because it would 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.

K. Energy Effects

We have analyzed this rule under E.O. 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 E.O. 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of OMB's 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 E.O. 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act, codified as a note to 15 U.S.C. 272, directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, 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 final rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards in this rule.

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969, 42 U.S.C. 4321–4370f, and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under section 2.B.2, figure 2–1, paragraph (34)(a) of the Instruction. This rule involves amendments to regulations which are editorial or procedural. An environmental analysis checklist and a categorical exclusion determination are available in the docket for this rule where indicated under **ADDRESSES**.

List of Subjects

46 CFR Part 1

Administrative practice and procedure, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

46 CFR Part 4

Administrative practice and procedure, Drug testing, Investigations, Marine safety, Nuclear vessels, Radiation protection, Reporting and recordkeeping requirements, Safety, Transportation.

46 CFR Part 6

Navigation (water), Reporting and recordkeeping requirements, Vessels.

46 CFR Part 10

Penalties, Reporting and recordkeeping requirements, Schools, Seamen.

46 CFR Part 11

Incorporation by reference, Penalties, Reporting and recordkeeping requirements, Schools, Seamen.

46 CFR Part 12

Penalties, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 13

Cargo vessels, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 14

Oceanographic research vessels, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 15

Reporting and recordkeeping requirements, Seamen, Vessels.

46 CFR Part 24

Marine safety.

46 CFR Part 27

Fire prevention, Marine safety, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 28

Alaska, Fire prevention, Fishing vessels, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 30

Cargo vessels, Foreign relations, Hazardous materials transportation, Penalties, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 35

Cargo vessels, Marine safety, Navigation (water), Occupational safety and health, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 38

Cargo vessels, Fire prevention, Gases, Hazardous materials transportation, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 42

Penalties, Reporting and recordkeeping requirements, Vessels.

46 CFR Parts 44, 52, 62, 67

Reporting and recordkeeping requirements, Vessels.

46 CFR Part 45

Great Lakes, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 69

Measurement standards, Penalties, Reporting and recordkeeping requirements, Vessels.

46 CFR Parts 70 and 71

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 72

Fire prevention, Marine safety, Occupational safety and health, Passenger vessels, Seamen.

46 CFR Part 76

Fire prevention, Marine safety, Passenger vessels.

46 CFR Part 77

Marine safety, Navigation (water), Passenger vessels.

46 CFR Part 78

Marine safety, Navigation (water), Passenger vessels, Penalties, Reporting and recordkeeping requirements.

46 CFR Part 90

Cargo vessels, Marine safety.

46 CFR Part 92

Cargo vessels, Fire prevention, Marine safety, Occupational safety and health, Seamen.

46 CFR Part 95

Cargo vessels, Fire prevention, Marine safety.

46 CFR Part 97

Cargo vessels, Marine safety, Navigation (water), Reporting and recordkeeping requirements.

46 CFR Part 105

Cargo vessels, Fishing vessels, Hazardous materials transportation, Marine safety, Petroleum, Seamen.

46 CFR Part 109

Marine safety, Occupational safety and health, Oil and gas exploration, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 111

Vessels.

46 CFR Parts 114 and 175

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Parts 115 and 176

Fire prevention, Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Parts 117 and 119

Marine safety, Passenger vessels.

46 CFR Part 121

Communications equipment, Marine safety, Navigation (water), Passenger vessels.

46 CFR Part 122

Marine safety, Passenger vessels, Penalties, Reporting and recordkeeping requirements.

46 CFR Part 131

Cargo vessels, Fire prevention, Marine safety, Navigation (water), Occupational safety and health, Reporting and recordkeeping requirements.

46 CFR Part 150

Hazardous materials transportation, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements.

46 CFR Part 151

Cargo vessels, Hazardous materials transportation, Marine safety, Reporting and recordkeeping requirements, Water pollution control.

46 CFR Part 153

Administrative practice and procedure, Cargo vessels, Hazardous materials transportation, Marine safety, Reporting and recordkeeping requirements, Water pollution control.

46 CFR Part 154

Cargo vessels, Gases, Hazardous materials transportation, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 159

Business and industry, Laboratories, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 160

Marine safety, Reporting and recordkeeping requirements.

46 CFR Parts 161 and 164

Fire prevention, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 162

Fire prevention, Marine safety, Oil pollution, Reporting and recordkeeping requirements.

46 CFR Part 163

Marine safety.

46 CFR Part 167

Fire prevention, Marine safety, Reporting and recordkeeping requirements, Schools, Seamen, Vessels.

46 CFR Part 169

Fire prevention, Marine safety, Reporting and recordkeeping requirements, Schools, Vessels.

46 CFR Parts 171 and 180

Marine safety, Passenger vessels.

46 CFR Part 172

Cargo vessels, Hazardous materials transportation, Marine safety.

46 CFR Part 174

Marine safety, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 181

Fire prevention, Marine safety, Passenger vessels.

46 CFR Part 182

Marine safety, Passenger vessels.

46 CFR Part 185

Marine safety, Passenger vessels, Reporting and recordkeeping requirements.

46 CFR Part 188

Marine safety, Oceanographic research vessels.

46 CFR Part 189

Marine safety, Oceanographic research vessels, Reporting and recordkeeping requirements.

46 CFR Part 190

Fire prevention, Marine safety, Occupational safety and health, Oceanographic research vessels.

46 CFR Part 194

Explosives, Hazardous materials transportation, Marine safety, Oceanographic research vessels.

46 CFR Part 196

Marine safety, Oceanographic research vessels, Reporting and recordkeeping requirements.

46 CFR Part 197

Benzene, Diving, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 199

Cargo vessels, Marine safety, Oil and gas exploration, Passenger vessels, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 46 CFR Parts 1, 4, 6, 10, 11, 12, 13, 14, 15, 24, 27, 28, 30, 35, 38, 42, 44, 45, 52, 62, 67, 69, 70, 71, 72, 76, 77, 78, 90, 92, 95, 97, 105, 109, 111, 114, 115, 117, 119, 121, 122, 131, 150, 151, 153, 154, 159, 160, 161, 162, 163, 164, 167, 169, 171, 172, 174, 175, 176, 180, 181, 182, 185, 188, 189, 190, 194, 196, 197, and 199 as follows:

Title 46—SHIPPING

PART 1—ORGANIZATION, GENERAL COURSE AND METHODS GOVERNING MARINE SAFETY FUNCTIONS

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

Authority: 5 U.S.C. 552; 14 U.S.C. 633; 46 U.S.C. 7701; 46 U.S.C. Chapter 93; Pub. L. 107–296, 116 Stat. 2135; Department of Homeland Security Delegation No. 0170.1; section 1.01–35 also issued under the authority of 44 U.S.C. 3507.

§ 1.01–15 [Amended]

■ 2. Amend 1.01–15 as follows:

■ a. In paragraph (a)(1), remove the text ''credentialiing,'' and add, in its place, the text ''credentialing,''; and

■ b. In paragraph (c)(2), after the text ''Refer to the'' and before the text ''detachment, the Suspension'', remove the text ''processingNMC'' and add, in its place, the text ''processing NMC''.

PART 4—MARINE CASUALTIES AND INVESTIGATIONS

■ 3. The authority citation for part 4 continues to read as follows:

Authority: 33 U.S.C. 1231; 43 U.S.C. 1333; 46 U.S.C. 2103, 2303a, 2306, 6101, 6301, and 6305; 50 U.S.C. 198; Department of Homeland Security Delegation No. 0170.1. Subpart 4.40 issued under 49 U.S.C. 1903(a)(1)(E).

§ 4.05–1 [Amended]

■ 4. In § 4.05–1(a)(1), after the text ''unintended strike of ('' and before the text ''with) a bridge'', remove the text ''allison'' and add, in its place, the text ''allision''.

PART 6—WAIVERS OF NAVIGATION AND VESSEL INSPECTION LAWS AND REGULATIONS [1]

■ 5. The authority citation for part 6 continues to read as follows:

Authority: Act Dec. 27, 1950, Ch. 1155, secs. 1, 2, 64 Stat. 1120 (*see* 46 U.S.C. App. note prec. 1); Department of Homeland Security Delegation No. 0170.1.

§ 6.06 [Amended]

■ 6. In § 6.06(b)(2), after the words ''national defense and is necessary for the Military'', and before the words ''to carry out an assigned mission;'' remove the words ''Sea Transportation Service'' and add, in their place, the words ''Sealift Command''.

PART 10—MERCHANT MARINER CREDENTIAL

■ 7. The authority citation for part 10 continues to read as follows:

Authority: 14 U.S.C. 633; 31 U.S.C. 9701; 46 U.S.C. 2101, 2103, 2110; 46 U.S.C. Chapter 71; 46 U.S.C. Chapter 73; 46 U.S.C. Chapter 75; 46 U.S.C. 2104; 46 U.S.C. 7701, 8903, 8904, and 70105; Executive Order 10173; Department of Homeland Security Delegation No. 0170.1.

§ 10.211 [Amended]

■ 8. In § 10.211(c), after the text ''Fingerprints.'' and before the text ''the Transportation Security Administration (TSA)'', remove the text ''Beginning April 15, 2009,''.

[1] This is also codified in 33 CFR part 19.

PART 11—REQUIREMENTS FOR OFFICER ENDORSEMENTS

■ 9. The authority citation for part 11 continues to read as follows:

Authority: 14 U.S.C. 633; 31 U.S.C. 9701; 46 U.S.C. 2101, 2103, and 2110; 46 U.S.C. Chapter 71; 46 U.S.C. 7502, 7505, 7701, 8906, and 70105; Executive Order 10173; Department of Homeland Security Delegation No. 0170.1. Section 11.107 is also issued under the authority of 44 U.S.C. 3507.

§ 11.201 [Amended]

■ 10. In § 11.201(h), after the text ''approved by the Coast Guard.'' and before the text ''The firefighting course must have been completed'', remove the text ''(1)''; and in § 11.201(h)(2), after the text ''advanced firefighting in'' and before the text ''and VI/3 of the STCW'', remove the text ''RegulationsVI/1'', and add in its place the text ''Regulations VI/1''.

§ 11.301 [Amended]

■ 11. In § 11.301(g)(3), after the words ''approved seagoing service that'' and before the words ''before March 24, 2014,'' remove the words ''was completed'' and add, in their place, the word ''commenced''.

§ 11.305 [Amended]

■ 12. Amend § 11.305 as follows:

■ a. In § 11.305 heading, after the words ''an STCW endorsement as master'' and before the words ''vessels of 3,000 GT or more'', remove the word ''on'' and add, in its place, the word ''of''; and

■ b. In Table 1 to § 11.305(E) heading, after the words ''STCW Endorsement as Master'' and before the words ''Vessels of 3,000 GT or More'', remove the word ''on'' and add, in its place, the word ''of''.

§ 11.307 [Amended]

■ 13. Amend § 11.307 as follows:

■ a. In the heading, after the words ''STCW endorsement as chief mate'' and before the words ''vessels of 3,000 GT or more'', remove the word ''on'' and add, in its place, the word ''of''; and

■ b. In Table 1 to § 11.307(E) heading, after the words ''STCW Endorsement as Chief Mate'' and before the words ''Vessels of 3,000 GT or More'', remove the word ''on'' and add, in its place, the word ''of''.

§ 11.309 [Amended]

■ 14. Amend § 11.309 as follows:

■ a. In paragraph (a)(4)(v), after the words ''than fast rescue boats'' and before the ''.'', add the words ''(PSC) or proficiency in survival craft and rescue boats other than lifeboats and fast rescue boats (PSC-limited)''; and

■ b. In Table 1 to § 11.309(E) heading, after the words ''STCW Endorsement as OICNW'' and before the words ''Vessels of 500 GT or More'', remove the word ''on'' and add, in its place, the word ''of''.

§ 11.311 [Amended]

■ 15. In Table 1 to § 11.311(D) heading, after the words ''STCW Endorsement as Master'' and before the words ''Vessels of 500 GT or More'', remove the word ''on'' and add, in its place, the word ''of''.

§ 11.313 [Amended]

■ 16. In Table 1 to § 11.313(D) heading, after the words ''STCW Endorsement as Chief Mate'' and before the words ''Vessels of 500 GT or More'', remove the word ''on'' and add, in its place, the word ''of''.

§ 11.317 [Amended]

■ 17. In § 11.317 (a)(3)(iii), after the words ''boats other than fast rescue boats'' and before the ''.'', add the words ''(PSC) or proficiency in survival craft and rescue boats other than lifeboats and fast rescue boats (PSC-limited)''.

§ 11.319 [Amended]

■ 18. In § 11.319(a)(4)(v), after the words ''other than fast rescue boats'' and before the period, add the words ''(PSC) or proficiency in survival craft and rescue boats other than lifeboats and fast rescue boats (PSC-limited)''.

§ 11.321 [Amended]

■ 19. In § 11.321(a)(3)(iii), after the words ''other than fast rescue boats'' and before the period, add the words ''(PSC) or proficiency in survival craft and rescue boats other than lifeboats and fast rescue boats (PSC-limited)''.

§ 11.329 [Amended]

■ 20. Amend § 11.329 as follows:

■ a. In § 11.329(a)(3)(iii), before the words ''boats other than fast rescue boats'' and before the period, add the words ''(PSC) or proficiency in survival craft and rescue boats other than lifeboats and fast rescue boats (PSC-limited)''; and

■ b. Add Table 1 to § 11.329(e) to read as follows:

§ 11.329 Requirements to qualify for an STCW endorsement as Officer in Charge of an Engineering Watch (OICEW) in a manned engineroom or designated duty engineer in a periodically unmanned engineroom on vessels powered by main propulsion machinery of 750 kW/1,000 HP propulsion power or more (operational level).

* * * * *

TABLE 1 TO § 11.329(E)—STCW ENDORSEMENT AS OICEW IN A MANNED ENGINE ROOM OR DESIGNATED DUTY ENGINEER IN A PERIODICALLY UNMANNED ENGINE ROOM ON VESSELS POWERED BY MAIN PROPULSION MACHINERY OF 750 KW/1,000 HP PROPULSION POWER OR MORE

[Operational level]

Entry path from national endorsements	Sea service *	Competence—STCW Table A–III/1 **	Training required by this section ***
Second assistant engineer any horsepower	None	Yes	Yes
Third assistant engineer any horsepower	None	Yes	Yes
Assistant engineer (limited)	None	Yes	Yes
Designated duty engineer, (unlimited) (less than 500 GRT)	None	Yes	Yes
Assistant engineer (MODU)	None	Yes	Yes
Assistant engineer (OSV)	None	Yes	Yes
Designated duty engineer, 3,000 kW/4,000 HP [1]	12 months	Yes	Yes
Designated duty engineer, 750 kW/1,000 HP [1]	24 months	Yes	Yes

* This column provides the minimum additional service required of the seafarer in order to meet the requirements of this section.
** Complete any items in paragraph (a)(3) of this section not previously satisfied.
*** Complete any items in paragraph (a)(4) of this section not previously satisfied.
[1] STCW certificate should be limited to vessels less than 500 GRT.

§ 11.331 [Amended]

■ 21. Amend § 11.331, in Table 1 to § 11.331(E) by revising the entries for ''Designated duty engineer, 3,000 kW/4,000 HP'' and ''Designated duty engineer, 750 kW/1,000 HP'' to read as follows:

§ 11.331 Requirements to qualify for an STCW endorsement as chief engineer officer on vessels powered by main propulsion machinery of 750 kW/1,000 HP or more and less than 3,000 kW/4,000 HP propulsion power (management level).

* * * * *

TABLE 1 TO § 11.331(E)—STCW ENDORSEMENT AS CHIEF ENGINEER OFFICER ON VESSELS POWERED BY MAIN PROPULSION MACHINERY OF 750 KW/1,000 HP OR MORE AND LESS THAN 3,000 KW/4,000 HP PROPULSION POWER

Entry path from national endorsements	Sea service [1]	Competence—STCW Table A–III/2 [2]	Training required by this section [3]
* * * *	*	*	*
Designated duty engineer, 3,000 kW/4,000 HP [4]	12 months	Yes	Yes.
Designated duty engineer, 750 kW/1,000 HP [4]	24 months	Yes	Yes.

* * * * *

(4) STCW certificate should be limited to vessels less than 500 GRT.

§ 11.335 [Amended]

■ 22. Amend § 11.335 as follows:

■ a. In paragraph (a)(3)(iii), after the text ''boats other than fast rescue boats'' and before the text ''; and'', add the text ''(PSC) or proficiency in survival craft and rescue boats other than lifeboats and fast rescue boats (PSC-limited)''; and

■ b. In paragraph (b), after the words ''not less than 12 months within the last 60 months'' and before the words ''must provide evidence of—'', remove the words ''and meets the standards of competence specified in Section A–III/6 of the STCW Code is considered by the Coast Guard to be suitably qualified but''.

§ 11.459 [Amended]

■ 23. In § 11.459 heading, after the words ''Requirements for national endorsement as master or mate'' and before the word ''rivers'', remove the word ''of'' and add, in its place, the word ''on''.

§ 11.465 [Amended]

■ 24. In § 11.465, in paragraph (a) introductory text, after the text ''in column 1 of Table 1 to'' and before the text ''(a) of this section'', remove the text ''paragaph'' and add, in its place, the text ''paragraph''.

§ 11.493 [Amended]

■ 25. Amend § 11.493 as follows:

■ a. In paragraph (b), after the text ''required to qualify an applicant for'', remove the text ''an endorsement as ''; and

■ b. In paragraph (c), after the text ''If an applicant for'', remove the text ''an endorsement as''.

§ 11.495 [Amended]

■ 26. In § 11.495, in paragraph (b), after the words ''required to qualify an applicant for'' and before the words ''as chief mate (OSV)'', remove the words ''an endorsement''; and in paragraph (c), after the words ''If an applicant for'' and before the words ''chief mate (OSV)'', remove the words ''an endorsements''.

§ 11.555 [Amended]

■ 27. In § 11.555(a)(2), after the words ''an approved or accepted'' and before the words ''engineer (OSV)'' add the word ''assistant''.

§ 11.821 [Amended]

■ 28. Amend § 11.821 as follows:

■ a. In paragraph (b), after the words ''high-speed craft type-rating'' and before the words ''for operating vessels'', remove the words ''certificate (TRC)'' and add, in their place, the words ''endorsement (TRE)''; and

■ b. In paragraphs (c), (d), and (e), remove the acronym ''TRC'' and add, in its place, the acronym ''TRE'', wherever it occurs.

§ 11.903 [Amended]

■ 29. In § 11.903(c)(1), after the words ''endorsements, or a license'' and before the words ''as chief mate of oceans'', remove the words ''and STCW endorsement''.

■ 30. In § 11.910, in Table 2 to § 11.910, revise page 7 to read as follows:

§ 11.910 Subjects for deck officer endorsements.

* * * * *

Table 2 to § 11.910—Subjects for Deck Officer Endorsements.

* * * * *

BILLING CODE 9110–04–P

Examination topics	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Vessels																								
Rules & Regulations for Inspected Vessels	X	X	X	7						X	X	X	X	7	X	X	X	7				X	X	X
Rules & Regulations for Inspected T-Boats				9										9				9						
Rules and Regulations for Uninspected Vessels					X	X	X	X	X										X	X				
Pollution Prevention Regulations	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X
Pilotage	X	X					X	X	X												X	X	X	
Credentialing of Seamen	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X
Shipment and Discharge, Manning	X	X		X			X			X		X			X	X						X	X	
Title 46, U.S. Code	X	X								X		X			X	X						X	X	
Captain of the Port Regulations, Vessel Traffic Service Procedures for the Route Desired																					X			
Shipboard Management and Training:																								
Personnel Management	X	X								X		X			X	X			X			X	X	
Shipboard Organization	X	X								X		X			X	X			X			X	X	
Required Crew Training	X	X								X		X			X	X			X			X	X	
Ship Sanitation	X	X		X	X	X	X	X	X	X		X		X	X	X		X	X			X	X	
Vessel Alteration/Repair Hot Work	X	X	X	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X
Safety	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X
Ship's Business:																								
Charters	X	X					X	X	X	X		X			X	X						X	X	
Liens and Salvage	X	X					X	X	X	X		X			X	X						X	X	
Insurance	X	X					X	X	X	X		X			X	X						X	X	
Entry and Clearance	X	X					X	X	X	X		X			X	X						X	X	
ISM and Safety Management Systems	X	X	X				X	X	X													X	X	X
Certificates and	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X

BILLING CODE 9110–04–C

* * * * *

PART 12—REQUIREMENTS FOR RATING ENDORSEMENTS

■ 31. The authority citation for part 12 continues to read as follows:

Authority: 31 U.S.C. 9701; 46 U.S.C. 2101, 2103, 2110, 7301, 7302, 7503, 7505, 7701, and 70105; Department of Homeland Security Delegation No. 0170.1.

§ 12.601 [Amended]

■ 32. In § 12.601(c)(3), after the words ''seagoing service that'' and before the words ''before March 24, 2014,'', remove the words ''was completed'' and add, in their place, the word ''commenced''.

PART 13—CERTIFICATION OF TANKERMEN

■ 33. The authority citation for part 13 continues to read as follows:

Authority: 46 U.S.C. 3703, 7317, 8105, 8703, 9102; Department of Homeland Security Delegation No. 0170.1.

§ 13.121 [Amended]

■ 34. In § 13.121, in Table 2 to § 13.121(E), in the entry for ''AuXiliary systems, including:'', revise ''AuXiliary'' to read ''Auxiliary''.

PART 14—SHIPMENT AND DISCHARGE OF MERCHANT MARINERS

■ 35. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. 552; 46 U.S.C. Chapters 103 and 104; 46 U.S.C. 70105.

§ 14.211 [Amended]

■ 36. In § 14.211, after the words ''shipping articles are required'' and before the words ''that a legible copy'', remove the word ''mustensure'' and add, in their place, the words ''must ensure''.

§ 14.213 [Amended]

■ 37. In § 14.213(a), after the words ''The master'' and before the words ''the original throughout'', remove the word ''mustkeep'' and add, in its place, the words ''must keep''.

§ 14.407 [Amended]

■ 38. Amend § 14.407 as follows:

■ a. In paragraph (b), after the words ''the vessel'' and before the words ''original shipping articles'', remove the word ''mustkeep'' and add, in its place, the words ''must keep''; and

■ b. In paragraph (e), after the words ''another company'' and before the words ''all original articles'', remove the word ''mustsend'' and add, in its place, the words ''must send''.

PART 15—MANNING REQUIREMENTS

■ 39. The authority citation for part 15 continues to read as follows:

Authority: 46 U.S.C. 2101, 2103, 3306, 3703, 8101, 8102, 8104, 8105, 8301, 8304, 8502, 8503, 8701, 8702, 8901, 8902, 8903, 8904, 8905(b), 8906, 9102, and 8103; and Department of Homeland Security Delegation No. 0170.1.

§ 15.610 [Amended]

■ 40. In § 15.610(b)(2), after the words ''one of the four'' and before the words ''was within the last'', remove the word ''reoundtrips'' and add, in its place, the word ''roundtrips''.

§ 15.815 [Amended]

■ 41. In § 15.815(c), after the words ''employment or service as'' and before the words ''mate onboard an uninspected towing vessel'', remove the word ''masteror'' and add, in its place, the words ''master or''.

PART 24—GENERAL PROVISIONS

■ 42. The authority citation for part 24 continues to read as follows:

Authority: 46 U.S.C. 2113, 3306, 4104, 4302; Pub. L. 103–206; 107 Stat. 2439; E.O. 12234; 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 24.05–1 [Amended]

■ 43. Amend § 24.05–1 as follows:

■ a. In paragraph (a) introductory paragraph, after the text ''in column 5 of table'' and before the text '', and is applicable to all'', remove the text ''24.05–1(a)'' and add, in its place, the text ''2.01–7(A)''; and

■ b. Remove Table 24.05–1(A).

PART 27—TOWING VESSELS

■ 44. The authority citation for part 27 continues to read as follows:

Authority: 46 U.S.C. 3306, 4102 (as amended by Pub. L. 104–324, 110 Stat. 3901); Department of Homeland Security Delegation No. 0170.1.

§ 27.301 [Amended]

■ 45. In § 27.301(b), after the words ''where the remote fire pump'' and before the words ''is located.'', remove the word ''contol'' and add, in its place, the word ''control''.

PART 28—REQUIREMENTS FOR COMMERCIAL FISHING INDUSTRY VESSELS

■ 46. The authority citation for part 28 continues to read as follows:

Authority: 46 U.S.C. 3316, 4502, 4505, 4506, 6104, 10603; Department of Homeland Security Delegation No. 0170.1.

■ 47. In § 28.50, definition of ''Currently corrected'', after the words ''Notice to Mariners published by the'' and before the ''.'', remove the words ''Defense Mapping Agency Hydrographic/Topographic Center'' and add, in their place, the words ''National Geospatial-Intelligence Agency''.

§ 28.120 [Amended]

■ 48. In § 28.120, in Table 28.120(C), in the ''Survival craft required'' column, in the fifth entry, remove the word ''bouyant'' and add in its place the word ''buoyant''. § 28.135 [Amended]

■ 49. In § 28.135, in Table 28.135, under the heading ''Markings Required,'' revise the column heading ''Retroflective material'' to read ''Retroreflective material''.

§ 28.225 [Amended]

■ 50. In § 28.225(a)(1), after the words ''by the National Ocean Service, the National'' and before the words ''Agency, U.S. Army Corps of Engineers'', remove the words ''Imagery and Mapping'' and add, in their place, the words ''Geospatial-Intelligence''.

§ 28.275 [Amended]

■ 51. In § 28.275(a)(2), after the words ''service as master of'' and before the words ''fishing industry vessels'', remove the word ''unispected'' and add, in its place, the word ''uninspected''.

PART 30—GENERAL PROVISIONS

■ 52. The authority citation for part 30 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. 5103, 5106; Department of Homeland Security Delegation No. 0170.1; Section 30.01–2 also issued under the authority of 44 U.S.C. 3507; Section 30.01–05 also issued under the authority of Sec. 4109, Pub. L. 101–380, 104 Stat. 515.

§ 30.01–5 [Amended]

■ 53. In § 30.01–5(d) introductory paragraph, after the text ''indicated in column 2 of table'' and before the text '', except as follows:'' remove the text ''30.01–5(d)'' and add, in its place, the text ''2.01–7(A)''; and remove Table 30.01–5(D) and its supplementary footnotes.

§ 30.10–27 [Amended]

■ 54. In the heading for Table § 30.10–27, after the words ''[In degrees'' and before the '']'', remove the word ''Farenheit'' and add, in its place, the word ''Fahrenheit''.

PART 35—OPERATIONS

■ 55. The authority citation for part 35 continues to read as follows:

Authority: 33 U.S.C. 1225, 1231, 1321(j); 46 U.S.C. 3306, 3703, 6101; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

§ 35.10–3 [Amended]

■ 56. In § 35.10–3 introductory paragraph, after the words ''six persons and all'' and before the words ''vessels shall have'', remove the word ''sef-propelled'' and add, in its place, the word ''self-propelled''; and in § 35.10–3(a), after the words ''ventilating systems including particulars of the'' and before the words ''fan controls'', remove the word ''maste'' and add, in its place, the word ''master''.

■ 57. Amend § 35.20–1 by revising paragraphs (a), (b), and (c) to read as follows:

§ 35.20–1 Notice to mariners; aids to navigation—T/OCLB.

(a) Licensed officers are required to acquaint themselves with the latest information published by the Coast Guard and the National Geospatial-Intelligence Agency regarding aids to navigation, and neglect to do so is evidence of neglect of duty. It is desirable that vessels navigating oceans and coastwise and Great Lakes water shall have available in the pilothouse for convenient reference at all times a file of the applicable Notice to Mariners.

(b) Local Notices to Mariners, published by each U.S. Coast Guard District, contain announcements and information on changes in aids to navigation and other marine information affecting the safety of navigation on oceans and coastwise and the Great Lakes. These notices may be obtained free of charge from the U.S. Coast Guard Navigation Center Web site found at *http://www.navcen.uscg.gov/?pageName=lnmMain.*

(c) Weekly Notices to Mariners (worldwide coverage) are prepared jointly by the National Geospatial-Intelligence Agency, National Ocean Service, and the U.S. Coast Guard. They include changes in aids to navigation and other important navigation safety information in assembled form for U.S. waters. Foreign marine information is also included in these notices. These notices are available without charge from the National Geospatial-Intelligence Agency Web site found at *http://msi.nga.mil/NGAPortal/MSI.portal.*

* * * * *

§ 35.20–7 [Amended]

■ 58. In § 35.20–7(a), after the words ''stability requirements in the'' and before the words ''trim and stability book'', remove the word ''vessels's'' and add, in its place, the word ''vessel's''.

PART 38—LIQUEFIED FLAMMABLE GASES

■ 59. The authority citation for part 38 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703; 49 U.S.C. 5101, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 38.10–15 [Amended]

■ 60. In § 38.10–15(c)(1), after the words ''The vapors evaporated by an'' and before the words ''air temperature of'', remove the word ''embient'' and add, in its place, the word ''ambient''.

§ 38.25–1 [Amended]

■ 61. In § 38.25–1(b), after the words ''at a pressure of 1½ times the'' and before the ''–'', remove the word ''tanks's'' and add, in its place, the word ''tank's''.

PART 42—DOMESTIC AND FOREIGN VOYAGES BY SEA

■ 62. The authority citation for part 42 continues to read as follows:

Authority: 46 U.S.C. 5101–5116; Department of Homeland Security Delegation No. 0170.1; section 42.01–5 also issued under the authority of 44 U.S.C. 3507.

§ 42.20–60 [Amended]

■ 63. In Table 42.20–60(B)(2), after the words ''Vessels with'' and before the words ''and detached bridge'', remove the word ''forecasle'' and add, in its place, the word ''forecastle''.

§ 42.50–15 [Amended]

■ 64. In § 42.50–15(d), after the words ''information on the face and'' and before the words ''sides of Form C1'', remove the word ''revese'' and add, in its place, the word ''reverse''.

PART 44—SPECIAL SERVICE LIMITED DOMESTIC VOYAGES

■ 65. The authority citation for part 44 continues to read as follows:

Authority: 46 U.S.C. 5101–5116; Department of Homeland Security Delegation No. 0170.1.

§ 44.05–35 [Amended]

■ 66. In § 44.05–35(a)(2), after the words ''stowage of cargo,'' and before the words ''etc., are such as to secure'', remove the word ''balast'' and add, in its place, the word ''ballast''.

PART 45—GREAT LAKES LOAD LINES

■ 67. The authority citation for part 45 continues to read as follows:

Authority: 46 U.S.C. 5104, 5108; Department of Homeland Security Delegation No. 0170.1.

§ 45.3 [Amended]

■ 68. In § 45.3(f)(2) definition, after the words ''or having topsides of'' and before the words ''form, the depth for'', remove the word ''unsual'' and add, in its place, the word ''unusual''.

§ 45.117 [Amended]

■ 69. In § 45.117(a), after the words ''bulwarks on the weather'' and before the words ''of freeboard or superstructure'', remove the word ''portins'' and add, in its place, the word ''portions''.

PART 52—POWER BOILERS

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

Authority: 46 U.S.C. 3306, 3307, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 52.25–5 [Amended]

■ 71. In § 52.25–5, after the words ''through PMB–21 of'' and before the words ''section I of the ASME'', remove the word ''of''.

PART 62—VITAL SYSTEM AUTOMATION

■ 72. The authority citation for part 62 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703, 8105; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 62.20–1 [Amended]

■ 73. In § 62.20–1(a)(5), after the words ''A description of'' and before the word ''features'', remove the word ''programable'' and add, in its place, the word ''programmable''.

§ 62.20–3 [Amended]

■ 74. In § 62.20–3(b)(6), after the words ''automation that, in the'' and before the words ''of the Commandant'', remove the word ''judgement'' and add, in its place, the word ''judgment''.

§ 62.25–20 [Amended]

■ 75. In § 62.25–20(b)(4), after the words ''operation, such as boiler'' and before the words ''control or reversing of'', remove the word ''programing'' and add, in its place, the word ''programming''.

§ 62.25–25 [Amended]

■ 76. In § 62.25–25, in the heading and paragraph (a), remove the word ''Programable'' and add, in its place, the word ''Programmable'' wherever it occurs.

§ 62.35–20 [Amended]

■ 77. In § 62.35–20, remove the words ''Programing'' and ''programing'' and add, in their place, the words ''Programming'' and ''programming'', respectively, wherever they occur; and in paragraph (d) introductory text, after the words ''control must provide a'' and before the words ''sequence of interlocks'', remove the word ''programed'' and add, in its place, the word ''programmed''.

§ 62.50–20 [Amended]

■ 78. In § 62.50–20(a)(2), after the words ''monitoring the plant, initiating'' and before the words ''control system sequences'', remove the word ''programed'' and add, in its place, the word ''programmed''.

PART 67—DOCUMENTATION OF VESSELS

■ 79. The authority citation for part 67 continues to read as follows:

Authority: 14 U.S.C. 664; 31 U.S.C. 9701; 42 U.S.C. 9118; 46 U.S.C. 2103, 2107, 2110, 12106, 12120, 12122; 46 U.S.C. app. 841a, 876; Department of Homeland Security Delegation No. 0170.1.

§ 67.259 [Amended]

■ 80. In § 67.259(b), after the words ''nature of the change being'' and before the words ''by the instrument'', remove the word ''effected'' and add, in its place, the word ''affected''.

PART 69—MEASUREMENT OF VESSELS

■ 81. The authority citation for part 69 continues to read as follows:

Authority: 46 U.S.C. 2301, 14103; Department of Homeland Security Delegation No. 0170.1.

§ 69.109 [Amended]

■ 82. In § 69.109(i)(4), after the words ''which rises or falls from'' and before the words ''to the wings'', remove the word ''certerline'' and add, in its place, the word ''centerline''.

§ 69.113 [Amended]

■ 83. In § 69.113(b)(2), after the words ''Divide the length under'' and before the words ''(b)(1) of this section'', remove the word ''paragaph'' and add, in its place, the word ''paragraph''.

PART 70—GENERAL PROVISIONS

■ 84. The authority citation for part 70 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1; Section 70.01–15 also issued under the authority of 44 U.S.C. 3507.

§ 70.05–1 [Amended]

■ 85. Amend § 70.05–1 as follows:

■ a. In paragraph (a) introductory text, after the text ''indicated in Column 3 of table'' and before the text ''that are 100 gross'', remove the text ''70.05–1(a)'' and add, in its place, the text ''2.01–7(A)''; and

■ b. Remove Table 70.05–1(A).

§ 70.05–3 [Amended]

■ 86. In § 70.05–3(e), before the words ''the other provisions of this section'', remove the words ''Not withstanding'' and add, in their place, the word ''Notwithstanding''.

PART 71—INSPECTION AND CERTIFICATION

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

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2113, 3205, 3306, 3307; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

■ 88. In § 71.25–20, amend the entry for ''Cartridge operated (water, antifreeze or loaded stream)'' in Table 71.25–20(A)(1) to read as follows:

§ 71.25 Fire detecting and extinguishing equipment.

* * * * *

TABLE 71.25–20(A)(1)

Type unit	Test
* *	* * * * * *
Cartridge operated (water, anti-freeze or loaded stream).	Examine pressure cartridge and replace if end is punctured or if cartridge is otherwise determined to have leaked or to be in unsuitable condition. Remove liquid. Clean hose and inside of extinguisher thoroughly. Recharge with clean water, solution or antifreeze. Insert charged cartridge.
* *	* * * * * *

§ 71.50–1 [Amended]

■ 89. In § 71.50–1, in the definition for ''Remotely operated vehicle (ROV),'' after the words ''operate the ROV in an effective'' and before the period, remove the word ''manor'' and add, in its place, the word ''manner''.

§ 71.50–27 [Amended]

■ 90. In § 71.50–27(b)(3), after the words ''must be present during the'' and before the words ''portion of the examination'', remove the word ''divers'' and add, in its place, the word ''diver's''.

§ 71.50–35 [Amended]

■ 91. In § 71.50–35(b), after the words ''internal structural'' and before the words ''underwater survey or whenever'', remove the word ''examinationor'' and add, in its place, the words ''examination or''.

PART 72—CONSTRUCTION AND ARRANGEMENT

■ 92. The authority citation for part 72 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 72.15–10 [Amended]

■ 93. In § 72.15–10(f), after the words ''or bilge on each side.'' and before the words ''exhaust ducts shall be led to'', remove the word ''Simliar'' and add, in its place, the word ''Similar''.

§ 72.20–5 [Amended]

■ 94. In § 72.20–5, before the words ''provided for officers and crew on all vessels'', remove the word ''Accomodations'' and add, in its place, the word ''Accommodations''.

PART 76—FIRE PROTECTION EQUIPMENT

■ 95. The authority citation for part 76 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 76.10–10 [Amended]

■ 96. In § 76.10–10 section heading, after the text ''Fire station hydrants,

hose and nozzles'', remove the text ''-T/ALL''.

§ 76.15–20 [Amended]

■ 97. In § 76.15–20(g), after the words ''with flexible or bent'' and before the words ''tubes may be inclined'', remove the word ''syphon'' and add, in its place, the word ''siphon''.

PART 77—VESSEL CONTROL AND MISCELLANEOUS SYSTEMS AND EQUIPMENT

■ 98. The authority citation for part 77 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 77.35–5 [Amended]

■ 99. In § 77.35–5(d), after the words ''shall be either inherently corrosion'' and before the words ''or made so by galvanizing'', remove the word ''resistent,'' and add, in its place, the word ''resistant,''.

PART 78—OPERATIONS

■ 100. The authority citation for part 78 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2103, 3306, 6101; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

■ 101. Revise § 78.05–1 to read as follows:

§ 78.05–1 Duty of officers.

(a) Licensed deck officers are required to acquaint themselves with the latest information published by the Coast Guard and the National Geospatial-Intelligence Agency regarding aids to navigation. Neglect to do so is evidence of neglect of duty. It is desirable that all vessels have available in the pilothouse for convenient reference at all times a file of the applicable Notice to Mariners.

(b) Local Notices to Mariners, published by each U.S. Coast Guard District, contain announcements and information on changes in aids to navigation and other marine information affecting the safety of navigation on oceans and coastwise and the Great Lakes. These notices may be obtained free of charge from the U.S. Coast Guard Navigation Center Web site found at *http://www.navcen.uscg.gov/?pageName=lnmMain.*

(c) Weekly Notices to Mariners (Worldwide coverage) are prepared jointly by the National Geospatial-Intelligence Agency, National Ocean Service, and the U.S. Coast Guard. They include changes in aids to navigation and other important navigation safety information in assembled form for U.S. waters. Foreign marine information is also included in these notices. These notices are available without charge from the National Geospatial-Intelligence Agency Web site found at *http://msi.nga.mil/NGAPortal/MSI.portal.*

§ 78.10–1 [Amended]

■ 102. In § 78.10–1, after the words ''United States Coast Guard, United States Navy,'' and before the words ''Agency, National Ocean Service,'', remove the words ''Imagery and Mapping'' and add, in their place, the words ''Geospatial-Intelligence''.

§ 78.36–20 [Amended]

■ 103. In § 78.36–20(a), after the words ''shall be destroyed or'' and before the words ''in the presence'', remove the word ''multilated'' and add, in its place, the word ''mutilated''.

§ 78.37–5 [Amended]

■ 104. In § 78.37–5(h), after the words ''Loading doors. Where'' and before the words ''every closing and any opening'', remove the word ''appliicable,'' and add, in its place, the word ''applicable,''.

§ 78.47–37 [Amended]

■ 105. In § 78.47–37(a), after the text ''''W. T. D. 1,'' ''2,'' ''3,'' etc. If a'' and before the text ''or similar notice is used'', remove the text ''stencilled'' and add, in its place, the text ''stenciled''.

§ 78.50–10 [Amended]

■ 106. In § 78.50–10(c), after the words ''datum line from which the draft'' and before the words ''be taken shall be obtained by'', remove the word ''shal'' and add, in its place, the word ''shall''.

PART 90—GENERAL PROVISIONS

■ 107. The authority citation for part 90 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 90.05–1 [Amended]

■ 108. In § 90.05–1, in paragraph (a) introductory text, after the text ''indicated in Column 4 of Table'' and before the text ''and to all such'', remove the text ''90.05–1(a)'' and add, in its place, the text ''2.01–7(A)''; and remove Table 90.05–1(A).

§ 90.10–20 [Amended]

■ 109. In § 90.10–20, after the words ''moveable legs capable of raising'' and before the words ''hull above the surface'', remove the word ''it's'' and add, in its place, the word ''its''.

PART 92—CONSTRUCTION AND ARRANGEMENT

■ 110. The authority citation for part 92 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 92.03–1 [Amended]

■ 111. In § 92.03–1 paragraphs (b)(3) and (4), remove the word ''fowad'' and add, in its place, the word ''forward'' wherever it occurs.

PART 95—FIRE PROTECTION EQUIPMENT

■ 112. The authority citation for part 95 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 95.50–5 [Amended]

■ 113. In § 95.50–5, in paragraph (c) introductory text, after the words ''suitable hose and nozzle or'' and before the words ''means so that all portions'', remove the word ''otherpracticable'' and add, in its place, the words ''other practicable''.

PART 97—OPERATIONS

■ 114. The authority citation for part 97 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2103, 3306, 5111, 6101; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757; 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

§ 97.01–2 [Amended]

■ 115. In § 97.01–2(a), after the text ''Washington, DC 20593–7509 or'' and before the text ''National Archives and Records Administration (NARA).'', remove the text ''contactthe'' and add, in its place, the text ''contact the''.

■ 116. Revise § 97.05–1 to read as follows:

§ 97.05–1 Duty of officers

(a) Licensed deck officers are required to acquaint themselves with the latest information published by the Coast Guard and the National Geospatial-Intelligence Agency regarding aids to navigation. Neglect to do so is evidence of neglect of duty. It is desirable that vessels other than motorboats shall have available in the pilothouse for convenient reference at all times a file of the applicable Notice to Mariners.

(b) Local Notices to Mariners, published by each U.S. Coast Guard District, contain announcements and information on changes in aids to navigation and other marine information affecting the safety of navigation on oceans and coastwise and the Great Lakes. These notices may be obtained free of charge from the U.S. Coast Guard Navigation Center Web site found at *http://www.navcen.uscg.gov/?pageName=lnmMain.*

(c) Weekly Notices to Mariners (Worldwide coverage) are prepared jointly by the National Geospatial-Intelligence Agency, National Ocean Service, and the U.S. Coast Guard. They include changes in aids to navigation and other important navigation safety information in assembled form for U.S. waters. Foreign marine information is also included in these notices. These notices are available without charge from the National Geospatial-Intelligence Agency Web site found at *http://msi.nga.mil/NGAPortal/MSI.portal.*

§ 97.10–5 [Amended]

■ 117. In § 97.10–5, after the words ''United States Navy, National'' and before the words ''Agency, National Ocean Service,'', remove the words ''Imagery and Mapping'' and add, in their place, the words ''Geospatial-Intelligence''.

PART 105—COMMERCIAL FISHING VESSELS DISPENSING PETROLEUM PRODUCTS

■ 118. The authority citation for part 105 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 3306, 3703, 4502; 49 U.S.C. App. 1804; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 793; Department of Homeland Security Delegation No. 0170.1.

§ 105.20–3 [Amended]

■ 119. In § 105.20–3, in Table 105.20–3(A)(1), in footnote 4, after the words ''common metals. Avoid'' and before the words ''contact with tank body'', remove the word ''dissimila-metal'' and add, in its place, the word ''dissimilar-metal''.

§ 105.20–5 [Amended]

■ 120. In § 105.20–5(c), before the words ''or aluminum alloy valves and fittings'', remove the word ''Aluminium'' and add, in its place, the word ''Aluminum''.

PART 109—OPERATIONS

■ 121. The authority citation for part 109 continues to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 3306, 6101, 10104; Department of Homeland Security Delegation No. 0170.1.

§ 109.301 [Amended]

■ 122. In § 109.301(g)(2), after the words ''serviced in accordance with the'' and before the words ''manual and meet the requirements'', remove the word ''owners'' and add, in its place, the word ''owner's''.

PART 111—ELECTRIC SYSTEMS—GENERAL REQUIREMENTS

■ 123. The authority citation for part 111 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; Department of Homeland Security Delegation No. 0170.1.

§ 111.10–1 [Amended]

■ 124. In § 111.10–1(a), before the words ''service loads mean electrical equipment for all'' remove the word ''Ships's'' and add, in its place, the word ''Ship's''.

PART 114—GENERAL PROVISIONS

■ 125. The authority citation for part 114 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. App. 1804; Department of Homeland Security Delegation No. 0170.1; § 114.900 also issued under 44 U.S.C. 3507.

§ 114.400 [Amended]

■ 126. In § 114.400, in the definition of ''Remotely Operated Vehicle (ROV),'' after the words ''operate the ROV in an effective'' and before the words ''The team must also have'', remove the word ''manor.'' and add, in its place, the word ''manner.''.

PART 115—INSPECTION AND CERTIFICATION

■ 127. The authority citation for part 115 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2103, 3205, 3306, 3307; 49 U.S.C. App. 1804; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 115.114 [Amended]

■ 128. In § 115.114(b)(1), after the text ''without the consent of the'' and before the text ''OCMI;'', remove the text ''congnizant'' and add, in its place, the text ''cognizant''.

§ 115.801 [Amended]

■ 129. In § 115.801(a), after the words ''a serious safety hazard to the vessel or'' and before the words ''passengers or crew'', remove the word ''it's'' and add, in its place, the word ''its''.

PART 117—LIFESAVING EQUIPMENT AND ARRANGEMENTS

■ 130. The authority citation for part 117 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 117.70 [Amended]

■ 131. In § 117.70(a)(2), after the text ''(65 feet), must carry a'' and before the text ''of one life buoy'', remove the text ''minumum'' and add, in its place, the text ''minimum''.

PART 119—MACHINERY INSTALLATION

■ 132. The authority citation for part 119 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 119.530 [Amended]

■ 133. In § 119.530(a)(1), after the words ''deepest load waterline, such as a'' and before the semicolon, remove the word ''lazerette'' and add, in its place, the word ''lazarette''.

PART 121—VESSEL CONTROL AND MISCELLANEOUS SYSTEMS AND EQUIPMENT

■ 134. The authority citation for part 121 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 121.240 [Amended]

■ 135. In § 121.240(e)(1), after the words ''CNG containers within the'' and before the words ''area, machinery spaces, bilges'', remove the word ''accomodation'' and add, in its place, the word ''accommodation''.

PART 122—OPERATIONS

■ 136. The authority citation for part 122 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 6101; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 122.304 [Amended]

■ 137. In § 122.304(a)(7), remove the word ''Vessels's'' and add, in its place, the word ''Vessel's''.

§ 122.520 [Amended]

■ 138. In § 122.520(g)(2), after the word ''General'' and before the words ''of the

drill scenario'', remove the word ''discription'' and add, in its place, the word ''description''.

§ 122.524 [Amended]

■ 139. In § 122.524(e)(2), after the word ''General'' and before the words ''of the drill scenario'', remove the word ''discription'' and add, in its place, the word ''description''.

§ 122.612 [Amended]

■ 140. In § 122.612(f), after the words ''sprinkler system must be'' and before the words ''marked in clearly legible letters'', remove the word ''conspicously'' and add, in its place, the word ''conspicuously''.

§ 122.728 [Amended]

■ 141. In § 122.728(a), after the words ''other than an EPIRB in an'' and before the words ''liferaft, must be tested'', remove the word ''inflable'' and add, in its place, the word ''inflatable''.

PART 131—OPERATIONS

■ 142. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 3306, 6101, 10104; E.O. 12234, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

§ 131.590 [Amended]

■ 143. In § 131.590(b), after the words ''at least once each 12 months,'' and before the words ''the performance of the tests'', remove the word ''nsure'' and add, in its place, the word ''ensure''.

§ 131.910 [Amended]

■ 144. In § 131.910, after the words ''the Coast Guard and the National'' and before the words ''Agency regarding aids to navigation'', remove the words ''Imagery and Mapping'' and add, in their place, the words ''Geospatial-Intelligence''.

PART 150—COMPATIBILITY OF CARGOES

■ 145. The authority citation for part 150 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; Department of Homeland Security Delegation No. 0170.1. Section 150.105 issued under 44 U.S.C. 3507; Department of Homeland Security Delegation No. 0170.1.

Appendix III to Part 150 [Amended]

■ 146. In Appendix III to Part 150, Step 2, paragraph 3, last sentence, after the words ''an inert material such as a'' and before the word ''hydrocarbon.'', remove the word ''flourinated'' and add, in its place, the word ''fluorinated''.

PART 151—BARGES CARRYING BULK LIQUID HAZARDOUS MATERIAL CARGOES

■ 147. The authority citation for part 151 continues to read as follows:

Authority: 33 U.S.C. 1903; 46 U.S.C. 3703; Department of Homeland Security Delegation No. 0170.1.

§ 151.04–5 [Amended]

■ 148. In § 151.04–5(h), after the word ''Pressure'' and before the words ''relief valves shall be examined'', remove the word ''vaccum'' and add, in its place, the word ''vacuum''.

§ 151.50–23 [Amended]

■ 149. In § 151.50–23(d), after the words ''at least to the height of the'' and before the words ''disk if such is installed.'', remove the word ''flangible'' and add, in its place, the word ''frangible''.

§ 151.50–31 [Amended]

■ 150. In § 151.50–31(d), after the words ''All valves, flanges, fittings and'' and before the words ''equipment shall be of'', remove the word ''accessary'' and add, in its place, the word ''accessory''.

§ 151.50–79 [Amended]

■ 151. In § 151.50–79(b)(1), after the text ''above 60 °C (140 °F) and 1.72 MPa'' and before the text ''(250 psig) during its operations'', remove the text ''guage'' and add, in its place, the text ''gauge''.

§ 151.50–84 [Amended]

■ 152. In § 151.50–84(e)(1), after the words ''one cargo tank at a time'' and before the words ''each tank is filled from'', remove the word ''unles'' and add, in its place, the word ''unless''.

PART 153—SHIPS CARRYING BULK LIQUID, LIQUEFIED GAS, OR COMPRESSED GAS HAZARDOUS MATERIALS

■ 153. The authority citation for part 153 continues to read as follows:

Authority: 46 U.S.C. 3703; Department of Homeland Security Delegation No. 0170.1. Section 153.40 issued under 49 U.S.C. 5103. Sections 153.470 through 153.491, 153.1100 through 153.1132, and 153.1600 through 153.1608 also issued under 33 U.S.C. 1903(b).

§ 153.240 [Amended]

■ 154. In § 153.240(b), after the words ''In an atmosphere whose'' and before the words ''is less than the temperature'', remove the word ''dewpoint'' and add, in its place, the words ''dew point''.

§ 153.330 [Amended]

■ 155. In § 153.330(a), after the words ''pump-room must open on the'' and before the period, remove the word ''weatheredeck'' and add, in its place, the word ''weatherdeck''.

§ 153.530 [Amended]

■ 156. In § 153.530(b), after the words ''steel and Teflon or similar'' and before the word ''polymer.'', remove the word ''flourinated'' and add, in its place, the word ''fluorinated''.

§ 153.940 [Amended]

■ 157. In § 153.940(b)(2), after the words ''Working pressure'' and before the words ''in paragraph (d)'', remove the word ''discribed'' and add, in its place, the word ''described''.

§ 153.1052 [Amended]

■ 158. In § 153.1052, after the words ''hydrochloric acid, or phosphoric acid'' and before the words ''specific authorization from'', remove the words ''with out'' and add, in their place, the word ''without''.

§ 153.1119 [Amended]

■ 159. In § 153.1119(c)(1), after the text ''Commandant (CG–ENG) (tel num'', and before the text ''if the prewash port is a foreign port'', remove the text ''; 202–372–1425'' and add, in its place, the text '': 202–372–1420; email: *HazmatStandards@uscg.mil*''.

§ 153.1602 [Amended]

■ 160. In § 153.1602 heading, after the words ''for determining the'' and before the word ''quantity'', remove the word ''strippinq'' and add, in its place, the word ''stripping''.

PART 154—SAFETY STANDARDS FOR SELF–PROPELLED VESSELS CARRYING BULK LIQUEFIED GASES

■ 161. The authority citation for part 154 continues to read as follows:

Authority: 46 U.S.C. 3703, 9101; Department of Homeland Security Delegation No. 0170.1.

§ 154.406 [Amended]

■ 162. In § 154.406(a)(4), after the text ''the design temperature is colder'' and before the text ''−55°C (−67°F) or'', remove the text ''that'' and add, in its place, the text ''than''.

§ 154.438 [Amended]

■ 163. In § 154.438(a), after the text ''type A are mostly flat'' and before the text ''P_o must not exceed 69 kPa gauge'', remove the text ''surfaces,the'' and add, in its place, the text ''surfaces, the''.

§ 154.453 [Amended]

■ 164. In § 154.453, after the text ''§ 154.451, and 154.452 and'' and before the text ''be redesigned to meet those standards'', remove the text ''can

not'' and add, in its place, the text ''cannot''.

§ 154.470 [Amended]

■ 165. In § 154.470(c), after the words ''must have supports with an'' and before the words ''system that withstands'', remove the word ''antiflotation'' and add, in its place, the word ''antifloatation''.

§ 154.522 [Amended]

■ 166. In § 154.522(a)(2), after the word ''Liquid'' and before the words ''discharge to the vent piping'', remove the words ''can not'' and add, in their place, the word ''cannot''.

§ 154.902 [Amended]

■ 167. In § 154.902, in paragraphs (c)(2) and (d), remove the word ''dewpoint'' and add, in its place, the words ''dew point''.

§ 154.903 [Amended]

■ 168. In § 154.903(b), after the words ''The boiling point and'' and before the words ''at atmospheric pressure of'', remove the word ''dewpoint'' and add, in its place, the words ''dew point''.

§ 154.1715 [Amended]

■ 169. In § 154.1715(b), after the text ''moisture content of air with a'' and before the text ''of −45°C (−49°F)'', remove the word ''dewpoint'' and add, in its place, the words ''dew point''.

§ 154.1725 [Amended]

■ 170. In § 154.1725(a)(4), after the words ''spirally wound stainless steel with'' and before the words ''or other material specially approved'', remove the word ''teflon'' and add, in its place, the word ''Teflon''.

PART 159—APPROVAL OF EQUIPMENT AND MATERIALS

■ 171. The authority citation for part 159 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; 49 CFR 1.45, 1.46; Section 159.001–9 also issued under the authority of 44 U.S.C. 3507.

§ 159.005–9 [Amended]

■ 172. In § 159.005–9(a)(5)(ii), after the words ''sets of specifications of the'' and before the words ''as inspected or tested'', remove the word ''materisl'' and add, in its place, the word ''material''.

PART 160—LIFESAVING EQUIPMENT

■ 173. The authority citation for part 160 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703 and 4302; E.O. 12234; 45 FR 58801; 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46; and Department of Homeland Security Delegation No. 0170.1.

§ 160.010–7 [Amended]

■ 174. In § 160.010–7(f), after the text ''145 N (32 lb.) per person capacity of the'' and before the text ''apparatus or 180 N (40 lb.)'', remove the text ''buouyant'' and add, in its place, the text ''buoyant''.

§ 160.021–4 [Amended]

■ 175. In § 160.021–4:

■ a. In paragraph (a), after the words ''of at least 100 signals'' and before the words ''which samples must be taken'', remove the word ''form'' and add, in its place, the word ''from'';

■ b. In paragraph (b)(1), after the words ''production line or on a previously'' and before the words ''production line'', remove the word ''discountinued'' and add, in its place, the word ''discontinued''; and

■ c. In paragraph (d)(8)(iii), after the words ''must remain in position until'' and before the words ''has cooled'', remove the word ''is'' and add, in its place, the word ''it''.

§ 160.024–4 [Amended]

■ 176. In § 160.024–4(c)(2)(iii), after the words ''known height, such as a tower or'' and before the words ''or by triangulation from two'', remove the word ''ballon,'' and add, in its place, the word ''balloon,''.

§ 160.031–6 [Amended]

■ 177. In § 160.031–6(a), after the words ''recessed in it a brass or other'' and before the words ''plate showing legible maintenance'', remove the word ''corrosion-restistant'' and add, in its place, the word ''corrosion-resistant''.

§ 160.036–4 [Amended]

■ 178. In § 160.036–4(c)(2)(i), after the words ''Conditioning of test specimens—water'' and before the words ''Immerse specimen horizontally'', remove the word ''resistence.'' and add, in its place, the word ''resistant.''.

§ 160.040–3 [Amended]

■ 179. In § 160.040–3(a), after the words ''purpose intended, and shall conform'' and before the words ''this subpart and to the specifications'', remove the word ''ot'' and add, in its place, the word ''to''.

§ 160.040–4 [Amended]

■ 180. In § 160.040–4(c), after the text ''minimum diameter with a minimum breaking'' and before the text ''of at least 2,250 N (500 lb.),'', remove the text ''strenght'' and add, in its place, the text ''strength''.

§ 160.041–4 [Amended]

■ 181. In § 160.041–4(a), after the words ''Each package shall be'' and before the words ''in a jacket of tough, transparent material'', remove the word ''inclosed'' and add, in its place, the word ''enclosed''.

§ 160.048–5 [Amended]

■ 182. In § 160.048–5(e), after the words ''In order to measure the actual'' and before the words ''provided by the pads'', remove the word ''buoyance'' and add, in its place, the word ''buoyancy''.

§ 160.052–7 [Amended]

■ 183. In § 160.052–7(e)(1), after the words ''buoyancy of the inserts. To'' and before the words ''the buoyancy of the inserts'', remove the word ''obtan'' and add, in its place, the word ''obtain''.

§ 160.055–2 [Amended]

■ 184. In § 160.055–2(c)(2), after the text ''Model,[1] child (for persons'' and before the text ''than 90 pounds).'', remove the text ''weighless'' and add, in its place, the text ''weighing less''.

§ 160.066–13 [Amended]

■ 185. In § 160.066–13(b)(2), after the words ''If for any reason it is not'' and before the words ''to operate the oven continuously'', remove the word ''possbie'' and add, in its place, the word ''possible''.

§ 160.066–15 [Amended]

■ 186. In § 160.066–15(c), after the text ''must be performed at least once every twelve'' and before the text ''at least once every 10 lots'', remove the text ''months,or'' and add, in its place, the text ''months, or''.

§ 160.171–9 [Amended]

■ 187. § 160.171–9(g)(2), after the word ''Galvanically'' and before the words ''with each other metal part'', remove the word ''compatable'' and add, in its place, the word ''compatible''.

§ 160.171–17 [Amended]

■ 188. Amend § 160.171–17 as follows:

■ a. In paragraph (c)(8), after the words ''wearing the suit in water'' and before the words ''any auxiliary means of buoyancy'', remove the word ''witiout'' and add, in its place, the word ''without''; and

■ b. In paragraph (f)(4), after the words ''Alternatively, the suits may be'' and before the words ''in the chamber'', remove the word ''upacked'' and add, in its place, the word ''unpacked''.

§ 160.176–5 [Amended]

■ 189. In § 160.176–5(d)(2), after the words ''by design or construction the

lifejacket'' and before the words ''fail the test.'', remove the words ''can not'' and add, in their place, the word ''cannot''.

§ 160.176–15 [Amended]

■ 190. In § 160.176–15(h)(9), after the words ''for a minimum of 30 minutes, and'' and before the words ''removed and immediately placed'', remove the word ''them'' and add, in its place, the word ''then''; and in § 160.176–15(j), after the words ''Each final lot examination and'' and before the words ''must show–'', remove the word ''inspectin'' and add, in its place, the word ''inspection''.

PART 161—ELECTRICAL EQUIPMENT

■ 191. The authority citation for part 161 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703, 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 161.012–1 [Amended]

■ 192. In § 161.012–1(a), after the words ''Coast Guard approved life preservers,'' and before the words ''vests, and other personal'', remove the word ''bouyant'' and add, in its place, the word ''buoyant''.

§ 161.012–17 [Amended]

■ 193. In § 161.012–17(c)(2), after the words ''Not require penetration of the'' and before the words ''material of the PFD.'', remove the word ''bouyant'' and add, in its place, the word ''buoyant''.

PART 162—ENGINEERING EQUIPMENT

■ 194. The authority citation for part 162 continues to read as follows:

Authority: 33 U.S.C. 1321(j), 1903; 46 U.S.C. 3306, 3703, 4104, 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

§ 162.018–5 [Amended]

■ 195. In § 162.018–5(b), after the words ''Safety relief valves having'' and before the words ''blow-down construction'', remove the word ''adjustible'' and add, in its place, the word ''adjustable''.

§ 162.039–3 [Amended]

■ 196. Amend § 162.039–3 as follows:

■ a. In paragraph (b), after the words ''additional source of extinguishing agent or'' and before the words ''energy for its operation;'', remove the word ''expellent'' and add, in its place, the word ''expellant''; and

■ b. In paragraph (c), after the words ''similar purposes, shall be'' and before the words ''or shall be protected by'', remove the word ''corrsion-resistant'' and add, in its place, the word ''corrosion-resistant''.

PART 163—CONSTRUCTION

■ 197. The authority citation for part 163 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703, 5115; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

§ 163.002–13 [Amended]

■ 198. In § 163.002–13(t), after the words ''capable of supporting 2.2 times the'' and before the words ''load with the cables'', remove the word ''workig'' and add, in its place, the word ''working''.

§ 163.003–27 [Amended]

■ 199. In § 163.003–27(c), after the words ''if each ladder in the lot is less'' and before the words ''3 m long, a ladder of the longest length'', remove the word ''then'' and add, in its place, the word ''than''.

PART 164—MATERIALS

■ 200. The authority citation for part 164 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703, 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

§ 164.003–3 [Amended]

■ 201. In § 164.003–3(c), after the words ''kapok shall not be used in'' and before the words ''products inspected by the'', remove the word ''lifesaying'' and add, in its place, the word ''lifesaving''.

§ 164.008–7 [Amended]

■ 202. In § 164.008–7(a)(7), after the words ''installation methods and indicating'' and before the words ''if any.'', remove the word ''limtations,'' and add, in its place, the word ''limitations,''.

§ 164.015–4 [Amended]

■ 203. In § 164.015–4, in paragraph (g)(1), remove the word ''bunsen'' and add, in its place, the word ''Bunsen'' wherever it occurs; and in paragraph (j), after the words ''bent 180° around a ½″ diameter steel'' and before the words ''within 5 seconds at the test temperature.'', remove the word ''mandril'' and add, in its place, the word ''mandrel''.

PART 167—PUBLIC NAUTICAL SCHOOL SHIPS

■ 204. The authority citation for part 167 continues to read as follows:

Authority: 46 U.S.C. 3306, 3307, 6101, 8105; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 167.20–10 [Amended]

■ 205. In § 167.20–10(a), after the words ''arrangements will possibly permit, all'' and before the words ''where persons may be quartered,'', remove the word ''inclosures'' and add, in its place, the word ''enclosures''.

§ 167.45–75 [Amended]

■ 206. In § 167.45–75, after the words ''emergency fuel tanks containing gasoline,'' and before the words ''or naphtha.'', remove the word ''benzine,'' and add, in its place, the word ''benzene,''.

§ 167.60–1 [Amended]

■ 207. In § 167.60–1(a), after the words ''certificate of inspection with the following'' and before the words ''''Nautical School Ship'' in lieu'', remove the word ''indorsement:'' and add, in its place, the word ''endorsement:''.

■ 208. Amend § 167.65–45 by revising paragraphs (a), (b), and (c) to read as follows:

§ 167.65–45 Notice to mariners; aids to navigation.

(a) Officers are required to acquaint themselves with the latest information published by the Coast Guard and the National Geospatial-Intelligence Agency regarding aids to navigation, and neglect to do so is evidence of neglect of duty. It is desirable that nautical school ships navigating oceans and coastwise and Great Lakes waters shall have available in the pilothouse for convenient reference at all times a file of the applicable Notice to Mariners.

(b) Local Notices to Mariners, published by each U.S. Coast Guard District, contain announcements and information on changes in aids to navigation and other marine information affecting the safety of navigation on oceans and coastwise and the Great Lakes. These notices may be obtained free of charge from the U.S. Coast Guard Navigation Center Web site found at *http://www.navcen.uscg.gov/?pageName=lnmMain.*

(c) Weekly Notices to Mariners (Worldwide coverage) are prepared jointly by the National Geospatial-Intelligence Agency, National Ocean Service, and the U.S. Coast Guard. They include changes in aids to navigation and other important navigation safety information in assembled form for U.S. waters. Foreign marine information is also included in these notices. These notices are available without charge from the National Geospatial-Intelligence Agency Web site found at

http://msi.nga.mil/NGAPortal/MSI.portal.

* * * * *

PART 169—SAILING SCHOOL VESSELS

■ 209. The authority citation for part 169 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 3306, 6101; Pub. L. 103–206, 107 Stat. 2439; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 793; Department of Homeland Security Delegation No. 0170.1; § 169.117 also issued under the authority of 44 U.S.C. 3507.

§ 169.313 [Amended]

■ 210. In § 169.313(d)(3), after the words ''The scuttle is located where it'' and before the words ''interfered with; and'', remove the words ''can not'' and add, in their place, the word ''cannot''.

§ 169.567 [Amended]

■ 211. In § 169.567(g), after the words ''For units that'' and before the words ''be readily recharged on the vessel,'', remove the word ''can not'' and add, in their place, the word ''cannot''.

§ 169.609 [Amended]

■ 212. Amend § 169.609 as follows:

■ a. In the introductory text, after the words ''exhaust installations and associated cooling'' and before the words ''must be built in accordance with'', remove the word ''sytems'' and add, in its place, the word ''systems''; and

■ b. In paragraph (b), after the words ''water from rough seas, and are'' and before the words ''of corrosion resistant material at the hull'', remove the word ''constucted'' and add, in its place, the word ''constructed''.

§ 169.667 [Amended]

■ 213. In § 169.667(a), after the words ''switchboard must be in as dry a location as'' and before the words ''accessible, protected from inadvertent entry,'', remove the word ''praticable,'' and add, in its place, the word ''practicable''.

§ 169.684 [Amended]

■ 214. In § 169.684(d), after the words ''Each manually started'' and before the words ''duty motor, rated at one horsepower'', remove the word ''continous'' and add, in its place, the word ''continuous''.

§ 169.837 [Amended]

■ 215. In § 169.837(b)(3), after the words ''lifefloat has been cleaned and'' and before the words ''overhauled once every twelve months.'', remove the word ''thorughly'' and add, in its place, the word ''thoroughly''.

PART 171—SPECIAL RULES PERTAINING TO VESSELS CARRYING PASSENGERS

■ 216. The authority citation for part 171 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 171.066 [Amended]

■ 217. In § 171.066(d), after the words ''completely enclosed in steel'' and before the words ''and is not a crew or passenger space'', remove the word ''buldheads'' and add, in its place, the word ''bulkheads''.

■ 218. In § 171.070, amend the entry for ''801 to 1000'' in Table 171.070(A) to read as follows:

§ 171.070 Subdivision requirements—Type II.

* * * * *

TABLE 171.070(A)—STANDARD OF FLOODING

Passengers carried	Part of vessel	Standard of flooding (compartments)
*	*	*
801 to 1000	All of the vessel forward of the first MTWB that is aft of a point 60% of the vessel's LBP aft of the forward perpendicular.	2
*	*	*

* * * * *

§ 171.072 [Amended]

■ 219. In § 171.072 introductory text, after the words ''When doing'' and before the words ''to show compliance with'', remove the word ''calcualtions'' and add, in its place, the word ''calculations''.

§ 171.080 [Amended]

■ 220. In § 171.080(h)(2), after the words ''in other than ocean service must meet the'' and before the colon, remove the word ''follmwing'' and add, in its place, the word ''following''.

§ 171.100 [Amended]

■ 221. In § 171.100(d), after the words ''If a vessel has more'' and before the words ''two shaft tunnels, only two doors'', remove the word ''then'' and add, in its place, the word ''than''.

PART 172—SPECIAL RULES PERTAINING TO BULK CARGOES

■ 222. The authority citation for part 172 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703, 5115; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 172.065 [Amended]

■ 223. In § 172.065, in paragraph (d) introductory text, after the text ''longer than 738 feet (225'' and before the text '') in length, design calculations must'', remove the text ''metes'' and add, in its place, the text ''meters''; and in paragraph (d)(3)(iii), after the text ''a step for the purpose of this'' and before the period, remove the text ''regulaton'' and add, in its place, the text ''regulation''.

PART 174—SPECIAL RULES PERTAINING TO SPECIFIC VESSEL TYPES

■ 224. The authority citation for part 174 continues to read as follows:

Authority: 42 U.S.C. 9118, 9119, 9153; 43 U.S.C. 1333; 46 U.S.C. 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 174.055 [Amended]

■ 225. In § 174.055(b)(4), after the text ''A=projected area in square feet ('' and before the text ''meters) of an exposed surface'', remove the text ''squrae'' and add, in its place, the text ''square''.

PART 175—GENERAL PROVISIONS

■ 226. The authority citation for part 175 continues to read as follows:

Authority: 46 U.S.C. 2103, 3205, 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; 49 U.S.C. App. 1804; Department of Homeland Security Delegation No. 0170.1; § 175.900 also issued under 44 U.S.C. 3507.

§ 175.122 [Amended]

■ 227. In § 175.122, after the words ''assignment, certification, and marking under'' and before the words ''E (Load Lines)'', remove the word ''suchapter'' and add, in its place, the word ''Subchapter''.

PART 176—INSPECTION AND CERTIFICATION

■ 228. The authority citation for part 176 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2103, 3205, 3306, 3307; 49 U.S.C. App. 1804; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 743; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 176.202 [Amended]

■ 229. In § 176.202(b), after the text ''Certificate of Inspection is turned over'' and before the text ''OCMI.'', remove the text ''tot he'' and add, in its place, the text ''to the''.

PART 180—LIFESAVING EQUIPMENT AND ARRANGEMENTS

■ 230. The authority citation for part 180 continues to read as follows:

Authority: 46 U.S.C. 2104, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 180.207 [Amended]

■ 231. In § 180.207(e), after the words ''route in shallow water where the vessel'' and before the words ''sink deep enough to submerge'', remove the words ''can not'' and add, in their place, the word ''cannot''.

§ 180.208 [Amended]

■ 232. In § 180.208(d), after the words ''shallow water where the vessel'' and before the words ''sink deep enough to submerge'', remove the words ''can not'' and add, in their place, the word ''cannot''.

PART 181—FIRE PROTECTION EQUIPMENT

■ 233. The authority citation for part 181 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 234. In § 181.500, revise the entry for ''Accomodation Space'' in Table 181.500(A) to read as follows:

§ 181.500 Required number, type, and location.

* * * * *

TABLE 181.500(A)

Space protected	Minimum number required	Type extinguisher permitted		
		CG class	Medium	Min size
* * *	* *		*	*
Accommodation Space	1 for each 232.3 square meters (2,500 square feet) or fraction thereof.	A–II	Foam Dry Chemical	9.5 L (2.5 gal). 4.5 kg (10 lb).
* * *	* *		*	*

* * * * *

PART 182—MACHINERY INSTALLATION

■ 235. The authority citation for part 182 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 182.455 [Amended]

■ 236. In § 182.455(b)(9), after the words ''from diesel fuel in water traps or'' and before the words ''are permitted.'', remove the word ''stainers'' and add, in its place, the word ''strainers''.

§ 182.610 [Amended]

■ 237. In § 182.610(f)(5), after the words ''stop the steering gear before'' and before the words ''reaches the rudder stops required'', remove the word ''its'' and add, in its place, the word ''it''.

PART 185—OPERATIONS

■ 238. The authority citation for part 185 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 6101; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 185.722 [Amended]

■ 239. In § 185.722, after the words ''must be inspected monthly, using the'' and before the words ''instructions to make sure it is'', remove the word ''manufacturers'' and add, in its place, the word ''manufacturer's''.

PART 188—GENERAL PROVISIONS

■ 240. The authority citation for part 188 continues to read as follows:

Authority: 46 U.S.C. 2113, 3306; Pub. L 103–206, 107 Stat. 2439; 49 U.S.C. 5103, 5106; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 188.05–1 [Amended]

■ 241. In § 188.05–1(a), after the text ''indicated in Column 6 of Table'' and before the text '' to the extent prescribed'', remove the text ''188.05–1(a)'' and add, in its place, the text ''2.01–7(A)''; and remove Table 188.05–1(A).

§ 188.10–56 [Amended]

■ 242. In § 188.10–56(a), after the words ''means a pilot ladder,'' and before the words ''ladder, pilot hoist, or combination'', remove the word ''accomodation'' and add, in its place, the word ''accommodation''.

PART 189—INSPECTION AND CERTIFICATION

■ 243. The authority citation for part 189 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2113, 3306, 3307; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

§ 189.25–10 [Amended]

■ 244. In § 189.25–10(a), after the words ''and their appurtenances, piping, main and'' and before the words ''machinery, electrical installations, life-saving'', remove the word ''auxilliary'' and add, in its place, the word ''auxiliary''.

PART 190—CONSTRUCTION AND ARRANGEMENT

■ 245. The authority citation for part 190 continues to read as follows:

Authority: 46 U.S.C. 2113, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 246. In § 190.05–20(d), after the words ''shall be similarly separated from'' and before the words ''spaces and high fire hazard areas'', remove the word ''accomodation'' and add, in its place, the word ''accommodation''.

§ 190.07–10 [Amended]

■ 247. Amend § 190.07–10 as follows:

■ a. In paragraph (c), after the words ''bulkheads and decks separating the'' and before the words ''and control stations from hold and machinery'', remove the word ''accomodations'' and add, in its place, the word ''accommodations''; and

■ b. In paragraph (d)(6), after the words ''used in thicknesses not exceeding'' and before the words ''of an inch.'', remove the word ''three-eights'' and add, in its place, the word ''three-eighths''.

PART 194—HANDLING, USE, AND CONTROL OF EXPLOSIVES AND OTHER HAZARDOUS MATERIALS

■ 248. The authority citation for part 194 continues to read as follows:

Authority: 46 U.S.C. 2103, 2113, 3306; 49 U.S.C. App. 1804; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

§ 194.15–17 [Amended]

■ 249. In § 194.15–17(d), after the words ''Systems providing gas for'' and before the words ''burners or similar semipermanent/permanent'', remove the word ''bunsen'' and add, in its place, the word ''Bunsen''.

PART 196—OPERATIONS

■ 250. The authority citation for part 196 continues to read as follows:

Authority: 33 U.S.C. 1321(j); 46 U.S.C. 2213, 3306, 5115, 6101; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 251. Revise § 196.05–1 to read as follows:

§ 196.05–1 Duty of officers.

(a) Licensed deck officers are required to acquaint themselves with the latest information published by the Coast Guard and the National Geospatial-Intelligence Agency regarding aids to navigation. Neglect to do so is evidence of neglect of duty. It is desirable that all vessels have available in the pilothouse for convenient reference at all times a file of the applicable Notice to Mariners.

(b) Local Notices to Mariners, published by each U.S. Coast Guard District, contain announcements and information on changes in aids to navigation and other marine information affecting the safety of navigation on oceans and coastwise and the Great Lakes. These notices may be obtained free of charge from the U.S. Coast Guard Navigation Center Web site found at *http://www.navcen.uscg.gov/?pageName=lnmMain.*

(c) Weekly Notices to Mariners (Worldwide coverage) are prepared jointly by the National Geospatial-Intelligence Agency, National Ocean Service, and the U.S. Coast Guard. They include changes in aids to navigation and other important navigation safety information in assembled form for U.S. waters. Foreign marine information is also included in these notices. These notices are available without charge from the National Geospatial-Intelligence Agency Web site found at *http://msi.nga.mil/NGAPortal/MSI.portal.*

§ 196.19–1 [Amended]

■ 252. In § 196.19–1(a)(4), after the words ''For each vessel with a'' and before the words ''pitch propeller a table of control settings'', remove the word ''controlable'' and add, in its place, the word ''controllable''.

§ 196.37–5 [Amended]

■ 253. In § 196.37–5(a), after the words ''in accordance with requirements in'' and before the words ''J (Electrical Engineering Regulations)'', remove the word ''Subpchapter'' and add, in its place, the word ''Subchapter''.

PART 197—GENERAL PROVISIONS

■ 254. The authority citation for part 197 continues to read as follows:

Authority: 33 U.S.C. 1509; 43 U.S.C. 1333; 46 U.S.C. 3306, 3703, 6101; Department of Homeland Security Delegation No. 0170.1.

§ 197.402 [Amended]

■ 255. In § 197.402(b), after the words ''Prior to permitting any'' and before the words ''diving operation involving liveboating'', remove the word ''commerical'' and add, in its place, the word ''commercial''.

§ 197.410 [Amended]

■ 256. In § 197.410(b)(3), after the words ''Communications are lost and'' and before the words ''be quickly reestablished'', remove the words ''can not'' and add, in their place, the word ''cannot''.

§ 197.550 [Amended]

■ 257. In § 197.550(g)(3), after the words ''period not to exceed eight hours,'' and before the words ''comes first.'', remove the words ''which ever'' and add, in their place, the word ''whichever''.

§ 197.560 [Amended]

■ 258. Amend § 197.560 as follows:

■ a. In paragraph (d)(1)(i), after the words ''employee's pre-exposure norms, if these findings'' and before the words ''be explained by other medical reasons.'', remove the words ''can not'' and add, in their place, the word ''cannot''; and

■ b. In paragraph (e)(1), after the words ''unavoidable circumstances the sample'' and before the words ''be tested by a laboratory within 72 hours'', remove the words ''can not'' and add, in their place, the word ''cannot''.

PART 199—LIFESAVING SYSTEMS FOR CERTAIN INSPECTED VESSELS

■ 259. The authority citation for part 199 is revised to read as follows:

Authority: 46 U.S.C. 3306, 3703; Pub. L. 103–206, 107 Stat. 2439; Department of Homeland Security Delegation No. 0170.1.

§ 199.190 [Amended]

■ 260. In § 199.190(g)(2), after the words ''must be serviced in accordance with the'' and before the words ''manual and meet the requirements of'', remove the word ''owners'' and add, in its place, the word ''owner's''.

Dated: September 9, 2014.

Katia Cervoni,

Chief, Office of Regulations and Administrative Law, U.S. Coast Guard.

[FR Doc. 2014–21994 Filed 9–26–14; 8:45 am]

BILLING CODE 9110–04–P

Proposed Rules

Federal Register
Vol. 79, No. 188
Monday, September 29, 2014

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2012–BT–STD–0045]

RIN 1904–AC87

Energy Efficiency Program for Consumer Products: Energy Conservation Standards for Ceiling Fans: Public Meeting and Availability of the Preliminary Technical Support Document

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

ACTION: Notice of public meeting and availability of preliminary technical support document.

SUMMARY: The U.S. Department of Energy (DOE) will hold a public meeting to discuss and receive comments on the preliminary analysis it has conducted for purposes of establishing energy conservation standards for ceiling fans. The meeting will cover the analytical framework, models, and tools that DOE is using to evaluate potential standards for this product; the results of preliminary analyses performed by DOE for this product; the potential energy conservation standard levels derived from these analyses that DOE could consider for this product; and any other issues relevant to the development of energy conservation standards for ceiling fans. In addition, DOE encourages written comments on these subjects. To inform interested parties and to facilitate this process, DOE has prepared an agenda, a preliminary technical support document (TSD), and briefing materials, which are available on the DOE Web site at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/65.*

DATES: DOE will hold a public meeting on Tuesday, November 18, 2014 from 9:00 a.m. to 5:00 p.m., in Washington, DC. Additionally, DOE plans to allow for participation in the public meeting via webinar. DOE will accept comments, data, and other information regarding this rulemaking before or after the public meeting, but no later than November 28, 2014. See section IV, ''Public Participation,'' of this notice of public meeting (NOPM) for details.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW., Washington, DC 20585–0121. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Brenda Edwards at (202) 586–2945 so that the necessary procedures can be completed. DOE requires visitors to have laptops and other devices, such as tablets, checked upon entry into the building. Please report to the visitor's desk to have devices checked before proceeding through security.

Interested persons may submit comments, identified by docket number EERE–2011–BT–STD–0045 and/or Regulation Identification Number (RIN) 1904–AC87, by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: CeilingFan2012STD0045@ee.doe.gov.* Include the docket number EERE–2011–BT–STD–0045 and/or RIN 1904–AC87 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies. [Please note that comments and CDs sent by mail are often delayed and may be damaged by mail screening processes.]
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone (202) 586–2945. If possible, please submit all items on CD, in which case it is not necessary to include printed copies.

Docket: The docket is available for review at *www.regulations.gov,* including **Federal Register** notices, framework documents, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The rulemaking Web page can be found at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/65.* This Web page contains a link to the docket for this notice on the regulation.gov site. The regulations.gov Web page contains instructions on how to access all documents in the docket, including public comments.

For detailed instructions on submitting comments and additional information on the rulemaking process, see section IV, ''Public Participation,'' of this document. For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–1604. Email: *ceiling_fans@ee.doe.gov* .

In the Office of the General Counsel, contact Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–7796. Email: *Elizabeth.Kohl@hq.doe.gov.*

For information on how to submit or review public comments and on how to participate in the public meeting, contact Ms. Brenda Edwards, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone (202) 586–2945. Email: *Brenda.Edwards@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Statutory Authority
II. Rulemaking for Ceiling Fans
A. Background
B. Current Rulemaking Process
III. Summary of the Analyses Performed by DOE
A. Engineering Analysis
B. Energy Use Analysis
C. Life-Cycle Cost and Payback Period Analyses
D. National Impact Analysis
IV. Public Participation
A. Attendance at Public Meeting
B. Procedure for Submitting Requests to Speak
C. Conduct of Public Meeting
D. Submission of Comments
V. Approval of the Office of the Secretary

I. Statutory Authority

Title III, Part B [1] of the Energy Policy and Conservation Act of 1975, as amended, (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified) sets forth a variety of provisions designed to improve energy efficiency and established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances (collectively referred to as ''covered products'').[2] These include ceiling fans, which are the subject of this rulemaking. (42 U.S.C. 6295(ff)) This program authorizes DOE to establish technologically feasible, economically justified energy efficiency regulations for certain products and equipment that would be likely to result in substantial national energy savings. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

DOE is required to consider standards for ceiling fans that: (1) Achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified; and (2) result in significant conservation of energy. (42 U.S.C. 6295(o)(2)(A) and (o)(3)(B)) To determine whether a proposed standard is economically justified, DOE will, after receiving comments on the proposed standard, determine whether the benefits of the standard exceed its burdens, considering, to the greatest extent practicable, the following seven factors:

1. The economic impact of the standard on manufacturers and consumers of products subject to the standard;

2. The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products which are likely to result from the standard;

3. The total projected amount of energy savings likely to result directly from the standard;

4. Any lessening of the utility or the performance of the covered products likely to result from the standard;

5. The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

6. The need for national energy conservation; and

7. Other factors the Secretary of Energy considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i))

DOE also adheres to additional statutory requirements of general applicability for prescribing new or amended standards set forth in other relevant sections of EPCA.

II. Rulemaking for Ceiling Fans

A. Background

The Energy Policy Act of 2005 (EPACT 2005), Public Law 109–58, amended EPCA and provided that DOE may establish energy conservation standards for ceiling fans, as well as requirements for determining whether these standards should be amended. (42 U.S.C. 6295(ff)) EPCA defines a ''ceiling fan'' as ''a nonportable device that is suspended from a ceiling for circulating air via the rotation of fan blades'' (42 U.S.C. 6291(49)) In addition to giving DOE the discretion to issue electrical energy conservation standards for ceiling fans, EPCA also includes certain statutorily-prescribed design standards (including a requirement for (i) fan speed controls separate from any lighting controls; (ii) adjustable speed controls (either more than one speed or variable speed); and (iii) the capability for reverse action (other than fans sold for industrial or outdoor application or where safety would be an issue)). (42 U.S.C. 6295(ff)(1)(A) and (6))

Under this statutory structure, DOE codified energy conservation standards and promulgated test procedures for ceiling fans, which are set forth in the Code of Federal Regulations (CFR). In a final rule technical amendment published in the **Federal Register** (FR) on October 18, 2005, DOE codified the statutorily prescribed design standards for ceiling fans at 10 CFR 430.32(s). 70 FR 60407, 60413. In a final rule published in the **Federal Register** on December 8, 2006, DOE adopted test procedures for ceiling fans at 10 CFR part 430, subpart B, appendix U. 71 FR 71340, 71366–71367.

This preliminary analysis is part of DOE's review to determine whether the standards in effect for ceiling fans should be amended, as directed by EPCA. (42 U.S.C. 6295(ff)(6)) It also addresses 42 U.S.C. 6295(gg)(3), in which DOE is directed to incorporate standby mode and off mode energy use in any amended (or new) standard adopted after July 1, 2010, if justified pursuant to 42 U.S.C. 6295(o). The statutory design standards for ceiling fans will remain in place and are not subject to review as part of this rulemaking process.

B. Current Rulemaking Process

In initiating this rulemaking, DOE prepared a Framework Document, ''Energy Conservation Standards Rulemaking Framework Document for Ceiling Fans and Ceiling Fan Light Kits,'' which describes the procedural and analytical approaches DOE anticipates using to evaluate energy conservation standards for ceiling fans. This document is available at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/65.*

DOE held a public meeting on March 22, 2013, at which it described the various analyses DOE would conduct as part of the rulemaking, such as the engineering analysis, the life-cycle cost (LCC) and payback period (PBP) analyses, and the national impact analysis (NIA). Representatives for manufacturers, trade associations, environmental and energy efficiency advocates, and other interested parties attended the meeting.

Comments received since publication of the Framework Document have helped DOE identify and resolve issues related to the preliminary analyses. Chapter 2 of the preliminary TSD summarizes and addresses the comments received.

III. Summary of the Analyses Performed by DOE

For the products covered in this rulemaking, DOE conducted in-depth technical analyses in the following areas: (1) Engineering; (2) markups to determine product price; (3) energy use; (4) life-cycle cost and payback period; and (5) national impacts. The preliminary TSD that presents the methodology and results of each of these analyses is available at *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/65.*

DOE also conducted, and has included in the preliminary TSD,

[1] For editorial reasons, upon codification in the U.S. Code, Part B was re-designated Part A.

[2] All references to EPCA in this document refer to the statute as amended through the American Energy Manufacturing Technical Corrections Act (AEMTCA), Pub. L. 112–210 (Dec. 18, 2012).

several other analyses that support the major analyses or are preliminary analyses that will be expanded upon for a notice of proposed rulemaking (NOPR) if DOE determines that amended energy conservation standards are technologically feasible, economically justified, and would save a significant amount of energy, based on the information presented to the Department. These analyses include: (1) The market and technology assessment; (2) the screening analysis, which contributes to the engineering analysis; and (3) the shipments analysis, which contributes to the LCC and PBP analysis and NIA. In addition to these analyses, DOE has begun preliminary work on the manufacturer impact analysis and has identified the methods to be used for the consumer subgroup analysis, the emissions analysis, the employment impact analysis, the regulatory impact analysis, and the utility impact analysis. DOE will expand on these analyses in the NOPR.

A. Engineering Analysis

The engineering analysis establishes the relationship between the cost and efficiency levels of the product that DOE is evaluating as potential energy conservation standards. This relationship serves as the basis for cost-benefit calculations for individual consumers, manufacturers, and the Nation. The engineering analysis identifies representative baseline products, which is the starting point for analyzing technologies that provide energy efficiency improvements. ''Baseline products'' refers to a model or models having features and technologies typically found in minimally-efficient products currently available on the market and, for products already subject to energy conservation standards, a model that just meets the current standard. After identifying the baseline models, DOE estimated manufacturer selling prices by using a consistent methodology and pricing scheme that includes material costs and manufacturer markups. Chapter 5 of the preliminary TSD discusses the engineering analysis.

B. Energy Use Analysis

The energy use analysis provides estimates of the annual energy consumption of ceiling fans. The energy use analysis seeks to estimate the range of energy consumption of the products that meet each of the efficiency levels considered in a given rulemaking as they are used in the field. DOE uses these values in the LCC and PBP analyses and in the NIA. Chapter 7 of the preliminary TSD addresses the energy use analysis.

C. Life-Cycle Cost and Payback Period Analyses

The LCC and PBP analyses determine the economic impact of potential standards on individual consumers. The LCC is the total cost of purchasing, installing and operating a considered product over the course of its lifetime. The LCC analysis compares the LCCs of products designed to meet possible energy conservation standards with the LCC of the product likely to be installed in the absence of standards. DOE determines LCCs by considering: (1) Total installed cost to the purchaser (which consists of manufacturer selling price, distribution chain markups, sales taxes, and installation cost); (2) the operating cost of the product (energy cost, water and wastewater cost in some cases, and maintenance and repair cost); (3) product lifetime; and (4) a discount rate that reflects the real consumer cost of capital and puts the LCC in present-value terms. The PBP represents the number of years needed to recover the increase in purchase price (including installation cost) of higher-efficiency products through savings in the operating cost of the product. PBP is calculated by dividing the incremental increase in installed cost of the higher efficiency product, compared to the baseline product, by the annual savings in operating costs. Chapter 8 of the preliminary TSD addresses the LCC and PBP analyses.

D. National Impact Analysis

The NIA estimates the national energy savings (NES) and the net present value (NPV) of total consumer costs and savings expected to result from amended standards at specific efficiency levels (referred to as candidate standard levels). DOE calculated NES and NPV for each candidate standard level for ceiling fans as the difference between a base-case forecast (without amended standards) and the standards-case forecast (with standards). Cumulative energy savings are the sum of the annual NES determined for the lifetime of the products shipped from 2019 to 2048.[3] The NPV is the sum over time of the discounted net savings each year, which consists of the difference between total operating cost savings and increases in total installed costs. Critical inputs to this analysis include shipments projections, estimated product lifetimes, product installed costs and operating costs, product annual energy consumption, the base case efficiency projection, and discount rates. Chapter 10 of the preliminary TSD addresses the NIA.

[3] For purposes of analysis, DOE assumes that 2019 would be the first year of compliance with amended standards.

IV. Public Participation

DOE invites input from the public on all the topics described above. The preliminary analytical results are subject to revision following further review and input from the public. A complete and revised TSD will be made available upon issuance of a NOPR. The final rule establishing any amended energy conservation standards will contain the final analytical results and will be accompanied by a final rule TSD.

DOE encourages those who wish to participate in the public meeting to obtain the preliminary TSD from DOE's Web site and to be prepared to discuss its contents. Once again, a copy of the preliminary TSD is available at: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/65.* However, public meeting participants need not limit their comments to the topics identified in the preliminary TSD; DOE is also interested in receiving views concerning other relevant issues that participants believe would affect energy conservation standards for this product or that DOE should address in the NOPR.

Furthermore, DOE welcomes all interested parties, regardless of whether they participate in the public meeting, to submit in writing by November 28, 2014 comments, data, and information on matters addressed in the preliminary TSD and on other matters relevant to consideration of energy conservation standards for ceiling fans.

The public meeting will be conducted in an informal conference style. A court reporter will be present to record the minutes of the meeting. There shall be no discussion of proprietary information, costs or prices, market shares, or other commercial matters regulated by United States antitrust laws.

After the public meeting and the closing of the comment period, DOE will consider all timely-submitted comments and additional information obtained from interested parties, as well as information obtained through further analyses. Afterwards, the Department will publish either a determination that the standards for ceiling fans need not be amended or a NOPR proposing to amend those standards. The NOPR will include proposed energy conservation standards for the products covered by the rulemaking, and members of the public will be given an opportunity to

submit written and oral comments on the proposed standards.

A. Attendance at Public Meeting

The time and date of the public meeting are listed in the **DATES** and **ADDRESSES** sections at the beginning of this notice. The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW., Washington, DC 20585–0121. To attend the public meeting, please notify Ms. Brenda Edwards at (202) 586–2945. Any foreign national wishing to participate in the meeting should advise DOE of this fact as soon as possible by contacting Ms. Brenda Edwards to initiate the necessary procedures.

You can attend the public meeting via webinar, and registration information, participant instructions, and information about the capabilities available to webinar participants will be published on the following Web site: *http://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/65.* Participants are responsible for ensuring their computer systems are compatible with the webinar software.

The purpose of the meeting is to receive comments and to help DOE understand potential issues associated with this rulemaking. DOE must receive requests to speak at the meeting before 5 p.m. on November 4, 2014. DOE must receive a signed original and an electronic copy of statements to be given at the public meeting before 5 p.m. on November 4, 2014.

B. Procedure for Submitting Requests to Speak

Any person who has an interest in today's notice or who is a representative of a group or class of persons that has an interest in these issues may request an opportunity to make an oral presentation. Such persons may hand-deliver requests to speak, along with a computer diskette or CD in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format to Ms. Brenda Edwards at the address shown in the **ADDRESSES** section at the beginning of this notice between 9:00 a.m. and 4:00 p.m. Monday through Friday, except Federal holidays. Requests may also be sent by mail to the address shown in the **ADDRESSES** section or email to *Brenda.Edwards@ee.doe.gov.*

Persons requesting to speak should briefly describe the nature of their interest in this rulemaking and provide a telephone number for contact. DOE requests persons selected to be heard to submit an advance copy of their statements at least two weeks before the public meeting. At its discretion, DOE may permit any person who cannot supply an advance copy of their statement to participate, if that person has made advance alternative arrangements with the Building Technologies Program. The request to give an oral presentation should ask for such alternative arrangements.

C. Conduct of Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also employ a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA. (42 U.S.C. 6306) A court reporter will record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. After the public meeting, interested parties may submit further comments on the proceedings as well as on any aspect of the rulemaking until the end of the comment period.

The public meeting will be conducted in an informal conference style. DOE will present summaries of comments received before the public meeting, allow time for presentations by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a prepared general statement (within DOE-determined time limits) prior to the discussion of specific topics. DOE will permit other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions from DOE and other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be posted on the DOE Web site and will also be included in the docket, which can be viewed as described in the Docket section at the beginning of this notice. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and other information regarding this rulemaking before or after the public meeting, but no later than the date provided at the beginning of this notice. Please submit comments, data, and other information as provided in the **ADDRESSES** section. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format and avoid the use of special characters or any form of encryption. Comments in electronic format should be identified by the Docket Number EERE–2011–BT–STD–0045 and/or RIN 1904–AC87 and, wherever possible, carry the electronic signature of the author. No telefacsimiles (faxes) will be accepted.

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

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

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this NOPM.

Issued in Washington, DC, on September 16, 2014.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2014–23098 Filed 9–26–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0108; Directorate Identifier 2011–NM–049–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposed airworthiness directive (AD) for certain The Boeing Company Model 767 airplanes. The NPRM proposed to supersede AD 2003–13–01, which currently requires an inspection to detect cracks and fractures of the outboard hinge fitting assemblies on the trailing edge of the inboard main flap, and follow-on and corrective actions if necessary. For certain airplanes, AD 2003–13–01 also requires inspecting to determine if a tool runout option has been performed in the area. The NPRM proposed to reduce a certain compliance time and adds airplanes to the applicability. The NPRM also provided optional terminating action for certain inspections. The NPRM was prompted by reports of hinge assembly fractures found before certain required compliance times in AD 2003–13–01. This action revises the NPRM by reducing repetitive inspection intervals for certain airplanes and limiting the inspection area. We are proposing this supplemental NPRM (SNPRM) to prevent the inboard aft flap from separating from the wing and potentially striking the airplane, which could result in damage to the surrounding structure and potential personal injury. Since these actions impose an additional burden over that proposed in the NPRM, we are reopening the comment period to allow the public the chance to comment on these proposed changes.

DATES: We must receive comments on this SNPRM by November 13, 2014.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Fax: 202–493–2251.
- Mail: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Delivery: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2012–0108; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6577; fax: 425–917–6590; email: *berhane.alazar@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2012–0108; Directorate Identifier 2011–NM–049–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 767–200, –300, and –300F, and –400ER series airplanes. The NPRM published in the **Federal Register** on February 9, 2012 (77 FR 6685). The NPRM proposed to supersede AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003). The NPRM proposed to continue to require an inspection to detect cracks and fractures of the outboard hinge fitting assemblies on the trailing edge of the inboard main flap, and follow-on and corrective actions if necessary; and, for certain airplanes, a one-time inspection to determine if a tool runout option has been performed in the area. The NPRM also reduced compliance times on certain airplanes (Model 767–400ER series airplanes), revised the applicability, and added an optional terminating action.

Actions Since Previous NPRM (77 FR 6685, February 9, 2012) Was Issued

Since we issued the NPRM (77 FR 6685, February 9, 2012), we have received reports of hinge assembly fractures found before the current inspection interval on Model 767–200, –300, and –300F series airplanes.

Comments

We gave the public the opportunity to comment on the NPRM (77 FR 6685, February 9, 2012). The following presents the comments received on the NPRM and the FAA's response to each comment.

Support for the NPRM (77 FR 6685, February 9, 2012)

An anonymous commenter supported the NPRM (77 FR 6685, February 9, 2012).

Request To Revise Applicability

American Airlines requested that we revise the applicability of the NPRM (77 FR 6685, February 9, 2012) to identify specific flap serial numbers instead of airplane line numbers. The commenter stated that a flap removed from the hinge assembly could then be installed on a different airplane.

We partially agree. We agree that the subject flaps are rotable parts that may be removed and reinstalled on different

airplanes after compliance with the AD. We have therefore added new paragraph (q) in this SNPRM (and redesignated subsequent paragraphs) to prohibit installation of an inboard main flap unless it has been inspected and repaired in accordance with the requirements of this SNPRM. But we do not agree to change the applicability as requested because this AD action applies to the airplane, not a component.

Since the flight cycles on the flaps may not be tracked by some operators, we mandated a compliance time tied to the total flight cycles of the airplane. Operators may request approval of an alternative compliance time, however, if the actual accumulated flight cycles on reinstalled flaps are known.

Request To Specify Additional Airplanes Subject to Repetitive Inspection Requirement

Boeing noted that paragraph (n) of the NPRM (77 FR 6685, February 9, 2012) specifies repetitive detailed and/or eddy current inspections for Model 767–400ER series airplanes. Boeing requested that we revise paragraph (n) of the NPRM to add the following revised service information: Boeing Alert Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012 (for Models 767–200, –300, and –300F airplanes); and Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012 (for Model 767–400ER series airplanes). Boeing noted that this revised service information improves crack detection by clarifying the HFEC inspection area, based on a recent finding of a crack located along the edge of the inspection area on a Model 767–300 series airplane. We infer that Boeing wants us to revise paragraph (n) of the NPRM to add Model 767–200, –300, and –300F series airplanes.

In addition, paragraph (o) of the NPRM (77 FR 6685, February 9, 2012) specifies a new optional terminating action. Boeing requested that we revise that paragraph to include terminating action for Model 767–200, –300, and –300F series airplanes (in addition to Model 767–400ER series airplanes), and to refer to Boeing Alert Service Bulletins 767–57A0076, Revision 3, dated April 4, 2012; and 767–57A0079, Revision 2, dated March 23, 2012.

Further, Boeing requested that we revise paragraph (p) of the NPRM (77 FR 6685, February 9, 2012) to provide credit for previous actions done using Boeing Service Bulletin 767–57A0076, Revision 2, dated November 22, 2006; and Boeing Service Bulletin 767–57A0079, Revision 1, dated May 6, 2010.

We agree with the requests, for the reasons provided by the commenter. We have revised paragraphs (n) and (o) in this SNPRM to add the referenced airplanes and service information. For information on the procedures and compliance times, see Boeing Alert Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012; and 767–57A0079, Revision 2, dated March 23, 2012; at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2012–0108.

We also have revised paragraph (p) of this SNPRM to provide credit for Boeing Service Bulletin 767–57A0076, Revision 2, dated November 22, 2006; and Boeing Service Bulletin 767–57A0079, Revision 1, dated May 6, 2010. We have determined that accomplishment of the actions specified in this revised service information before the effective date of the AD would provide an adequate level of safety.

Request for Approval of AMOCs

Boeing, American Airlines, and UPS requested that AMOCs previously approved for paragraph (i) of AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003), be considered acceptable for compliance with the requirements of paragraphs (g), (h), and (i) of the NPRM (77 FR 6685, February 9, 2012).

We agree. We have determined that the referenced AMOCs would provide an adequate level of safety. We have included this provision in new paragraph (r)(4) of this SNPRM.

FAA's Determination

We are proposing this SNPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of the NPRM (77 FR 6685, February 9, 2012). As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Proposed Requirements of This SNPRM

This SNPRM would require accomplishing the actions specified in Boeing Alert Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012; and 767–57A0079, Revision 2, dated March 23, 2012.

Costs of Compliance

We estimate that this proposed AD affects 440 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained detailed inspections	10 work-hours × $85 per hour = $850 per inspection cycle.	$0	$850 per inspection cycle.	$374,000 per inspection cycle.
Retained detailed and eddy current inspections.	13 work-hours × $85 per hour = $1,105 per inspection cycle.	$0	$1,105 per inspection cycle.	$486,200 per inspection cycle.

We estimate the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	32 work-hours × $85 per hour = $2,720	$45,400	$48,120

Authority for This Rulemaking

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

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

Regulatory Findings

We 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 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),

(3) Will not affect intrastate aviation in Alaska, and

(4) 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 39

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

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA 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. Amend § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2012–0108; Directorate Identifier 2011–NM–049–AD.

(a) Comments Due Date

We must receive comments by November 13, 2014.

(b) Affected ADs

This AD replaces AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003).

(c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Model 767–200, –300, and –300F series airplanes, as specified in Boeing Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012.

(2) Model 767–400ER series airplanes, as specified in Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports of hinge assembly fractures found before certain required compliance times on certain airplanes subject to AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003). We are issuing this AD to prevent the inboard aft flap from separating from the wing and potentially striking the airplane, which could result in damage to the surrounding structure and potential personal injury.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Inspection

This paragraph restates the requirements of paragraph (a) of AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003), with revised service information. Perform either a detailed inspection, or a detailed inspection plus an eddy current inspection, of the outboard hinge fitting assemblies on the trailing edge of the inboard main flap to detect cracks and fractures and evidence of a tool runout option, as applicable. 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.

(1) For Model 767–200, –300, and –300F series airplanes identified in Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001: Inspect before the airplane accumulates 2,700 total flight cycles, or within 90 days after July 29, 2003 (the effective date of AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003)), whichever occurs later, in accordance with Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001; or Boeing Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012. As of the effective date of this AD, only Boeing Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012, may be used for the inspection.

(2) For Model 767–400ER series airplanes identified in Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002: Inspect before the airplane accumulates 12,000 total flight cycles, except as required by paragraph (m) of this AD, in accordance with Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002; or Boeing Alert Service Bulletin 767–57A0079, Revision 1, dated May 6, 2010; or Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012. As of the effective date of this AD, only Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012, may be used for the inspection.

(h) Retained Follow-On/Corrective Actions

This paragraph restates the requirements of paragraph (b) of AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003), with revised service information. Following the initial inspections required by paragraph (g) of this AD, perform applicable follow-on and corrective actions at the times specified in Figure 1 of Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001 (for Model 767–200, –300, and –300F series airplanes); or Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002 (for Model 767–400ER series airplanes); until the initial inspection required by paragraph (n) of this AD is accomplished and repeat thereafter at the applicable times specified in paragraph (n) of this AD. Do the follow-on and corrective actions (including repetitive inspections and replacement of the fittings with new fittings) in accordance with Part 1 or Part 2 of Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001; or Boeing Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012 (for Model 767–200, –300, and –300F series airplanes); or Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002, or Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012 (for Model 767–400ER series airplanes); except as required by paragraph (i)(2) of this AD. For Model 767–200, –300, and –300F series airplanes: If the fitting has the tool runout, and no cracking or fracture is found during the inspection, this AD requires no further action for that hinge fitting. As of the effective date of this AD, for the actions required by this paragraph, only Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012, may be used for Model 767–400ER series airplanes; and only Boeing Alert Service Bulletin 767–57A0076,

Revision 3, dated April 4, 2012, may be used for Model 767–200, –300, and –300F airplanes.

(i) Retained Exceptions to Service Bulletin Procedures

This paragraph restates the requirements of paragraph (c) of AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003). The following exceptions specified in paragraphs (i)(1) and (i)(2) of this AD apply.

(1) Where the terminating action in Part 3 of Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001; and Revision 3, dated April 4, 2012; and Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002; Revision 1, dated May 6, 2010; and Revision 2, dated March 23, 2012; as applicable; is specified as corrective action, this AD requires that the terminating action, if required, be accomplished before further flight.

(2) Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001; and Revision 3, dated April 4, 2012; specify to contact Boeing before the terminating action is done as corrective action for any cracking or fracture found on a Model 767–200, –300, or –300F series airplane with the tool runout. However, this AD requires that any such crack or fracture on those airplanes be repaired in accordance with Part 3 of Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001; or Revision 3, dated April 4, 2012. This AD does not require a report.

(j) Retained Optional Terminating Action

This paragraph restates the provisions of paragraph (f) of AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003), with revised service information. Unless required to do so by paragraph (h) of this AD, operators may choose to accomplish the terminating action (including replacement of the fittings with new fittings, and reinstallation of existing upper skin access panels and fairing midsections on the trailing edge of the main flap) in accordance with Part 3 of the Work Instructions of Boeing Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001; or Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002; as applicable; or do the terminating actions specified in paragraph (o) of this AD. As of the effective date of this AD, use only the terminating action specified in paragraph (o) of this AD. Accomplishment of the terminating action terminates the repetitive inspection requirements of paragraph (h) of this AD.

(k) Parts Installation Limitations

As of the effective date of this AD, no person may install on any airplane identified in paragraph (c) of this AD, a hinge fitting assembly that has P/N 113T2271–13, 113T2271–14, 113T2271–23, 113T2271–24, 113T2271–29, 113T2271–30, 113T2271–33, 113T2271–34, 113T2271–401, or 113T2271–402, unless the applicable requirements of this AD have been accomplished for that fitting.

(l) Retained Credit for Previous Actions

This paragraph restates the provisions of paragraph (g) of AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003), with revised service information. Actions done before July 29, 2003 (the effective date of AD 2003–13–01), in accordance with Boeing Alert Service Bulletin 767–57A0076, dated October 26, 2000, are acceptable for compliance with the corresponding requirements of paragraphs (g)(1), (h), and (j) of this AD. Boeing Alert Service Bulletin 767–57A0076, dated October 26, 2000 is not incorporated by reference in this AD.

(m) New Initial Inspection

For Model 767–400ER airplanes identified in Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012, on which the inspection required in paragraph (g) of this AD has not been done as of the effective date of this AD: Before the accumulation of 6,000 total flight cycles, or within 750 flight cycles after the effective date of this AD, whichever occurs later, perform either a detailed inspection or a detailed inspection plus an eddy current inspection to detect cracks or fractures of the outboard hinge fitting assemblies on the trailing edge of the inboard main flap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012 Accomplishment of this inspection terminates the inspection requirement of paragraph (g)(2) of this AD. If any cracking or fracture is found, before further flight, replace the fittings in accordance with Part 3 of the Work Instructions of Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012.

(n) New Repetitive Inspections

Repeat either inspection specified in paragraph (h) or (m) of this AD, as applicable, at intervals not to exceed the time specified in paragraph (n)(1) or (n)(2) of this AD, as applicable, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012 (for Model 767–200, –300, and –300F series airplanes); or Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012 (for Model 767–400ER series airplanes); until the actions specified in paragraph (o) of this AD are done.

(1) If the most recent inspection was a detailed inspection: Do the next inspection within 300 flight cycles after doing the detailed inspection, and continue to repeat the inspection(s) thereafter at the time specified in paragraph (n) of this AD.

(2) If the most recent inspections were a detailed inspection and an eddy current inspection: Do the next inspections at the applicable time specified in paragraph (n)(2)(i) or (n)(2)(ii) of this AD, and continue to repeat the inspection(s) thereafter at the time specified in paragraph (n) of this AD.

(i) For Model 767–200, –300, and –300F series airplanes: Do the next inspection at the applicable time specified in paragraph (n)(2)(i)(A) or (n)(2)(i)(B) of this AD.

(A) If the detailed inspection and eddy current inspection were done before the effective date of this AD: Do the next inspection within 1,500 flight cycles after doing the detailed and eddy current inspections.

(B) If the detailed inspection and eddy current inspection were done on or after the effective date of this AD: Do the next inspection within 750 flight cycles after doing the detailed and eddy current inspection.

(ii) For Model 767–400ER series airplanes: Do the next inspection within 750 flight cycles after doing the detailed inspection and eddy current inspection.

(o) New Optional Terminating Action

Replacement of the fittings in accordance with Part 3 of the Work Instructions of Boeing Alert Service Bulletin 767–57A0079, Revision 2, dated March 23, 2012 (for Model 767–400ER series airplanes); or Part 3 of the Work Instructions of Boeing Alert Service Bulletin 767–57A0076, Revision 3, dated April 4, 2012 (for Model 767–200, –300, and –300F series airplanes); terminates the repetitive inspections required by paragraphs (h) and (n) of this AD.

(p) Credit for Previous Actions

(1) Actions done before the effective date of this AD in accordance with the service information identified in paragraph (p)(1)(i) or (p)(1)(ii) of this AD are acceptable for compliance with the corresponding requirements of paragraphs (h), (n), and (o) of this AD.

(i) Boeing Alert Service Bulletin 767–57A0076, Revision 1, dated March 29, 2001, which is incorporated by reference in AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003); or Boeing Alert Service Bulletin 767–57A0076, Revision 2, dated November 22, 2006, which is not incorporated by reference in this AD.

(ii) Boeing Alert Service Bulletin 767–57A0079, dated June 20, 2002, which is incorporated by reference in AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003); and Boeing Alert Service Bulletin 767–57A0079, Revision 1, dated May 6, 2010, which is not incorporated by reference in this AD.

(2) Actions done before the effective date of this AD in accordance with the service information identified in paragraph (p)(2)(i) or (p)(2)(ii) of this AD are acceptable for compliance with the corresponding requirements of paragraph (j) of this AD.

(i) Boeing Alert Service Bulletin 767–57A0076, Revision 2, dated November 22, 2006, which is not incorporated by reference in this AD.

(ii) Boeing Alert Service Bulletin 767–57A0079, Revision 1, dated May 6, 2010, which is not incorporated by reference in this AD.

(q) Parts Installation Limitation

As of the effective date of this AD, no person may install an inboard main flap on any airplane, unless the flap has been inspected and all applicable corrective actions have been performed in accordance with the requirements of this AD.

(r) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (s)(1) of this AD. Information may be emailed to *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved previously in accordance with AD 2003–13–01, Amendment 39–13201 (68 FR 37402, June 24, 2003), are approved as AMOCs for the corresponding provisions of paragraphs (g), (h), and (i) of this AD.

(s) Related Information

(1) For more information about this AD, contact Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6577; fax: 425–917–6590; email: *berhane.alazar@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may view copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on September 19, 2014.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–23138 Filed 9–26–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2013–1009]

RIN 1625–AA87

Security Zones; Dignitary Arrival/Departure and United Nations Meetings, New York, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Coast Guard proposes to amend 33 CFR 165.164 by establishing three security zones to replace the three regulated navigation areas (RNAs) currently contained within this section. The Coast Guard also proposes to disestablish these three RNAs. The three proposed security zones, just like the RNAs they replace, are meant to promote public safety and to protect dignitaries who visit the United Nations in New York, NY.

DATES: Comments and related material must be received by the Coast Guard on or before October 29, 2014.

Requests for public meetings must be received by the Coast Guard on or before October 6, 2014.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Jeff Yunker, Coast Guard Sector New York, Waterways Management Division; telephone (718) 354–4195, email *Jeff.M.Yunker@uscg.mil* or Lieutenant Myles Greenway, Coast Guard First District Waterways Management Branch, telephone (617) 223–8385, email *Myles.J.Greenway@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
MOA Memorandum of Agreement
NPRM Notice of Proposed Rulemaking
RNA Regulated Navigation Area
SNPRM Supplemental Notice of Proposed Rulemaking
UN United Nations
UNGA United Nations General Assembly
USSS United States Secret Service

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number [USCG–2013–1009] in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments 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 and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number (USCG–2013–1009) in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of 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 a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before October 6, 2014, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Regulatory History and Information

On August 30, 2013, we published a final rule entitled ''Regulated Navigation Areas, Security Zones: Dignitary Arrival/Departure and United Nations Meetings, New York, NY in the **Federal Register** (78 FR 53671). In so doing, the Coast Guard, among other things, established within 33 CFR 165.164 three RNAs on the waters of the East River and Bronx Kill, in the vicinity of Wall Street Heliport, Randalls and Wards Islands, and the United Nations Building, New York.

C. Basis and Purpose

The legal basis for this rule is 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define security zones.

As mentioned above, the Coast Guard previously established three RNAs on the waters of the East River and Bronx Kill, near Wall Street Heliport, Randalls and Wards Islands, and the United Nations Building. The primary purpose of these three RNAs is to protect dignitaries, such as the President of the United States, who visit the United Nations. Although these RNAs serve their intended purpose, the Coast Guard proposes to replace them with security zones to best communicate the federal government's security posture in these particular water areas.

D. Discussion of Proposed Rule

For the reasons discussed in the previous paragraph, the Coast Guard proposes to amend 33 CFR 165.164 by establishing three security zones to replace the three RNAs that currently exist in that section. Specifically, the Coast Guard proposes to establish a security zone at 33 CFR 165.164(a)(1), (a)(2), and (a)(6) in place of the RNAs currently described in those same three subparagraphs. Because these proposed security zones will replace the three RNAs, the Coast Guard also proposes to disestablish the three RNAs. The size, location, boundaries, and enforcement periods for these three proposed security zones will be identical to the size, location, boundaries, and enforcement periods for the existing RNAs.

This proposed rule would make no substantive changes to the security zones described at 33 CFR 165.164(a)(3), (a)(4), and (a)(5) (respectively, the ''Marine Air Terminal, La Guardia Airport Security Zone,'' ''United Nations Security Zone,'' and ''United Nations West Channel Closure Security Zone''). As a purely administrative matter, this proposed rule would re-title the security zones located at 33 CFR 165.164(a)(4) and (a)(5) to ''United Nations Manhattan Shoreline'' and ''United Nations West Channel Closure,'' respectively.

This proposed rule would revise 33 CFR 165.164 to contain six security zones, each with the intended purpose of protecting dignitaries visiting the United Nations. One of these security zones, that located at 33 CFR 165.164(a)(4), would be subject to enforcement at all times. All others would be subject to enforcement only periodically, and the public would be notified of their enforcement in accordance with 33 CFR 165.7.

E. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes or executive orders.

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. This determination is based on the fact that the RNAs would simply be designated as security zones as the more appropriate means to regulate the movement of vessels or individuals in the areas. We are not proposing to make any changes to the size, boundaries, or enforcement duration of these proposed security zones.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

This determination is based on the fact that the RNAs would simply be designated as security zones as the more appropriate means to regulate the movement of vessels or individuals in the areas. We are not proposing to make any changes to the size, boundaries, or enforcement duration of the proposed security zones.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement

Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. 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 the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this proposed rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. 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 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

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

9. Civil Justice Reform

This proposed 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.

10. Protection of Children From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

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

12. Energy Effects

This proposed rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves designating three RNAs as security zones. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination will be available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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 proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREA

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

Authority: 33 U.S.C. 1231; 46 U.S.C Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 165.164 to read as follows:

§ 165.164 Security Zones; Dignitary Arrival/Departure and United Nations Meetings, New York, NY.

(a) *Location.* The following areas are security zones:

(1) *Wall Street Heliport.* All waters of the East River within the following boundaries: East of a line drawn between approximate position 40°42′01″ N, 074°00′39″ W (east of The Battery) to 40°41′36″ N, 074°00′52″ W (point north of Governors Island) and north of a line drawn from the point north of Governors Island to the southwest corner of Pier 7 North, Brooklyn; and south of a line drawn between 40°42′14.8″ N, 074°00′20.3″ W (Wall Street, Manhattan), and the northwest corner of Pier 2 North, Brooklyn (NAD 1983).

(2) *Randalls and Wards Islands Security Zone:* All waters of the East River between the Hell Gate Rail Road Bridge (mile 8.2), and a line drawn from a point at approximate position 40°47′27.12″ N, 073°54′35.14″ W (Lawrence Point, Queens) to a point at approximate position 40°47′52.55″ N, 073°54′35.25″ W (Port Morris Stacks), and all waters of the Bronx Kill southeast of the Bronx Kill Rail Road Bridge (mile 0.6) (NAD 1983).

(3) *Marine Air Terminal, La Guardia Airport Security Zone:* All waters of Bowery Bay, Queens, New York, south of a line drawn from the western end of La Guardia Airport at approximate position 40°46′47″ N, 073°53′05″ W to

the Rikers Island Bridge at approximate position 40°46′51″ N, 073°53′21″ W and east of a line drawn between the point at the Rikers Island Bridge to a point on the shore in Queens, New York, at approximate position 40°46′36″ N, 073°53′31″ W (NAD 1983).

(4) *United Nations Manhattan Shoreline.* All waters of the East River bound by the following points: 40°44′37″ N, 073°58′16.5″ W (the base of East 35th Street, Manhattan), then east to 40°44′34.5″ N, 073°58′10.5″ W (about 180 yards offshore of Manhattan), then northeasterly to 40°45′29″ N, 073°57′26.5″ W (about 125 yards offshore of Manhattan at the Queensboro Bridge), then northwesterly to 40°45′31″ N, 073°57′30.5″ W (Manhattan shoreline at the Queensboro Bridge), then southerly along the shoreline to the starting point at 40°44′37″ N, 073°58′16.5″ W (NAD 1983).

(5) *United Nations West Channel Closure.* All waters of the East River north of a line drawn from approximate position 40°44′37″ N, 073°58′16.5″ W (the base of East 35th Street, Manhattan), to approximate position 40°44′31.04″ N, 073°58′03.10″ W (approximately 400 yards east of the Manhattan shoreline), all waters west of a line drawn from approximate position 40°44′31.04″ N, 073°58′03.10″ W (approximately 400 yards east of the Manhattan shoreline), to the southern tip of Roosevelt Island at approximate position 40°44′57.96″ N, 073°57′41.57″ W, then along the western shoreline of Roosevelt Island to the Queensboro Bridge, and all waters south of the Queensboro Bridge (NAD 1983).

(6) *United Nations Full River Closure.* All waters of the East River north of a line drawn from approximate position 40°44′37″ N, 073°58′16.5″ W (the base of East 35th Street, Manhattan), to approximate position 40°44′23″ N, 073°57′44.5″ W (Hunters Point, Long Island City), and south of the Queensboro Bridge (NAD 1983).

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

Designated representative means any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on the COTP's behalf. The designated representative may be on a Coast Guard vessel, or onboard a federal, state, or local agency vessel that is authorized to act in support of the Coast Guard.

Dignitary means the President or Vice President of the United States, or visiting heads of foreign states or governments.

(c) *Regulations.* In accordance with the general regulations in 33 CFR 165.33, no person or vessel may enter or move within a security zone created by this section while that security zone is being enforced unless granted permission to do so by the Coast Guard's First District Commander, the COTP New York, or the designated representative. Vessel operators and persons given permission to enter or operate in a security zone must comply with all directions given to them by the First District Commander, the COTP, or the designated representative. Upon being hailed by a U.S. Coast Guard or other duly authorized law enforcement vessel (e.g. New York City police) by siren, radio, flashing lights, or other means, the operator of a vessel must proceed as directed and follow any instructions to anchor or moor up to a waterfront facility.

(d) *Enforcement Periods.* The security zone described in paragraph (a)(4) of this section is subject to enforcement at all times. All other security zones established by this section will only be enforced when necessary to protect dignitaries, as determined by the COTP New York.

(e) *Notification.* Because the security zone described in paragraph (a)(4) of this section is subject to enforcement at all times, the Coast Guard will not necessarily take any action to further notify the public about the enforcement of that zone. As for the enforcement periods for the other security zones contained herein, the Coast Guard will rely on the methods described in 33 CFR 165.7 to notify the public of the time and duration of any enforcement period. The COTP New York may also notify the public about enforcement of these security zones via *http://homeport.uscg.mil/newyorkinformation.*

(f) *Contact Information.* Vessel operators desiring to enter or operate within a security zone established by this section shall telephone the COTP New York at 718–354–4356 or the designated representative via VHF channel 16 to obtain permission to do so.

Dated: September 16, 2014.

V.B. Gifford,

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

[FR Doc. 2014–23171 Filed 9–26–14; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0538; FRL–9915–50–Region 9]

Revision of Air Quality Implementation Plan; California; Placer County Air Pollution Control District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Placer County Air Pollution Control District (PCAPCD) portion of the California State Implementation Plan (SIP). This revision concerns a permitting rule that regulates construction and modifications of major stationary sources of air pollution. The revisions correct deficiencies in PCAPCD Rule 502, New Source Review, previously identified by EPA in a final rule dated September 24, 2013. We are proposing to approve revisions that correct the identified deficiencies.

DATES: Any comments must arrive by October 29, 2014.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2014–0538, by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions.
2. *Email: R9airpermits@epa.gov.*
3. *Mail or deliver:* Gerardo Rios (Air-3), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or email. *http://www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact

you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: EPA has established a docket for this action under EPA–R09–OAR–2014–0538. Generally, documents in the docket for this action are available electronically at *http://www.regulations.gov* or in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents are listed at *http://www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps, multi-volume reports), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: La weeda Ward, EPA Region IX, (213) 244–1812, *ward.laweeda@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposal addresses PCAPCD Rule 502, New Source Review. In the Rules and Regulations section of this **Federal Register**, we are approving this local rule in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in a subsequent action based on this proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: July 31, 2014.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2014–23002 Filed 9–26–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0586; FRL–9917–22–Region–9]

Approval and Promulgation of State Implementation Plans; California; Regional Haze Progress Report

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the California Regional Haze (RH) State Implementation Plan (SIP) submitted by the California Air Resources Board (CARB) documenting that the State's existing plan is making adequate progress to achieve visibility goals by 2018. The California RH SIP revision addresses the Regional Haze Rule (RHR) requirements under the Clean Air Act (CAA) to submit a report describing progress in achieving reasonable progress goals (RPGs) to improve visibility in Federally designated Class I areas in California and in nearby states that may be affected by emissions from sources in California. EPA is proposing to approve California's determination that the existing RH SIP is adequate to meet the visibility goals, and requires no substantive revision at this time.

DATES: Comments must be received by the designated contact at the address listed below on or before October 29, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2014–0586, by one of the following methods:

- Federal Rulemaking portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Email: *webb.thomas@epa.gov.*
- Fax: 415–947–3579 (Attention: Thomas Webb).
- Mail, Hand Delivery, or Courier: Thomas Webb, EPA Region 9, Air Division (AIR–2), 75 Hawthorne Street, San Francisco, California 94105. Hand and courier deliveries are only accepted Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: EPA's policy is to include all comments received in the public docket without change. We may make comments available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CBI or that is otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through *http://www.regulations.gov,* we will include your email address as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption, and be free of any defects or viruses.

Docket: All documents for this proposed action are listed in the index for docket number EPA–R09–OAR–2014–0586 on *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, such as CBI or other information that is restricted by statute. Certain other material, such as copyrighted material, is publicly available only in hard copy form. Publicly available docket materials are available electronically at *http://www.regulations.gov* or in hard copy during normal business hours at the Planning Office of the Air Division, AIR–2, EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105. To view hard copies of documents listed in the docket index, EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Thomas Webb, U.S. EPA, Region 9, Planning Office, Air Division, AIR–2, 75 Hawthorne Street, San Francisco, CA 94105. Thomas Webb may be reached at telephone number (415) 947–4139 and via electronic mail at *webb.thomas@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Overview of Proposed Action
II. Background on Regional Haze
III. Background on Regional Haze Plans
IV. Requirements for Regional Haze Progress Reports

V. EPA's Evaluation of California's Progress Report
A. Status of Control Strategies
B. Emission Reductions and Progress
C. Visibility Progress
D. Assessment of Changes Impeding Visibility Progress
E. Assessment of Current Strategy
F. Review of Visibility Monitoring Strategy
G. Determination of Adequacy
H. Consultation with Federal Land Managers
VI. EPA's Proposed Action
VII. Statutory and Executive Order Reviews

I. Overview of Proposed Action

EPA is proposing to approve CARB's determination that the existing California RH SIP is adequate to achieve the established RPGs for Class I areas by 2018, and therefore requires no substantive revision at this time. The State's determination and EPA's proposed approval are based on the California Regional Haze Plan 2014 Progress Report (''Progress Report'' or ''Report'') submitted by CARB to EPA on June 16, 2014, that addresses 40 CFR 51.308(g) and (h) of the RHR. The Progress Report demonstrates that the emission control measures in the existing RH SIP are sufficient to enable California, as well as other states with Class I areas affected by emissions from sources in California, to meet all established RPGs for 2018. We are also proposing to find that CARB fulfilled the requirements in 51.308(i)(2), (3), and (4) to provide Federal Land Managers (FLMs) with an opportunity to consult on the RH SIP revision, describe how CARB addressed the FLMs' comments, and provide procedures for continuing the consultation.

II. Background on Regional Haze

Regional haze is visibility impairment produced by many sources and activities located across a broad geographic area that emit fine particles that impair visibility by scattering and absorbing light, thereby reducing the clarity, color, and visible distance that one can see. These fine particles also can cause serious health effects and mortality in humans and contribute to environmental impacts, such as acid deposition and eutrophication of water bodies.

The RHR uses the deciview as the principle metric for measuring visibility and for the RPGs that serve as interim visibility goals toward meeting the national visibility goal of reaching natural conditions by 2064. A deciview expresses uniform changes in haziness in terms of common increments across the entire range of visibility conditions, from pristine to extremely hazy conditions. Deciviews are determined by using air quality measurement to estimate light extinction, and then transforming the value of light extinction using a logarithmic function. Deciview is a more useful measure for tracking progress in improving visibility than light extinction because each deciview change is an equal incremental change in visibility perceived by the human eye. Most people can detect a change in visibility at one deciview.

III. Background on Regional Haze Plans

In section 169A(a)(1) of the CAA Amendments of 1977, Congress created a program to protect visibility in designated national parks and wilderness areas, establishing as a national goal the ''prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas which impairment results from manmade air pollution.'' In accordance with section 169A of the CAA and after consulting with the Department of Interior, EPA promulgated a list of 156 mandatory Class I Federal areas where visibility is identified as an important value (44 FR 69122, November 30, 1979). In this notice, we refer to mandatory Class I Federal areas as ''Class I areas.'' California has 29 Class I areas, the most of any state.

With the CAA Amendments of 1990, Congress added section 169B to address regional haze issues. EPA promulgated a rule to address regional haze on July 1, 1999, known as the Regional Haze Rule (64 FR 35713). The RHR revised the existing visibility regulations in 40 CFR 51.308 to integrate provisions addressing regional haze impairment and to establish a comprehensive visibility protection program for Class I areas.

CARB submitted its initial RH SIP to EPA on March 17, 2009, in accordance with the requirements of 40 CFR 51.308 for the first regional haze planning period ending in 2018. EPA approved the California RH SIP for the first planning period on June 14, 2011 (76 FR 34608). The Progress Report from CARB is the first evaluation of whether the existing California RH SIP is sufficient to enable California, and other states affected by emissions from sources in California, to meet the established visibility goals for 2018.

IV. Requirements for Regional Haze Progress Reports

The RHR in 40 CFR 51.308(g) requires states to submit a report every five years in the form of a SIP revision to evaluate progress toward achieving the RPGs for each Class I area in the state and for those areas outside the state that may be affected by emissions from within the state. The first progress reports are due five years from the submittal date of each state's initial RH SIP. These reports must contain an evaluation of seven elements, at a minimum, and include a determination of the adequacy of the state's existing RH SIP. In summary,[1] the seven elements are: (1) A description of the status of implementation of all measures included in the current RH SIP for achieving the RPGs in Class I areas within and outside the State; (2) a summary of the emission reductions achieved in the State through implementation of these measures; (3) an assessment of visibility conditions and changes on the most impaired and least impaired days for each Class I area in the State in terms of 5-year averages of the annual values; (4) an analysis of changes in emissions over the past 5 years contributing to visibility impairment from all sources and activities within the State based on the most recently updated emissions inventory; (5) an assessment of any significant changes in anthropogenic emissions within or outside the State over the past 5 years that have limited or impeded progress in reducing pollutant emissions and improving visibility; (6) an assessment of whether the elements and strategies in the current RH SIP are sufficient to enable the State, or other states affected by its emissions, to achieve the established RPGs; and (7) a review of the State's visibility monitoring strategy and any necessary modifications.

Based on an evaluation of the factors listed above as well as any other relevant information, a state is required in 40 CFR 51.308(h) to determine the adequacy of its existing RH SIP. The state must take one of four possible actions based on the analysis in its progress report. In summary,[2] these actions are to (1) provide a negative declaration to EPA that no further substantive revisions to the State's existing RH SIP is needed to achieve the RPGs; (2) provide notification to EPA and to other states in its region that its RH SIP is or may be inadequate to ensure reasonable progress due to emissions from sources in other states, and collaborate with other states to develop additional strategies to address the deficiencies; (3) provide notification and available information to EPA that the State's RH SIP is or may be inadequate to ensure reasonable

[1] Please refer to 40 CFR 51.308(g) for the exact Rule requirements.

[2] Please refer to 40 CFR 51.308(h) for the exact Rule requirements.

progress due to emissions from sources in another country; or (4) revise its RH SIP within one year to address the deficiencies if the State determines that its existing plan is or may be inadequate to ensure reasonable progress in one or more Class I areas due to emissions from sources within the State.

A state must document that it provided FLMs with an opportunity for consultation prior to holding a public hearing on a RH SIP or plan revision as required in 40 CFR 51.308(i)(2). In addition, a state must include a description of how it addressed any comments from the FLMs, and provide procedures for continuing consultation with the FLMs as required in 40 CFR 51.308(i)(3) and (4).

V. EPA's Evaluation of California's Progress Report

This section describes California's Progress Report and EPA's evaluation of the Report in relation to the seven elements listed in 40 CFR 51.308(g) and the determination of adequacy in 40 CFR 51.308(h). We also review the requirement in 40 CFR 51.308(i)(2) for state and FLM coordination on a plan revision. However, to facilitate a better understanding of the Report's contents, we first provide background information on the framework for measuring visibility progress, the causes of haze in California, and the sources of data used in the Report.

Framework for Measuring Progress: Visibility conditions at California's 29 Class I areas are calculated in deciviews using data collected from 17 Interagency Monitoring of Protected Visual Environments (IMPROVE) monitors. These deciview values are then compared to the State's RPGs (i.e., visibility goals) for 2018 in each Class I area. The RPGs are based on the annual average of the projected deciview level for the 20 percent best days and the 20 percent worst days measured at each Class I area. The RPGs in 2018 for the worst days, the key indicator of progress, are the result of atmospheric modeling based on projected emission reductions from control strategies in the California RH SIP as well as emission reductions expected to result from other Federal, state and local air quality programs among other factors. The RPGs must provide for an improvement in visibility on the 20 percent worst days and ensure no degradation on the 20 percent best days, compared to average visibility conditions during the baseline period from 2000 to 2004.

Causes of Haze: The three primary drivers of haze on the worst days in California are nitrates mostly from mobile sources, sulfates mostly from offshore and international sources, and organic carbon (OC) mostly from natural sources. Accordingly, California's control strategies target reducing the precursors of these pollutants: nitrogen oxide (NO_X) for nitrates, sulfur oxide (SO_X) for sulfates, and reactive organic gases (ROG) [3] for organic carbon, along with fine particulate matter ($PM_{2.5}$) that is directly emitted. For more information regarding the causes of haze in California and other background information, please refer to the California RH SIP and EPA's evaluation of that SIP, both of which are available in the docket for this rulemaking.[4]

Data Sources for the Progress Report: CARB's analysis is primarily based on IMPROVE monitoring data for the five-year period from 2007 to 2011 (i.e., current conditions) compared to monitoring data from 2000 to 2004 (i.e., baseline conditions). For each of these time periods, the RHR requires the use of a five-year average of annual average deciview values to represent the baseline and current conditions. CARB also relied on the ''Western Regional Air Partnership (WRAP) Regional Summary Report,'' dated June 2013, that focuses on the five years (2005 to 2009) following the baseline period. While the most recent IMPROVE data for 2012 was not available in time for the Progress Report's analysis, a summary of the 2012 monitoring data is appended to the Report, and is referenced to support the analysis of current conditions.

A. Status of Control Strategies

1. CARB's Analysis

The California RH SIP relies on the continued implementation of adopted Federal, state and local control measures, which were developed primarily to meet the National Ambient Air Quality Standards (NAAQS), to address the anthropogenic sources of haze in California. In its Progress Report, CARB confirms that mobile sources are the primary contributor of NO_X, while also contributing SO_X, OC, and $PM_{2.5}$ to haze at Class I areas. Although many aspects of mobile sources are regulated by Federal laws, the Progress Report notes that California has some of the most aggressive and innovative State and local regulations for mobile sources in the country. The Progress Report lists strategies adopted and implemented by the State that target emission reductions from light-duty passenger vehicles, heavy-duty diesel trucks, and off-road equipment, which are some of the largest sources of NO_X emissions. Actual measures include fuel and engine standards, pollution control technology, goods movement and transportation rules, and consumer product requirements. In addition, local air districts implement stationary source and other control programs including New Source Review and Prevention of Significant Deterioration permits that also reduce or prevent emissions that might contribute to haze.

The Progress Report includes a list of two dozen new control strategies that were not in the emission inventory used to project the deciview level for the RPGs in 2018. Due to nonattainment of NAAQS, CARB and local districts are regularly adopting or revising rules and creating new incentives to reduce emissions. These new control measures should further reduce emissions beyond those projected from the control strategies in the California RH SIP.

The Progress Report also includes an update on the State's single stationary source, the Valero Refinery in Benicia, California, that was required to install and operate Best Available Retrofit Technology (BART) controls. The new control equipment includes low-NO_X burners and selective catalytic reduction to reduce NO_X, and scrubbers to remove SO_2 and PM_{10} (large particulate matter). These controls, installed and in operation at the Valero Refinery since February 2011, two years before the deadline for compliance, are already reducing emissions. The deciview and light extinction data from 2011 (20.2 dv) and 2012 (20.1) for Point Reyes National Seashore, the most affected Class I area by emissions from this source, are already showing a reduction in nitrates and sulfates compared to 2010 (22 dv).

2. EPA's Evaluation

EPA proposes to find that CARB adequately addresses the requirement in 40 CFR 51.308(g)(1) to describe the status of all measures included in the California RH SIP. CARB generally describes the types of measures in its RH SIP, and includes new control strategies that should contribute to further improvement in visibility. The report identifies NO_X emissions from mobile sources as the primary source of anthropogenic emissions causing or contributing to haze, and focuses on related control measures. The report

[3] CARB defines ROG emissions as reactive organic gases that are a precursor to organic carbon aerosols. ROG means any compound of carbon, which is how EPA defines volatile organic compounds (VOC). However, the lists of compounds of carbon that are excluded from the respective lists of ROGs and VOCs differ to some extent.

[4] California RH SIP Section 4.7: Regional Analysis of Source Categories, Proposed rule at 76 FR 13944 (March 15, 2011), and Final rule at 76 FR 34608 (June 14, 2011).

also includes the status of BART controls at the Valero Refinery, the only identified source in California subject to BART. In response to a comment from FLMs requesting additional information regarding Federal and state regulations that were accounted for in California's RPGs, CARB noted that its RH SIP submitted in 2009 included a discussion of the regulations used to establish the RPGs for 2018.[5] The RH SIP is included in the docket for this action. A listing of state and local California air district rules within the federally enforceable SIP, is available at: *http://www.epa.gov/region9/air/sips/index.html*.

B. Emission Reductions and Progress

1. CARB's Analysis

CARB provides a recently updated California Statewide Emission Inventory from 2000 to 2020 at five-year intervals that demonstrates steadily decreasing emissions of regional haze precursors (i.e., NO_X, ROG, SO_X, and $PM_{2.5}$) from about 75 categories of sources.[6] NO_X emissions are expected to decrease from about 1.4 million tons per year (tpy) in 2000 to 567,000 tpy in 2020. ROG emissions are expected to decrease from about 1 million tpy in 2000 to 570,000 tpy in 2020. SO_X emissions are expected decrease from about 106,000 tpy in 2000 to 30,000 tpy in 2020. $PM_{2.5}$ emissions are expected to decrease from about 241,000 tpy in 2000 to 151,000 tpy in 2020.

Statewide emissions also are summarized by pollutant for each of the three major categories of sources: Stationary, area, and mobile.[7] Of particular interest are NO_X emissions from mobile sources, which are expected to decrease from about 1.1 million tpy in 2000 to 995,000 tpy in 2005; 706,000 tpy in 2010; 557,000 tpy in 2015; and 434,000 tpy in 2020. The statewide emissions inventory and summary are accompanied by a graph of statewide inventory trends that shows decreasing emissions for all four visibility-impairing pollutants from 2000 to 2020. Mobile source emissions of NO_X, ROG, SO_X, and $PM_{2.5}$, listed above in tpy, are projected to decline by about 60, 65, 85, and 50 percent, respectively, from 2000 to 2020.[8] Stationary and area sources for these four pollutants are also projected to decline over this 20-year period. Overall statewide emissions of NO_X, ROG, SO_X, and $PM_{2.5}$ for stationary, area, and mobile sources are expected to decline by almost 40 percent from 2000 to 2020.

2. EPA's Evaluation

EPA proposes to find that CARB adequately addresses the requirements in 40 CFR 51.308(g)(2) to provide a summary of the emission reductions achieved through implementation of the control measures relied upon to achieve the RPGs. The trend analysis for the largest category of emissions, NO_X from mobile sources, indicates that these emissions are expected to decline from 1,131,500 tons per year in 2000 to 433,620 tons per year by 2020, a reduction of almost 62 percent. As reported by CARB, statewide emissions of ROG, SO_X, and $PM_{2.5}$ are also declining over this 20-year time period.

We also propose to find that CARB adequately addresses the requirement in 40 CFR 51.308(g)(4) to analyze the change in emissions over the past five years of pollutants contributing to visibility impairment from all sources and activities within the state, using the most recently updated emissions inventory. The California Statewide Emission Inventory is recently updated and includes inventories for 2005 and 2010 that represent the past five years.

C. Visibility Progress

1. CARB's Analysis

CARB addresses progress on the 20 percent best days and 20 percent worst days by comparing current conditions (five-year average from 2007 to 2011) to baseline conditions (five-year average from 2000 to 2004), and current conditions on worst days to the RPGs in 2018. A summary of progress on best and worst days is shown in Tables 1 and 2 that are adapted from the Progress Report.[9] As shown in the tables, CARB divides the 17 monitors and 29 Class I areas into four regional zones for its analysis: Northern California, Sierra California, Coastal California, and Southern California.

TABLE 1—SUMMARY OF PROGRESS ON BEST DAYS

[In deciviews]

IMPROVE Monitor	Class I Areas	Baseline best days (2000–04)	Current best days (2007–11)	Visibility change
Northern California				
TRIN	Marble Mountain WA	3.4	3.0	0.4
	Yolla Bolly-Middle Eel WA			
LABE	Lava Beds NM	3.2	2.9	0.3
	South Warner WA			
LAVO	Lassen Volcanic NP	2.7	2.3	0.4
	Caribou WA			
	Thousand Lakes WA			
Sierra California				
BLIS	Desolation WA	2.5	2.1	0.4
	Mokelumne WA			
HOOV	Hoover WA	1.4	1.3	0.1
YOSE	Yosemite NP	3.4	2.5	0.9
	Emigrant WA			
KAIS	Ansel Adams WA	2.3	1.5	0.8
	Kaiser WA			
	John Muir WA			

[5] Progress Report Appendix E: Comments of Federal Land Management Agencies with CARB Responses.

[6] *Id.* Appendix B: Emission Inventory 2013 Almanac.

[7] *Id.* California Statewide Inventory Summary, Table 2, page 9.

[8] *Id.* California Statewide Inventory Trends, Figure 3, page 10.

[9] *Id.* Statewide 2018 Reasonable Progress Goal Summary, Table 3, page 12, and Revised Table 3.

TABLE 1—SUMMARY OF PROGRESS ON BEST DAYS—Continued

[In deciviews]

IMPROVE Monitor	Class I Areas	Baseline best days (2000–04)	Current best days (2007–11)	Visibility change
SEQU	Sequoia NP	8.8	7.6	1.2
	Kings Canyon NP			
DOME	Dome Lands WA	5.1	4.9	0.2
Coastal California				
REDW	Redwood NP	6.1	5.8	0.3
PORE	Point Reyes NS	10.5	8.6	1.9
PINN	Pinnacles WA	8.9	7.8	1.1
	Ventana WA			
RAFA	San Rafael WA	6.4	5.2	1.2
Southern California				
SAGA	San Gabriel WA	4.8	4.5	0.3
	Cucamonga WA			
SAGO	San Gorgonio WA	5.4	4.0	1.4
	San Jacinto WA			
AGTI	Agua Tibia WA	9.6	7.1	2.5
JOSH	Joshua Tree NP	6.1	4.8	1.3

WA = Wilderness Area NM = National Monument NP = National Park NS = National Seashore

TABLE 2—SUMMARY OF PROGRESS ON WORST DAYS

[In deciviews]

IMPROVE Monitor	Class I Areas	Baseline worst days (2000–04)	Current worst days (2007–11)	Visibility change	RPG (2018)	Current progress to RPG
Northern California						
TRIN	Marble Mountain WA	17.4	15.2	2.1	16.4	210%
	Y.B.-Middle Eel WA					
LABE	Lava Beds NM	15.1	13.0	2.1	14.4	300%
	South Warner WA					
LAVO	Lassen Volcanic NP	14.1	15.6	−1.5	13.3	−188%
	Caribou WA					
	Thousand Lakes WA					
Sierra California						
BLIS	Desolation WA	12.6	13.0	−0.4	12.3	−133%
	Mokelumne WA					
HOOV	Hoover WA	12.9	11.5	1.4	12.5	350%
YOSE	Yosemite NP	17.6	16.0	1.6	16.7	178%
	Emigrant WA					
KAIS	Ansel Adams WA	15.5	14.9	0.6	14.9	100%
	Kaiser WA					
	John Muir WA					
SEQU	Sequoia NP	25.4	22.3	3.1	22.7	115%
	Kings Canyon NP					
DOME	Dome Lands WA	19.4	18.3	1.1	18.1	85%
Coastal California						
REDW	Redwood NP	18.5	18.5	0	17.8	0%
PORE	Point Reyes NS	22.8	21.6	1.2	21.3	80%
PINN	Pinnacles WA	18.5	17.5	1.0	16.7	56%
	Ventana WA					
RAFA	San Rafael WA	18.8	18.0	0.8	17.3	53%
Southern California						
SAGA	San Gabriel WA	19.9	18.0*	1.9	17.4	76%*
	Cucamonga WA					
SAGO	San Gorgonio WA	22.2	18.7	3.5	19.9	152%
	San Jacinto WA					
AGTI	Agua Tibia WA	23.5	19.8	3.7	21.6	195%

TABLE 2—SUMMARY OF PROGRESS ON WORST DAYS—Continued

[In deciviews]

IMPROVE Monitor	Class I Areas	Baseline worst days (2000–04)	Current worst days (2007–11)	Visibility change	RPG (2018)	Current progress to RPG
JOSH	Joshua Tree NP	19.6	16.1	3.5	17.9	206%

WA = Wilderness Area NM = National Monument NP = National Park NS = National Seashore
* This data is from 2005 to 2008 due to fire damage to the monitor in 2009.

Current visibility conditions have improved on the 20 percent best days at all California's Class I areas as indicated in the last column of Table 1 that shows positive visibility change compared to the best days baseline for all 17 monitors.[10] On the 20 percent worst days, the current conditions already meet the RPGs for 2018 at nine of the 17 monitors as shown in Table 2. At five monitors, current conditions on worst days range from 53 to 85 percent of the improvement in visibility needed to meet the respective RPGs. At the remaining three monitors, current conditions on worst days indicate that six Class I areas are not making progress in achieving the RPGs.

The Progress Report explains that the limited progress in improving visibility at six Class I areas, all located in northern California, is due to smoke from wildfires as documented in Appendix D of the Progress Report.[11] The six Class I areas and the associated monitors are Lassen Volcanic National Park, Caribou Wilderness Area, and Thousand Lakes Wilderness Area (LAVO); Desolation Wilderness Area and Mokelumne Wilderness Area (BLIS); and Redwood National Park (REDW). CARB explains that wildfire smoke has caused unusually high deciviews on the worst days at the LAVO monitor in 2008 and 2009, at the BLIS monitor in 2007 and 2008, and at the REDW monitor in 2008. CARB provides technical analyses of how wildfire smoke can elevate the deciview value on a sufficient number of the 20 percent worst days to increase the annual average deciview as well as skew the five-year average deciview at a given monitor. CARB also notes that offshore emissions from ocean vessels may contribute to sulfate formation that impairs visibility at some remote monitors near the coast where there are no other major sources of sulfates.[12] This may be the case for Pinnacles Wilderness Area and Ventana Wilderness Area (PINN), and Redwood National Park (REDW), where visibility improvement during the current five-year period is slower than elsewhere, although these three Class I areas are affected by wildfire smoke in some years as well.

CARB also includes a Statewide 2018 Reasonable Progress Goal Summary using 2012 Data[13] that represents the five-year average for current conditions from 2008 to 2012. This updated table shows that on the worst days only three Class I areas represented by one monitor (LAVO) have worse visibility during current conditions (15.6 dv) compared to the baseline (14.1 dv). Of the remaining 16 monitors, 14 already exceed and two (REDW and PINN) are expected to meet the RPGs in 2018 for the worst days based on trends reflected by the updated current conditions. On the best days, the average current conditions from 2008 to 2012 meet or exceed the RPGs at all 17 monitors.

2. EPA's Evaluation

EPA proposes to find that CARB adequately addresses the requirement in 40 CFR 51.308(g)(3) to assess the visibility conditions and changes in each of the State's Class I areas for the least and most impaired days in terms of the five-year averages of the annual values. CARB describes progress at each of the Class I areas on the best and worst days using data from the IMPROVE monitors to analyze changes in visibility conditions for current conditions (2007 to 2011), current conditions compared to baseline conditions, and over the past five years, which is essentially equivalent to the baseline comparison.

D. Assessment of Changes Impeding Visibility Progress

1. CARB's Analysis

The Progress Report includes an assessment of changes in natural and anthropogenic emissions that impede visibility progress based on a review of emission inventories, monitoring data, and other sources of information.[14] CARB identifies three factors, largely beyond the State's control, that interfere with progress toward improved visibility on worst days at some of its Class I areas. These factors are wildfire smoke from natural sources, offshore shipping emissions from anthropogenic sources largely outside California's jurisdiction, and Asian dust from natural and anthropogenic sources outside of California's jurisdiction. Each of these types of emissions can cause a spike in pollutants at a sampling monitor that could be included in the 20 percent worst days. Wildfire smoke results in elevated levels of organic carbon. Offshore shipping results in elevated levels of sulfates at monitors near the coast during the summer. Asian dust combined with industrial pollution in the form of coarse mass and fine soils are transported in the jet stream over the Pacific Ocean, especially during the spring.

CARB provides documentation and analysis supporting the fact that wildfires are occurring more frequently in California over the past decade.[15] Wildfire smoke can cause increases in organic carbon concentrations at monitors for several consecutive days or weeks. In some cases, the effect of wildfires is high enough to increase the deciview value of the annual as well as five-year averages on the 20 percent worst days. The Progress Report includes the example of a large number of wildfires in northern California known as the ''2008 Lightning Strike Complex'' that occurred in June through August 2008. These fires had an overwhelming impact on visibility progress at many monitors throughout California and the West.[16] CARB includes in the Report a satellite photo of smoke plumes on July 9, 2008, that indicates the location of the three monitors (REDW, BLIS, and LAVO) where visibility progress was lagging during the current conditions time period (2007 to 2011).[17] Moreover, with

[10] See Revised Table 3, Technical Correction for Current Best Days (2007–2011), August 6, 2014.

[11] *Id.* Appendix D: Technical Analyses of Factors Impeding Progress.

[12] *Id.* Page 11.

[13] *Id,* Appendix C: Deciview Record (2000–2012), Table C–3.

[14] *Id.* Section 4, pages 13–17.

[15] *Id.* Wildfire Acreage Burned in California, 1950–2010, Figure 4, page 14.

[16] *Id,* The 2008 ''Lightning Strike Complex,'' Figure 5, page 15.

[17] *Id,* NASA Satellite Photo: July 9, 2008, Figure 6, page 16.

80 percent of the State considered wildland [18] and smoke drifting long distances, all of California's Class I areas are susceptible to wildfires.

2. EPA's Evaluation

EPA proposes to find that CARB adequately addresses the requirement in 40 CFR 51.308(g)(5) to assess any significant changes in anthropogenic emissions within or outside the State over the past five years that have limited or impeded progress in reducing emissions and improving visibility. While CARB's analysis primarily focuses on wildfires, it also discusses the effects of emissions from offshore shipping and Asian dust.

E. Assessment of Current Strategy

1. CARB's Analysis

The Progress Report asserts that California's current control strategy is on track to meet the RPGs for 2018 at all 29 Class I areas throughout the State. CARB cites the IMPROVE data for 2011 in which each of the Class I areas is already below the 2018 visibility goal. Moreover, the State continues to strengthen existing control measures, adopt new control measures, and develop plans with even newer measures to meet upcoming NAAQS as well as other new Federal and State air quality requirements.

The Progress Report indicates that the current strategy also is sufficient to lessen the impact of California's emissions on neighboring states. In the California RH SIP, CARB determined that the State's emissions contributed about three percent or less of nitrate on the worst days at Jarbidge Wilderness Area in Nevada; Kalmiopsis Wilderness Area and Crater Lake National Park in Oregon; and Sycamore Canyon Wilderness Area and Grand Canyon National Park in Arizona. With California NO_X emissions projected to decrease by about 60 percent from 2000 to 2020, these small contributions will be further reduced.

2. EPA's Evaluation

EPA proposes to find that CARB adequately addresses the requirement in 40 CFR 51.308(g)(6) to assess whether the current elements and strategies in the RH SIP are sufficient to enable California, or other states affected by California's emissions, to meet all established RPGs. As described above, monitoring data indicates current visibility conditions already meet or exceed the RPGs for the 20 percent best days at all of the State's Class I areas. In addition, 26 of the State's 29 Class I areas have already achieved the 2018 RPGs for the worst days or are on track to meet those RPGs by 2018. The lack of progress at the three remaining areas on the worst 20 percent days is largely due to wildfires. Significant emission reductions within California are also expected to benefit Class I areas outside the State that are affected by California's emissions. CARB provides sufficient evidence to demonstrate that its current strategy is adequate to enable all affected Class I areas to meet the RPGs for 2018.

F. Review of Visibility Monitoring Strategy

1. CARB's Analysis

California will continue to rely on the IMPROVE network to collect and analyze the visibility data, and has no need to make any changes. CARB reports that the Station Fire in August 2009 destroyed the SAGA monitor that represents San Gabriel Wilderness Area and Cucamonga Wilderness Area. For this reason, the current conditions on the worst days for the SAGA monitor are based on 2005 to 2008, instead of 2007 to 2011. However, the monitoring site was reestablished in October 2011.

2. EPA's Evaluation

EPA proposes to find that CARB adequately addresses the requirement in 40 CFR 51.308(g)(7) to review its visibility monitoring strategy and make any modifications as necessary. We agree that there is no need to modify California's monitoring network for measuring visibility at this time.

G. Determination of Adequacy

1. CARB's Determination

CARB has determined that no substantive revision of the RH SIP is warranted at this time in order to achieve the RPGs for visibility improvement by 2018. Visibility trends for the worst days show improvement at every monitor except for the three monitors (LAVO, BLIS, and REDW) influenced by years with wildfires. Further, current visibility conditions on best days (2007 to 2011) at all monitors are better than the baseline period. Based on reductions in anthropogenic sources of emissions in California and the concurrent improvement in visibility at all of California's Class I area monitors, CARB determines that the current RH SIP strategies are sufficient to enable California and its neighboring states to meet their RPGs for 2018.

2. EPA's Evaluation

EPA proposes to find that CARB adequately addresses the requirements in 40 CFR 51.308(h) by determining that the existing California RH SIP requires no substantive revisions at this time to achieve the established RPGs at Class I areas affected by the State's sources. EPA concurs with the State's determination based on the analysis and documentation presented in the Progress Report. The Report provides evidence of declining emissions from anthropogenic sources within the State's control and improving visibility on worst days at all the monitors except when influenced by wildfires. Visibility on best days is also improving at all monitors, which are already meeting the RPGs for the best days.

H. Consultation With Federal Land Managers

1. CARB's Consultation

CARB conducted timely outreach in January 2014 to the FLMs including the U.S. National Park Service (NPS) and the U.S. Forest Service (USFS), which manage the national parks and wildlife areas in California. The NPS responded in a letter dated March 27, 2014, that agreed with CARB's conclusion that emission reductions are sufficient to meet the RPGs for 2018, and offered suggestions to strengthen the Report. The USFS responded in a letter dated April 8, 2014, that CARB has demonstrated it is on a technically sound path for improving visibility in Class I areas. CARB's responses to the comments from NPS and USFS are included in Appendix E of the Report.

CARB has submitted to EPA a Public Notice and Hearing Transcript along with a certified copy of Air Resources Board Resolution 14–15 dated May 22, 2014, the date of the public hearing at which the Board approved the Progress Report. Resolution 14–15 certifies that CARB provided a copy of the draft Progress Report to the FLMs on January 28, 2014, and on March 11, 2014, held a conference call to discuss the draft Report. In the response to comments, CARB commits to continuing policy discussions through the regular Air and Land Mangers meetings held between the State and FLMs.

2. EPA's Evaluation

EPA proposes to find that CARB has addressed the requirements in 40 CFR 51.308(i)(2), (3), and (4) to provide FLMs with an opportunity for consultation in person and at least 60 days prior to a public hearing on the SIP revision; include a description in the SIP revision of how it addressed any

[18] *Id,* Wildfire Frequency and Intensity, Figure 7, page 17.

comments from the FLMs; and provide procedures for continuing consultation between the State and FLMs.

VI. EPA's Proposed Action

EPA is proposing to approve the California Regional Haze Plan 2014 Progress Report submitted to EPA on June 16, 2014, as meeting the applicable RHR requirements as set forth in 40 CFR 51.308(g), (h), and (i).

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations.[19] Thus, in reviewing SIP submissions, EPA's role is to approve state decisions, provided that they meet the criteria of the CAA. Accordingly, this proposed action is to approve state law as meeting Federal requirements, and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state. EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Organic carbon, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Visibility, Volatile organic compounds.

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

Dated: September 17, 2014.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2014–23101 Filed 9–26–14; 8:45 am]

BILLING CODE 6560–50–P

[19] 42 U.S.C. 7410(k); 40 CFR 52.02(a).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2014–0713; FRL–9917–20–Region–8]

Approval and Promulgation of Air Quality Implementation Plans; Montana; Revisions to Administrative Rules of Montana—Prevention of Significant Deterioration

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Montana on June 4, 2013. This SIP revision revises the Administrative Rules of Montana that pertain to the issuance of Montana air quality permits. The June 4, 2013 revisions contain amended and renumbered rules. In this proposed rulemaking, we are taking action on portions of the June 4, 2013 submittal. This action is being taken under section 110 of the Clean Air Act (CAA).

DATES: Comments must be received on or before October 29, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2014–0713, by one of the following methods:

- *www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Email: *leone.kevin@epa.gov.*
- Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- Mail: Carl Daly, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- Hand Delivery: Carl Daly, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2014–0713. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on

submitting comments, go to section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly-available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Kevin Leone, Air Program, Mailcode 8P–AR, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6227, or *leone.kevin@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information
II. What is being addressed in this document?
III. What is the state process to submit these materials to EPA?
IV. What are the changes that EPA is proposing to approve?
V. What action is EPA taking today?
VI. Statutory and Executive Orders Review

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The initials *ARM* mean or refer to the Administrative Rules of Montana.

(iii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iv) The initials *MDEQ* mean or refer to the Montana Department of Environmental Quality.

(v) The initials NO_X mean or refer to nitrogen oxides.

(vi) The initials *NSR* mean or refer to New Source Review.

(vii) The initials *PSD* mean or refer to Prevention of Significant Deterioration.

(viii) The initials *SIP* mean or refer to State Implementation Plan.

(ix) The initials SO_2 mean or refer to sulfur dioxide.

(x) The words *State* or *Montana* mean the State of Montana, unless the context indicates otherwise.

I. General Information

A. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. What is being addressed in this document?

EPA is proposing to approve (with one exception) the revisions to Title 17, Chapter 8, subchapter 8 of the Administrative Rules of Montana (ARM) submitted by the State on June 4, 2013, that relate to the State's prevention of significant deterioration (PSD) program. The revisions to the State PSD SIP were adopted by the Montana Department of Environmental Quality (MDEQ) on September 27, 2012, and became effective October 12, 2012.

Specifically, the submittal contains revisions to ARM 17.8.801 (Definitions) and 17.8.818 (Review of Major Source and Major Modifications—Source Applicability and Exemptions) to include nitrogen oxides (NO_X) as an ozone precursor pollutant for reviewing major stationary sources of air pollutants and to amend portions of the SIP for consistency of language when referring to sulfur dioxide (SO_2) and NO_X. The submittal also corrected an error in an August 15, 2012 submittal regarding the treatment of fine particulate matter ($PM_{2.5}$). We have not acted on the August 15, 2012 submittal; EPA will act on the correction in the June 4, 2013 submittal in tandem with our future action on the August 15, 2012 submittal.

On November 29, 2005, EPA published the ''Final Rule to Implement the 8-Hour Ozone National Ambient Air Quality Standards—Phase 2'' in 70 FR 71612 (''Phase 2 Ozone Implementation Rule''). This regulation required revisions to state programs for major source permitting. One of the requirements in EPA regulations was to address ozone formation by regulating precursor pollutants (see 40 CFR 51.166(b)(49)(i) and 52.21(b)(50)(i)). ''Precursor pollutants'' are pollutants that combine to form another pollutant; NO_X reacts with volatile organic compounds to form ozone. In the Phase 2 Ozone Implementation Rule, EPA identified NO_X as an ozone precursor pollutant in attainment and unclassifiable areas. Accordingly, the Phase 2 Ozone Implementation Rule amended the definition of ''major stationary source,'' ''major modification,'' ''significant,'' and ''regulated NSR pollutant'' to include NO_X as an ozone precursor [1].

In a November 29, 2005, final rule (Approval and Disapproval and Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standards; Montana), EPA disapproved a Montana SIP revision because we found Montana's PSD rules for ozone inadequate because the rules did not

[1] See 40 CFR 51.166(b)(1)(ii), (b)(2)(ii), (b)(23), and (b)(49). See also 40 CFR 52.21(b)(1)(ii), (b)(2)(ii), (b)(23), and (b)(50). EPA also amended the footnote to 40 CFR 51.166(i)(5)(i)(e) (40 CFR 51.166(i)(5)(i)(f) in the current CFR) and 40 CFR 52.21(i)(5)(i) to require sources with a net increase of 100 tons per year or more of NO_X to perform an ambient impact analysis.

address NO_X as an ozone precursor pollutant as required by the Phase 2 Ozone Implementation Rule. 76 FR 28934. This disapproval started a FIP clock, and as we are now proposing to approve Montana's June 4, 2013, submittal, this would cure the deficiency identified in our prior disapproval and extinguish our FIP obligations because the proposed amendments in this notice would address EPA's concerns and make Montana's rules for PSD permitting adequate to implement the 1997 8-hour ozone NAAQS.

III. What is the state process to submit these materials to EPA?

Section 110(k) of the CAA addresses EPA's actions on submissions of revisions to a SIP. The CAA requires states to observe certain procedural requirements in developing SIP revisions for submittal to EPA. Section 110(a)(2) of the CAA requires that each SIP revision be adopted after reasonable notice and public hearing. This must occur prior to the revision being submitted by a state to EPA. The MDEQ held a public hearing on July 12, 2012 to propose revisions consistent with the Phase 2 Ozone Implementation Rule at 70 FR 71612 in its regulations at ARM 17.8. The Governor submitted these SIP revisions to EPA on June 4, 2013.

We have evaluated the Governor's submittal of the PSD SIP revisions and have determined that the State met the requirements for reasonable notice and public hearing under Section 110(a)(2) of the CAA.

IV. What are the changes that EPA is proposing to approve?

EPA is proposing to approve revisions to the Montana SIP that would bring the State PSD program provisions into conformance with the requirements of the Phase 2 Ozone Implementation Rule.

Generally, the proposed amendments to the Montana SIP would add NO_X as a regulated ozone precursor pollutant for purposes of PSD. The MDEQ and applicants for permits to construct or modify major sources would be required to analyze the applicability of PSD requirements for ozone based on a source's NO_X emissions. The following are descriptions of the proposed amendments:

ARM 17.8.801(20)(a) would be amended by modifying the definition of ''major modification,'' adding NO_X as an ozone precursor pollutant when NO_X emissions exceed a significance threshold. This revision is consistent with the federal definition of ''major modification'' in 40 CFR 51.166(b)(2)(ii).

ARM 17.8.801(22)(b) would be amended by modifying the definition of ''major stationary source,'' adding NO_X as an ozone precursor pollutant thereby triggering consideration of a source as ''major'' for ozone when the source emits or has the potential to emit 100 tons per year of NO_X. This revision is consistent with the federal definition of ''major stationary source'' in 40 CFR 51.166(b)(1)(ii).

ARM 17.8.801(25) would be amended by adding a definition of the term ''nitrogen oxides or NO_x,'' defining it as the sum of nitric oxide and nitrogen dioxide in the flu gas or emission point.

ARM 17.8.801(27)(a) would be amended by modifying the definition of ''significant.'' The SIP revision would add a significance level of 40 tons per year of NO_X as a precursor for ozone. We propose to find that these revisions are consistent with the federal definition of ''significant'' in 40 CFR 51.166(b)(23)(i). The State also proposed to amend this definition by substituting the term ''nitrogen oxides'' for ''nitrogen dioxide (NO_2)'' as a precursor for $PM_{2.5}$ formation. The use of ''nitrogen dioxide (NO_2)'' was a mistake when the definition was adopted in September 2011. The State intended to use the term ''nitrogen oxides,'' which include the sum of nitric oxide and nitrogen dioxide in the flue gas or emission point because they are precursors to the formation of $PM_{2.5}$, and the State is proposing to correct that mistake. The State is also proposing to delete the symbol ''SO_2'' from the definition so that it is consistent with the Federal definition. EPA will act on the changes with respect to $PM_{2.5}$ when we act on the August 15, 2012 submittal.

ARM 17.8.818(7)(a)(vi) would be amended to add that a net increase of 100 tons per year of NO_X, as an ozone precursor pollutant, triggers an ambient impact analysis. This revision is consistent with the footnote related to 40 CFR 51.166(i)(5)(i)(f) in the federal regulations.

The State has not adopted a definition of ''regulated NSR pollutant,'' but instead continues to use the prior phrase ''pollutant subject to regulation under the CAA'' in its regulations to identify pollutants subject to PSD requirements. In support thereto, the State has provided a statement of basis indicating that it understands that ''EPA found Montana's PSD rules for ozone inadequate because the rules do not address NO_X as a precursor pollutant for ozone,'' and asserting that the ''proposed amendments in this notice would address EPA's concerns and make Montana's rules for PSD permits adequate to implementing the 1997 8-hour ozone NAAQS.'' The State further explains that:

> Generally, the proposed amendments to the rules would add NO_X as a precursor pollutant that contributes to the formation of ozone. The department and applicants for permits to construct or modify major sources would be required to analyze the applicability of PSD requirements based on NO_X as a precursor to ozone.

Thus, we understand this to mean that the State interprets the phrase ''pollutant subject to regulation under the CAA'' to include NO_X as a precursor to ozone, consistent with the application of Regulated NSR Pollutant in the federal regulations. Based on this explanation and Montana's proper revision of the other relevant PSD provisions described above, we therefore propose to find that Montana's regulations appropriately regulate NO_X as an ozone precursor by requiring sources to analyze PSD applicability as to ozone based on the sources' NO_X emissions.

The requirements included in Montana's PSD program, as specified in ARM 17.8.801 and 17.8.818, are substantively the same as the federal provisions. As part of EPA's review of the Montana submittal, EPA performed a line-by-line review of the proposed revisions and has determined that they are consistent with the program requirements for the preparation, adoption and submittal of implementation plans for the Prevention of Significant Deterioration of Air Quality, as set forth at 40 CFR 51.166.

V. What action is EPA taking today?

EPA is proposing to approve the revisions to the ARM 17.8.801 and 17.8.818 as outlined in Section IV of this rulemaking and as submitted to EPA by the State of Montana on June 4, 2013.

VI. Statutory and Executive Orders Review

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under

Executive Order 12866 (58 FR 51735, October 4, 1993);

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

• is certified as not having a significant economic impact in a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: September 19, 2014.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2014–23108 Filed 9–26–14; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 79, No. 188

Monday, September 29, 2014

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

Submission for OMB Review; Comment Request

September 23, 2014.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Natural Resources Conservation Service

Title: Long Term Contracting.

OMB Control Number: 0578–0013.

Summary of Collection: The Long Term Contracting regulations at 7 CFR Part 630, and the Conservation program regulations at 7 CFR 12, 622, 624, 625, 701 set forth the basic policies, program provisions, and eligibility requirements for owners and operators to enter into and carry out long-term conservation program contracts with technical assistance under the various program. These programs are administered by the Natural Resources Conservation Service (NRCS). These programs authorize federal technical and financial long term cost sharing assistance for conservation treatment with eligible land users and entities. Under the terms of the agreement, the participant agrees to apply, or arrange to apply, the conservation treatment specified in the conservation plan. In return for this agreement, federal financial assistance payments are made to the land user, or third party, upon successful application of the conservation treatment.

Need and Use of the Information: NRCS will collect information using several NRCS forms. The forms are needed to administer NRCS long-term contracting programs as authorized. NRCS uses the information to ensure the proper utilization of program funds.

Description of Respondents: Individuals or households; Farms; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 5,315.

Frequency of Responses: Reporting; Annually, Other (As required).

Total Burden Hours: 3,657.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2014–23103 Filed 9–26–14; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection; United States Warehouse Act (USWA)

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension with a revision of a currently approved information collection process associated with the regulations, licensing, and electronic provider agreements issued as specified in the United States Warehouse Act (USWA).

DATES: We will consider comments that we receive by November 28, 2014

ADDRESSES: We invite you to submit comments on this Notice. In your comment, include volume, date and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- Federal eRulemaking Portal: Go to *www.regulations.gov.* Follow the online instructions for submitting comments.
- Mail: Judy Fry, Agricultural Marketing Specialist, Commodity Operations Division, Farm Service Agency (FSA), United States Department of Agriculture, STOP 0553, 1400 Independence Avenue SW., Washington, DC 20250–0553.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, OMB, Washington, DC 20503. Copies of the information collection may be requested by contacting Judy Fry as provided below.

FOR FURTHER INFORMATION CONTACT: Judy Fry, telephone (202) 720–3822. Persons with disabilities who require alternative means for communication of regulatory information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION:

Title: United States Warehouse Act (USWA).

OMB Control Number: 0560–0120.

Expiration Date of Approval: March 31, 2015

Type of Request: Extension with a revision of a currently approved information collection.

Abstract: The Secretary of Agriculture authorizes FSA as specified in the USWA to license public warehouse operators that are in the business of storing agricultural products; to examine such federally-licensed warehouses and to license qualified

persons to sample, inspect, weigh, and classify agricultural products. The FSA licenses under the USWA cover approximately half of all commercial grain and cotton warehouse capacities in the United States. The regulations that implement the USWA govern the establishment and maintenance of systems under which documents, including title documents on shipment, payment and financing, may be issued or transferred for agricultural products. Some of these systems and documents issued may be electronic.

This information collection allows the FSA to effectively administer the regulations, licensing, and electronic provider agreements and related reporting and recordkeeping requirements as specified in the USWA.

The forms in this information collection are used to provide those charged with issuing licenses under the USWA a basis to determine whether the warehouse and the warehouse operator meet application requirements to receive a license, and to determine compliance once the license is issued.

This information collection package is being revised to reflect a decrease in the reporting burden hours. This reduction is the result of warehouse operators continuing to consolidate warehouse licenses, which reduces the number of documents needed for continued operation of the warehouse facilities.

The formula used to calculate the total burden hour is estimated average time per responses hours times total annual responses.

Estimate of Burden: Public reporting burden for this information collection is estimated to average 0.46 hours per response.

Respondents: Warehouse operators and electronic providers.

Estimated Number of Respondents: 3,000.

Estimated Number of Responses Per Respondent: 5.96.

Estimated Total Annual Responses: 17,872.

Estimated Average Time per Response: 0.46.

Estimated Total Annual Burden on Respondents: 8,238 Hours.

We are requesting comments on all aspects of this information collection to help us to:

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

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used;

(3) Evaluate the quality, utility, and clarity of the information technology; and

(4) Minimize the burden of the information collection on those who are to respond through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be made a matter of public record. Comments will be summarized and included in the request for OMB approval of the information collection.

Signed on September 18, 2014.

Val Dolcini,

Administrator, Farm Service Agency.

[FR Doc. 2014–23085 Filed 9–26–14; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Solicitation of Applications for the Advanced Biofuels Payment Program

AGENCY: Rural Business-Cooperative Service, United States Department of Agriculture (USDA).

ACTION: Initial Notice.

SUMMARY: This Notice announces the timeframes to submit applications for participation in the Advanced Biofuels Payment Program. The Advanced Biofuels Payment Program funds were provided through the Agricultural Act of 2014, Public Law 113–79, on February 7, 2014, (2014 Farm Bill). Under the Advanced Biofuel Payment Program, payments are made to advanced biofuel producers for the production of eligible advanced biofuels.

DATES: Applications for participation in fiscal year 2015 are accepted between October 1 through October 31, 2014, in accordance with 7 CFR 4288.120(b). Applicants must also comply with the quarterly submission dates referenced in this Notice under IV(C)(2) and also contained in 7 CFR 4288.130(d).

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** for addresses concerning information for the Advanced Biofuel Payment Program for fiscal year 2015 funds.

FOR FURTHER INFORMATION CONTACT: For information about the Advanced Biofuel Payment Program assistance, please contact a USDA Rural Development Energy Coordinator, as provided in the **SUPPLEMENTARY INFORMATION** section of this Notice, or Lisa Noty, Energy Division, USDA Rural Development, 511 W. 7th Street, Atlantic, IA 50022. Telephone: (712) 243–2107 extension 116. Email: *lisa.noty@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Fiscal Year 2015 Applications for the Advanced Biofuel Payment Program

Complete applications must be submitted to the Rural Development State Office in the State in which the applicant's principal place of business is located.

Universal Identifier and System for Awards Management (SAM)

An applicant (unless the applicant is an individual) must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number, which can be obtained at no cost via a toll-free request line at 1–866–705–5711 or online at *http://fedgov.dnb.com/webform.*

Unless exempt under 2 CFR 25.110, the applicant must:

(a) Be registered in the SAM prior to submitting an application or plan;

(b) Maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by the Agency; and

(c) Provide its DUNS number in each application or plan it submits to the Agency.

Rural Development Energy Coordinators

For further information on this program, please contact the applicable USDA Rural Development Energy Coordinator for your respective State, as identified via the following link: *http://www.rurdev.usda.gov/BCP_Energy_CoordinatorList.html.*

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirements associated with the Advanced Biofuel Payments Program, as covered in this Notice, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 0570–0057.

Overview

Federal Agency Name: Rural Business-Cooperative Service (RBS) (an agency of USDA).

Contract Proposal Title: Advanced Biofuel Payment Program.

Announcement Type: Annual announcement.

Catalog of Federal Domestic Assistance Number (CFDA): The CFDA number for this Notice is 10.867.

Dates: The Advanced Biofuels Program sign-up period for fiscal year 2015 participation is October 1 to October 31, 2014.

Availability of Notice and Rule: This Notice and the interim rule for the Advanced Biofuel Payment Program are available on the USDA Rural Development Web site at *http://www.rurdev.usda.gov/BCP_Biofuels.html.*

I. Funding Opportunity Description

A. *Purpose of the program.* The purpose of this program is to support and ensure an expanding production of advanced biofuels by providing payments to eligible advanced biofuel producers. Implementing this program not only promotes the Agency's mission of promoting sustainable economic development in rural America, but is an important part of achieving the Administration's goals for increased biofuel production and use by providing economic incentives for the production of advanced biofuels.

B. *Statutory authority.* This program is authorized under 7 U.S.C. 8105.

C. *Definition of terms.* The definitions applicable to this Notice are published at 7 CFR 4288.102.

II. Award Information

A. *Available funds.* This Notice is announcing application dates for applying for participation in the Advanced Biofuel Payment Program. The 2014 Farm Bill provides $15 million in mandatory funding and authorizes additional appropriations of up to $25 million for each fiscal year through 2018. This Notice is being published prior to the Congressional Enactment of a full-year appropriation for fiscal year 2015. Once the full year appropriation is known, RBS will announce the total funds available (mandatory and discretionary) for the Advanced Biofuel Payment Program on the following Web site: *http://www.rurdev.usda.gov/BCP_Biofuels.html.*

B. *Approximate number of awards.* The number of awards will depend on the number of participating advanced biofuel producers.

C. *Range of amounts of each payment.* There is no minimum or maximum payment amount that an individual producer can receive. The amount that each producer receives will depend on the number of eligible advanced biofuel producers participating in the program for the respective fiscal year, the amount of advanced biofuels being produced by such advanced biofuel producers, and the amount of funds available.

D. *Contract.* For producers participating in this program for the first time, a contract will need to be entered into with the Agency and the contract period will continue indefinitely until terminated as provided for in 7 CFR 4288.121(d). For producers that participated in this program in the previous fiscal year, the contract period continues indefinitely until terminated as provided for in 7 CFR 4288.121(d).

E. *Production period.* Payments to participating advanced biofuel producers under this Notice will be made on actual eligible advanced biofuels produced from October 1, 2014, through September 30, 2015, in accordance with 7 CFR part 4288, subpart B.

F. *Type of instrument.* Payment.

III. Eligibility Information

A. *Eligible applicants.* To be eligible for this program, an applicant must meet the eligibility requirements specified in 7 CFR 4288.110.

B. *Biofuel eligibility.* To be eligible for payment, an advanced biofuel must meet the eligibility requirements specified in 7 CFR 4288.111.

C. *Payment eligibility.* To be eligible for program payments, an advanced biofuel producer must maintain the records specified in 7 CFR 4288.113.

IV. Application and Submission Information

A. *Address to request applications.* Annual Application, Contract, and Payment Request forms are available from the USDA Rural Development State Office, Rural Development Energy Coordinator. The list of Rural Development Energy Coordinators is provided in the **SUPPLEMENTARY INFORMATION** section of this Notice.

B. *Content and form of submission.* The enrollment provisions, including application content and form of submission, are specified in 7 CFR 4288.120 and 4288.121.

C. *Submission dates and times.*

(1) *Enrollment.* Advanced biofuel producers who expect to produce eligible advanced biofuel at any time during fiscal year 2015 must enroll in the program by the dates identified in this Notice. Applications received after the identified dates, regardless of their postmark, will not be considered by the Agency. Producers who participated in this Program in any previous fiscal year must submit a new application as identified above to be considered.

(2) *Payment applications.* Advanced biofuel producers must submit Form RD 4288–3, ''Advanced Biofuel Payment Program—Payment Request,'' for each of the four Federal fiscal quarters for each fiscal year. Pay requests for the first quarter of fiscal year 2015 must be submitted by 4:30 p.m., January 31, 2015. Second quarter pay requests must be submitted by 4:30 p.m., April 30, 2015; third quarter submitted by 4:30 p.m., July 31, 2015; and fourth quarter submitted by 4:30 p.m., October 31, 2015. Neither complete nor incomplete payment applications received after such dates and times will be considered, regardless of the postmark on the request. If any of these deadlines falls on a weekend or a federally-observed holiday, the deadline is the next Federal business day.

D. *Funding restrictions.* Not more than 5 percent of the funds in each fiscal year will be made available to eligible producers with a refining capacity (as determined for the prior fiscal year) exceeding 150,000,000 gallons per year of a liquid advanced biofuel or exceeding 15,900,000 million British Thermal Units per year of biogas and solid advanced biofuel. (In calculating whether a producer meets either of these capacities, production of all advanced biofuel facilities in which the producer has 50 percent or more ownership will be totaled.) The Agency will provide payments to eligible solid advanced biofuels produced from forest biomass of not more than 5 percent of available program funds in each fiscal year. The remaining funds will be made available to all other producers.

E. *Payment provisions.* Payments will be made according to the provisions specified in 7 CFR 4288.130 through 4288.137. Payment requests are required to be submitted in accordance with 7 CFR 4288.130(d).

V. Administration Information

A. *Notice of eligibility.* The provisions of 7 CFR 4288.112 apply to this Notice. These provisions include the notification process for eligible and ineligible applicants.

B. *Administrative and national policy requirements.*

(1) *Review or appeal rights.* A person may seek a review of an adverse agency decision or appeal to the National Appeals Division as provided in 7 CFR 4288.103.

(2) *Compliance with other laws and regulations.* The provisions of 7 CFR 4288.104 apply to this Notice, which includes requiring advanced biofuel producers to be in compliance with other applicable Federal, State, and local laws.

(3) *Oversight and monitoring.* The provisions of 7 CFR 4288.105 apply to this Notice.

(4) *Exception authority.* The provisions of 7 CFR 4288.107 apply to this Notice.

(5) *Unauthorized Assistance.* The provision of 7 CFR 4288.135 apply to this Notice.

C. *Environmental review.* This document has been reviewed in accordance with 7 CFR part 1940, subpart G, ''Environmental Program.'' RBS has determined that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act (NEPA) of 1969, 42 U.S.C. 4321 et seq., this regulation is a Categorical Exclusion. Payment applications will be reviewed individually to determine compliance with NEPA.

VII. Agency Contacts

For assistance on this payment program, please contact a USDA Rural Development Energy Coordinator, as provided in the **SUPPLEMENTARY INFORMATION** section of this Notice, or Lisa Noty, Energy Division, USDA Rural Development, 511 W. 7th Street, Atlantic, IA. Telephone: (712) 243–2107 extension 116. Email: *lisa.noty@wdc.usda.gov*.

VIII. Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET center at (202) 720–2600 (voice and TDD).

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at *http://www.ascr.usda.gov/complaint_filing_cust.html,* or at any USDA office, or call (866) 632–9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, by fax (202) 690–7442 or email at *program.intake@usda.gov.*

Individuals who are deaf, hard of hearing, or have speech disabilities and you wish to file a program complaint please contact USDA through the Federal Relay Service at (800) 877–8339 or (800) 845–6136 (in Spanish). USDA is an equal opportunity provider and employer. The full ''Non-Discrimination Statement'' is found at: *http://www.usda.gov/wps/portal/usda/usdahome?navtype=FT&navid=Non_Discrimination.*

Dated: September 23, 2014.

Lillian E. Salerno,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2014–23128 Filed 9–26–14; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Industry and Security (BIS).

Title: Additional Protocol Report Forms.

OMB Control Number: 0694–0135.

Form Number(s): AP–A, AP–B, AP–C, AP–D, AP–E, AP–F, AP–G, AP–H, AP–I, AP–J, AP–K, AP–L, AP–M, AP–N, AP–O, AP–P, and AP–Q.

Type of Request: Regular submission (extension of a currently approved information collection).

Number of Respondents: 500.

Average Hours per Response: 22 to 6 hours, varies depending on form.

Burden Hours: 844.

Needs and Uses: The Additional Protocol requires the United States to submit declaration forms to the International Atomic Energy Agency (IAEA) on a number of commercial nuclear and nuclear-related items, materials, and activities that may be used for peaceful nuclear purposes, but also would be necessary elements for a nuclear weapons program. These forms provides the IAEA with information about additional aspects of the U.S. commercial nuclear fuel cycle, including: mining and milling of nuclear materials; buildings on sites of facilities selected by the IAEA from the U.S. Eligible Facilities List; nuclear-related equipment manufacturing, assembly, or construction; import and export of nuclear and nuclear-related items and materials; and research and development. The Protocol also expands IAEA access to locations where these activities occur in order to verify the form data.

Affected Public: Businesses or other for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to Obtain Benefits.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: September 23, 2014.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–23022 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Industry and Security.

Title: Import, End-User, and Delivery Verification Certificates.

OMB Control Number: 0694–0093.

Form Number(s): N/A.

Type of Request: Regular submission.

Number of Respondents: 5,874.

Average Hours Per Response: 15 to 30 minutes per response.

Burden Hours: 1,619.

Needs and Uses: This collection of information provides the certification of the overseas importer to the U.S. Government that specific commodities will be imported from the U.S. and will not be reexported, except in accordance with U.S. export regulations.

Affected Public: Businesses or other for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain benefits.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of

Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: September 23, 2014.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–23021 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: For-Hire Telephone Survey.

OMB Control Number: 0648–xxxx.

Form Number(s): NA.

Type of Request: Regular submission (request for a new information collection).

Number of Respondents: 22,421.

Average Hours per Response: 3 minutes.

Burden Hours: 1,121.

Needs and Uses: This request is for a new information collection.

Marine recreational anglers are surveyed to collect catch and effort data, fish biology data, and angler socioeconomic characteristics. These data are required to carry out provisions of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 et seq.), as amended, regarding conservation and management of fishery resources.

The For-Hire Survey (FHS) will collect recreational fishing catch and effort data through a telephone, Web-based data collection, and log sheet methods. Amendments to the Magnuson-Stevens Fishery Conservation and Management Act require the development of an improved data collection program for recreational fisheries. To meet these requirements, NOAA Fisheries has designed a telephone questionnaire in the Computer Assisted Telephone Interview (CATI) system for surveying and collecting catch and effort data from recreational anglers. The FHS will sample a week's activity from 10% of vessels that are permitted for-hire or charter vessel trips. Each interview will collect the number of recreational fishing trips, and log sheets submitted by the permit holders will show corresponding effort data (e.g. time at sea, amounts of catch from each fishery), within the sample selected week. In lieu of telephone interviews, respondents may also provide information via a Web-based application.

Affected Public: Business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: September 23, 2014.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–23020 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility to Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Department of Commerce.

ACTION: Notice and Opportunity for Public Comment.

Pursuant to Section 251 of the Trade Act 1974, as amended (19 U.S.C. 2341 et seq.), the Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of these firms contributed importantly to the total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[09/16/2014 through 09/23/2014]

Firm name	Firm address	Date accepted for investigation	Product(s)
AR Wilfley & Sons Inc	7350 E Progress Place #200, Englewood, Co 80111.	9/22/2014	The firm manufactures centrifugal pumps.
Pro Machine & Engineering, Inc.	603 South 29th Street, Colorado Springs, CO 80904.	9/19/2014	The firm manufactures machined components produced from a range of alloys, including stainless steel and aluminum.
NAAB Electric, Inc	2013 W. Jones Street, Garden City, KS 67846.	9/23/2014	The firm produces electrical equipment for agriculture industry including geothermal air conditioning for pressure controlled irrigation systems and variable speed pumps.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance for Firms Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Dated: September 23, 2014.

Michael DeVillo,

Eligibility Examiner.

[FR Doc. 2014–23083 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–66–2014]

Foreign-Trade Zone 93—Raleigh-Durham, North Carolina; Application for Reorganization (Expansion of Service Area) Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Triangle J Council of Governments, grantee of FTZ 93, requesting authority to reorganize the zone to expand its service area under the alternative site framework (ASF) adopted by the Board (15 CFR 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on September 23, 2014.

FTZ 93 was approved by the FTZ Board on November 4, 1983 (Board Order 233, 48 FR 52108, 11/16/83) and reorganized under the ASF on November 30, 2012 (Board Order 1872, 77 FR 73978–73979, 12/12/12). The zone currently has a service area that includes the Counties of Chatham, Durham, Franklin, Granville, Harnett, Johnston, Lee, Moore, Orange, Person, Vance, Wake and Warren.

The applicant is now requesting authority to expand the service area of the zone to include Sampson County, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The application indicates that the proposed expanded service area is adjacent to the Raleigh-Durham Customs and Border Protection port of entry.

In accordance with the Board's regulations, Kathleen Boyce of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is November 28, 2014. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 15, 2014.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.* For further information, contact Kathleen Boyce at *Kathleen.Boyce@trade.gov* or (202) 482–1346.

Dated: September 23, 2014.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2014–23121 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–67–2014]

Foreign-Trade Zone 58—Bangor, Maine; Application for Reorganization Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the City of Bangor, grantee of FTZ 58, requesting authority to reorganize the zone under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on September 23, 2014.

FTZ 58 was approved by the FTZ Board on June 19, 1980 (Board Order 159, 45 FR 43455, 6/27/80). The current zone includes the following site: *Site 1* (33 acres), Bangor International Airport, 287 Godfrey Blvd., Bangor.

The grantee's proposed service area under the ASF would be the Counties of Hancock, Penobscot, Piscataquis, Waldo and Washington, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The proposed service area is within and adjacent to the Bangor Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize its existing zone to include the existing site as a ''magnet'' site. The ASF allows for the possible exemption of one magnet site from the ''sunset'' time limits that generally apply to sites under the ASF, and the applicant proposes that Site 1 be so exempted. No subzones/usage-driven sites are being requested at this time.

In accordance with the FTZ Board's regulations, Kathleen Boyce of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is November 28, 2014. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 15, 2014.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.* For further information, contact Kathleen Boyce at *Kathleen.Boyce@trade.gov* or (202) 482–1346.

Dated: September 23, 2014.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2014–23127 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–818, C–475–819]

Certain Pasta From Italy: Final Results of Antidumping Duty and Countervailing Duty Changed Circumstances Reviews and Revocation, in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On August 15, 2014, the Department of Commerce (the Department) published its notice of initiation and preliminary results of changed circumstances review, and intent to revoke, in part, the antidumping and countervailing duty orders on certain pasta from Italy.[1] We invited parties to comment and received no comments. Therefore, we are now revoking the orders, in part, with respect to certain cheese- and/or vegetable-filled (stuffed) ravioli and tortellini pasta (ravioli and tortellini filled with cheese and/or vegetables).

DATES: *Effective Dates:* July 1, 2012 (AD order) and January 1, 2012 (CVD order).

FOR FURTHER INFORMATION CONTACT: Jennifer Meek at (202) 482–2778; AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On July 24, 1996, the Department published in the **Federal Register** the *Orders* on certain pasta from Italy.[2] On May 16, 2014, in accordance with sections 751(b) and 751(d)(1) of the Tariff Act of 1930, as amended (the Act), 19 CFR 351.216(b), and 19 CFR 351.222(g)(1), Grandi Pastai Italiani, Inc. and Grandi Pastai Italiani S.p.A. (together, GPI), an importer of subject merchandise, requested revocation, in part, of the *Orders* with respect to its Italian ravioli and tortellini filled with cheese and/or vegetables, as part of a changed circumstances review. GPI requested that the Department conduct the changed circumstances review on an expedited basis pursuant to 19 CFR 351.221(c)(3)(ii). As noted above, we gave interested parties an opportunity to comment on the *Initiation and Preliminary Results.* We received no comments from interested parties. Therefore, we are now revoking the *Orders,* in part, with respect to ravioli and tortellini filled with cheese and/or vegetables.

Scope of the Orders

Imports covered by these *Orders* are shipments of certain non-egg pasta in packages of five pounds four ounces or less, whether or not enriched or fortified or containing milk or other optional ingredients such as chopped vegetables, vegetable purees, milk, gluten, diastasis, vitamins, coloring and flavorings, and up to two percent egg white. The pasta covered by this scope is typically sold in the retail market, in fiberboard or cardboard cartons, or polyethylene or polypropylene bags of varying dimensions.

Excluded from the scope of these *Orders* are refrigerated, frozen, or canned pastas, as well as all forms of egg pasta, with the exception of non-egg dry pasta containing up to two percent egg white. Also excluded are imports of organic pasta from Italy that are accompanied by the appropriate certificate issued by the Instituto Mediterraneo Di Certificzione, by QC&I International Services, by Ecocert Italia, by Consorzio per il Controllo dei Prodotti Biologici, by Associazion Italiana per l'Agricoltra Biologica, by Ambientale.[3] Effective July 1, 2008, gluten-free pasta is also excluded from the AD order.[4] Effective January 1, 2009, gluten-free pasta is also excluded from the scope of the CVD order.[5]

The merchandise subject to these *Orders* is currently classifiable under items 1901.90.9095 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the description of the merchandise subject to the *Orders* is dispositive.

Scope Rulings

The Department issued the following scope rulings to date:

(1) On August 25, 1997, the Department issued a scope ruling finding that multicolored pasta, imported in kitchen display bottles of decorative glass that are sealed with cork or paraffin and bound with raffia, is excluded from the scope of the *Orders*.[6]

(2) On July 30, 1998, the Department issued a scope ruling finding that multipacks consisting of six one-pound packages of pasta that are shrink-wrapped into a single package are within the scope of the *Orders*.[7]

(3) On October 26, 1998, the Department self-initiated a scope inquiry to determine whether a package weighing over five pounds as a result of allowable industry tolerances is within the scope of the *Orders.* On May 24, 1999, we issued a final scope ruling finding that, effective October 26, 1998, pasta in packages weighing or labeled up to (and including) five pounds four ounces is within the scope of the *Orders*.[8]

(4) On April 27, 2000, the Department self-initiated an anti-circumvention inquiry to determine whether Pastificio Fratelli Pagani S.p.A.'s importation of pasta in bulk and subsequent repackaging in the United States into packages of five pounds or less constitutes circumvention with respect to the *Orders* pursuant to section 781(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(b).[9] On September 19, 2003, we published an affirmative finding in the anti-circumvention inquiry.[10]

(5) On July 18, 2013, the Department issued a scope ruling finding that Valdigrano di Flavio Pagani S.r.L. product which is made from a dough that contains 2.5 percent egg white, by weight, is within the scope of the *Orders*.[11]

---

[1] *See Certain Pasta From Italy: Initiation and Preliminary Results of Antidumping Duty and Countervailing Duty Changed Circumstances Review, and Intent To Revoke Orders, In Part,* 79 FR 48121 (August 15, 2014) (*Initiation and Preliminary Results*).

[2] *See Notice of Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination: Certain Pasta From Italy,* 61 FR 38544 (July 24, 1996) and *Notice of Antidumping Duty Order and Amended Final Determination of Sales at Less Than Fair Value: Certain Pasta From Italy,* 61 FR 38547 (July 24, 1996) (collectively, the *Orders*).

[3] *See* Memorandum from Yasmin Nair to Susan Kuhbach, entitled ''Recognition of EU Organic Certifying Agents for Certifying Organic Pasta from Italy'' (October 10, 2012), which is on file in the Department's Central Records Unit (''CRU'') in Room 7046 of the main Department building.

[4] *See Certain Pasta from Italy: Notice of Final Results of Antidumping Duty Changed Circumstances Review and Revocation,* in Part, 74 FR 41120 (August 14, 2009).

[5] *See Final Results of Countervailing Duty Changed Circumstances Review and Revocation, In Part,* 76 FR 27634 (May 12, 2011) (*Pasta From Italy CVD CCR*).

[6] *See* Memorandum from Edward Easton to Richard Moreland, dated August 25, 1997, which is on file in the CRU.

[7] *See* Letter from Susan H. Kuhbach to Barbara P. Sidari, dated July 30, 1998, which is on file in the CRU.

[8] *See* Memorandum from John Brinkman to Richard Moreland, dated May 24, 1999, which is on file in the CRU.

[9] *See Certain Pasta From Italy: Notice of Initiation of Anti-Circumvention Inquiry on the Antidumping and Countervailing Duty Orders,* 65 FR 26179 (May 5, 2000).

[10] *See Anti-Circumvention Inquiry of the Antidumping and Countervailing Duty Orders on Certain Pasta from Italy: Affirmative Final Determinations of Circumvention of Antidumping and Countervailing Duty Orders,* 68 FR 54888 (September 19, 2003).

[11] *See* Memorandum from Joseph Shuler to Christian Marsh, dated July 18, 2013, which is on file in the CRU.

Final Results of Antidumping and Countervailing Duty Changed Circumstances Reviews, and Revocation of the Orders in Part

At the request of GPI, and in accordance with sections 751(b)(1) and 751(d)(1) of the Act, 19 CFR 351.216, and 19 CFR 351.222(g)(1), the Department initiated a changed circumstances review of ravioli and tortellini filled with cheese and/or vegetables from Italy to determine whether a partial revocation of the *Orders* is warranted with respect to these products.[12] In addition, we determined that expedited action is warranted and, consistent with 19 CFR 351.221(c)(3)(ii), combined the notices of initiation and preliminary results.[13] Based on the expression of no interest by Petitioners,[14] which stated that they are producers accounting for substantially all of the production of the domestic like product in support of *the Orders,*[15] and absent any objections by other domestic interested parties, we preliminarily determined that substantially all of the domestic producers of the like product have no interest in the continued application of the *Orders* to the merchandise that is subject to GPI's request and that partial revocation of the *Orders* is appropriate. Accordingly, we notified the public of our intent to revoke, in part, the AD and CVD *Orders* as they relate to imports of ravioli and tortellini filled with cheese and/or vegetables from Italy.[16] We did not receive any comments from parties objecting to the partial revocation. Because all parties to the proceeding agree to the outcome of the review, we are issuing these final results of changed circumstances review within 45 days of initiation in accordance with 19 CFR 351.216(e). Therefore, in accordance with sections 751(d)(1) and 782(h) of the Act and 19 CFR 351.222(g)(1)(i) of the Department's regulations, we are partially revoking the Orders with regard to the specific products meeting the specifications described below. This partial revocation will be applied retroactively to entries of ravioli and tortellini filled with cheese and/or vegetables, entered or withdrawn from warehouse, for consumption, on or after July 1, 2012 for the AD order and January 1, 2012 for the CVD order, which correspond to the day following the last day of the most recently completed administrative reviews under each order.[17] The scope of the AD and CVD orders are modified to read as follows:

Imports covered by these orders are shipments of certain non-egg pasta in packages of five pounds four ounces or less, whether or not enriched or fortified or containing milk or other optional ingredients such as chopped vegetables, vegetable purees, milk, gluten, diastasis, vitamins, coloring and flavorings, and up to two percent egg white. The pasta covered by this scope is typically sold in the retail market, in fiberboard or cardboard cartons, or polyethylene or polypropylene bags of varying dimensions.

Excluded from the scope of these orders are refrigerated, frozen, or canned pastas, as well as all forms of egg pasta, with the exception of non-egg dry pasta containing up to two percent egg white. Also excluded are imports of organic pasta from Italy that are accompanied by the appropriate certificate issued by the Instituto Mediterraneo Di Certificzione, by QC&I International Services, by Ecocert Italia, by Consorzio per il Controllo dei Prodotti Biologici, by Associazion Italiana per l'Agricoltra Biologica, by Ambientale.[18] Effective July 1, 2008, gluten-free pasta is also excluded from the AD order.[19] Effective January 1, 2009, gluten-free pasta is also excluded from the scope of the CVD order.[20] *Effective July 1, 2012, ravioli and tortellini filled with cheese and/or vegetables are also excluded from the scope of the AD order. Effective January 1, 2012, ravioli and tortellini filled with cheese and/or vegetables are also excluded from the scope of the CVD order.*

The merchandise subject to these orders is currently classifiable under items 1901.90.9095 and 1902.19.20 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the description of the merchandise subject to the orders is dispositive.

Instructions to U.S. Customs and Border Protection

As we stated in our *Initiation and Preliminary Results,* we will instruct U.S. Customs and Border Protection to end the suspension of liquidation for the merchandise covered by the revocation on the effective dates of this notice of revocation, in part, and to release any cash deposit or bond, pursuant to 19 CFR 351.222(g)(4).

Notification

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.306. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is published in accordance with sections 751(b)(1) and 777(i)(1) of the Act and 19 CFR 351.216(e), 351.221(b)(5), and 351.222(g).

Dated: September 22, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–23129 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–DS–P

[12] *See Initiation and Preliminary Results.*

[13] *Id.*

[14] Petitioners in this proceeding include A. Zerega's Sons, Inc., American Italian Pasta Company, Dakota Growers Pasta Company, New World Pasta Company, Philadelphia Macaroni Company, and ST Specialty Foods. *See* Letter from Petitioners, ''Changed Circumstances Review Request—Certain Pasta From Italy''(May 16, 2014).

[15] *See* Letter from Petitioner, ''Changed Circumstances Review Request—Certain Pasta From Italy'' (May 16, 2014).

[16] *See Initiation and Preliminary Results.*

[17] *See, e.g., Wooden Bedroom Furniture from the People's Republic of China: Final Results of Changed Circumstances Review and Determination to Revoke Order in Part,* 74 FR 8506 (February 25, 2009) (retroactively revoking an order, in part, to unliquidated entries not subject to a final determination by the Department).

[18] *See* Memorandum from Yasmin Nair to Susan Kuhbach, entitled ''Recognition of EU Organic Certifying Agents for Certifying Organic Pasta from Italy'' (October 10, 2012), which is on file in the Department's Central Records Unit (CRU) in Room 7046 of the main Department building.

[19] *See Certain Pasta from Italy: Notice of Final Results of Antidumping Duty Changed Circumstances Review and Revocation,* in Part, 74 FR 41120 (August 14, 2009).

[20] *See Pasta from Italy CVD CCR.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–015]

Countervailing Duty Investigation of 53-Foot Domestic Dry Containers From the People's Republic of China: Preliminary Determination and Alignment of Final Determination With Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the ''Department'') preliminarily determines that countervailable subsidies are being provided to producers and exporters of 53-foot domestic dry containers (''domestic dry containers'') from the People's Republic of China (the ''PRC''). We invite interested parties to comment on this preliminary determination.

DATES: *Effective Date:* September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Yasmin Nair, David Cordell or Ilissa

Shefferman, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone 202.482.3813, 202.482.0408 or 202.482.4684, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Investigation

The merchandise subject to investigation is closed (*i.e.,* not open top) van containers exceeding 14.63 meters (48 feet) but generally measuring 16.154 meters (53 feet) in exterior length, which are designed for the intermodal transport [1] of goods other than bulk liquids within North America primarily by rail or by road vehicle, or by a combination of rail and road vehicle (domestic containers). The merchandise is known in the industry by varying terms including ''53-foot containers,'' ''53-foot dry containers,'' ''53-foot domestic dry containers,'' ''domestic dry containers'' and ''domestic containers.'' Imports of the subject merchandise are provided for under subheading 8609.00.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Imports of the subject merchandise which meet the definition of and requirements for ''instruments of international traffic'' pursuant to 19 U.S.C. § 1322 and 19 C.F.R. § 10.41a may be classified under subheading 9803.00.50, HTSUS. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive. For a complete description of the scope of this investigation, *see* the Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Countervailing Duty Investigation of 53-Foot Domestic Dry Containers from the People's Republic of China: Decision Memorandum for the Preliminary Determination,'' dated concurrently with, and hereby adopted by, this notice (''Preliminary Decision Memo'').

Methodology

The Department is conducting this countervailing duty (''CVD'') investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the ''Act''). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[2] For a full description of the methodology underlying our preliminary conclusions, see the Preliminary Decision Memo. The Preliminary Decision Memo is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov,* and is available to all parties in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memo can be accessed directly at *http://trade.gov/enforcement.* The signed Preliminary Decision Memo and the electronic versions of the Preliminary Decision Memo are identical in content.

The Department notes that, in making these findings, we relied, in part, on facts available and, because one or more respondents did not act to the best of their ability to respond to the Department's requests for information, we drew an adverse inference where appropriate in selecting from among the facts otherwise available.[3] For further information, see ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memo.

Alignment

As noted in the Preliminary Decision Memo, in accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), we are aligning the final CVD determination in this investigation with the final determination in the companion antidumping duty (''AD'') investigation of domestic dry containers from the PRC based on a request made by the petitioner. Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than February 2, 2015, unless postponed.

Preliminary Determination and Suspension of Liquidation

In accordance with section 703(d)(1)(A)(i) of the Act, we calculated an individual rate for each exporter/producer of the subject merchandise individually investigated. We preliminarily determine the countervailable subsidy rates to be:

Exporter/Producer	Subsidy rate
CIMC International Marine Containers (Group) Co., Ltd. (CIMC Group); CIMC Containers Holding Co., Ltd. (CIMC Holding); CIMC Wood Development Co., Ltd. (CIMC Wood); Guangdong Xinhui CIMC Special Transportation Equipment Co., Ltd. (Xinhui Special); Qingdao CIMC Containers Manufacture Co., Ltd. (Qingdao CIMC); Nantong CIMC-Special Transportation Equipment Manufacture Co., Ltd. (Nantong CIMC); Xinhui CIMC Container Co., Ltd. (Xinhui Container); and Xinhui CIMC Wood Co., Ltd. (Xinhui Wood) (collectively, "CIMC")	10.46%
Hui Zhou Pacific Container Co., Ltd.; Qingdao Pacific Container Co., Ltd.; and Qidong Singamas Energy Equipment Co., Ltd. (collectively, "Singamas")	7.13%
All-Others	8.79%

In accordance with sections 703(d)(1)(B) and (d)(2) of the Act, we are directing U.S. Customs and Border Protection to suspend liquidation of all entries of domestic dry containers from the PRC that are entered, or withdrawn from warehouse, for consumption on or after the date of the publication of this notice in the **Federal Register**, and to require a cash deposit for such entries of merchandise in the amounts indicated above.

In accordance with sections 703(d) and 705(c)(5)(A) of the Act, for companies not investigated, we apply an ''all-others rate'', which is normally calculated by weighting the subsidy rates of the individual companies selected as respondents by those companies' exports of the subject merchandise to the United States. Notwithstanding the language of section 705(c)(5)(A)(i) of the Act, we have not calculated the ''all-others'' rate by

[1] ''Intermodal transport'' refers to a movement of freight using more than one mode of transportation, most commonly on a container chassis for on-the-road transportation and on a rail car for rail transportation.

[2] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[3] *See* sections 776(a) and (b) of the Act.

weight averaging the rates of the two individually investigated respondents, because doing so risks disclosure of proprietary information. Therefore, for the ''all-others'' rate, we calculated a simple average of the two responding firms' rates.

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information submitted by the respondents prior to making our final determination.

Disclosure and Public Comment

The Department will disclose calculations performed for this preliminary determination to the parties within five days of the date of public announcement of this determination in accordance with 19 CFR 351.224(b). Case briefs or other written comments for all non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in this proceeding, and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[4] A table of contents, list of authorities used and an executive summary of issues should accompany any briefs submitted to the Department. This summary should be limited to five pages total, including footnotes.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using IA ACCESS. An electronically filed request for a hearing must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice.[5] Requests should contain the party's name, address, and telephone number; the number of participants; and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a date and time to be determined. Parties will be notified of the date and time of any hearing. The hearing will be limited to issues raised in the respective briefs.[6]

International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission (''ITC'') of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information relating to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Assistant Secretary for Enforcement and Compliance.

In accordance with section 705(b)(2) of the Act, if our final determination is affirmative, the ITC will make its final determination within 45 days after the Department makes its final determination.

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: September 22, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memo

I. Summary
II. Background
  A. Case History
  B. Period of Investigation
III. Scope Comments
IV. Scope of the Investigation
V. Alignment
VI. Respondent Selection
VII. Injury Test
VIII. Application of the Countervailing Duty Law to Imports from the PRC
IX. Subsidies Valuation
  A. Allocation Period
  B. Attribution of Subsidies
  C. Denominators
X. Benchmarks and Discount Rates
  A. Short-Term RMB-Denominated Loans
  B. Long-Term RMB-Denominated Loans
  C. Foreign Currency-Denominated Loans
  D. Discount Rates
XI. Use of Facts Otherwise Available and Adverse Inferences
XII. Analysis of Programs
  A. Programs Preliminarily Determined to Be Countervailable
  1. Preferential Loans to SOEs
  2. Export Seller's Credits from China Ex-Im
  3. Provision of Electricity for LTAR
  4. Provision of Hot-Rolled Sheet and Plate for LTAR
  5. Provision of Hot-Rolled Steel I-Beams for LTAR
  6. Two Free/Three Half Program for Foreign Invested Enterprises (FIEs)
  7. Preferential Tax Programs for Enterprises Recognized as High or New Technology Enterprises (HNTEs)
  8. Enterprise Tax Law Research and Development Program Grants
  B. Programs Preliminary Determined Not to Be Used During the POI
  1. Export Buyer's Program
  C. Programs With No Measurable Benefit
  1. ''Famous Brands'' Program
  2. Other Grants to Singamas
  D. Programs For Which Additional Information is Needed
  1. Other Grants to CIMC
XIII. Verification
XIV. Conclusion

[FR Doc. 2014–23130 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–DS–P

[4] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[5] *See* 19 CFR 351.310(c).

[6] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–818]

Low-Enriched Uranium From France: Final Results of Antidumping Duty Administrative Review; 2012–2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On March 24, 2014, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on low-enriched uranium (LEU) from France.[1] The review covers one producer or exporter of the subject merchandise, Eurodif S.A., AREVA NC, and AREVA NC, Inc. (collectively AREVA). The Department determines that AREVA made no shipments of subject merchandise during the POR.

DATES: *Effective Date:* September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION:

Background

Since the *Preliminary Results,* the following events have taken place: the Department received timely case briefs from USEC Inc., and the United States Enrichment Corporation (collectively Petitioners), and AREVA on April 23, 2014. Petitioners, AREVA, and Global

[1] *See Low Enriched Uranium from France; Preliminary Results of Antidumping Duty Administrative Review; 2012–2013,* 79 FR 15955 (March 24, 2014) (*Preliminary Results*).

Nuclear Fuel—Americas, filed timely rebuttal briefs on April 28, 2014.

Period of Review

The period of review (POR) is February 1, 2012, through January 31, 2013.

Scope of the Order

The product covered by the order is all low-enriched uranium. Low-enriched uranium is enriched uranium hexafluoride (UF_6) with a U^{235} product assay of less than 20 percent that has not been converted into another chemical form, such as UO_2, or fabricated into nuclear fuel assemblies, regardless of the means by which the LEU is produced (including low-enriched uranium produced through the down-blending of highly enriched uranium).[2]

Analysis of Comments Received

All issues raised by the parties in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is appended to this notice. The Issues and Decision Memorandum is a public document and is available electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (IA ACCESS). IA ACCESS is available to registered users at *http://iaacess.trade.gov,* and it is available to all parties in the Central Records Unit of the main Commerce Building, room 7046. In addition, a complete version of the Issues and Decision Memorandum is also accessible on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

There has been no change to the Department's preliminary decision that AREVA had no shipments subject to the antidumping duty order. We revised the entry requirements and review process for merchandise conditionally excluded from the scope of the order, as discussed in the Issues and Decision Memorandum.[3]

Determination of No Shipments

We determine that AREVA had no shipments of merchandise subject to the antidumping duty order on LEU from France during the POR.

Determination of Revised Entry Requirements

To ensure proper enforcement of the order, the Department now determines that it is appropriate to suspend liquidation for shipments of LEU from France that previously entered without the suspension of liquidation. Such entries will be suspended, effective the date of publication of these final results of review, and cash deposits of estimated antidumping duties will be required, at a rate of zero percent *ad valorem.* Such entries will be examined and liquidated in accordance with the procedures described in the Issues and Decision Memorandum.[4]

Assessment Rates

Since the Department found that AREVA had no shipments during the POR, we did not calculate importer-specific assessment rates.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the POR produced by companies included in the final results of review for which these companies did not know that the merchandise was destined for the United States. In such instances, we will instruct U.S. Customs and Border Protection (CBP) to liquidate un-reviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[5]

We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of LEU from France entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for AREVA will remain unchanged from the rate assigned to the company in the most recently completed review of that company, except for entries for which the importer claims to be excluded from the order under the re-export provision of the scope, which will require a cash deposit rate of zero percent; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period with a completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period with a completed segment of this proceeding for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 19.95 percent, the all-others rate established in the investigation.[6] Entries accompanied by certifications from the exporter, the importer, and the end user, indicating that the LEU will be re-exported within 18 months will be subject to a cash deposit requirement of zero percent *ad valorem.* These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification Regarding Administrative Protective Orders

This notice is the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Importers

This notice serves as a final reminder to the importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping

[2] For a full description of the scope of the order, *see* ''Decision Memorandum for the Final Results of Antidumping Duty Administrative Review: Low-Enriched Uranium from France: 2012–2013'' from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Paul Piquado, Assistant Secretary for Enforcement and Compliance (Issues and Decision Memorandum), dated concurrently with these results and herby adopted by this notice.

[3] *See* Comment 3 and ''Suspension of Liquidation'' section of the Issues and Decision Memorandum.

[4] *Id.*

[5] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[6] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Low Enriched Uranium From France,* 67 FR 6680 (February 13, 2002).

duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These final results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 22, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

Issues in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Issues
  Comment 1: Preliminary Finding of ''No Shipments''
  Comment 2: Filing of Entry Documents
  Comment 3: Administrative Review Process for Merchandise Conditionally Excluded From the Scope of the Order
V. Determination of No Shipments
VI. Revised Entry Requirements
VII. Recommendation

[FR Doc. 2014–23133 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–851–803]

Grain-Oriented Electrical Steel From the Czech Republic: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that grain-oriented electrical steel (GOES) from the Czech Republic is being, or is likely to be, sold in the United States at less than fair value (LTFV), as provided in section 735 of the Tariff Act of 1930, as amended (the Act). In addition, we determine that critical circumstances exist with respect to imports of the subject merchandise from the Czech Republic. The period of investigation (POI) is July 1, 2012, through June 30, 2013. The final dumping margins of sales at LTFV are listed below in the ''Final Determination'' section of this notice.

DATES: *Effective Date:* September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Stephen Bailey at (202) 482–0193 or Dennis McClure at (202) 482–5973; AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On May 9, 2014, the Department published the *Preliminary Determination* of sales at LTFV of GOES from the Czech Republic.[1] The following events occurred since the *Preliminary Determination* was issued.

In May 2014, the Department verified the sales data submitted by ArcelorMittal Frydek-Mistek (AMFM) and its U.S. affiliate, ArcelorMittal International America LLC, in accordance with section 782(i) of the Act. We also issued a supplemental cost of production (COP) questionnaire to AMFM on May 9, 2014, and received the response to this supplemental questionnaire on June 3, 2014.

In June 2014, we verified the COP information submitted by AMFM, and we attempted to verify the sales information submitted by Sujani Enterprises, Ltd. (Sujani), in accordance with section 782(i) of the Act.

We invited interested parties to comment on the *Preliminary Determination.* On July 28 and August 4, 2014, the domestic industry,[2] AMFM, and Sujani submitted case and rebuttal briefs, respectively.

Scope of the Investigation

The scope of the investigation covers GOES, which is a flat-rolled alloy steel product containing by weight specific levels of silicon, carbon, and aluminum. For a complete description of the scope of the investigation, see Appendix I of this notice.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the issues raised is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and it is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Verification

As provided in section 782(i) of the Act, in May and June 2014, we verified the sales and cost information submitted by AMFM for use in our final determination. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by AMFM.[3]

In addition, as provided in section 782(i) of the Act, in June 2014, we also attempted to verify the sales information submitted by Sujani, using standard verification procedures.[4] However, as noted in the Sujani Sales Verification Report, Sujani was unable to substantiate the data in its accounting system using independent sources, and it withheld information when requested by the Department's verifiers. As a consequence, we find that Sujani's reported data is unverifiable, and so incomplete that it cannot serve as a reliable basis for reaching a determination in this investigation.[5]

---

[1] *See Grain-Oriented Electrical Steel From the Czech Republic: Preliminary Determination of Sales at Less Than Fair Value, Negative Preliminary Determination of Critical Circumstances, and Postponement of Final Determination,* 79 FR 26717 (May 9, 2014) (*Preliminary Determination*).

[2] The domestic industry includes AK Steel Corporation, Allegheny Ludlum, LLC, and the United Steelworkers (*i.e.,* the parties filing the petition), as well as one additional domestic interested party, the International Union, United Automobile, Aerospace, and Agricultural Implemental Workers of America (UAW).

[3] *See* Memorandum to the File from Stephen Bailey and Dennis McClure, Senior Analysts, entitled ''Verification of ArcelorMittal International America LLC in the Less-Than-Fair-Value Investigation of Grain-Oriented Electrical Steel from the Czech Republic,'' dated June 11, 2014; Memorandum to the File from Stephen Bailey and Dennis McClure, Senior Analysts, entitled ''Verification of Sales Response of ArcelorMittal Frýdek-Místek in the Less-Than-Fair-Value Investigation of Grain-Oriented Electrical Steel from the Czech Republic,'' dated July 3, 2014; and Memorandum to the File from Christopher J. Zimpo, Senior Accountant, entitled ''Verification of Cost Response of ArcelorMittal Frydek-Mistek (''AMFM'') in the Antidumping Duty Investigation of Grain-Oriented Electrical Steel from the Czech Republic,'' dated July 18, 2014.

[4] *See* Memorandum to the File from Dennis McClure, Senior Analyst, and Stephen Banea, Analyst, Office II, AD/CVD Operations, entitled, ''Verification of Sujani Enterprises, Inc. in the Less-Than-Fair-Value Investigation of Grain-Oriented Electrical Steel from the Czech Republic,'' dated July 16, 2013 (Sujani Sales Verification Report).

[5] *See* sections 782(e)(2) and (3) of the Act.

Changes Since the Preliminary Determination

Based on our analysis of the comments received and our findings at verification, we made certain changes to the margin calculation for AMFM. For a discussion of these changes, see the ''Margin Calculations'' section of the Issues and Decision Memorandum.

With respect to Sujani, as noted in the ''Verification'' section above, we found that Sujani's reported sales information could not be verified. As a consequence, for purposes of the final determination, we find that necessary information is not available on the record, and that Sujani withheld information requested by the Department, significantly impeded the proceeding, and provided information that could not be verified, within the meaning of sections 776(a)(1) and 776(a)(2)(A), (C), and (D) of the Act. Furthermore, we find that Sujani failed to cooperate by not acting to the best of its ability in this proceeding because it failed to provide complete information at the Department's request, although it possessed this information. Thus, pursuant to section 776(b) of the Act and 19 CFR 351.308(a), and consistent with sections 782(e)(2) and (3) of the Act, we have based Sujani's dumping margin on total adverse facts available (AFA). For further discussion, see Issues and Decision Memorandum at Comment 11.

''All Others'' Rate

Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding any zero or *de minimis* margins, and margins determined entirely under section 776 of the Act. In the *Preliminary Determination,* the Department calculated the ''all others'' rate based on the average of AMFM's and Sujani's margins. In light of the Department's use of total AFA for Sujani for purposes of this final determination, Sujani's rate is no longer appropriate for use in calculating the ''all others'' rate. Therefore, the Department has assigned AMFM's weighted-average dumping margin of 13.76 percent to all other entities not individually examined.

Final Determination

The final weighted-average dumping margins are as follows:

Manufacturer/Exporter	Dumping margin (percent)
ArcelorMittal Frydek-Mistek ..	13.76
Sujani Enterprises, Ltd.	35.93
All Others	13.76

Final Determination of Critical Circumstances

For AMFM and the companies covered by the all others rate, we made no changes to our critical circumstances analysis announced in the *Preliminary Determination* and described in the ''Decision Memorandum for the Preliminary Determination of the Antidumping Duty Investigation of Grain-Oriented Electrical Steel from the Czech Republic.'' [6] Thus, pursuant to 735(a)(3) of the Act, we continue to find that critical circumstances do not exist with respect to imports of GOES from the Czech Republic from AMFM and the companies covered by the all others rate.

For Sujani, because we now find it to be uncooperative, we are determining for Sujani, as AFA, a final dumping margin of 35.93 percent, which is the highest model-specific margin calculated for AMFM. In performing its critical circumstances analysis, the Department normally considers margins of 25 percent or more for export price sales and 15 percent or more for constructed export price sales sufficient to impute importer knowledge of sales at LTFV.[7] Because Sujani's final dumping margin exceeds the threshold sufficient to impute knowledge of dumping, this margin provides a sufficient basis for imputing knowledge of sales of subject merchandise at LTFV to the importers, as set forth in section 735(a)(3)(ii) of the Act.

In determining whether an importer knew or should have known that there was likely to be material injury caused by reason of such imports, the Department normally will look to the preliminary injury determination of the International Trade Commission (ITC).[8] If the ITC finds a reasonable indication of material injury to the relevant U.S. industry, the Department will determine that a reasonable basis exists to impute importer knowledge that material injury is likely by reason of such imports.[9] Here, the ITC found that ''there is a reasonable indication that an industry in the United States is materially injured by reason of imports from China, Czech Republic, Germany, Japan, Korea, Poland, and Russia of grain-oriented electrical steel, provided for in subheadings 7225.11.00, 7226.11.10, and 7226.11.90 of the Harmonized Tariff Schedule of the United States. . . .'' [10] Therefore, the ITC's preliminary injury determination in this investigation is sufficient to impute knowledge of the likelihood of material injury.

Section 351.206(h)(1) of the Department's regulations provides that, in determining whether imports of the subject merchandise were ''massive,'' the Department normally will examine: (i) The volume and value of the imports; (ii) seasonal trends; and (iii) the share of domestic consumption accounted for by the imports. In addition, 19 CFR 351.206(h)(2) provides that, ''{i}n general, unless the imports during the 'relatively short period' . . . have increased by at least 15 percent over the imports during an immediately preceding period of comparable duration, the Secretary will not consider the imports massive.'' It is the Department's practice to conduct its massive imports analysis based on the experience of investigated companies, using the reported monthly shipment data for the base and comparison periods.[11] However, as noted above, we

[6] *See Preliminary Determination,* 79 FR at 26717, and accompanying Preliminary Issues and Decision Memorandum at 16–18.

[7] *See, e.g., Carbon and Alloy Steel Wire Rod From Germany, Mexico, Moldova, Trinidad and Tobago, and Ukraine: Preliminary Determination of Critical Circumstances,* 67 FR 6224, 6225 (February 11, 2002) (*Steel Wire Rod Preliminary Determination*), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Carbon and Certain Alloy Steel Wire Rod From Moldova,* 67 FR 55790 (*Steel Wire Rod Moldova Final Determination*); *Affirmative Preliminary Determination of Critical Circumstances: Magnesium Metal From the People's Republic of China,* 70 FR 5606, 5607 (February 3, 2005) (*Magnesium Metal Preliminary Critical Circumstances Determination*), unchanged in *Final Determination of Sales at Less Than Fair Value and Affirmative Critical Circumstances: Magnesium Metal From the People's Republic of China,* 70 FR 9037 (*Magnesium Metal Final Determination*) (February 24, 2005).

[8] *See, e.g., Certain Potassium Phosphate Salts From the People's Republic of China: Preliminary Affirmative Determination of Critical Circumstances in the Antidumping Duty Investigation,* 75 FR 24572, 24573 (May 5, 2010), unchanged in *Certain Potassium Phosphate Salts From the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Termination of Critical Circumstances Inquiry,* 75 FR 30377 (June 1, 2010).

[9] *See, e.g., Steel Wire Rod Preliminary Determination, Unchanged in Steel Wire Rod Moldova Final Determination;* and *Magnesium Metal Preliminary Critical Circumstances Determination,* unchanged in *Magnesium Metal Final Determination.*

[10] *See Grain-Oriented Electrical Steel From China, Czech Republic, Germany, Japan, Korea, Poland, and Russia; Determinations,* 78 FR 70574 (November 26, 2013).

[11] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances: Circular Welded Carbon Quality Steel Pipe From the*

Continued

determined that Sujani has not acted to the best of its ability in responding to our requests for information.[12] Therefore, the Department determines that the use of adverse facts available is warranted. Accordingly, we find that there were massive imports of subject merchandise from Sujani, pursuant to our practice.[13]

Given the analysis above, we determine that critical circumstances exist with respect to imports of GOES from Sujani.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of GOES from the Czech Republic, as described in Appendix I of this notice, for AMFM and the companies covered by the all others rate which were entered, or withdrawn from warehouse, for consumption on or after May 9, 2014, the date of publication of the preliminary determination of this investigation in the **Federal Register**. For entries made by Sujani, in accordance with section 735(c)(4)(B) of the Act, we will instruct CBP to suspend liquidation of all appropriate entries of GOES from the Czech Republic, as described in Appendix I of this notice which were entered, or withdrawn from warehouse, for consumption on or after February 8, 2014, which is 90 days prior to the date of publication of the preliminary determination of this investigation in the **Federal Register**.

Further, the Department will instruct CBP to require a cash deposit equal to the amount by which normal value exceeds U.S. price as follows: (1) For the mandatory respondents listed above, the cash deposit rate will be equal to the dumping margin which the Department determined in this final determination; (2) if the exporter is not a mandatory respondent identified in this investigation, but the producer is, the cash deposit rate will be the rate established for the producer of the subject merchandise; and (3) the cash deposit rates for all other producers or exporters will be 13.76 percent. The suspension of liquidation instructions will remain in effect until further notice.

ITC Notification

In accordance with section 735(d) of the Act, we will notify the ITC of the final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of GOES from the Czech Republic no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all cash deposits will be refunded. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Orders (APO)

This notice serves as a reminder to parties subject to APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act.

Dated: September 22, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The scope of this investigation covers grain-oriented silicon electrical steel (GOES). GOES is a flat-rolled alloy steel product containing by weight at least 0.6 percent but not more than 6 percent of silicon, not more than 0.08 percent of carbon, not more than 1.0 percent of aluminum, and no other element in an amount that would give the steel the characteristics of another alloy steel, in coils or in straight lengths. The GOES that is subject to this investigation is currently classifiable under subheadings 7225.11.0000, 7226.11.1000, 7226.11.9030, and 7226.11.9060 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive. Excluded are flat-rolled products not in coils that, prior to importation into the United States, have been cut to a shape and undergone all punching, coating, or other operations necessary for classification in Chapter 85 of the HTSUS as a transformer part (*i.e.,* laminations).

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

General Comments

1. Affiliation Between AMFM and Sujani
2. The Knowledge Test

Company-Specific Comments

AMFM

3. Home Market Sale Outside the Ordinary Course of Trade
4. Indirect Selling Expenses
5. Packing Expenses
6. CEP Offset
7. Electricity
8. Rolls and Roller Adjustment to Cost of Manufacturing
9. Verification Changes to AMFM's Cost Data
10. Profit

Sujani

11. Total Facts Available for Sujani
12. Other Sujani Adjustments

[FR Doc. 2014–23124 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–992]

Monosodium Glutamate From the People's Republic of China: Final Determination of Sales at Less Than Fair Value and the Final Affirmative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* September 29, 2014.

SUMMARY: The Department of Commerce (the Department) determines that monosodium glutamate (MSG) from the People's Republic of China (PRC) is being, or is likely to be, sold in the United States at less than fair value (LTFV), as provided in section 735 of the Tariff Act of 1930, as amended (the Act). The final weighted-average

---

People's Republic of China, 73 FR 31970, 31972–31973 (June 5, 2008); and *Small Diameter Graphite Electrodes From the People's Republic of China,* 74 FR 2049, 2052–2053 (January 14, 2009) (*SDGE Final Determination*).

[12] *See* the ''Verification'' section of this memorandum, above.

[13] *See SDGE Final Determination,* 74 FR at 2052–2053.

dumping margins for this investigation are listed in the ''Final Determination Margins'' section below.

FOR FURTHER INFORMATION CONTACT: Milton Koch or Jun Jack Zhao, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–2584 or (202) 482–1396, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the preliminary determination in the LTFV investigation of MSG from the PRC on May 8, 2014.[1] The following events occurred since the preliminary determination. The Department published the amended preliminary determination on June 13, 2014.[2] Between June 16, 2014 and June 24, 2014, the Department conducted verification of the mandatory respondent, the Meihua Group.[3] On July 21, 2014, Petitioner filed scope comments. On July 31, 2014 and August 7, 2014, both the Meihua Group and Petitioner filed case briefs and rebuttal briefs respectively.

Period of Investigation

The period of investigation is January 1, 2013, through June 30, 2013. This period corresponds to the two most recent fiscal quarters prior to the month of the filing of the petition, which was September 2013.[4]

Scope of the Investigation

The product covered by this investigation is MSG, whether or not blended or in solution with other products. Specifically, MSG that has been blended or is in solution with other product(s) is included in this scope when the resulting mix contains 15 percent or more of MSG by dry weight.[5]

Changes to the Scope of the Investigation

As detailed in the accompanying Issues and Decision Memorandum,[6] we clarified the scope language with respect to the written descriptions of anhydrous and monohydrous forms of MSG and their chemical formula references.[7] The revised scope of the investigation for this final determination is detailed in Appendix I, below.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this investigation are addressed in the Issues and Decision Memorandum. A list of the issues which the parties raised and to which the Department responded in the Issues and Decision Memorandum is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and it is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/*. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Determination

Based on the Department's analysis of the comments received and our findings at verification, we made certain changes to the margin calculations. For a discussion of these changes, *see* the Issues and Decision Memorandum and the Final Analysis Memorandum.[8]

Verification

As provided in section 782(i) of the Act and 19 CFR 351.307(b)(1)(i), in June 2014, the Department verified the information submitted by the Meihua Group for use in the final determination. The Department used standard verification procedures, including examination of relevant accounting and production records and original source documents provided by the Meihua Group.

Final Determination Margins

The Department determines that the following weighted-average dumping margins exist for the period January 1, 2013, through June 30, 2013.

Exporter	Producer	Weighted-average dumping margin (percent)
Langfang Meihua Bio-Technology Co., Ltd./Meihua Group International Trading (Hong Kong) Limited.	Tongliao Meihua Biological SCI–TECH Co., Ltd./Meihua Holdings Group Co., Ltd., Bazhou Branch.	8.30
Fujian Province Jianyang Wuyi MSG Co., Ltd.	Fujian Province Jianyang Wuyi MSG Co., Ltd.	8.30
Neimenggu Fufeng Biotechnologies Co., Ltd.	Neimenggu Fufeng Biotechnologies Co., Ltd.	8.30
Baoji Fufeng Biotechnologies Co., Ltd.	Baoji Fufeng Biotechnologies Co., Ltd.	8.30
PRC-wide Entity		8.32

The PRC-wide entity includes Shandong Linghua Monosodium Glutamate Incorporated Company (Shandong Linghua), a mandatory

[1] *See Monosodium Glutamate From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, and Postponement of Final Determination,* 79 FR 26408 (May 8, 2014) (*Preliminary Determination*).

[2] *See Monosodium Glutamate From the People's Republic of China: Amended Preliminary Determination of Sales at Less Than Fair Value of the Antidumping Duty Investigation,* 79 FR 33907 (June 13, 2014) (*Amended Preliminary Determination*).

[3] Langfang Meihua Bio-Technology Co., Ltd., Tongliao Meihua Biological SCI–TECH Co., Ltd., Meihua Group International Trading (Hong Kong) Limited, Meihua Holdings Group Co., Ltd, and Meihua Holdings Group Co., Ltd, Bazhou Branch (collectively, Meihua, or the Meihua Group); *see* ''Verification'' section below.

[4] 19 CFR 351.204(b)(1).

[5] *See* Appendix I.

[6] *See* Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Monosodium Glutamate From the People's Republic of China: Issues and Decision Memorandum for the Final Determination of Sales at Less Than Fair Value,'' dated concurrently with this notice (Issues and Decision Memorandum).

[7] *See* the Issues and Decision Memorandum at the section, ''Scope of the Investigation.''

[8] *See* Memorandum from Milton Koch, International Trade Compliance Analyst, AD/CVD Operations, Office VII, to the File, ''Antidumping Duty Investigation of Monosodium Glutamate from the People's Republic of China: Meihua Analysis Memorandum for the Final Determination,'' dated concurrently with this notice (Final Analysis Memorandum).

respondent in this investigation.[9] Shandong Linghua withheld necessary information within the meaning of section 776(a) of the Act, and failed to act to the best of its ability to comply with the Department's requests for information within the meaning of section 776(b) of the Act. Therefore, we applied adverse facts available, determining that Shandong Linghua was a part of the PRC-wide entity. *See* Issues and Decision Memorandum for further discussion.

Disclosure

We intend to disclose to parties the calculations performed in this proceeding within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Final Affirmative Determination of Critical Circumstances

No parties made any comments on and we made no changes to our critical circumstances analysis announced in the *Preliminary Determination,* which is hereby adopted by this notice. Thus, pursuant to 735(a)(3) of the Act, we continue to find that critical circumstances exist with respect to imports of MSG from the PRC from the Meihua Group, the separate rate companies, and the companies covered by the PRC-wide rate.

Continuation of Suspension of Liquidation

As noted above, the Department reached an affirmative critical circumstances determination at both the *Preliminary Determination* and this final determination with respect to imports of MSG from the Meihua Group, the separate rate companies, and the PRC-wide entity. Therefore, in accordance with section 735(c)(4)(A) of the Act, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of entries of MSG from the PRC from the Meihua Group, the separate rate companies, and the PRC-wide entity that were entered, or withdrawn from warehouse, for consumption on or after February 7, 2014, the date which is 90 days prior to publication of the *Preliminary Determination.* Further, the Department will instruct CBP to require a cash deposit equal to the weighted-average amount by which the normal value exceeds U.S. price as follows: (1) For the exporter/producer combination listed in the table above, the cash deposit rate will be equal to the dumping margin which the Department determined in this final determination; (2) for all combinations of PRC exporters/producers of merchandise under consideration which have not received their own separate rate above, the cash deposit rate will be equal to the dumping margin established for the PRC-wide entity; and (3) for all non-PRC exporters of merchandise under consideration which have not received their own separate rate above, the cash deposit rate will be equal to the cash deposit rate applicable to the PRC exporter/producer combination that supplied that non-PRC exporter. These suspension-of-liquidation instructions will remain in effect until further notice.

ITC Notification

In accordance with section 735(d) of the Act, we notified the International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. As the Department's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will determine, within 45 days, whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of subject merchandise, or sales (or the likelihood of sales) for importation, of the subject merchandise. If the ITC determines that such injury does not exist, this proceeding with be terminated and all securities posted will be refunded or canceled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Return or Destruction of Proprietary Information

This notice also serves as a reminder to the parties subject to administrative protective order (APO) of their responsibility concerning the disposition of propriety information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act.

Dated: September 22, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation covers monosodium glutamate (MSG), whether or not blended or in solution with other products. Specifically, MSG that has been blended or is in solution with other product(s) is included in this scope when the resulting mix contains 15% or more of MSG by dry weight. Products with which MSG may be blended include, but are not limited to, salts, sugars, starches, maltodextrins, and various seasonings. Further, MSG is included in this investigation regardless of physical form (including, but not limited to, in monohydrate or anhydrous form, or as substrates, solutions, dry powders of any particle size, or unfinished forms such as MSG slurry), end-use application, or packaging.

MSG in monohydrate form has a molecular formula of $C_5H_8NO_4Na - H_2O$, a Chemical Abstract Service (CAS) registry number of 6106–04–3, and a Unique Ingredient Identifier (UNII) number of W81N5U6R6U. MSG in anhydrous form has a molecular formula of $C_5H_8NO_4Na$, a CAS registry number of l42–47–2, and a UNII number of C3C196L9FG.

Merchandise covered by the scope of this investigation is currently classified in the Harmonized Tariff Schedule (HTS) of the United States at subheading 2922.42.10.00. Merchandise subject to the investigation may also enter under HTS subheadings 2922.42.50.00, 2103.90.72.00, 2103.90.74.00, 2103.90.78.00, 2103.90.80.00, and 2103.90.90.91. The tariff classifications, CAS registry numbers, and UNII numbers are provided for convenience and customs purposes; however, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Use of Adverse Facts Available
V. Margin Calculations
VI. Discussion of the Issues
1. The Department's Inland Freight Calculation
2. Letter of Credit Costs From the Brokerage and Handling Surrogate Value
3. Meihua's Steam and Other Energy Inputs
4. The Department's Co-Product Allocation
5. Meihua's Sulfuric Acid and Sulfur Dioxide Inputs
6. Meihua's Organic Bacterial Protein (OBP) By-Product Valuation
7. Whether To Allow Offsets when Aggregating the A–A and A–T Margins for the Department's Mixed Methodology To Calculate Meihua's Margin
8. Meihua's Reported Tape Distance
9. The Valuation of Wind Power
10. The Valuation of Water
11. Limiting a By-Product Offset

[9] *See Preliminary Determination,* and accompanying Preliminary Decision Memorandum at 10.

12. Meihua's Irrecoverable Value Added Taxes
13. Meihua's Weighted-Average Factors of Production
14. Whether the Department Should Use Indonesian Import Statistics To Value Lignite Coal
15. Whether the Department Should Use Domestic Prices in Indonesia To Value Corn
16. The Valuation of High Protein Scrap

VII. Recommendation

[FR Doc. 2014–23136 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–826]

Monosodium Glutamate From the Republic of Indonesia: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that monosodium glutamate (MSG) from the Republic of Indonesia (Indonesia) is being, or is likely to be, sold in the United States at less than fair value, as provided in section 735 of the Tariff Act of 1930, as amended (the Act). The period of investigation is July 1, 2012, through June 30, 2013. The final weighted-average dumping margins are listed below in the section, ''Final Determination.''

DATES: *Effective Date:* September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Gene Calvert or Justin Neuman, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3586 or (202) 482–0486, respectively.

SUPPLEMENTARY INFORMATION:

Background

The events that have occurred since the Department published the *Preliminary Determination* on May 8, 2014,[1] are discussed in the Issues and Decision Memorandum.[2]

Scope of the Investigation

The product covered by this investigation is MSG, whether or not blended or in solution with other products. Specifically, MSG that has been blended or is in solution with other product(s) is included in this scope when the resulting mix contains 15 percent or more of MSG by dry weight. The full scope of the investigation is set forth in Appendix I, below.

Changes to the Scope of the Investigation

As detailed in the accompanying Issues and Decision Memorandum, we clarified the scope language with respect to the written descriptions of anhydrous and monohydrous forms of MSG and their chemical formula references.[3]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues raised in the case and rebuttal briefs is attached to this notice.[4] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov,* and is available to all parties in the Department's Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Determination

Based on our analysis of the comments received, and our findings at verification, we made certain changes to the weighted-average dumping margin calculations. For a discussion of these changes, *see* the ''Margin Calculations'' section of the Issues and Decision Memorandum.

Verification

As provided in section 782(i) of the Act, in July 2014, we verified the sales and cost information submitted by PT Cheil Jedang Indonesia and CJ America, Inc. (collectively, Cheil Jedang) for use in our final determination. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by Cheil Jedang.[5]

Final Determination

The weighted-average dumping margins for this final determination are as follows:

Producer or Exporter	Weighted-average dumping margin (percent)
PT Cheil Jedang Indonesia ..	6.19
All Others	6.19

Section 735(c)(5)(A) of the Act provides that the estimated ''all others'' rate shall be an amount equal to the weighted average of the weighted-average dumping margins calculated for the producers or exporters individually examined, excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act. Because we calculated a weighted-average dumping margin for only one respondent, and that rate was not zero, *de minimis,* or determined entirely under section 776 of the Act, we assigned to all other producers and exporters the rate calculated for PT Cheil Jedang Indonesia.

Disclosure

We intend to disclose the calculations performed for this final determination within five days after the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend

[1] *See Monosodium Glutamate From the Republic of Indonesia: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 79 FR 26406 (May 8, 2014) (*Preliminary Determination*).

[2] *See* the Department Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less than Fair Value Investigation of Monosodium Glutamate from the Republic of Indonesia,'' which is dated concurrently with and hereby adopted by this notice (Issues and Decision Memorandum).

[3] *See* the Issues and Decision Memorandum at the section, ''Scope of the Investigation.''

[4] *See* Appendix II.

[5] *See* the Department Memoranda, ''Verification of the Cost Response of PT Cheil Jedang Indonesia in the Less-Than-Fair-Value Investigation of Monosodium Glutamate from Indonesia,'' (July 11, 2014); ''Verification of the Sales Responses of Cheil Jedang Indonesia in the Antidumping Duty Investigation of Monosodium Glutamate (MSG) from Indonesia,'' (July 21, 2014) and; ''Verification of the CEP Sales Responses of CJ America, Inc. in the Antidumping Duty Investigation of Monosodium Glutamate (MSG) from Indonesia,'' (July 21, 2014).

liquidation of all entries of MSG from Indonesia. We will also instruct CBP to require cash deposits equal to the amount as indicated above. These instructions suspending liquidation will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (the ITC) of our final determination. As our final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will determine within 45 days whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of subject merchandise. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction from the Department, antidumping duties on all imports of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation. We are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Return or Destruction of Proprietary Information

This notice serves as the final reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

We are issuing and publishing this determination and notice in accordance with sections 735(d) and 777(i) of the Act.

Dated: September 22, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation covers monosodium glutamate (MSG), whether or not blended or in solution with other products. Specifically, MSG that has been blended or is in solution with other product(s) is included in this scope when the resulting mix contains 15 percent or more of MSG by dry weight. Products with which MSG may be blended include, but are not limited to, salts, sugars, starches, maltodextrins, and various seasonings. Further, MSG is included in this investigation regardless of physical form (including, but not limited to, in monohydrate or anhydrous form, or as substrates, solutions, dry powders of any particle size, or unfinished forms such as MSG slurry), end-use application, or packaging.

MSG in monohydrate form has a molecular formula of $C_5H_8NO_4Na \bullet H_2O$, a Chemical Abstract Service (CAS) registry number of 6106–04–3, and a Unique Ingredient Identifier (UNII) number of W81N5U6R6U. MSG in anhydrous form has a molecular formula of $C_5H_8NO_4$ Na, a CAS registry number of l42–47–2, and a UNII number of C3C196L9FG.

Merchandise covered by the scope of this investigation is currently classified in the Harmonized Tariff Schedule (HTS) of the United States at subheading 2922.42.10.00. Merchandise subject to the investigation may also enter under HTS subheadings 2922.42.50.00, 2103.90.72.00, 2103.90.74.00, 2103.90.78.00, 2103.90.80.00, and 2103.90.90.91. The tariff classifications, CAS registry numbers, and UNII numbers are provided for convenience and customs purposes; however, the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Investigation
IV. Margin Calculations
V. Discussion of the Issues
  1. Treatment of CJI's Import Duties on Imported Raw Materials Into Bonded Zones
  2. Treatment of CJA's Indirect Selling Expenses
  3. Treatment of CJA's Royalty Expenses
  4. Treatment of CJI's Credit Expenses
  5. Minor Calculation Error Regarding Currency Conversions
VI. Recommendation

[FR Doc. 2014–23126 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD521

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Salmon Advisory Subpanel (SAS) and ad hoc Lower Columbia River Natural Coho Workgroup (LRC Workgroup) will hold a public work session in Portland, OR. The meeting is open to the public, but is not intended as a public hearing. Public comments will be taken as time allows.

DATES: The work session will begin at 9 a.m. on Wednesday, October 15, 2014 and will proceed until 5 p.m. or until business for the day is completed.

ADDRESSES: The work session will be held at the Sheraton Portland Airport Hotel, Cascade A and B Rooms, 8235 Northeast Airport Way, Portland, OR 97220; telephone: (503) 281–2500.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220; telephone: (503) 820–2280.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Burner, Pacific Council; telephone: (503) 820–2414.

SUPPLEMENTARY INFORMATION: The SAS and LRC Workgroup will discuss proposed revisions to the Lower Columbia River natural (LCN) coho harvest matrix and prepare for the November 2014 Council meeting. Focus topics include; a review of Council guidance from the September 2014 Council meeting, the assessment of coho impacts in Columbia River tributary fisheries, and recommendations on a final range of alternative harvest strategies for LCN coho. The SAS and LRC Workgroup may also address one or more matters on the Council's November 2014 agenda. The SAS and LRC Workgroup reports and recommendations are scheduled to be presented to the Council at its November 2014 meeting in Costa Mesa, CA.

Although nonemergency issues not contained in the SAS and the LRC Workgroup meeting agendas may come before the SAS and the LRC Workgroup for discussion, those issues may not be the subject of formal action during this

meeting. The SAS and the LRC Workgroup action will be restricted to those issues specifically listed in this document and to any issues arising after publication of this document requiring emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This public meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820–2425 (voice), or (503) 820–2299 (fax) at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 24, 2014.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2014–23096 Filed 9–26–14; 8:45 am]

BILLING CODE 3510–22–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its proposed renewal of the Social Innovation Fund Pay for Success Grant Competition Application Instructions. Funding for this competition was created as a result of the FY 2014 Omnibus Appropriations Act. This competition responds to the need in the social sector for new ways of funding as traditional resources are declining and demands are increasing. It offers the opportunity to support innovation in the social sector while driving better results and conserving government resources. The affected public includes nonprofit organizations, funders and intermediary organizations.

Copies of the information collection request can be obtained by contacting the office listed in the Addresses section of this Notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by November 28, 2014.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Social Innovation Fund—Pay for Success Grant Competition; Attention Lois Nembhard, Deputy Director Social Innovation Fund, Room 9601; 1201 New York Avenue NW., Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Lois Nembhard, 202–606–6827, or by email at *lnembhard@cns.gov.*

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected 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 submissions of responses).

Background

The affected public includes nonprofit organizations, funders and intermediary organizations. Comments may be submitted, identified by the title of the information collection activity, by email to *lnembhard@cns.gov* or via *http://www.regulations.gov.*

Current Action

CNCS seeks to renew the current information collection. The current application is due to expire on 12/31/2014. The information collection will otherwise be used in the same manner as the existing application. CNCS also seeks to continue using the current application until the revised application is approved by OMB.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: Social Innovation Fund Pay for Success Grant Competition Application Instructions.

OMB Number: 3045–0160.

Agency Number: None.

Affected Public: Nonprofit organizations, funders and intermediary organizations.

Total Respondents: 20.

Frequency: One time.

Average Time per Response: 30 hours.

Estimated Total Burden Hours: 600 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: September 15, 2014.

Lois Nembhard,

Deputy Director, Social Innovation Fund.

[FR Doc. 2014–23102 Filed 9–26–14; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 14–44]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a

section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 14–44 with attached transmittal, policy justification, and sensitivity of technology.

Dated: September 24, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

SEP 17 2014

Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 14-44, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Poland for defense articles and services estimated to cost $500 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 14–44

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Poland

(ii) *Total Estimated Value:*

Major Defense Equipment * ..	$270 million
Other	$230 million
TOTAL	$500 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* 40 AGM–158A Joint Air-to-Surface Standoff Missiles (JASSM), 2 AGM–158A JASSM Live with Test Instrumentation Kit (TIK) and Flight Termination Systems (FTS), 2 AGM–158A JASSM Inert with TIK and FTS, and 2 Flight Certification Test Vehicles. Also included: Operational Flight Plan upgrade to M6.5 tape for the Polish F–16C/D Block 52 aircraft to include JASSM integration, missile containers, spare and repair parts, support and test equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor engineering, technical, and logistics support services, and other related elements of logistical and program support.

(iv) *Military Department:* Air Force (YAB)

(v) *Prior Related Cases, if any:* FMS case SAC and amendments-$3.5B–23Apr03

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 17 Sep 14

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Poland—Joint Air-to-Surface Standoff Missiles and F–16 Operational Flight Plan Upgrade

The Government of Poland has requested a possible sale of 40 AGM–158A Joint Air-to-Surface Standoff Missiles (JASSM), 2 AGM–158A JASSM Live with Test Instrumentation Kit (TIK) and Flight Termination Systems (FTS), 2 AGM–158A JASSM Inert with TIK and FTS, and 2 Flight Certification Test Vehicles. Also included: Operational Flight Plan upgrade to M6.5 tape for the Polish F–16C/D Block 52 aircraft to include JASSM integration, missile containers, spare and repair parts, support and test equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor engineering, technical, and logistics support services, and other related elements of logistical and program support. The estimated cost is $500 million.

The proposed sale will contribute to the foreign policy and the national security objectives of the United States by helping to improve the security of a NATO ally. Poland continues to be an important force for political stability and economic progress in Central Europe.

The proposed sale will improve Poland's capability to meet current and future threats of enemy air and ground weapons systems. Poland will use the enhanced capability as a deterrent to regional threats and to strengthen its homeland defense. These weapon and capability upgrades will allow Poland to strengthen its air-to-ground strike capabilities and increase its contribution to future NATO operations.

The proposed sale of the weapons, equipment, and support will not alter the basic military balance in the region.

The principal contractor will be Lockheed Martin in Ft. Worth, Texas. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Poland.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 14–44

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AGM–158 is a 200+ nautical mile range low-observable, highly survivable subsonic cruise missile designed to penetrate next generation air defense systems en route to target. It is designed to kill hard, medium-hardened, soft and area type targets. It uses a Selective Availability Anti-Spoofing Module based Global Positioning System (GPS) receiver and a scene matching infrared seeker that uses a wire-frame Terminal Area Model (TAM) of the target area to hit fixed and relocatable targets with greater accuracy than GPS alone. Classification of the technical data and information on the AGM–158's performance, capabilities, systems, sub-systems, operations, and maintenance will range from Unclassified to Secret. The highest level of classified information required for training, operation and maintenance is Secret.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that the recipient country can provide the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

4. All defense articles and services listed in this transmittal have been authorized for release and export to Poland.

[FR Doc. 2014–23076 Filed 9–26–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 14–32]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 14–32 with attached transmittal, policy justification, and sensitivity of technology.

Dated: September 24, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

SEP 19 2014

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 14-32, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Pakistan for defense articles and services estimated to cost $198 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 14–32

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Pakistan

(ii) *Total Estimated Value:*

Major Defense Equipment* ..	$ 0 million
Other	$198 million
TOTAL	$198 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* 160 Navistar Mine Resistant Ambush Protected (MRAP) vehicles to include (110 MaxxPro Dash DXM, 30 MaxxPro Base DXM, 10 MaxxPro Dash DXM Ambulances, and 10 MaxxPro Recovery Vehicles with protection kits), spare and repair parts, support and test equipment, publications and technical documentation, personnel training and equipment training, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support.

(iv) *Military Department:* Army (WAW)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or*

Defense Services Proposed to be Sold: See Annex attached

(viii) *Date Report Delivered to Congress:* 19 Sep 14

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Pakistan—Mine Resistant Ambush Protected (MRAP) Vehicles

The Government of Pakistan has requested a possible sale of 160 Navistar Mine Resistant Ambush Protected (MRAP) vehicles to include (110 MaxxPro Dash DXM, 30 MaxxPro Base DXM, 10 MaxxPro Dash DXM Ambulances, and 10 MaxxPro Recovery Vehicles with protection kits), spare and repair parts, support and test equipment, publications and technical documentation, personnel training and equipment training, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support. The estimated cost is $198 million.

The proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a country vital to U.S. foreign policy and national security goals in South Asia.

The proposed sale of MRAPs will ensure that Pakistan can effectively operate in hazardous areas in a safe, enhanced survivability vehicle, and improves Pakistan's interoperability with U.S. forces. By acquiring this capability, Pakistan will be able to provide the same level of protection for its own forces as the United States provides for its forces. Pakistan, which currently possesses MRAPS, has successfully demonstrated the ability to operate and maintain the vehicles in counterinsurgency and counterterrorism operations, and will have no difficulty absorbing these additional vehicles into its armed forces.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The principal contractor will be Navistar Defense Corporation in Madison Heights, Michigan. There are no known offset agreements proposed in connection with this potential sale.

Implementation of the proposed sale will require approximately two (2) U.S. Government and twenty-four (24) contractor representatives in Pakistan for a period of approximately 18 months to perform inspections and de-processing of vehicles upon delivery; provide assistance in installation of vehicle accessory kits; provide fault diagnosis and repairs; perform corrective maintenance, to include accident and battle damage assessment and repairs; conduct operator and maintainer training; and conduct inventories and maintain accountability of USG provided material.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 14–32

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Mine Resistant Ambush Protected (MRAP) vehicle is an armored, multi-purpose combat vehicle designed to support mounted urban operations to include convoy security support and dismounted patrols. It is designed to increase crew survivability. The vehicle has a blast-resistant underbody designed to protect the crew from mine blasts, fragmentation, and direct fire weapons.

2. All MRAP vehicle information needed to operate, train, and maintain the vehicles is Unclassified; some design and test data, design performance parameters, armoring methodology, vulnerabilities, armor types and configuration data are classified up to Secret.

3. If a technologically advanced adversary were to obtain knowledge of the design performance and functional characteristics of specific hardware and software elements, the information could be used to develop countermeasures which might reduce the weapon system's effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that the recipient country can provide the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Pakistan.

[FR Doc. 2014–23075 Filed 9–26–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 14–20]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 14–20 with attached transmittal, and policy justification.

Dated: September 24, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

SEP 17 2014

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 14-20, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Lebanon for defense articles and services estimated to cost $180 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified Document Provided Under Separate Cover)

BILLING CODE 5001–06–C

Transmittal No. 14–20

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Lebanon

(ii) *Total Estimated Value:*

Major Defense Equipment* ..	$ 0 million
Other	$180 million
TOTAL	$180 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* 18 Huey II rotary wing aircraft, spare and repair parts, maintenance, support equipment, publications and technical documentation, personnel training and training equipment, repair and return, aircraft preparation for shipment, ferry and refueling support, component improvement program, U.S. Government and contractor engineering and logistics support services, and other related elements of logistics support.

(iv) *Military Department:* Army (WBL, Amendment #1)

(v) *Prior Related Cases, if any:*
FMS case WBL–$58M–9Dec12
FMS case UZU–$8M–20Dec96
FMS case JAE–$18M–3Jan95

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or*

Defense Services Proposed to be Sold: None.

(viii) *Date Report Delivered to Congress:* 17 Sep 14

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Lebanon—Huey II Rotary Wing Aircraft and Support

The Government of Lebanon has requested a possible sale of 18 Huey II rotary wing aircraft, spare and repair parts, maintenance, support equipment, publications and technical documentation, personnel training and training equipment, repair and return, aircraft preparation for shipment, ferry and refueling support, component improvement program, U.S. Government and contractor engineering and logistics support services, and other related elements of logistics support.

The estimated cost is $180 million.

This proposed sale serves U.S. national, economic, and security interests by providing Lebanon with mobility capabilities needed to maintain internal security, enforce United Nation's Security Council Resolutions 1559 and 1701, and counter terrorist threats.

The proposed sale of these aircraft will enable Lebanon to meet present and future challenges posed by internal and border security threats, evacuations, search and rescue, and drug interdiction operations. The Huey II will augment Lebanon's recently-purchased Huey II aircraft, help replace its aging fleet of UH–1H aircraft and provide the Lebanese Armed Forces with mission-capable assets. Lebanon will have no difficulty absorbing these additional aircraft into its armed forces.

The proposed sale of these vehicles and support will not alter the basic military balance in the region.

The prime contractor will be Bell Helicopter in Fort Worth, Texas. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require multiple trips to Lebanon involving U.S. Government and contractor representatives over a period of up to three years to provide program support and training.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2014–23074 Filed 9–26–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2014–0036]

Proposed Collection; Comment Request

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Army announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by November 28, 2014.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Mail: Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Department of the Army, U.S. Army Corps of Engineers, Institute for Water Resources, Waterborne Commerce Statistics Center, P.O. Box 61280, New Orleans, LA 70161–1260, or call 703–428–6440.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Record of Arrivals and Departures of Vessels at Marine Terminals; ENG Form 3926; OMB Control Number 0710–0005.

Needs and Uses: The Corps of Engineers uses ENG Form 3926 in conjunction with ENG 3925, 3925B, 3925C, and 3925P as the basic source of input to conduct the Waterborne Commerce Statistics data collection program. The data are used to justify maintenance and improvements of Federal navigation projects and to produce annual tonnage and trip statistics for U.S. waterways and channels.

Affected Public: Business or other for profit.

Annual Burden Hours: 1,800.

Number of Respondents: 300.

Responses per Respondent: 12.

Average Burden per Response: 30 minutes.

Frequency: Monthly.

The Corps of Engineers uses ENG Form 3926 as a quality control instrument by comparing the data collected on the Corps Vessel Operation report with that collected on ENG Form 3926. The information is voluntarily submitted by the respondents to assist the Waterborne Commerce Statistics Center in the identification of vessel operators who fail to report significant vessel moves and tonnage. For example, this information is invaluable in documenting the movement of petroleum out of Valdez, Alaska, without the information furnished on the ENG Form 3926, millions of tons of petroleum would go unreported each year. Under-reporting results in increased difficulty justifying maintenance of Federal navigation channels.

Dated: September 23, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–23004 Filed 9–26–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2014–ICCD–0137]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Application for Grants Under the Student Support Services Program (1894–0001)

AGENCY: Office of Post-Secondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before October 29, 2014.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2014–ICCD–0137 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E103, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact ReShone Moore, 202–502–7893.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for Grants Under the Student Support Services Program (1894–0001).

OMB Control Number: 1840–0017.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 1,633.

Total Estimated Number of Annual Burden Hours: 54,466.

Abstract: The application is needed to conduct a national competition under the Student Support Services Program for program years 2014–2015. The program provides grants to institutions of higher education and combinations of institutions of higher education for projects designed to increase the retention and graduation rates of eligible students; increase the transfer rate of eligible students from two-year to four-year institutions; and foster an institutional climate supportive of the success of low-income and first generation students and individuals with disabilities through the provision of support services.

Dated: September 23, 2014.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2014–23023 Filed 9–26–14; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

State Energy Advisory Board

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

ACTION: Notice of open teleconference.

SUMMARY: This notice announces a teleconference call of the State Energy Advisory Board (STEAB). The 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 16, 2014 from 3:30 p.m. to 4:00 p.m. (EDT). To receive the call-in number and passcode, please contact the Board's Designated Federal Officer (DFO) at the address or phone number listed below.

FOR FURTHER INFORMATION CONTACT: Julie Hughes, STEAB Designated Federal Officer, Policy Advisor, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, 1000 Independence Ave. SW., Washington DC 20585. Phone number 202–320–9703, and email *Julie.Hughes@ee.doe.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: To make recommendations to the Assistant Secretary for the Office of Energy Efficiency and Renewable Energy regarding goals and objectives, programmatic and administrative policies, and to otherwise carry out the Board's responsibilities as designated in the State Energy Efficiency Programs Improvement Act of 1990 (Pub. L. 101–440).

Tentative Agenda: Receive STEAB Task Force updates on action items and next steps, review of the details and discussion during the Small Business Voucher Workshop from early October, discuss potential engagement with EERE staff during upcoming 2015 meetings of STEAB, and receive updates on member activities within their states.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Julie Hughes at the address or telephone number listed above. Requests to make oral comments must be received five days prior to the meeting; reasonable provision will be made to include requested topic(s) on the agenda. The Chair of the Board is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes: The minutes of the meeting will be available for public review and copying within 60 days on the STEAB Web site at: *www.steab.org*.

Issued at Washington, DC, on September 23, 2014.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2014–23097 Filed 9–26–14; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Fusion Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open teleconference meeting.

SUMMARY: This notice announces a teleconference meeting of the Fusion Energy Sciences Advisory Committee (FESAC). 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: Friday, October 10, 2014, 1:00 p.m. to 4:00 p.m. EDT

ADDRESSES: Public participation is welcomed. Information concerning the call-in number can be found on the Web site: *http://science.energy.gov/fes/fesac/meetings/* or by contacting Dr. Samuel J. Barish by email *sam.barish@science.doe.gov* or by phone (301) 903–2917.

FOR FURTHER INFORMATION CONTACT: Dr. Edmund J. Synakowski, Designated Federal Officer, FESAC, U.S. Department of Energy, Office of Science, Office of Fusion Energy Sciences, SC–24/Germantown Building, 1000 Independence Avenue SW., Washington, DC 20585–1290. Phone 301–903–4941; fax (301) 903–8584 or email: *ed.synakowski@science.doe.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: To consider final approval of the report of the FESAC Strategic Plan Subcommittee. The report was requested in a letter from the Acting Director of the Office of Science (SC), dated April 8, 2014, in response to the FY 2014 Omnibus Appropriations Act which requires the Department to submit a ten-year strategic plan for the Fusion Energy Sciences (FES) program by January 2015.

Tentative Agenda:

- Approval of the Report of the FESAC Strategic Plan Subcommittee. (*http://science.energy.gov/~/media/fes/fesac/pdf/2014/FESAC_Charge_Feb_19_2014.pdf*)
- Other Business as Necessary
- Public Comments
- Adjourned

Public Participation: The teleconference 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 an oral statement regarding the primary item on the agenda, you should contact Sam Barish at the Email address or telephone number listed above. You must make your request for an oral statement at least five business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. An Acting 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 45 days at the Freedom of Information Public Reading Room; 1G–033, Forrestal Building; 1000 Independence Avenue SW., Washington, DC 20585; between 9:00 a.m. and 4:00 p.m., Monday through Friday, except holidays, and on the Fusion Energy Sciences Advisory Committee Web site—*http://science.energy.gov/fes/fesac/*

Issued at Washington, DC, on September 23, 2014.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2014–23090 Filed 9–26–14; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2010–0173; FRL–9916–70]

Announcement of Meeting Dates and Opportunity for Public Comments on Proposed List of Potential Peer Reviewers for an Approach for Estimating Exposures and Incremental Health Effects From Lead Due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Agency is requesting public comments on the proposed list of candidate peer reviewers for the independent contractor-managed external peer review of the draft documents released for public comment in the August 6, 2014 **Federal Register** notice entitled ''Approach for Estimating Exposures and Incremental Health Effects from Lead Due to Renovation, Repair, and Painting Activities in Public and Commercial Buildings.'' This notice provides the names and professional affiliations of the proposed peer reviewers. The public is requested to provide relevant information or documentation on the candidates who are being evaluated by the external peer review contractor, Versar, Inc. (Versar). Versar will consider the public comments on the proposed list of peer reviewers and will select the final peer reviewers who, collectively, best provide expertise spanning the multiple subject matter areas covered by the draft documents and, to the extent feasible, best provide a balance of perspectives according to EPA peer review guidance. This notice provides the public peer review meeting dates as well as Versar's Web site that will provide details about the meeting location, how to register to attend the meeting either in person or electronically, and how to provide comments at the meeting. The date, time, and conference call-in number of the initial meeting of the peer review panel can be obtained at Versar's peer review Web site.

DATES:

Meeting: A 2-day panel meeting will be held on January 13, and 14, 2015, see Unit IV. of the **SUPPLEMENTARY INFORMATION.**

Comments: Comments must be received on or before October 20, 2014.

ADDRESSES: *Meeting:* Details regarding the meeting in Washington, DC, will be posted on Versar's Web site, see Unit IV. of the **SUPPLEMENTARY INFORMATION.**

Comments: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2010–0173, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more

information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Stan Barone, Jr., Risk Assessment Division (7403M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number (202) 564–1169; email address: *barone.stan@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@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 in the environmental and human health assessment field; independent contractors and contracting companies involved in renovation, repair, and painting; or members of the public interested in the assessment of chemical risks. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Building construction (NAICS code 236).
- Specialty trade contractors (NAICS code 238).
- Real estate (NAICS code 531).
- Other general governmental support (NAICS code 921).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. Background

EPA has prepared draft documents related to estimating exposures and incremental health effects from lead due to renovation, repair, and paining activities (RRP) in public and commercial buildings (P&CBs) for purposes of public comment (scientific views) and peer review. As discussed in the **Federal Register** of August 6, 2014 (79 FR 45796) (FRL–9914–12) (*http://www.gpo.gov/fdsys/pkg/FR-2014-08-06/pdf/2014-18357.pdf*), when finalizing the draft documents, EPA will consider any public comments and peer reviewer comments submitted.

Once the analytical support documents are finalized, they will be utilized in the process of determining whether or not lead-based paint hazards are created by RRP activities in P&CBs, as required under TSCA, Subtitle IV (15 U.S.C. 2681 *et seq.*). For those renovation activities in P&CBs that create lead-based paint hazards, TSCA directs EPA to address the hazards through regulation.

The draft documents are available through *http://www.regulations.gov* (docket ID number EPA–HQ–OPPT–2010–0173).

III. Process of Obtaining Candidate Reviewers

Consistent with guidelines for the peer review of influential scientific assessments, EPA tasked Versar to assemble approximately 10–12 scientific experts to evaluate the draft documents cited in this notice. As part of the peer review process, a public nomination period was held from June 27, 2014, to July 18, 2014, during which members of the public were able to nominate scientific experts with knowledge and experience in one or more of the following areas:

1. Multimedia routes of human exposure to lead.
2. Modeling of multimedia human exposures.
3. Lead exposure pathway assessment.
4. Lead uptake/absorption.
5. Internal biokinetic distribution and physiological effects of lead.
6. Tissue concentrations of lead.
7. Human growth and activity patterns.
8. Exposure assessment modeling.
9. Lead-induced health effects.
10. Risk assessment and uncertainty characterization.

Versar also conducted an independent search for scientific experts to augment the list of publically nominated candidates. In total, Versar evaluated the 18 candidates nominated during the public nomination period and Versar identified more than 40 additional candidates.

- *Selection process.* Versar considered and screened all candidates against the selection criteria described in the **Federal Register** notice of June 27, 2014 (79 FR 36511) (FRL–9912–63) (*http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15123.pdf*), which included having demonstrated expertise in the areas described, being free of any conflict of interest, being free of appearance of bias, and being available to participate in-person in a 2-day peer review meeting in the Washington, DC area on January 13 and 14, 2015. Following the screening process, Versar narrowed the list of potential reviewers to 15 proposed candidates. This notice solicits comments on the proposed list of 15 candidates. The public is requested to provide relevant information or documentation on the candidates who are being evaluated by Versar. Versar will consider the public comments on the proposed list of peer reviewers and will post the final list of peer reviewers on their Web site (*https://peerreview.versar.com/epa/lead*).
- *Responsibilities of Peer Reviewers.* Peer reviewers will be charged with evaluating and preparing written comments on the draft documents. Specifically, reviewers will provide general comments, their overall impressions of the draft documents, and respond to the peer review charge questions. They will consider public comments submitted to the docket (docket ID number EPA–HQ–OPPT–2010–0173).

Following the peer review meeting, Versar will provide a peer review summary report to EPA containing the comments and recommendations from the peer reviewers. The final peer review report will also be made available to the public on Versar's Web site. In preparing the final form of analytical support document, EPA will consider Versar's peer review report which includes comments and recommendations from the external peer review meeting, as well as written public comments received through the docket.

IV. Registration for Initial Conference Call and Public Panel Meeting

Registrations can be made via Versar's Web site (*https://peerreview.versar.com/epa/lead*) for a public peer review panel

meeting via conference call/webinar that will cover initial ground rules of the peer review, overview of the peer review charge and overview of draft documents provided to the peer reviewers. The date, time, and access code for this conference call/webinar will be available on the same registration Web site.

Following the initial conference call/webinar, a 2-day panel meeting will be held on January 13 and 14, 2015, in the Washington, DC area. Specific details regarding the meeting location, registration for personal or electronic attendance, and presentation of comments will be posted on Versar's Web site (*https://peerreview.versar.com/epa/lead*).

V. Proposed List of Peer Reviewers

EPA requests that no individual or organization contact in any way its contractor or the subcontractor panel members regarding the subject of the peer review meeting, send contractor written materials regarding the subject of the meeting, or make any offers or requests to any of them that appear to be linked to their participation in the peer review. The contractor shall direct the panel members to report any such contacts, who will take appropriate action in consultation with EPA to ensure the independence and impartiality of the peer review.

Following are the names and professional affiliations of the current candidates being considered for the external peer review of the draft documents. A biosketch for the proposed peer reviewers will be posted in the docket (docket ID number EPA–HQ–OPPT–2010–0173) and on Versar's Web site (*https://peerreview.versar.com/epa/lead*). Versar will select peer reviewers who, collectively, best provide expertise spanning the multiple required areas of expertise listed Unit III. and, to the extent feasible, best provide a balance of perspectives.

1. Deborah Cory-Slechta, Ph. D., University of Rochester, Proposed Chairperson.
2. Panos Georgopoulos, Ph.D., Rutgers University.
3. Phillip Goodrum, Ph.D., Integral Consulting, Inc.
4. Dale Hattis, Ph.D., Clark University.
5. Andrew Hunt, Ph.D., University of Texas, Arlington, TX.
6. Naila Khalil, Ph.D., M.B.B.S., M.P.H., Wright State University.
7. Andy Menke, Ph.D., M.P.H., Social & Scientific Systems, Inc.
8. Howard Mielke, Ph.D., Tulane University.
9. Paul Mushak, Ph.D., PB Associates.
10. Rosalind Schoof, Ph.D., ENVIRON.
11. Joel Schwartz, Ph.D., M.D., Harvard University.
12. Anne Steenhout, Ph.D., Université Libre de Buxelles.
13. Ken Unice, M.S., Cardno ChemRisk.
14. Ian von Lindern, Ph.D., PE, Terra Graphics Environmental Engineering, Inc.
15. Kathleen Vork, Ph.D., M.P.H., California Environmental Protection Agency.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: September 19, 2014.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2014–23114 Filed 9–26–14; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice 2014–0048]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP088896XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction.

DATES: Comments must be received on or before October 24, 2014 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through Regulations.gov at *WWW.REGULATIONS.GOV.* To submit a comment, enter EIB–2014–0048 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2014–0048 on any attached document.

Reference: AP088896XX.

Purpose and Use:

Brief description of the purpose of the transaction:

To support the export of U.S.-manufactured commercial aircraft to Morocco.

Brief non-proprietary description of the anticipated use of the items being exported:

To be used by Royal Air Maroc for passenger transport primarily between Morocco and North America, South America, Europe, Asia and Africa.

To the extent that Ex-Im Bank is reasonably aware, the items being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Supplier: The Boeing Company.

Obligor: Compagnie Nationale Royal Air Maroc.

Guarantor(s): None.

Description of Items Being Exported:

Boeing 787 aircraft.

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Lloyd Ellis,

Program Specialist, Office of the General Counsel.

[FR Doc. 2014–23043 Filed 9–26–14; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this

opportunity to comment on the following information collection. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; 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; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC 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 PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before November 28, 2014. 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: Submit your PRA comments to Benish Shah, Federal Communications Commission, via the Internet at *Benish.Shah@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Benish Shah, Office of Managing Director, (202) 418–7866.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0329.

Title: Section 2.955, Equipment Authorization—Verification (Retention of Records).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit and not-for-profit institutions.

Number of Respondents: 8,000 respondents; 8,000 responses.

Estimated Time Per Response: 18 hours (average).

Frequency of Response: One time and on occasion reporting requirements, recordkeeping requirement; and Third party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154(i), 302 and 303(r).

Total Annual Burden: 144,000 hours.

Total Annual Cost: $1,600,000.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: Commission rules require equipment testing to determine performance and compliance with FCC standards. This testing is typically done by independent testing laboratories whose measurement facility has been reviewed by the Commission, or by an accrediting organization recognized by the Commission.

Needs and Uses: This collection will be submitted as an extension (no change in reporting requirements), after this 60 day comment period to the Office of Management and Budget (OMB) in order to obtain the full three year clearance.

Section 2.955 describes for each equipment device subject to verification, the responsible party, as shown in 47 CFR 2.909 shall maintain the records listed as follows:

(1) A record of the original design drawings and specifications and all changes that have been made that may affect compliance with the requirements of § 2.953.

(2) A record of the procedures used for production inspection and testing (if tests were performed) to insure the conformance required by § 2.953. (Statistical production line emission testing is not required.)

(3) A record of the measurements made on an appropriate test site that demonstrates compliance with the applicable regulations in this chapter. The record shall:

(i) Indicate the actual date all testing was performed;

(ii) State the name of the test laboratory, company, or individual performing the verification testing. The Commission may request additional information regarding the test site, the test equipment or the qualifications of the company or individual performing the verification tests;

(iii) Contain a description of how the device was actually tested, identifying the measurement procedure and test equipment that was used;

(iv) Contain a description of the equipment under test (EUT) and support equipment connected to, or installed within, the EUT;

(v) Identify the EUT and support equipment by trade name and model number and, if appropriate, by FCC Identifier and serial number;

(vi) Indicate the types and lengths of connecting cables used and how they were arranged or moved during testing;

(vii) Contain at least two drawings or photographs showing the test set-up for the highest line conducted emission and showing the test set-up for the highest radiated emission. These drawings or photographs must show enough detail to confirm other information contained in the test report. Any photographs used must be focused originals without glare or dark spots and must clearly show the test configuration used;

(viii) List all modifications, if any, made to the EUT by the testing company or individual to achieve compliance with the regulations in this chapter;

(ix) Include all of the data required to show compliance with the appropriate regulations in this chapter; and

(x) Contain, on the test report, the signature of the individual responsible for testing the product along with the name and signature of an official of the responsible party, as designated in § 2.909.

(4) For equipment subject to the provisions in part 15 of this chapter, the records shall indicate if the equipment was verified pursuant to the transition provisions contained in § 15.37 of this chapter.

(b) The records listed in paragraph (a) of this section shall be retained for two years after the manufacture of said equipment item has been permanently discontinued, or until the conclusion of an investigation or a proceeding if the manufacturer or importer is officially notified that an investigation or any other administrative proceeding involving his equipment has been instituted.

The Commission needs and requires the information under FCC Rules at 47 CFR parts 15 and 18, that RF equipment manufacturers (respondents) 'self determine'' their responsibility for adherence to these rules, as guided by the following criteria:

(a) Whether the RF equipment device that is being marketed complies with the applicable Commission Rules; and

(b) If the operation of the equipment is consistent with the initially documented test results, as reported to the Commission.

The information collection is essential to controlling potential interference to radio communications.

(a) Companies that manufacture RF equipment are the anticipated respondents to this information collection.

(b) This respondent ''public'' generally remains the same, although the types of equipment devices that they manufacture may change in response to changing technologies and to new spectrum allocations made by the Commission.

(c) In addition, the Commission may establish new technical operating

standards in response to these changing technologies and in allocation spectrum, which these RF equipment manufacturers must meet to receive their equipment authorization from the FCC.

(d) However, the process that RF equipment manufacturers must follow to verify their compliance, as mandated by 47 CFR 2.955 of FCC Rules, will not change despite new technical standards established for specific equipment.

This information collection, therefore, applies to a variety of equipment, which is currently manufactured in the future, and that operates under varying technical standards.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2014–23067 Filed 9–26–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATION COMMISSION

Sunshine Act Meeting; Open Commission Meeting; Tuesday, September 30, 2014

September 23, 2014.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Tuesday, September 30, 2014. The meeting is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street SW., Washington, DC.

Item No.	Bureau	Subject
1	MEDIA	TITLE: Sports Blackout Rules, Report and Order (MB Docket No. 12–3) SUMMARY: The Commission will consider a Report and Order that would eliminate the Commission's sports blackout rules, which can prevent consumers from watching their teams' games on local television.
2	INTERNATIONAL	TITLE: Comprehensive Review of Licensing and Operating Rules for Satellite Services (IB Docket No. 12–267) SUMMARY: The Commission will consider a Further Notice of Proposed Rulemaking to streamline and update Part 25 of the Commission's rules, which governs licensing and operation of space stations and earth stations for the provision of satellite communication services. These proposals will streamline, clarify or eliminate numerous rule provisions and reduce regulatory burdens.
3	OFFICE OF ENGINEERING AND TECHNOLOGY.	TITLE: Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions (GN Docket No. 12–268) SUMMARY: The Commission will consider a Declaratory Ruling that clarifies that the Commission intends to make all reasonable efforts to preserve both the "coverage area" and "population served" of eligible broadcast television stations in the repacking process associated with the Incentive Auction.
4	OFFICE OF ENGINEERING AND TECHNOLOGY.	TITLE: Amendment of Part 15 of the Commission's Rules for Unlicensed Operations in the Television Bands, Repurposed 600 MHz Band, 600 MHz Guard Bands and Duplex Gap, and Channel 37, and Amendment of Part 74 of the Commission's Rules for Low Power Auxiliary Stations in the Repurposed 600 MHz Band and 600 MHz Duplex Gap; Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions (GN Docket No. 12–268) SUMMARY: The Commission will consider a Notice of Proposed Rulemaking to revise rules for unlicensed operations in the TV bands and new 600 MHz Band, including fixed and personal/portable white space devices and unlicensed microphones. The proposed changes and new rules are intended to allow more robust and spectrally efficient unlicensed operations without increasing the risk of harmful interference to other users.
5	OFFICE OF ENGINEERING AND TECHNOLOGY.	TITLE: Promoting Spectrum Access for Wireless Microphone Operations; Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions (GN Docket No. 12–268) SUMMARY: The Commission will consider a Notice of Proposed Rulemaking to address the needs of wireless microphone users, while recognizing that they must share spectrum with other wireless uses in an increasingly crowded spectral environment.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Additional information concerning this meeting may be obtained from Meribeth McCarrick, Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Copies of materials adopted at this meeting can be purchased from the FCC's duplicating contractor, Best Copy and Printing, Inc. (202) 488–5300; Fax (202) 488–5563; TTY (202) 488–5562. These copies are available in paper format and alternative media, including large print/type; digital disk; and audio and video tape. Best Copy and Printing, Inc. may be reached by email at *FCC@BCPIWEB.com.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2014–23201 Filed 9–25–14; 11:15 am]

BILLING CODE 6712–07–P

FEDERAL COMMUNICATIONS COMMISSION

[CG Docket No. 14–97; DA 14–1329]

Termination of Dormant Proceedings

AGENCY: Federal Communications Commission.

ACTION: Final rule; termination of proceedings.

SUMMARY: In this document, the Consumer and Governmental Affairs Bureau (CGB or Bureau), terminates, as dormant, certain docketed Commission proceedings. The Commission believes that termination of these proceedings furthers the Commission's organizational goals of increasing the efficiency of its decision-making, modernizing the agency's processes in the digital age, and enhancing the openness and transparency of Commission proceedings for practitioners and the public.

DATES: Effective September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Gayle Radley Teicher, Consumer and Governmental Affairs Bureau at (202) 418–1515 or by email at *gayle.teicher@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Order, *Termination of Certain Proceedings as Dormant,* document DA 14–1329, adopted on September 15, 2015, and released on September 15, 2014 in CG Docket No. 14–97.

The full text of document DA 14–1329 and copies of any subsequently filed documents in this matter will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. Copies may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (800) 378–3160, fax: (202) 488–5563, or Internet: *www.bcpiweb.com.* Document DA 14–1329 can also be downloaded in Word or Portable Document Format (PDF) at: *http://www.fcc.gov/document/termination-certain-proceedings-dormant-1.* The spreadsheet associated with document DA 14–1329 listing the proceedings proposed for termination for dormancy is available in Word or Portable Document Format at *http://www.fcc.gov/article/da-14–1329a2.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY).

Final Paperwork Reduction Act of 1995 Analysis

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Synopsis

1. On June 30, 2014, CGB released the *Third Dormant Proceedings Termination Public Notice, DA 14–897,* published at 79 FR 42320, July 21, 2014. On July 22, 2014, CGB released a Public Notice announcing that comments and reply comments were due August 20, 2014 and September 4, 2014, respectively. In response to the *Third Dormant Proceedings Termination Public Notice,* the Commission received one Opposition, one comment, one reply comment, and one *ex parte* filing.

2. Based on the Commission's review of the record received in response to the *Third Dormant Proceedings Termination Public Notice,* the Commission terminates the proceedings listed in document DA 14–1329 and leaves open one proceeding that had been listed in document DA 14–897. *See https://apps.fcc.gov/edocs_public/attachmatch/DA–14–897A2.doc.*

3. W. Scott McCollough filed an opposition requesting that WC Docket No. 04–6 remain open. Based upon further evaluation of the record, the Commission finds that it may be appropriate to address issues raised in this proceeding in the future. Accordingly, the Commission will not terminate this proceeding at this time.

4. PCS Partners, L.P. (''PCSP'') requests that the Commission release a revised Attachment A to document DA 14–1329 in order to include the Multilateration Location and Monitoring Service (M–LMS) rulemaking proceeding in WT Docket No. 06–49 in the list of proceedings that the Commission proposed to terminate. As noted by PCSP, on June 10, 2014, the Commission released its Order terminating the M–LMS rulemaking proceeding in WT Docket No. 06–49, finding that the ''various proposals for broad revisions of the applicable rules do not merit further consideration at this time.'' PCSP asserts that the Commission did not issue a public notice and did not provide an opportunity for public input prior to release of the *M–LMS Termination Order,* and claims that the *M–LMS Termination Order* ''therefore does not comply with applicable rules.'' PCSP also claims that the Commission did not adequately support its decision in the *M–LMS Termination Order.* The Commission rejects the request by PCS Partners that we release a revised list of dockets under consideration in this proceeding. The Commission's delegation of authority to the Bureau to terminate certain proceedings does not require the process requested by PCSP in this case, because the Commission itself appropriately and expressly terminated the WT Docket No. 06–49 proceeding in the *M–LMS Termination Order.* Further, to the extent that PCSP raises substantive arguments regarding the *M–LMS Termination Order,* those arguments should have been raised in a petition for reconsideration in the WT Docket No. 06–49 proceeding and not here.

5. Upon publication of document DA 14–1329 in the **Federal Register**, these proceedings will be terminated in the Electronic Comment Filing System (ECFS). The record in the terminated proceedings will remain part of the Commission's official records, and the various pleadings, orders, and other documents in these dockets will continue to be accessible to the public, post-termination.

Regulatory Flexibility Act

6. The Commission's action does not require notice and comment and is not subject to the Regulatory Flexibility Act of 1980, as amended. *See* 5 U.S.C. 601(2), 603(a). The Commission nonetheless notes that it anticipates that the rules adopted will not have a significant economic impact on a substantial number of small entities. As described above, the Commission primarily changes its own internal procedures and organizations and does not impose substantive new responsibilities on regulated entities. There is no reason to believe termination of certain dormant proceedings would impose significant costs on parties to Commission proceedings. To the contrary, the Commission takes the actions herein

with the expectation that overall they will make dealings with the Commission quicker, easier, and less costly for entities of all size.

Congressional Review Act

The Commission will not send a copy of document DA 14–1329 pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A) because the Commission is not adopting, amending, revising, or deleting any rules.

Ordering Clauses

Pursuant to the authority contained in sections 4(i), and 4(j) of the Communications Act, 47 USC 154(i) and (j), and § 0.141 of the Commission's rules, that the proceedings set forth in document DA 14–1329 are *terminated.*

Federal Communications Commission.

Kris Anne Monteith,

Acting Chief, Consumer and Governmental Affairs Bureau.

[FR Doc. 2014–23140 Filed 9–26–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov.*

A&A Contract Customs Brokers, USA, Inc., dba A&A International Freight Forwarding (NVO & OFF), #2–12th Street, P.O. Box 4772, Blaine, WA 98230, Officers: Jodi D. Lefler, Vice President (QI), Graham S. Robins, President, Application Type: QI Change.

Black Pearl Int'l Freight Fwdg and CHB LLC (OFF), 20331 Anza Avenue, #2, Torrance, CA 90503, Officer: David M. Turner, CEO (QI), Application Type: New OFF License.

BP Harvest International LLC (NVO & OFF), 1735 Townsend Avenue, Store A, Bronx, NY 10453, Officers: Blado Y. Caimares Vega, Commerical Manager (QI), Rosa M. Fernandez, General Manager, Application Type: New NVO & OFF License.

Brownstone International Customs Brokerage & Compliance, Inc. (NVO & OFF), 6623 NE 78th Court, Suite B6, Portland, OR 97218, Officers: Michael S. Brown, President (QI), Hope M. Brown, CFO, Application Type: New NVO & OFF License.

C.E.I. Logistics, Inc. (NVO), 340 E. Maple Avenue, Suite 305, Langhorne, PA 19047, Officers: Robert M. Pfender, President (QI), Patricia A. Pfender, Vice President, Application Type: New NVO License.

C. H. Robinson International, Inc. dba C. H. Robinson Freight Services, Ltd., dba Christal Lines (NVO & OFF), 14701 Charlson Road, Suite 450, Eden Prairie, MN 55347, Officers: Emil R. Sanchez, Vice President (QI), Stephane Rambaud, CEO, Application Type: QI Change.

Comage Container Lines Inc. dba Assurance Global Logistics Group (NVO), 2112 Truscott Drive, Mississauga, Ontario L5J2A6 Canada, Officers: Joshua Kochath, Director (QI), Wilma Kochath, Vice President, Application Type: New NVO License.

Cur-Ant Transfer and Logistics Inc (NVO), 13644 SW 142th Avenue, Suite A & B, Miami, FL 33186, Officers: Deborah A. Jesurun, President (QI), Ivar A. Jesurun, Secretary, Application Type: New NVO License.

Deluxe Freight, Inc. (NVO), 11013 NW 30th Street, Suite 100, Doral, FL 33172, Officers: William Munoz, President (QI), William H. Girard, III, Vice President, Application Type: Business Structure Change to Deluxe Freight, LLC.

Demetrios Air Freight Company, Inc. dba Demetrios International Shipping, Company (NVO & OFF), 215 Salem Street, Woburn, MA 01801, Officers: Demetrios Tsiaousopoulos, President (QI), Mary Tsiaousopoulous, Secretary, Application Type: New NVO & OFF License.

Diana Shipping Line LLC (OFF), 333 Dominion Drive, Suite 1333, Katy, TX 77450, Officer: Diana Corona, Member (QI), Application Type: New OFF License.

Export Trade Service, Inc. dba Export Trade Service (NVO & OFF), 804 John Street, Dalton, GA 30721, Officers: Patricia A. Walls, President (QI), Linda Albertson, Vice President, Application Type: Change Trade Name to Export Trade Logistics and Add NVO Service.

Global Logistics Providers LLC (NVO), 37 Westminister Road, Stamford, CT 06902, Officers: Michael S. Chapell, President (QI), Ahsan Sawar, Manager, Application Type: New NVO License.

Hybrid Global Logistics Inc. (OFF), 57 Kara Lane, Feasterville, PA 19053, Officer: Joseph A. Cimino, President (QI), Application Type: New OFF License.

Incopro Corporation dba International Commerce and Projects (NVO & OFF), 10827 Tower Oaks Blvd., Houston, TX 77070, Officers: Steve Licursi, Senior Vice President (QI), Francisco Guzman, Jr., Application Type: QI Change.

Miac Logistics Corp. (OFF), 8300 SW 8th Street, Suite 104, Miami, FL 33144, Officers: Yelena Jimenez, Secretary (QI), Pedro Carrillo, President, Application Type: New OFF License.

Northstar Logistics LLC (NVO & OFF), 44330 Mercure Circle, Suite 120, Sterling, VA 20166, Officers: Mazen T. Farouki, Member (QI), Sari T. Farouki, Member, Application Type: New NVO & OFF License.

Perimeter International dba Perimeter Logistics (NVO & OFF), 2700 Sory Road West, Suite 150, Irving, TX 75038, Officers: Dennis Garcia, Assistant Secretary (QI), Merry L. Lamothe, President, Application Type: QI Change.

Polaris Development Corporation dba Polaris Worldwide Logistics (NVO & OFF), 6675 Amberton Drive, Suite 1, Elkridge, MD 21075, Officers: Mary E. Mullen, Vice President (QI), Ronald C. Brooks, President, Application Type: New NVO & OFF License.

RFC Logistics LLC dba RFC Logistics (OFF), 1749 NE Miami Court, Suite 204, Miami, FL 33132, Officer: Jennifer R. Ahrens, Manager (QI), Application Type: New OFF License.

Spartan Global Logistics LLC (NVO & OFF), 11323 Alcott Drive, Montgomery, TX 77356, Officer: Maureen Renaud, Member (QI), Application Type: New NVO & OFF License.

Streamline Trade Management Inc. (OFF), 138 Bay 53rd Street, 1st Floor, Brooklyn, NY 11214, Officer: Bo Yu Zheng, President (QI), Application Type: New OFF License.

Valley Cargo International Inc. (OFF), 2025 NW 102nd Avenue, Unit 109, Miami, FL 33172, Officers: Victor

H. Sierra, Director (QI), Stella Rincon, Director, Application Type: QI Change.

WD Global Logistics Corp (NVO), 1515 Kona Drive, Compton, CA 90220, Officer: Woon Dong Huh, President (QI), Application Type: New NVO License.

XYZ Global Express Corp. (NVO), 1200F Woodruff Avenue, Suite #D, Downey, CA 90241, Officers: Benedict Simborio, Assistant Secretary (QI), Ian Hazel Co, CEO, Application Type: New NVO License.

Pursuant to the Commission's direct final rule (79 FR 56522), beginning October 20, 2014, these notices will no longer be posted in the **Federal Register**. After October 20, 2014, this information will be available on the Commission's Web site at *http://www.fmc.gov.*

By the Commission.

Dated: September 24, 2014.

Karen V. Gregory,

Secretary.

[FR Doc. 2014–23093 Filed 9–26–14; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 14, 2014.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. *Harold T. Keen,* Four Oaks, North Carolina, individually and together with Barbara A. Keen, Four Oaks, North Carolina, Matthew Keen, Annapolis, Maryland, and Catherine Keen Hock, Greensboro, North Carolina, as a group acting in concert; to acquire voting shares of KS Bancorp, Inc., and thereby indirectly acquire voting shares of KS Bank, Inc., both in Smithfield, North Carolina.

Board of Governors of the Federal Reserve System, September 24, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–23088 Filed 9–26–14; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on July 18th, 2014 and allowed 60 days for public comment. AHRQ did not receive any substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 29, 2014.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Patient Safety Organization Certification for Initial Listing and Related Forms, Patient Safety Confidentiality Complaint Form, and Common Formats

The Patient Safety and Quality Improvement Act of 2005 (hereafter the Patient Safety Act), 42 U.S.C. 299b-21 to 299b–26, was enacted in response to growing concern about patient safety in the United States and the Institute of Medicine's 1999 report, To Err is Human: Building a Safer Health System. The goal of the statute is to improve patient safety by providing an incentive for health care providers to work voluntarily with experts in patient safety to reduce risks and hazards to the safety and quality of patient care. The Patient Safety Act signifies the Federal Government's commitment to fostering a culture of patient safety among health care providers; it offers a mechanism for creating an environment in which the causes of risks and hazards to patient safety can be thoroughly and honestly examined and discussed without fear of penalties and liabilities. It provides for the voluntary formation of Patient Safety Organizations (PSOs) that can collect, aggregate, and analyze confidential information reported voluntarily by health care providers. By analyzing substantial amounts of patient safety event information across multiple institutions, PSOs will be able to identify patterns of failures and propose measures to eliminate or reduce patient safety risks and hazards.

In order to implement the Patient Safety Act, the Department of Health and Human Services (HHS) issued the Patient Safety and Quality Improvement Final Rule (hereafter the Patient Safety Rule), 42 CFR Part 3, which became effective on January 19, 2009. The Patient Safety Rule establishes a framework by which hospitals, doctors, and other health care providers may voluntarily report information to PSOs, on a privileged and confidential basis, for the aggregation and analysis of patient safety events. In addition, the Patient Safety Rule outlines the requirements that entities must meet to become PSOs and the process by which the Secretary of HHS (hereafter the Secretary) will review and accept certifications and list PSOs.

In addition to the Patient Safety Act and the Patient Safety Rule, HHS issued Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005 (hereafter Guidance) on December 30, 2010. The Guidance addresses questions that have

arisen regarding the legal obligations of PSOs when they or the organization of which they are a part report certain information to the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. This includes providing the FDA with access to its records, including access during an inspection of its facilities. This Guidance applies to all entities that seek to be a PSO, or are one currently, either alone or as a component if another organization that have mandatory FDA-reporting obligations under the FDCA and its implementing regulations (''FDA-regulated reporting entities''). It also covers PSOs that are organizationally related to such FDA-regulated reporting entities (e.g., parent organizations, subsidiaries, sibling organizations).

When PSOs meet the requirements of the Patient Safety Act, the information collected and the analyses and deliberations regarding the information receive Federal confidentiality and privilege protections under this legislation. The Secretary delegated authority to the Director of the Office for Civil Rights (OCR) to enforce the confidentiality protections of the Patient Safety Act. 71 FR 28701–28702 (May 17, 2006). OCR is responsible for enforcing protections regarding patient safety work product (PSWP), which generally includes information that could improve patient safety, health care quality, or health care outcomes and (1) is assembled or developed by a provider for reporting to a PSO and is reported to a PSO or (2) is developed by a PSO for the conduct of patient safety activities. Civil money penalties may be imposed for knowing or reckless impermissible disclosures of PSWP. AHRQ implements and administers the rest of the Patient Safety Act's provisions.

Pursuant to 42 CFR 3.102, an entity that seeks to be listed as a PSO by the Secretary must certify that it meets certain requirements and, upon listing, will meet other criteria. To remain listed for renewable three-year periods, a PSO must recertify that it meets these obligations and will continue to meet them while listed. The Patient Safety Act and Patient Safety Rule also impose other obligations, discussed below, that a PSO must meet to remain listed. In order for the Secretary to administer the Patient Safety Act and Rule, the entities seeking to be listed and to remain listed must complete the proposed forms.

Method of Collection

With this submission, AHRQ is requesting approval of the following proposed administrative forms:

1. PSO Certification for Initial Listing Form. This form, which is to be completed by an entity seeking to be listed by the Secretary as a PSO for an initial three-year period, contains certifications that the entity meets the requirements for listing as a PSO, in accordance with 42 U.S.C. 2996–24(a)(1) and 42 CFR 3.102.

2. PSO Certification for Continued Listing Form. In accordance with 42 U.S.C. 299b–24(a)(2) and the Patient Safety Rule, this form is to be completed by a listed PSO seeking continued listing as a PSO by the Secretary for an additional three year period.

3. PSO Two Bona Fide Contracts Requirement Certification Form. To remain listed, a PSO must have contracts with more than one provider, within successive 24 month periods, beginning with the date of its initial listing. 42 U.S.C. 2996–24(b)(1)(C). This form is to be used by a PSO to certify whether it has met this requirement.

4. PSO Disclosure Statement Form. A PSO must submit this form when it (i) has a Patient Safety Act contract with a health care provider and (ii) it has financial, reporting, and contractual relationships with that contracting provider or is not independent of that contracting provider. 42 U.S.C. 299b–24(b)(1)(E); 42 CFR 3.102(d)(2).

5. PSO Profile Form. This form, previously called the PSO Information Form, gathers information on PSOs and the type of health care providers and settings that they are working with to conduct patient safety activities in order to improve patient safety. It is designed to collect a minimum level of data necessary to develop aggregate statistics relating to the Patient Safety Act, including types of institutions participating and their general location in the U.S. This information will be included in AHRQ's annual quality report, required by 42 U.S.C. 299b–23(c).

6. PSO Change of Listing Information Form. The Secretary is required under 42 U.S.C. 299b–24(d) and the Patient Safety Rule to maintain a publicly available list of PSOs that includes, among other information, contact information for each entity. The Patient Safety Rule, section 3.102(a)(vi), also requires that a PSO must promptly notify the Secretary during its period of listing if there have been any changes in the accuracy of the information submitted for listing, along with the pertinent changes. This form is to be used by a PSO to revise its listing information, to include updating its contact information that will be used in the Secretary's list of PSOs.

The forms described above, other than the PSO Change of Listing Information Form, are revised collection instruments that were previously approved by OMB in 2008 and 2011. These forms, along with the new PSO Change of Listing Information Form, will be used by AIIRQ to obtain information necessary to implement the Patient Safety Act and Patient Safety Rule, e.g., obtaining initial and subsequent certifications from entities seeking to be listed as PSOs and for making the statutorily-required determinations prior to and during an entity's period of listing as a PSO. This information is used by the PSO Program Office housed in AHRQ's Center for Quality Improvement and Patient Safety.

OCR is requesting approval of the following administrative form:

Patient Safety Confidentiality Complaint Form. The purpose of this collection is to allow OCR to collect the minimum information needed from individuals filing patient safety confidentiality complaints with the OCR so that there is a basis for initial processing of those complaints.

In addition, AHRQ is requesting approval for a set of common definitions and reporting formats (hereafter Common Formats). Pursuant to 42 U.S.C. 29913–23(b), AHRQ coordinates the development of the Common Formats that allow PSOs and health care providers to voluntarily collect and submit standardized information regarding patient safety events.

Estimated Annual Respondent Burden

While there are a number of information collection forms described below, the forms will be implemented at different times and frequency due to the voluntary nature of seeking listing and remaining listed as a PSO, filing a Patient Safety Confidentiality Complaint Form, and using the Common Formats. Exhibit 1 shows the estimated annualized burden hours for the respondent to provide the requested information, and Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to provide the requested information. The total burden hours are estimated to be 100,704 hours annually and the total cost burden is estimated to be $3,618,294.72 annually.

PSO Certification for Initial Listing Form

The average annual burden for the collection of information requested by the certification forms for initial listing

is based upon a total average estimate of 17 respondents per year and an estimated time of 18 hours per response. The estimated response number not only includes submissions by entities that are successfully listed as PSOs, but also submissions by entities that submit an initial listing form that do not become a PSO. During the past three years, AHRQ has provided substantial technical assistance about the PSO Program, including to entities seeking initial listing. After submitting an initial listing form, an entity may withdraw its form or submit a revised form, particularly after receiving technical assistance from AHRQ. In addition, AHRQ, on behalf of the Secretary, may deny listing if an entity does not meet the requirements of the Patient Safety Act and Patient Safety Rule or if the entity does not provide other information determined to be necessary to make the listing determination, such as a lack of response to requests for clarifications by AHRQ on the attestations and responses on the form. This collection of information takes place on an ongoing basis.

Certification for Continued Listing Form

The average annual burden for the collection of information requested by the certification form for continued listing is an estimated time of eight hours per response and 16 responses annually. The Certification for Continued Listing Form must be completed by any interested PSO at least 75 days before the end of its current three-year listing period. The number of respondents is based upon the estimate that 65% of the projected 77 listed PSOs will submit forms for continued listing. The estimated number of responses reflects the fact that a PSO can choose to voluntarily relinquish its status as a PSO for any reason or that a PSO can choose to not seek continued listing and allow its listing to expire. In addition, AHRQ, on behalf of the Secretary, can revoke the listing of a PSO if it is found to no longer meet the requirements of the Patient Safety Act or Patient Safety Rule. Therefore, AHRQ estimates that approximately two thirds of PSOs will seek continued listing and submit the form.

Two Bona Fide Contracts Requirement Certification

The average annual burden for the collection of information requested by the two-contract requirement is based upon an estimate of 30 respondents per year and an estimated one hour per response. This collection of information takes place when the PSO notifies the Secretary that it has entered into two contracts.

Disclosure Statement Form

AHRQ assumes that only a small percentage of entities will need to file a disclosure form. However, AHRQ is providing a high estimate of 2 respondents and thus presumably overestimating respondent burden. The average annual burden estimate of six hours for the collection of information requested by the disclosure form is based upon an estimated three hours per response. This information collection takes place when a PSO first reports having any of the specified types of additional relationships with a health care provider with which it has a contract to carry out patient safety activities.

Profile Form

The overall annual burden estimate of 231 hours for the collection of information requested by the PSO Profile Form is based upon an estimate of 77 respondents per year and an estimated three hours per response. Newly listed PSOs first report in the calendar year after their listing by the Secretary.

Patient Safety Confidentiality Complaint Form

The overall annual burden estimate of one hour for the collection of information requested by the form is based on an estimate of three respondents per year and an estimated 20 minutes per response. OCR's information collection using this form will not begin until after there is an allegation of a violation of the statutory protection of PSWP.

PSO Change of Listing Information Form

The average annual burden for the collection of information requested by the change of listing information forms is based upon a total average estimate of 24 respondents per year and an estimated time of five minutes per response. This collection of information takes place when the PSO notifies the Secretary that its listing information has changed.

Common Formats

AHRQ estimates that 5% FTE of a Patient Safety Manager at a hospital will be spent to administer the Common Formats, which is approximately 100 hours a year. In the previous submission, AHRQ estimated that 1,000 hospitals would be using the Common Formats in year 3. AHRQ estimates the number of hospitals using Common Formats will remain level for the next three years at 1,000 hospitals.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Certification for Initial Listing Form *	17	1	18	306
Certification for Continued Listing Form *	16	1	8	128
Two Bona Fide Contracts Requirement Form **	30	1	1	30
Disclosure Statement Form ***	2	1	3	6
Profile Form ****	77	1	3	231
Patient Safety Confidentiality Complaint Form ***	3	1	20/60	1
Change of Listing Information ***	24	1	05/60	2
Common Formats	1,000	1	100	100,000
Total ***	1,169	NA	NA	100,704

* AHRQ expects the number of PSOs to remain relatively stable, with 65% of listed PSOs seeking continued listing. The number of new entities seeking listing as PSOs and PSOs seeking continued listing will be offset by the number of entities that will voluntarily relinquish their status as a PSO, allow their listing to expire, or have their listing revoked for cause by AHRQ.

** The Two Bona Fide Contracts Requirement Form will be completed by each PSO within the 24-month period after listing by the Secretary.

*** The Disclosure Statement Form and the Change of Listing Information form may be submitted by individual PSOs in different years. Due to changes in their operations, a PSO can submit more than one Change of Listing Information in a year. OCR is anticipating considerable variation in the number of complaints per year. Hence, the total for each year is expressed as an average of the expected total over the three year collection period.

**** The Profile Form collects data from listed PSOs each calendar year. The prior version of this form, the PSO Information Form, began collecting data from listed PSOs each calendar year in 2011.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form	Number of respondents	Total burden hours	Average hourly wage rate	Total cost
Certification for Initial Listing Form	17	306	$35.93	$10,994.58
Certification for Continued Listing Form	16	128	35.93	4,599.04
Two Bona Fide Contracts Requirement Form	30	30	35.93	1,077.90
Disclosure Statement Form	2	6	35.93	215.58
Profile Form	77	231	35.93	8,299.83
Patient Safety Confidentiality Complaint Form	3	1	35.93	35.93
Change of Listing Information	24	2	35.93	71.86
Common Formats	1,000	100,000	35.93	3,593,000.00
Total	1,169	100,704	NA	3,618,294.72

* Based upon the mean of the hourly wages for healthcare practitioner and technical occupations, 29–0000, National Compensation Survey, May 2013, ''U.S. Department of Labor, Bureau of Labor Statistics.'' (*http://www.bls.gov/oes/current/oes_nat.htm#29-0000*).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 18, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2014–22700 Filed 9–26–14; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Improving Hospital Informed Consent with Training on Effective Tools and Strategies.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously titled and published as ''Improving Hospital Informed Consent with an Informed Consent Toolkit'' in the **Federal Register** on July 9th, 2014 and allowed 60 days for public comment. AHRQ received one substantive comment. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 29, 2014.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Improving Hospital Informed Consent With Training on Effective Tools and Strategies

The ultimate aim of this project is to pilot test training modules to improve the informed consent process in U.S. hospitals.

Clinical informed consent is the process by which a patient is told about the risks and benefits of proposed treatments or procedures, as well as alternatives, and makes a decision based on that information. Informed consent may be jeopardized by incorrect clinician assumptions about patient comprehension, the manner in which consent is sought, and poor readability of consent forms (Paasche-Orlow et al., 2013). All too frequently, patients do not understand the risks, benefits, and alternatives of their treatments even after signing a consent form (Braddock et al., 1999; Sudore et al., 2006). De-identified accreditation data analyzed as part of AHRQ's preliminary research for this data collection effort suggest that some hospitals are not following the basic ethical principles underlying informed consent. These data, as well as the guidance from the study's Expert and Stakeholder Panel, indicate that hospital administrators and clinicians could benefit from training on evidence-based practices to improve the informed

consent process. These include, improving communication, using interpreters to meet the communication needs of patients with limited English proficiency, using high-quality decision aids to support the informed consent discussion, and using teach-back to verify patient understanding (Temple University Health System, 2009). Hospital system changes that can facilitate these practices include improving hospitals' informed consent policies and the infrastructure that supports the informed consent process (e.g., interpreter services, high-quality decision aids, easy-to-understand forms).

Building upon a previously published guide, a review of the literature, and the aforementioned analysis of de-identified accreditation data, AHRQ has developed two new Informed Consent training modules of approximately 1 hour each (one for hospital leaders, the other for health care professionals), to be offered through a Learning Management System. Health care professionals taking the training will be eligible for continuing education (CE) credit.

In the project's next phase, AHRQ will pilot test the training modules to assess:

- Facilitators and barriers of implementing the tools and recommended improvements in the training modules
- Effectiveness of the training modules in improving informed consent processes and relevant outputs and outcomes

Pilot test results will be used to improve the training modules and provide information to hospitals considering using the training modules to improve their informed consent processes. The pilot test will take place in four hospitals. Each participating hospital will be asked to:

- Deliver the leader training module to hospital leaders of their choosing
- Champion improvements in their informed consent policies and processes based on the information and tools in the leader training
- Deliver the health care professional training module to health care professionals in four units, including at least one surgical unit
- Implement improvement initiatives over a period of two to six months in participating units based on materials presented in the health care professional training
  - ○ In at least one unit: Implementation will last at least three months and use at least one of the techniques presented in the training (e.g., use teach-back to confirm patient understanding, use high quality decision aids, overcome communication barriers)
- Conduct and cooperate with assessment activities.
  - ○ In at least one unit, use the Rapid Feedback Patient Survey.
  - ○ In at least one surgical unit, collect surgical cancellation and delay rates.
  - ○ Collect other metrics to assess the effectiveness of the informed consent training modules.
  - ○ Cooperate with project team in the data collection efforts described below.

This study is being conducted by AHRQ through its contractor, Abt Associates Inc., pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

The following data collections efforts will be pursued in participating hospitals to achieve project goals:

1. The Hospital Informed Consent Baseline and Final Assessment will be completed by the four hospitals participating in the pilot testing at baseline and upon completion of the implementation period. The assessment, completed by the hospital's designated liaison to the project and the leaders of the participating units (unit leaders), will describe each hospital's informed consent policies and processes (e.g., procedures that require signed informed consent forms, clinical staff roles and responsibilities in informed consent, when interpreter services should be used), and document any changes that occurred as a result of implementing the training modules. Questions will include both open-ended questions (e.g., descriptions of process) and Likert scale questions (1 to 5) regarding the extent to which essential components are covered in informed consent discussions (e.g., benefits and risks of alternatives) and evidence-based practices to improve the informed consent process are used.

2. Pre-/Post-Training Quiz. The purpose of the Pre/post-Training Quiz is to measure whether knowledge (related to the content in the training modules) increases after completing the training module(s) and to identify potential training module improvements. The pre-test is given after the participant registers for the training but before they begin the course content. Immediately after the participant completes the course content, they will be given the post test. The post quiz will also include a separate section with questions regarding learner's reactions to and evaluation of the training modules. A post quiz score of 80% will be used as the threshold to obtain CE credits. There will be a pre/post quiz for each training module.

3. The Monthly Check-In Call. A project team member will hold a monthly check-in call with hospital liaisons and unit leaders to assess the progress of implementation of training and improvement initiatives at each hospital and within each unit. Check-in calls will occur monthly for up to six months. Each call will be up to 30 minutes in duration.

4. Health Care Professional Survey. A brief survey will be administered electronically to all clinicians who take the health care professionals training, both prior to training and approximately 2–3 months after completing it. Hospital liaisons will provide email addresses for the staff who will be invited to complete the training from each participating unit. These email addresses will be used to send health care professionals the pre and post-training surveys. The survey will collect information about clinicians' self-reported use of evidence-based practices described in the training module, a self-assessment rating of their informed consent effectiveness, attitudes regarding patients' rights in informed consent, and reported learning and implementation experiences. The survey will also collect information about the clinician and their background (e.g., years in practice, practitioner type) and department. The survey will consist largely of closed-ended questions (e.g., scale or Liken response options) with several open-ended questions.

5. Interview and Site Visit Guide. Site visits and interviews will be conducted at each of the four participating hospitals. Each site visit will occur over a two-day period at least 3 months after sites have trained the majority of their staff on the participating units. The project team will conduct up to 18 in-depth interviews at each pilot site with hospital leaders and frontline clinicians. Leaders will include hospital champions spearheading the pilot test in their hospital (such as chiefs of surgery, department chairs, chief anesthesiologist/head of anesthesiology, nurse managers, charge nurses, nurse educators, patient safety/quality officers, legal/risk management officers) and leaders of units where the training modules were piloted. Health care professional interviewees will be selected by unit leaders or hospital liaisons from the units where the training modules were piloted. Liaisons

and unit leaders will be asked to nominate a range of clinicians from those who embraced changes to those who were less willing to implement changes. Site visits will also involve limited observation (e.g., to observe documentation of informed consent completion, view new signage to remind clinicians to verify patient understanding in an informed consent discussion). The project team will also obtain relevant organizational documents (e.g., informed consent policies, training completion rates, implementation tracking data) and data (e.g., surgical cancellation rates). Interviews will capture qualitative data regarding clinician learning, training modules implementation, behavior, and results pertaining to patient engagement.

6. Rapid Feedback Patient Survey. Hospitals participating in the pilot test will be required to implement the Rapid Feedback Patient Survey provided in the training modules in a subset of patients in at least one participating unit to capture patient's understanding of the information conveyed during the informed consent process, and their satisfaction with the informed consent discussion and process. Time to complete the rapid feedback patient survey is estimated at 5 minutes. We expect hospitals to administer this survey to at least 50 patients before implementation and 50 patients after implementation in at least 1 unit.

Other outcome and output data from administrative records or electronic medical records (Secondary Data). Hospitals will also be asked to report on their rates of surgical cancellations and delays in at least one participating surgical unit, since prior research suggests that these rates can be improved (i.e., reduction in cancellations and some delays) when strategies such as teach-back were used in the informed consent process (NQF, 2005). Hospitals may also select other outcome measures of interest based on administrative records or electronic medical records. They may also report on output data such as number of informed consent forms improved or number of staff present during a teach-back or quality improvement exercise. Since these data collections involve extractions from existing clinic records or use of administrative records, they pose only minimal data collection burden to the hospital, specifically the person who needs to collect the data (i.e., hospital liaison or unit leader).

The purpose of the proposed data collection effort is to obtain information needed to modify and enhance the Informed Consent training modules and to provide information to hospitals considering using the training modules to improve their informed consent processes. Since this is only a pilot study in 4 sites, outcomes or impacts will not be generalizable.

The data collected will help the project team: (1) Understand the facilitators and barriers of implementing the tools and recommended improvements to informed consent policies and processes, and (2) assess the effectiveness of the training modules in improving informed consent processes and other outcomes in four pilot implementation sites. The data collection effort may also provide insights that could guide dissemination of the training modules. For example, if it was found that specific units (e.g., surgical units) across the pilot test hospitals strongly benefited from implementing a specific strategy suggested in the training modules, then AHRQ could tailor and target its dissemination of the training modules to those individuals and organizations that represent them. Once revisions are made based on results of the pilot study, the training modules will be published on AHRQ's Web site. A manuscript describing the pilot study and its results will also be produced for publication in a peer-reviewed journal.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on prior experiences with pilot testing materials in hospitals and what can reasonably be requested of participating hospitals. The number of respondents listed in column A, Exhibit 1 reflects a projected 80% response rate for data collection efforts 2a, 2b, 4, and 6 below.

1. The Hospital Informed Consent Baseline and Final Assessment will establish a baseline and final assessment of each hospital's informed consent policies and processes that is completed by the site liaisons (1 per hospital) and unit leaders (4 per hospital) and will take each person 30 minutes to complete each time.

2. Pre-/Post-Training Quiz will be administered after participants register for the training but before they begin the course (pre-test), and immediately after participants complete the course content (post-test). There will be a pre-post quiz for each module. Each quiz will take 20 minutes to complete:

a. Health care professionals Pre-/Post-Training Quiz: We assumed 40 health care professionals per unit for a total of 160 staff per hospital and a total of 640 across all four hospitals. We assumed 512 health care professionals will complete the pre-/post-training quiz based on an estimated 80% response rate.

b. Hospital Leader Pre-/Post-Training Quiz: We assumed 8 leaders per hospital for a total of 32 across all four hospitals. We assumed 26 will complete the pre-/post-training quiz based on an estimated 80% response rate.

3. The Monthly Check-In Calls will occur with hospital liaisons and four unit leaders for a total of 5 individuals per hospital to assess the progress of implementation of training programs at each site and within each unit. Check-in calls will occur monthly for six months and will each take 30 minutes.

4. Health Care Professional Survey. A brief survey will be emailed to all clinicians both prior to training and approximately 2–3 months after completing the training. We assumed 40 health care professionals per unit for a total of 160 staff per hospital and a total of 640 across all four hospitals. We assumed 512 health care professionals will complete the survey based on an 80% response rate. It is expected to take 15 minutes to complete.

5. Interview and Site Visit Guide. Each site visit will occur over a two-day period and include up to 18 1-hour interviews in each pilot site, with:

a. Two hospital leaders (e.g., legal, risk management) and four unit leaders (six per hospital);

b. Three front-line clinicians in each of four units (12 per hospital).

6. Rapid Feedback Patient Survey. The Rapid Feedback Patient Survey will be given to 100 patients (50 patients before implementation and 50 patients after) immediately following an informed consent discussion. It should take 5 minutes to complete. We assumed 100 patients per hospital for a total of 400 across all four hospitals. We assumed 320 patients will complete the survey based on an 80% response rate.

7. Other outcome and output data from administrative records or electronic medical records (Secondary Data). These secondary data will be provided by the hospital liaison or unit leaders. We have assumed 5 hours for each hospital liaison and unit lead to collect and provide these data.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method or project activity	A. Number of respondents	B. Number of responses per respondent	C. Hours per response	D. Total burden hours
1. Hospital Informed Consent Baseline and Final Assessment (Attachment C)	20	2	1	40
2a. Health care professionals Pre-/Post-Training Quiz * (Attachment D)	512	2	20/60	341
2b. Hospital Leader Pre-/Post-Training Quiz * (Attachment E)	26	2	20/60	17
3. Monthly Check-in (Attachment F)	20	6	30/60	60
4. Health Care Professional Survey * (Attachment G)	512	1	15/60	128
5a. Interview—Clinical Staff (Attachment H)	48	1	1	48
5b. Interview—Hospital Leaders (Attachment H)	24	1	1	24
6. Rapid Feedback Patient Survey * (Attachment I)	320	1	5/60	27
7. Secondary data	4	1	5	20
Total		na	na	705

* Number of respondents (Column A) reflects a sample size assuming an 80% response rate for these data collection efforts.

Exhibit 2, below, presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be about $25,270.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection method or project activity	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
1. Hospital Informed Consent Baseline and Final Assessment (Attachment C)	20	40	$42.78	$1,711
2a. Health care professionals pre-/post-training quiz (Attachment D)	512	341.33	33.62	11,476
2b. Hospital leader pre-/post-training quiz (Attachment E)	26	17.33	51.95	900
3. Monthly Check-in Attachment F)	20	60	42.78	2,567
4. Health Care Professional Survey (Attachment G)	512	128	33.62	4,303
5a. Interview—Clinical Staff (Attachment H)	48	48	33.62	1,614
5b. Interview—Hospital Leaders (Attachment H)	24	24	51.95	1,247
6. Rapid Feedback Patient Survey (Attachment I)	320	26.67	22.33	596
7. Secondary data	4	20	42.78	856
Total				25,270

The average hourly wage rate of $42.78 for the informed consent baseline, readiness assessment, and monthly check-in was calculated based on the 2013 average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions) of $33.62 and mean hourly wage rate for medical and health services managers, $51.95.

The average hourly rate of $33.62 of hospital staff pre- and post-training quiz and in-depth interviews was calculated based on the 2013 average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions), $33.62.

The average hourly rate of $51.95 for hospital leaders pre- and post-training quiz and in-depth interview was calculated based on the 2013 mean hourly wage rate for medical and health services managers, $51.95.

The average hourly wage rate for patients of $22.33 was calculated on the 2013 mean hourly wage rate for all occupations. Mean hourly wage rates for these groups of occupations were obtained from the Bureau of Labor & Statistics on ''Occupational Employment and Wages, May 2013'' found at the following URL: *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of Me proposed information collection. All comments will become a matter of public record.

Dated: September 18, 2014.

Richard Kronick,

Director.

[FR Doc. 2014–22698 Filed 9–26–14; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2013–0022, NIOSH 153–B]

Issuance of Final Publications

AGENCY: National Institute for Occupational Safety and Health

(NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of 10 Final Skin Notation Profile publications

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following 10 Skin Notation Profiles:

Substance(s)

Allyl glycidyl ether: *http://www.cdc.gov/niosh/docs/2014-143/pdfs/2014-143.pdf*.

2-Diethylaminoethanol: *http://www.cdc.gov/niosh/docs/2014-140/pdfs/2014-140.pdf*.

2-Ethoxyethyl acetate: *http://www.cdc.gov/niosh/docs/2014-141/pdfs/2014-141.pdf*.

Ethyl acrylate: *http://www.cdc.gov/niosh/docs/2014-144/pdfs/2014-144.pdf*.

Isophorone diisocyanate: *http://www.cdc.gov/niosh/docs/2014-144/pdfs/2014-144.pdf*.

2-Mercaptobenzothiazole (MBT); Sodium 2–MBT; Zinc 2–MBT: *http://www.cdc.gov/niosh/docs/2014-142/pdfs/2014-142.pdf*.

Methyl isocyanate: *http://www.cdc.gov/niosh/docs/2014-145/pdfs/2014-145.pdf*.

Nitrobenzene: *http://www.cdc.gov/niosh/docs/2014-146/pdfs/2014-146.pdf*.

Phenylhydrazine: *http://www.cdc.gov/niosh/docs/2014-147/pdfs/2014-147.pdf*.

Propargyl alcohol: *http://www.cdc.gov/niosh/docs/2014-149/pdfs/2014-149.pdf*.

ADDRESSES: These documents are available at the following Web site: *http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html*

FOR FURTHER INFORMATION CONTACT: Naomi Hudson, Dr.P.H.: NIOSH, 1090 Tusculum Ave., MS–C32, Cincinnati, OH 45226, Telephone: (513) 533–8540, email: *iuz8@cdc.gov*.

Dated: September 22, 2014.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2014–23086 Filed 9–26–14; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 8:30 a.m.–3:00 p.m. (EDT), October 23, 2014.

Place: CDC, Building 21, Rooms 1204 A/B, 1600 Clifton Road NE., Atlanta, Georgia 30333

Status: Open to the public, limited only by the space and phone lines available. The meeting room accommodates approximately 50 people. (Advance registration for in-person participation is required by October 16, 2014.) The public is welcome to participate during the public comment period, which is tentatively scheduled from 2:40 p.m. to 2:45 p.m. This meeting will also be available by:

Teleconference: Please dial (877) 930–8819 and enter code 1579739.

Web links: Windows Media: (Closed captioning will be available) *http://wm.onlinevideoservice.com/CDC1*

Flash: http://www.onlinevideoservice.com/clients/CDC/?mount=CDC3.

If you are unable to connect using the link, copy and paste the link into your Web browser. For technical support please call: (404) 639–3737.

Purpose: The committee will provide advice to the CDC Director on strategic and other broad issues facing CDC.

Matters for Discussion: The Advisory Committee to the Director will receive updates from the State, Tribal, Local and Territorial Subcommittee; the Health Disparities Subcommittee, the Global Workgroup, the Internal and External Laboratory Safety Workgroups, and the Public Health—Health Care Collaboration Workgroup, the Ebola response, as well as an update from the CDC Director. Agenda items are subject to change as priorities dictate.

For More Information Contact: Carmen Villar, MSW, Designated Federal Officer, ACD, CDC, 1600 Clifton Road, NE., M/S D–14, Atlanta, Georgia 30333. Telephone (404) 639–7158, Email: *GHickman@cdc.gov*. The deadline to register for in-person attendance at this meeting is October 16, 2014. To register, please send an email to *GHickman@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–23054 Filed 9–26–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the BSC, OID. This board consists of 17 experts in fields related to infectious diseases who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The board advises the HHS Secretary; the CDC Director; the OID Director; and the Directors of the National Center for Immunization and Respiratory Diseases (NCIRD), the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) concerning strategies, goals, and priorities for the programs and research within the national centers; and monitors the overall strategic direction and focus of OID and the national centers.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishment of the board's mission. Nominees will be selected by the HHS Secretary or designee from authorities knowledgeable in the fields of infectious diseases and related disciplines, including epidemiology, microbiology, bacteriology, virology, pathogen genomics, bioinformatics, clinical medicine, and veterinary medicine, as well as from the general public. Members may be invited to serve for terms of up to four years.

The U.S. Department of Health and Human Services policy stipulates that committee membership shall be balanced in terms of professional training and background, points of view represented, and the committee's function. In addition to a broad range of expertise, consideration is given to a broad representation of geographic areas within the U.S., with diverse

representation of both genders, ethnic and racial minorities, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government.

Candidates should submit the following items:

- Current *curriculum vitae,* including complete contact information (name, affiliation, mailing address, telephone number, email address)
- A letter of recommendation stating the qualifications of the candidate

Nomination materials must be postmarked by October 24, 2014, and sent to: Kim Distel, Office of Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D10, Atlanta, Georgia 30333, telephone (404) 639–2100.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–23055 Filed 9–26–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10492]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *November 28, 2014:*

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**). CMS–10492 Data Submission for the Federally-faciliated Exchange User Fee Adjustment

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Data Submission for the Federally-facilitated Exchange User Fee Adjustment; *Use:* The final rule ''Coverage of Certain Preventive Services Under the Affordable Care Act'' published by the Departments of Health and Human Services (HHS), the Treasury, and Labor on July 2, 2013 (78 FR 39870), sets forth regulations regarding coverage for certain preventive services under section 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the Public Health Service Act requires coverage without cost sharing of certain preventive health services, including certain contraceptive services, in non-exempt, non-grandfathered group health plans and health insurance coverage. The final rules establish accommodations with respect to group health plans established or maintained by eligible organizations (and group health insurance coverage offered in connection with such plans). Eligible organizations are required to self-certify that they are eligible for this accommodation and provide a copy of such self-certification to their third party administrators. The final rules also set forth processes and standards to fund the payments for the contraceptive services that are provided for participants and beneficiaries in self-insured plans of eligible organizations

under the accommodation described previously, through an adjustment in the Federally-facilitated Exchange (FFE) user fee payable by an issuer participating in an FFE.

In order to facilitate the FFE user fee adjustment, and ensure that these user fee adjustments reflect payments for contraceptive services provided under this accommodation and that the adjustment is applied to the appropriate participating issuer in an FFE, the final rule requires an information collection from applicable participating issuers and third party administrators. In particular, the final regulations at 45 CFR 156.50(d)(2)(i) provide that a participating issuer who seeks an FFE user fee adjustment must submit to HHS in the year following the benefit year in which payments for contraceptive services were made under the previously mentioned accommodation, identifying information for the participating issuer, each third party administrator, and each self-insured group health plan, as well as the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year under the accommodation. The final regulation at 45 CFR 156.50(d)(2)(iii) also requires the third party administrator to submit to HHS identifying information for the third party administrator, the participating issuer, and each self-insured group health plan, as well as the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year, the total dollar amount of payments made for contraceptive services, and an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

Furthermore, to determine the potential number of submissions provided by third party administrators and allow HHS to prepare to receive submissions in calendar year 2015, the final regulation at 45 CFR 156.50(d)(2)(ii) requires third party administrators to submit to HHS a notification that the third party administrator intends for a participating issuer to seek an FFE user fee adjustment, by the later of January 1, 2014, or the 60th calendar day following the date on which the third party administrator receives a copy of a self-certification from an eligible organization. Additionally, a health insurance issuer providing payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations to provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments.

The burden associated with these processes includes the time for applicable participating issuers and third party administrators to submit identifying information and total payments made for contraceptive services in the prior calendar year, and for third party administrators to notify HHS of their intent to seek the user fee adjustment. HHS estimates 488 third party administrators, 48 QHP issuers, and 325 fully insured issuers of eligible organizations will submit this information. HHS anticipates that participating issuers in an FFE seeking a user fee adjustment and third party administrators with respect to which the FFE user fee adjustment is received will submit this information electronically. *Form Number:* CMS–10492 (OMB Control Number: 0938–NEW); *Frequency:* Once, Yearly. *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 861; *Total Annual Responses:* 861 *Total Annual Hours:* 12,930. (For policy questions regarding this collection contact Jaya Ghildiyal at (301) 492–5149.)

Dated: September 24, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–23132 Filed 9–26–14; 8:45 am]

BILLING CODE 4120–01–U–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1409]

Agency Information Collection Activities; Proposed Collection; Comment Request; Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on adverse event reporting by FDA on new animal drugs and product/manufacturing defects collected on paper forms.

DATES: Submit either electronic or written comments on the collection of information by November 28, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports on Paper Forms FDA 1932, 1932a, and 2301—21 CFR 514.80; OMB Control Number 0910–0284—Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(l) and 514.80 (21 CFR 514.80) of FDA regulations require applicants of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects (see § 514.80)(b)). Additionally, Section 571(e)(3) of the FD&C Act (21 U.S.C. 360ccc(e)(3)) requires that applicants for conditional approval of new animal drugs (CNADAs) maintain adequate reports and records of adverse drug experiences and product/manufacturing defects as applicable under section 512(l) of the FD&C Act.

The continuous monitoring of approved NADAs, ANADAs, and CNADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Post-approval marketing surveillance is important because data previously submitted to FDA may not be adequate as animal drug effects can change over time and less apparent effects may take years to manifest.

Under § 514.80(d), an applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs,'' (see § 514.80). Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,'' allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

In 2010, electronic versions of Forms FDA 1932 and 1932a were incorporated into the FDA Safety Reporting Portal. This electronic system is used for collecting, submitting, and processing adverse event reports and other safety information for all FDA-regulated products. Burden for the electronic version of these forms is accounted for under OMB control number 0910–0645. This approval request accounts for the collection of information using existing paper Forms FDA 1932, 1932a, and 2301 and is currently approved under OMB control number 0910–0284. FDA estimates that, at this time, approximately 50 percent of the respondents utilize paper forms for submitting this information. We expect this number to decrease as more respondents make use of the FDA Safety Reporting Portal.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section or section of the FD&C Act	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.80(b)(1), 514.80(b)(2)(i) and (ii), 514.80(b)(3)	1932	22	81.05	1,783	1	1,783
Voluntary reporting FDA Form 1932a for the public	1932a	197	1	197	1	197
514.80(b)(4)	2301	200	8.11	1,622	16	25,952
514.80(b)(5)(i)	2301	200	0.57	114	2	228
514.80(b)(5)(ii)	2301	200	20.12	4,024	2	8,048
514.80(b)(5)(iii)	2301	190	0.1	20	2	40
Total Hours						36,248

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of record keepers	Number of records per record keeper	Total annual records	Average burden per record keeping	Total hours
514.80(e)	646	7.20	4651	14	65117

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23059 Filed 9–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0623]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Voluntary Cosmetic Registration Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On July 8, 2014, the Agency submitted a proposed collection of information entitled ''Voluntary Cosmetic Registration Program'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0027. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23066 Filed 9–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0397]

Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability of the draft guidance entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices,'' published in the **Federal Register** of June 18, 2014. FDA is reopening the comment period in response to a request for additional time and to allow interested persons more time to submit comments.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments by October 29, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Jean-Ah Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, 301–796–1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding animal prescription drugs: Dorothy McAdams, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9300.

Regarding medical devices for human use: Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993, 301–796–5732.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 18, 2014 (79 FR 34759), FDA announced the availability of a draft guidance for industry entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.'' In that document, FDA requested comments on the draft guidance, which responds to (among other things) stakeholder requests for specific guidance. The draft guidance describes FDA's current thinking on how manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use, including biological products, that choose to present benefit information should present both benefit and risk information within advertising and promotional labeling of their FDA-regulated medical products on electronic/digital platforms that are associated with character space limitations, specifically on the Internet and through social media or other technological venues. The draft guidance represents FDA's current thinking on specific aspects of FDA's evolving consideration of social media platforms and other Internet-related matters. FDA actively continues to review, analyze, and develop approaches to a variety of topics related to the labeling and advertising of medical products, including the development of this and other guidance addressing the use of social media platforms and the Internet.

Interested persons were originally given until September 16, 2014, to submit comments on the draft guidance.

II. Request for Comments

Following publication of the June 18, 2014, notice, FDA received a request for additional time to develop meaningful and thoughtful comments, especially in light of the concurrent comment period with another draft guidance entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices'' published elsewhere in this volume of the **Federal Register**.

FDA has considered the request and will reopen the comment period for an additional 30 days. The Agency believes that an additional 30 days allows

adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

III. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23063 Filed 9–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0125]

Guidance for Industry and Food and Drug Administration Staff; Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.'' This guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. The guidance includes a description of the types of evidence recommended to demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007'' to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.'' In this guidance, FDA provides recommendations on how a manufacturer can demonstrate that a tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007. In the guidance document, FDA refers to tobacco products that were commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007, as grandfathered tobacco products. Grandfathered tobacco products are not considered new tobacco products and thus are not subject to the premarket requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (section 910; 21 U.S.C. 387j). A grandfathered tobacco product may serve as the predicate tobacco product in a 905(j) report (demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)A)(i) of the FD& C Act, 21 U.S.C. 387e(j)(1)(A)(i)). FDA recommends that information supporting a grandfather designation may include, among other things, dated copies of advertisements, dated catalog pages, and dated promotional material.

In the **Federal Register** of April 25, 2011 (76 FR 22903), FDA announced the availability of the draft guidance of the same title. After considering the comments on the draft guidance, FDA made minor editorial changes to improve clarity.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0775.

IV. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

V. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23058 Filed 9–26–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0447]

Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability of the draft guidance entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices,'' published in the **Federal Register** of June 18, 2014. FDA is reopening the comment period in response to a request for additional time and to allow interested persons more time to submit comments.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments by October 29, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding human prescription biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding animal prescription drugs: Thomas Moskal, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9300.

Regarding medical devices for human use: Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993–0002, 301–796–5732.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 18, 2014 (79 FR 34760), FDA announced the availability of a draft guidance for industry entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices.'' In that document, FDA requested comments on the draft guidance, which responds to (among other things) stakeholder requests for specific guidance. The draft guidance describes FDA's current thinking on how manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use, including biological products, should respond, if they choose to respond, to misinformation related to a firm's own FDA-approved or cleared products when that information is created or disseminated by independent third parties. The draft guidance also updates and clarifies FDA's policies on the correction of misinformation created or disseminated by independent third parties on the Internet or through social media platforms, regardless of whether that misinformation appears on a firm's own forum, an independent third-party forum, or a Web site. The draft guidance represents FDA's current thinking on specific aspects of FDA's evolving consideration of social media platforms and other Internet-related matters. FDA actively continues to review, analyze, and develop approaches to a variety of topics related to the labeling and advertising of medical products, including the development of this and other guidance addressing the use of social media platforms and the Internet.

Interested persons were originally given until September 16, 2014, to submit comments on the draft guidance.

II. Request for Comments

Following publication of the June 18, 2014, notice, FDA received a request for additional time to develop meaningful and thoughtful comments, especially in light of the concurrent comment period with another draft guidance entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices'' published elsewhere in this volume of the **Federal Register**.

FDA has considered the request and will reopen the comment period for an additional 30 days. The Agency believes that an additional 30 days allows adequate time for interested persons to submit comments without significantly delaying the Agency's consideration of these important issues.

III. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23064 Filed 9–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Final Policy on Conferring With Urban Indian Organizations

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: The Indian Health Service (IHS or ''the Agency'') is issuing this Notice to implement the final Policy for conferring with Urban Indian Organizations (UIOs). In March 2010, the Indian Health Care Improvement Act (IHCIA) was reauthorized and amended as part of the Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act (together, the Affordable Care Act), Public Law 111–152. One of the changes made to the IHCIA was to create a new requirement that the IHS ''confer'' with UIOs, to the maximum extent practicable, in carrying out the IHCIA.

DATES: This Policy will become effective on October 29, 2014.

FOR FURTHER INFORMATION CONTACT: Office of Management Services, Management Policy and Internal Control Staff, Indian Health Service, 801 Thompson Avenue, Suite 625A, Rockville, Maryland 20852. Telephone 301/443–2650 (This is not a toll free number).

SUPPLEMENTARY INFORMATION: The IHS published a proposed draft Policy in a notice in the **Federal Register** on July 26, 2012 (77 FR 43846). In response to the notice, the Agency received thirty-two comments on the draft Policy. All comments were considered and appropriate changes were made to the policy. In addition, a Listening Session was held on January 22, 2013, following publication of a meeting notice in the **Federal Register** (78 FR 2413).

Inspection of Public Comments

Comments are available for public inspection at the following address: Indian Health Service, Division of Regulatory Affairs, 12300 Twinbrook Parkway, TMP Suite 430, Rockville MD 20852, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone 1–301–443–1116 (not a toll free number).

Summary and Discussion of Comments Received

The Agency received thirty-two comments on the draft Policy. All comments were considered and appropriate changes were made to the policy. Fifteen of the comments were in support of the Policy as it was written. Numerous comments addressed topics that would require no change to the Policy; however, some comments did raise critical issues that may require additional conferring activities. It is expected that the confer process may result in the need to update this policy from time to time.

Several commenters recommended that UIOs confer with the respective Area Offices rather than with Service Units. The Policy identifies a conferring role to be available at every level of IHS, including both Area Offices and Service Units, if applicable. UIOs are not limited or required to confer at any specific level. IHS will conduct special trainings and provide technical assistance for the Service Units, if necessary.

One commenter recommended that application of the Federal Advisory Committee Act (FACA) be clarified. The policy is updated to clarify the applicability of FACA when federal advisory groups are convened for the purpose of generating consensus recommendations, and the inapplicability of the ''intergovernmental'' exemption. In the event questions arise regarding application of FACA, the following was added at the end of the FACA section in the Policy: ''For questions regarding the applicability of FACA, please contact the Director, IHS Division of Regulatory Affairs, Office of Management Services.''

Several commenters were concerned about the authority in the draft Policy for the Director, IHS, and the Director, Office of Urban Indian Health Programs, to determine when to confer, and expressed objection to the proposal to require conference between the IHS and UIOs upon the occurrence of a critical event as determined by IHS, and further commented that either party should be able to identify a critical event. In response to the comments, IHS removed the subject language from the final Policy. Consistent with the IHCIA, the Policy requires IHS to confer, to the maximum extent practicable, on any critical event or issue, which is defined broadly as ''an event or issue that significantly affects one or more UIOs.'' Section 5–26.4(A) provides that a critical event or issue may be identified by IHS and/or UIOs. Subsection (A)(2) was amended to further clarify that the identification of a critical event or issue is intended to be a collaborative one.

Several commenters suggested that the provisions that were developed by the ''conferring policy'' workgroup established in 2010 be incorporated into the Policy. While, IHS is not required to adopt any recommendations of a workgroup or committee, it was determined that the ''conferring policy'' workgroup was convened in a manner that may not have complied with the requirements of the FACA. Therefore, although IHS considered the workgroup's discussion and recommendation to the same extent it considered all other recommendations received on this issue, federal staff developed a draft policy based on the statute and all comments received to that point, and published the draft in the **Federal Register** for comment. Many of the points raised in the discussion of the workgroup actually are consistent with the draft policy and were raised and responded to in the comments that were subsequently received. Some issues raised by the workgroup, but not included in the final policy, may require further conferring with UIOs.

One commenter expressed concern regarding violation of trust responsibility. The IHCIA defines ''confer'' to mean ''to engage in an open and free exchange of information and opinions that—(1) leads to mutual understanding and comprehension; and (2) emphasizes trust, respect, and shared responsibility.'' 25 U.S.C. § 1660d(a). IHS believes this will be accomplished through the various confer mechanisms that will be conducted in response to a critical event or issue.

A few commenters suggested that it was the intent of the IHCIA that the IHS confers only with UIOs funded by the IHS under the IHCIA. Similarly, another commenter suggested the definition of a UIO be inclusive to ensure adequate input and participation from the nonprofit organizations providing services to Tribal members living away from the reservation. The Policy is inclusive of all UIOs that meet the IHCIA definition of UIO, 25 U.S.C. 1603(29), which is not limited, per the statute, to organizations that are receiving funding from the IHS under the IHCIA. In practice, UIOs funded by the IHS under the IHCIA will have opportunities to raise issues specific to their relationship with IHS during the confer process and can also continue to approach IHS directly regarding such specific concerns, without relying on the conferring process set out in this policy.

Two commenters urged the IHS to consider coordination with the IHS Tribal Consultation Policy and Executive Order 13175. The commenters suggested that UIO matters could have Tribal implications that may trigger consultation and, therefore, Tribal governments should be included as a required party in the confer process with UIOs. The Policy published in this **Federal Register** notice addresses IHS's responsibility to confer with UIOs under the IHCIA. The IHS Urban Confer Policy does not change the Tribal Consultation Policy. IHS will continue to follow the Tribal Consultation Policy for consulting Indian Tribes on matters that will significantly affect Tribes. For issues of interest to both Tribes and UIOs, both policies will apply.

Final Policy, With Revisions Incorporated in Response to Above Comments

Policy on Conferring With Urban Indian Organizations

5–26.1 *Introduction*

A. *Purpose.* Congress has specifically declared that it is the policy of the Nation ''to ensure the highest possible health status for Indians and urban Indians.'' 25 United States Code (U.S.C.) § 1602(1). The U. S. Department of Health and Human Services (HHS) is committed to working with Indian and urban Indian communities to meet this policy. This policy applies to the Indian Health Service (IHS).

This Policy establishes the Indian Health Service (IHS) policy and procedures for conferring with urban Indian organizations (UIOs). The IHS will use this conferring Policy to ensure that the health care needs of the urban

Indian population are considered at the local, Area, and national levels, when implementing and carrying out the Indian Health Care Improvement Act (IHCIA or Act).

B. *Background.* Urban Indian organizations are a major provider of health care to urban AI/ANs across the country. When the IHCIA was enacted into law in 1976, it identified the authorities, responsibilities, and functions of the IHS, the primary Federal Agency charged with providing health care to American Indians and Alaska Natives (AI/AN). The IHCIA included the authority for the IHS to ''establish programs in urban centers to make health services more accessible to urban Indians'' [Indian Health Care Improvement Act, Title V, section 501, Public Law No. (Pub. L. No.) 94–437, 90 Statute (Stat.) 1400, 1410 (1976), codified at 25 U.S.C. § 1651]. The IHS carries out this authority through contracts with and grants to UIOs. In March 2010, as part of the Affordable Care Act, Congress reauthorized and amended the IHCIA. The reauthorization of the IHCIA included a requirement that the IHS ''confer,'' to the maximum extent practicable, with UIOs in carrying out the IHCIA.

C. *Policy.* It is IHS policy to confer with UIOs, to the maximum extent practicable, whenever a critical event or issue, as defined in this Policy, arises in implementing or carrying out the IHCIA.

D. *Requirement.* The IHCIA, as amended, includes four provisions that require the IHS to confer with UIOs.

(1) Indian Health Care Improvement Act, 25 U.S.C. § 1660d(b). ''The Secretary shall ensure that the Service confers, to the maximum extent practicable, with urban Indian organizations in carrying out this [Act].''

(2) Indian Health Care Improvement Act, 25 U.S.C. § 1602(5). ''Congress declares . . . that all actions under this [Act] shall be carried out with . . . conference with urban Indian organizations, to implement this [Act]. . . .''

(3) Indian Health Care Improvement Act, 25 U.S.C. § 1631(f). ''The Secretary shall . . . confer with urban Indian organizations, in developing innovative approaches to address all or part of the total unmet need for construction of health facilities. . . .''

(4) Indian Health Care Improvement Act, 25 U.S.C. § 1665k(a)(2)(A)(vii). ''Funding provided pursuant to [25 U.S.C. § 1665k ''fetal alcohol spectrum disorders programs''] shall be used . . . [t]o develop and implement . . . in conference with urban Indian organizations, culturally sensitive assessment and diagnostic tools including dysmorphology clinics and multidisciplinary fetal alcohol spectrum disorders clinics for use in Indian communities and urban centers.''

E. *Authorities.*

(1) Indian Health Care Improvement Act, 25 U.S.C. §§ 1601–1683, as amended, including, §§ 1602(1), 1603(29), 1651, 1653(a), 1660d.

F. *Definitions.*

(1) *Confer.* The term ''confer'' means to engage in an open and free exchange of information and opinions that:

a. Leads to mutual understanding and comprehension, and

b. emphasizes trust, respect, and shared responsibility. 25 U.S.C. § 1660d(a).

(2) *Conferring Activities.* The term ''conferring activities'' means implementing confer mechanisms, such as face-to-face meetings, teleconferences, and mailings, to solicit comments and discuss critical events or issues.

(3) *Critical Event or Issue.* A ''critical event or issue,'' as used in this Policy, is an event or issue that significantly affects one or more UIOs. Critical events or issues are complex, have significant implications, and are time sensitive. Examples of critical events or issues include developing program regulations, formulating the budget, allocating new resources, and changing policy, as well as public health or environmental events.

(4) *IHS Confer with UIOs Report.* The term ''IHS Confer with UIOs Report'' means an annual report to the Secretary, HHS, describing critical events or issues to UIOs arising in implementing or carrying out the IHCIA.

(5) *Urban Indian Organization.* The term ''urban Indian organization'' means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in [25 U.S.C. 1653(a)]. 25 U.S.C. 1603(29).

5–26.2 Objectives

A. To formalize the IHS approach to conferring with UIOs to ensure that urban Indian health priorities and goals are considered.

B. To establish a minimum set of requirements and expectations with respect to conferring for the three levels of IHS management: Headquarters, Area Offices, and Service Units.

C. To identify critical events or issues arising in implementing or carrying out the IHCIA for which conferring with UIOs will be required for the three levels of IHS management: Headquarters, Area Offices, and Service Units.

D. To identify critical events or issues arising in implementing or carrying out the IHCIA where partnerships and the inclusion of UIOs would complement consultation with Indian Tribes.

E. To require conferring with UIOs on proposed, new, and existing health policies and programs that qualify as critical events or issues arising in implementing or carrying out the IHCIA.

F. To promote and develop innovative methods of involving UIOs in IHS policy development and in the decision-making processes of the IHS.

G. To charge and hold responsible all levels of management within the IHS for the implementation of this Policy.

5–26.3 Roles

A. *Headquarters.* The Director, IHS, is responsible for providing overall guidance and direction to the Office of Urban Indian Health Programs (OUIHP) and ensuring that the IHS confers, to the maximum extent practicable, with UIOs in accordance with this Policy.

The IHS has the responsibility to engage in an open and free exchange of information and opinions with UIOs that leads to mutual understanding and comprehension; and emphasizes trust, respect, and shared responsibility whenever a critical event or issue, as defined in this Policy, arises in implementing or carrying out the IHCIA.

The Director, OUIHP, is responsible for monitoring compliance with this Policy, including submissions to the OUIHP conferring email address: *urbanconfer@ihs.gov.* The Director, OUIHP, will ensure that all levels of the IHS conduct official conferring sessions that are publicized through correspondence or, when necessary, **Federal Register** Notices (FRN) and receive conferring reports. The Director, OUIHP, will also receive and acknowledge receipt of written correspondence from UIOs identifying critical events or issues arising in implementing or carrying out the IHCIA. Such correspondence should identify the critical events or issue, the affected UIO(s), and the proposed conferring activity. After receiving such correspondence, or upon identification of a critical event or issue by IHS, all affected UIOs will be notified through a ''Dear Urban Indian Organization Letter'' and broadcast emails, and, if necessary, through the **Federal Register**, when IHS will undertake conferring activity. The notice will identify the issue, the method for conferring, and the

timeline for the conferring activity. The Director, OUIHP, is responsible for preparing the annual IHS Confer with Urban Indian Organizations Report.

All IHS Headquarters Office Directors will provide leadership to identify potential critical events or issues arising in implementing or carrying out the IHCIA for which conferring with UIOs will be recommended to the Director, OUIHP, and assist the OUIHP in completion of the annual IHS Confer with UIOs Report, when necessary.

B. *Area Offices.* The Area Director will provide the support and assistance to ensure that IHS confers, in accordance with this Policy, with UIOs at the Area level. The Area Director will conduct official conferring sessions through meetings or conferring actions with UIOs. The Area Director will ensure that the Director, OUIHP is informed of the Area conferring activities and outcomes for inclusion in the annual IHS Confer with UIOs Report.

C. *Service Units.* The Service Unit Chief Executive Officer (CEO) is responsible for ensuring compliance with this Policy by conferring with UIOs that are located in the Service Unit, if applicable. The CEO shall provide the Service Unit conferring activities and results or outcomes reports to the Area Director, who will report them to the OUIHP.

5–26.4 Confer Management

A. *Identification of Conferring Activities.* A potential critical event or issue arising in implementing or carrying out the IHCIA may be identified by either the IHS and/or UIOs.

(1) If a potential critical event or issue is identified by a UIO, written correspondence must be submitted to the Director, IHS, (with a copy to the appropriate Area Director) describing the event or issue, the affected UIO(s), and the proposed conferring activity. The IHS shall acknowledge receipt of the request within 60 business days.

(2) Within 60 business days of acknowledging the request, IHS shall provide an official response to all affected/potentially affected UIO(s), identifying the conferring activity that has been selected and the timeline for the activity. In addition, if IHS itself determines that a critical event or issue has arisen in implementing or carrying out the IHCIA, the IHS will issue notices to all affected/potentially affected UIOs through correspondence such as a ''Dear Urban Indian Organization Letter'' and broadcast emails, as well as through a FRN, if necessary. The communication will identify the critical events or issues to be discussed, as well as the mechanism for conferring.

B. *Conferring Activity.* The IHS will conduct official conferring activities that shall be publicized, both through correspondence such as a ''Dear Urban Indian Organization Letter'' and broadcast emails, and, if necessary, through a FRN. The notices will include information such as the mechanism, dates, and locations of the conferring activity, the agenda, and any critical events or issues that will be discussed. In the event that a confer activity will be conducted, the degree and extent of the conferring and the mechanism for conferring shall depend upon several factors, including:

(1) The nature of the critical event or issue,

(2) the number of potentially affected UIOs, and

(3) the most cost effective and efficient conferring mechanism, based on the nature of the critical event or issue and the number of potentially affected UIOs.

C. *Confer Mechanisms.* The IHS will consider the following confer mechanisms as options that provide the opportunity for an open and free exchange of information and opinions that lead to mutual understanding and comprehension and emphasize trust, respect, and shared responsibility:

(1) Mailings

(2) Teleconferences/Webinars

(3) Regular or special program level conferring sessions

(4) Conferences or meetings, such as the annual Urban Indian Health Leadership Conference

(5) Opportunities for comment, including submissions to *urbanconfer@ihs.gov*

(6) Face-to-face meetings, including meetings conducted at the Area Office level or at the national-level Indian health system meetings that include the IHS, Tribes, and UIO(s).

(7) **Federal Register** Notices with request for comment.

D. *Contract- and Grant-Specific Issues.* A UIO may request to meet one-on-one with an IHS representative to confer on issues specific to that UIO and its contract and grant awards from the IHS.

E. *Unresolved Issues.* Upon the completion of any of the conferring activities in this section, the IHS will document and follow-up on any unresolved issue(s) that would benefit from the ongoing involvement of the affected UIO(s). Documentation of the conferring process and outcomes will be maintained by the OUIHP and the Area Office(s) in which the affected UIO(s) are located.

F. *Annual IHS Confer With UIOs Report to HHS.* The IHS shall prepare and submit the annual IHS Confer with UIOs Report to the Secretary, HHS, describing critical events or issues arising in implementing or carrying out the IHCIA, related conferring activities, and the results and outcomes of conferring with UIOs.

The report shall include a description of each critical event or issue(s) that was the subject of conferring, a description of the process that was used, a discussion of the recommendations that resulted from the conferring activity, a list of any follow-up action items, a timeline for addressing these items, and a discussion of the level of satisfaction with the conferring process.

G. *Conflict Resolution.*

(1) The intent of this Policy is to promote mutual understanding and comprehension, and to emphasize trust, respect, and shared responsibility between the IHS and UIOs.

(2) However, the IHS and UIOs may not always agree. Where such disagreement occurs, nothing in this Policy creates a right of action against the IHS or the HHS for failure to comply with this Policy.

5–26.5 Federal Advisory Committee Act

The Federal Advisory Committee Act (FACA), 5 U.S.C. App. § 1–16, may apply to conferring activities. The FACA is implicated when an Agency establishes, manages, or controls a group that includes one or more participants who are not Federal employees for the purpose of obtaining the group's consensus advice or recommendations on Agency issues or policies. The FACA imposes several procedural requirements on Federal Agencies that convene advisory committees. Although FACA may not apply to groups consisting solely of Tribal leaders serving on the group in their official capacities, UIOs do not meet the requirements of the ''inter-governmental'' exemption. Accordingly, any conferring activities that qualify as an advisory committee under the FACA that is convened for the purpose of developing consensus recommendations will be required to comply with the procedures set out in FACA. For questions regarding the applicability of FACA, please contact the Director, IHS Division of Regulatory Affairs, Office of Management Services.

5–26.6 Summary

This policy considers a wide range of needs and unique characteristics in crafting these guidelines; therefore, it is important for the IHS urban confer

policy to remain dynamic and be responsive to changing circumstances that affect UIOs. It is expected that the confer process may result in the need to update the policy from time to time.

5–26.7 Deliberative Process Privilege

Nothing in this Policy waives the Government's deliberative process privilege. Examples of the government's deliberative process privilege are as follows:

(1) When the Secretary, HHS, is specifically requested by a member or members of Congress to respond to or report on proposed legislation, the development of such responses and of related policy is a part of the Executive Branch's deliberative process privilege and should remain confidential.

(2) In specified instances, when Congress requires the HHS to work with UIOs on the development of recommendations that may require legislation, such as reports, recommendations, or other products that are developed independent of a Department position, the development of which is governed by Office of Management and Budget Circular A–19.

Dated: September 22, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014–23005 Filed 9–26–14; 8:45 am]

BILLING CODE 4160–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; A Generic Submission for Formative Research, Pre-Testing, Stakeholder Measures and Advocate Forms at NCI

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 18, 2014 (Volume 79, P. 42023) and allowed 60-days for public comment. There were no comments received.

Direct comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Kelley Landy, Acting Director of the Office of Advocacy Relations (OAR), NCI, NIH, 31 Center Drive, Bldg. 31, Room 10A28, MSC 2580, Bethesda, MD 20892, call non-toll-free number 301–594–3194, or email your request, including your address, to *kelley.landy@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: A Generic Submission for Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI, 0925–0641, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The Office of Advocacy Relations (OAR) disseminates cancer-related information to a variety of stakeholders, seeks input and feedback, and facilitates collaboration to advance NCI's authorized programs. It is beneficial for NCI, through the OAR, to pretest strategies, concepts, activities and materials while they are under development. Additionally, administrative forms are a necessary part of collecting demographic information and areas of interest for advocates. Pre-testing, or formative evaluation, helps ensure that the products and services developed by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since OAR is responsible for matching advocates to NCI programs and initiatives across the cancer continuum, it is necessary to measure the satisfaction of both internal and external stakeholders with this collaboration. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many initiatives and products that OAR and NCI produce. The OAR will use a variety of qualitative (focus groups, interviews) and quantitative (paper, phone, in-person, and web surveys) methodologies to conduct this research, allowing NCI to: 1) Understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective strategies, concepts, activities; 2) use a feedback loop to help refine, revise, and enhance OAR's efforts—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and 3) expend limited program resource dollars wisely and effectively. The anticipated individual respondents will consist of: Adult cancer research advocates, members of the public, health care professionals, and organizational representatives.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,025.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent type	Form name	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Individuals	Self-Administered Questionnaires	800	1	1	800
	Individual In-Depth Interviews	75	1	1	75
	Focus Group Interviews	100	1	90/60	150

Dated: September 23, 2014

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–23081 Filed 9–26–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Pilot Clinical Trials to Eliminate the Latent HIV Reservoir (U01).

Date: November 24, 2014.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4F100 Bldg. FL, 5601 Fisher Lane, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Dharmendar Rathore, Ph.D., Senior Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Rm 3134, Bethesda, MD 20892, 301–435–2766, *rathored@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS).

Dated: September 23, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–23037 Filed 9–26–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel NIAMS Small Grant Program for New Investigators (R03)

Date: October 22–23, 2014

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications

Place: National Institutes of Health One Democracy Plaza 6701 Democracy Boulevard, Suite 800 Bethesda, MD 20892 (Virtual Meeting)

Contact Person: Xincheng Zheng, MD, Ph.D. Scientific Review Officer Scientific Review Branch National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–594–4953, *xincheng.zheng@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: September 23, 2014.

Carolyn Baum

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–23019 Filed 9–26–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Pregnancy and Neonatology Study Section.

Date: October 21–22, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Knecht, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435–1046, *knechtm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Vectors and Pathogens.

Date: October 22–23, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20892, (301) 435–1149, *elzaataf@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Societal and Ethical Issues in Research Study Section.

Date: October 22, 2014.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Marines' Memorial Club and Hotel, 609 Sutter Street, San Francisco, CA 94102.

Contact Person: Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3144, MSC 7770, Bethesda, MD 20892, (301) 254–9975, *helmersk@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Physiology of Obesity and Diabetes Study Section.

Date: October 23–24, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Reed A Graves, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 6166, MSC 7892, Bethesda, MD 20892, (301) 402–6297, *gravesr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bioinformatics in Surgical Sciences, Imaging and Independent Living.

Date: October 27, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Molecular Pathobiology Study Section.

Date: October 27–28, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery for Aging, Neuropsychiatric and Neurologic Disorders.

Date: October 27–28, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Yuan Luo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301–915–6303, *luoy2@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Innovation Research Grant.

Date: October 27, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Rebecca Henry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, 301–435–1717, *henryrr@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Orthopedic and Skeletal Biology.

Date: October 27, 2014.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Baljit S Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, *moongabs@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Clinical Neurophysiology, Devices, Neuroprosthetics, and Biosensors.

Date: October 27–28, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: Cristina Backman, Ph.D., Scientific Review Officer, ETTN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211 MSC7846, Bethesda, MD 20892, *cbackman@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Psycho/Neuropathology, Lifespan Development, and Science Education.

Date: October 27–28, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Long Beach and Executive Center, 701 West Ocean Boulevard, Long Beach, CA 90831.

Contact Person: John H Newman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 435–0628, *newmanjh@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry A Study Section.

Date: October 27–28, 2014.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott Hotel New Orleans, 614 Canal St., New Orleans, LA 70130.

Contact Person: Mike Radtke, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, 301–435–1728, *radtkem@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Motor Function, Speech and Rehabilitation.

Date: October 27, 2014.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Dana Jeffrey Plude, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, *pluded@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Therapeutic Approaches to Genetic Diseases.

Date: October 27–28, 2014.

Time: 6:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel & Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Genes, Genomes, and Genetics IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2200, MSC 7890, Bethesda, MD 20892, 301 435–2514, *riverase@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology, Developmental Biology and Bioengineering.

Date: October 28–29, 2014.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301–435–1789, *kenneth.ryan@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal Oral and Skin Sciences Area Review.

Date: October 28–29, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–451–0996, *ybi@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Advances in Neurotechnology.

Date: October 28, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, Bethesda, MD 20892, 301–435–4577, *tuoj@nei.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–13–190: Detection of Pathogen Induced Cancer.

Date: October 28, 2014.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701

Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301–435–1167, *pandyaga@mai.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: September 23, 2014.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–23044 Filed 9–26–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Age-Related Hearing Loss.

Date: October 29, 2014.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC–9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Assessment of Sleep, EEG and Cognition in Aging.

Date: October 30, 2014.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *PARSADANIANA@NIA.NIH.GOV.*

Name of Committee: National Institute on Aging Special Emphasis Panel; ADGC.

Date: November 3, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC–9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Mitochondrial Dysfunction in Aging.

Date: November 3, 2014.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *PARSADANIANA@NIA.NIH.GOV.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Nuclear Dynamics and Aging.

Date: December 1, 2014.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC–9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: September 23, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–23045 Filed 9–26–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; NIH Support for Conference and Scientific Meetings (Parent R13/U13).

Date: October 21, 2014.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Rahat Khan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing, Translational Sciences, 6701 Democracy Blvd., Rm 1078, Bethesda, MD 20892, 301–894–7319, *khanr2@csr.nih.gov.*

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; R13 Conference Grant Review.

Date: October 28, 2014.

Time: 1:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Sailaja Koduri, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing, Translational Sciences, 6701 Democracy Blvd., Room 1074, Bethesda, MD 20892, 301–435–0813, *Sailaja.koduri@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS).

Dated: September 23, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–23036 Filed 9–26–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR11–315 Systems Science and Health in the Behavioral and Social Sciences.

Date: October 16, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Tomas Drgon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, 301–435–1017, *tdrgon@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR13–185: Image-Guided Drug Delivery in Cancer.

Date: October 16, 2014.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484, *mohsenim@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR14–166: Early Phase Clinical Trials in Imaging and Image-Guided Interventions.

Date: October 17, 2014.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Chiayeng Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, MSC 7852, Bethesda, MD 20892, 301–435–2397, *chiayeng.wang@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Risk, Prevention and Intervention for Addictions.

Date: October 20–21, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street NW., Washington, DC 20037.

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, *prenticekj@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Applications: Child Psychopathology.

Date: October 21, 2014.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Immunology.

Date: October 21–22, 2014.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Patrick K Lai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2215, MSC 7812, Bethesda, MD 20892, 301–435–1052, *laip@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training in Biomedical Big Data Science.

Date: October 21–22, 2014.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–379–9351, *allen.richon@nih.hhs.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: September 23, 2014.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–23035 Filed 9–26–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5752–N–79]

30-Day Notice of Proposed Information Collection: Request for Prepayment of Section 202 or 202/8 Direct Loan Project

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date: October 29, 2014.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email at *Colette Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 11, 2014.

A. Overview of Information Collection

Title of Information Collection: Request for Prepayment of Section 202 or 202/8 Direct Loan Project.

OMB Approval Number: 2502–0554.

Type of Request: Extension of a currently approved collection.

Form Number: HUD–9808.

Description of the need for the information and proposed use: Owners of Section 202 projects use the form as the initial application to prepay their Section 202 Direct Loan and provide narrative information relative to the prepayment that must be reviewed by HUD staff.

Respondents: Business, not for profit institutions.

Estimated Number of Respondents: 185.

Estimated Number of Responses: 185.

Frequency of Response: On occasion.

Average Hours per Response: 2 hours.

Total Estimated Burdens: 370.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: September 23, 2014.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2014–23118 Filed 9–26–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5752–N–82]

30-Day Notice of Proposed Information Collection: Planning Phase Evaluation of the LGBTQ Youth Homelessness Prevention Initiative

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date: October 29, 2014.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email at *Colette Pollard* @hud.gov or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 25, 2014.

A. Overview of Information Collection

Title of Information Collection: Planning Phase Evaluation of the LGBTQ Youth Homelessness Prevention Initiative.

OMB Approval Number: 2506-New.

Type of Request: New collection.

Form Number: None.

Description of the need for the information and proposed use: The LGBTQ Youth Homelessness Prevention Initiative began in the summer of 2013 as part of a federal interagency initiative. The initiative's goal is to prevent homelessness among lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth, and to intervene early when homelessness occurs for these youth. Federal partners from the U.S. Departments of Education, Health, and Juvenile Justice, as well as the U.S. Interagency Council on Homelessness, support this HUD initiative. The initiative supports the federal goal to end youth homelessness by 2020 and contributes to the development of a model for preventing LGBT youth homelessness that other communities can replicate. There are two communities participating in this initiative and both receive technical assistance (TA) to support their initiative planning (and later in the process, their initiative implementation).

At this time, both communities are in the midst of their strategic planning and we do not currently have information on the strategies they plan to implement starting in fall 2014. Hence, this request for OMB clearance only covers the first evaluation phase. This planning phase evaluation will document how the two participating communities have approached their local plan development. Furthermore, it will examine the resources required to carry out the planning process, what worked well, what challenges emerged and how they were addressed, and lessons learned. To produce this information, HUD will collect quantitative and qualitative data from primary sources using four methods: interviews, surveys, focus groups, and document review. Participants will consist of the local initiative leads as well as individuals involved in local initiative steering committees and subcommittees. Documents to be reviewed will not require new data collection—they are available through the ongoing TA to the two communities.

This first evaluation phase will focus on nine aspects of the planning process: (1) Role of local leads, (2) timeline; (3) needs assessment, (4) logic model; (5) local plan development; (6) role of steering committee; (7) role of subcommittees; (8) community involvement; and (9) technical assistance supports. These areas were chosen to better understand development of the local plans, including learned lessons, overall strengths/assets, and weaknesses/challenges of the planning phase. A separate OMB clearance request will be submitted as part of the second evaluation phase, which will examine

each community's implementation of their local plans.

Respondents (i.e. affected public): Organizations participating in the two local initiatives, including local lead organizations and participants on the local steering committees and subcommittees.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Planning Phase Interview: Local leads, steering committee members, and subcommittee members (n=96)	13	1	1	1	13	$25.46	$331
Planning Phase Focus Group: Local leads, steering committee members, and subcommittee members (n=96)	24	1	1	1	24	25.46	611
Planning Phase Survey: Local leads, steering committee members, and subcommittee members (n=96)	110	1	1	.25	27.5	25.46	700
Total	110	1	1	.25–1	64.5	25.46	1,642

*$25.46 is a GS–11 equivalent hourly cost. Hourly cost per response will vary at participating nonprofit and local government offices.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: September 22, 2014.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2014–23120 Filed 9–26–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5752–N–81]

30-Day Notice of Proposed Information Collection: Closeout Instructions for Community Development Block Grant (CDBG) Programs Grants

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date: October 29, 2014.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email at *Colette Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 25, 2014.

A. Overview of Information Collection

Title of Information Collection: Closeout Instructions for Community Development Block Grant (CDBG) Programs Grants.

OMB Approval Number: 2506–0193.

Type of Request: Extension of a currently approved collection.

Form Number: Notice CPD–14–02 Includes HUD Forms: 40151, 40152, 40153, 40154, 40155, 40156, 40157, 40158, 40159, 40161, 40164, 40175, 40176, 40177, 40178, 40179, 40180, 40181, 40182, 40183, and 40184.

Description of the need for the information and proposed use: This information collection is being conducted by CPD Office of Block Grant Assistance to assist the Administrator of HUD in determining, as required by Section 104 (e) of the (HCDA) of 1974, and outlined in Subpart I (for States) and Subpart J (for entitlements) of the CDBG regulation, whether Grantees, have carried out eligible activities and its certifications in accordance with the statutory and regulatory requirements governing State CDBG, CDBG–R, Disaster Recovery, NSP1, NSP2 and NSP3 grants prior to closing the grant allocation.

Respondents (i.e. affected public): Entitlement communities, Nonprofits, States and units of general local governments.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Total	3,088	Once during the grant	204.5	17	738.5	$24.10	$17,797.85

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: September 22, 2014.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2014–23119 Filed 9–26–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5752–N–80]

30-Day Notice of Proposed Information Collection: Housing Opportunities for Persons With AIDS (HOPWA) Program: Annual Grantee Performance Reporting Requirements and Competitive/Renewal Grant Project Budget Summary

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date: October 29, 2014.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA__Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email at *Colette Pollard@hud.gov* or telephone 202–402–3400. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 25, 2014.

A. Overview of Information Collection

Title of Information Collection: Housing Opportunities for Persons With AIDS (HOPWA) Program: Annual Grantee Performance Reporting Requirements and Competitive/Renewal Grant Project Budget Summary.

OMB Approval Number: 2506–0133.

Type of Request: Extension of a currently approved collection, without change.

Form Number: HUD–40110–B, HUD–40110–C; and HUD–40110–D.

Description of the need for the information and proposed use: The HOPWA Competitive Application and Renewal of Permanent Supportive Housing Project Budget Summary, HUD–40110–B, is a grant applicant submission requirement for new competitive grant applications solicited through a Notice of Funding Availability (NOFA) and for all annual expiring renewal grant reviews. The budget form enables an evaluation of competitive grant applications to determine if the proposed project activity is feasible within the context of the overall program design inclusive of proposed planned and actual accomplishments. The Annual Progress Report (APR), HUD–40110–C, for competitive grantees, and the Consolidated Annual Performance and Evaluation Report (CAPER), HUD–40110–D, for formula grantees, are critical reporting requirements necessary to aggregate individual and national performance data, both program output data and program beneficiary outcomes to inform HUD's strategic management plan goals including requested reports to Congress. The data collection informs local communities on the use of these federal resources and in planning and coordination with other leveraged and available resources.

Respondents: HOPWA program formula and competitive grant recipients and competitive/renewal grant applicants.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD–40110–B	35	annual	1	12	420	40	$16,800
HUD–40110–C	92	annual	1	56	5,152	40	206,080
HUD–40110–D	126	annual	1	42	5,292	40	211,680
Total	253	annual	1		10,864		434,560

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: September 22, 2014.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2014–23122 Filed 9–26–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5753–N–08]

60-Day Notice of Proposed Information Collection: Survey Questions for Small Contractor Marketplace

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date: November 28, 2014.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: James Baltazar, Management Analyst, FPM, Department of Housing and Urban Development, 920 Second Avenue South, Suite 1300; email James Baltazar at *james.a.baltazar@hud.gov* or telephone 612–370–3000. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Survey Form for Small Contractor Initiative.

OMB Approval Number: N/A.

Type of Request: New.

Description of the need for the information and proposed use: Survey collection form for the Small Contractor Initiative. HUD is partnering with the U.S. Small Business Administration (SBA) and BusinessUSA to promote the HUD Small Contractor Initiative through the BusinessUSA FBOpen Web site. The Web site will be used by HUD and other federal agencies to notify small contractors for bid opportunities nationwide in one place online. Surveys will be collected from grantees in the BusinessUSA online system and follow-up user surveys for different user groups such as HUD grantees, contracting companies, lenders, surety bond agents, and business counseling organizations.

Respondents: State, local, and tribal governments. HUD grantees, contracting companies, lenders, surety bond agents, and business counseling organizations.

Estimated Number of Respondents: 5,000.

Estimated Number of Responses: 20,000.

Frequency of Response: 4.

Average Hours per Response: 1.

Total Estimated Burdens: 20,000.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Survey Form	5,000	4	20,000	1	20,000	$0	$0
Total	5,000	4	20,000	1	20,000	$0	$0

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

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

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: September 22, 2014.

Clifford Taffet,

General Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2014–23116 Filed 9–26–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5763–N–09]

Implementation of the Privacy Act of 1974, as Amended; New System of Records Notice, Digital Identity Access Management System

AGENCY: Office of the Chief Information Officer.

ACTION: Notification.

SUMMARY: Pursuant to the Privacy Act of 1974 (U.S.C. 552a (e)(4)), as amended, and Office of Management and Budget (OMB), Circular No. A–130, notice is hereby given that the Department of Housing and Urban Development (HUD), Office of the Chief Information Officer (OCIO) proposes to establish a new system of records, the Digital Identity Access Management System (DIAMS). DIAMS will manage core digital identification, credential and access management (ICAM) data elements. The system will support the administration of the Homeland Security Presidential Directive 12 (HSPD–12) program that directs the use of a common identification credential for both logical and physical access to Federally controlled facilities and information systems. This system will enhance security, increase efficiency, protect personal privacy, and provide synchronization of core identity management data for Departmental systems.

DATES: *Effective Date:* This action shall be effective without further notice on October 29, 2014 unless comments are received that would result in a contrary determination.

Comments Due Date: October 29, 2014.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Room 10276, Washington, DC 20410–0500. Communication should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: Donna Robinson-Staton, Chief Privacy Officer, 451 Seventh Street SW., Washington, DC 20410 (Attention: Capitol View Building, 4th Floor), telephone number: (202) 402–8073. [The above telephone number is not a toll free number.] A telecommunications device for hearing- and speech-impaired persons (TTY) is available by calling the Federal Information Relay Service's toll-free telephone number (800) 877–8339.

SUPPLEMENTARY INFORMATION: This system of records is maintained by HUD's Office of the Chief Information Officer, and includes users of HUD's information technology personally identifiable information that is retrieved by a name or unique identifier. The new system encompasses programs and services of the Department's data collection and management practices. Publication of this notice allows HUD to satisfy its reporting requirement and keep an up-to-date accounting of its system of records publication. The new system proposal will incorporate Federal privacy requirements and HUD policy requirements. The Privacy Act provides certain safeguards for an individual against an invasion of personal privacy by requiring Federal agencies to protect records contained in an agency system of records from unauthorized disclosure, by ensuring that information is current and collected only for its intended use, and by providing adequate safeguards to prevent misuse of such information. Additionally, this notice demonstrates the Department's focus on industry best practices in protecting the personal privacy of the individuals covered by each system notification. This notice states the name and location of the record system, the authority for and manner of its operations, the categories of individuals that it covers, the type of records that it contains, the sources of the information for those records, the routine uses made of the records, and the type of exemption in place for the records. In addition, this notice includes the business address of the HUD officials who will inform interested persons of the procedures whereby they may gain access to and/or request amendments to records pertaining to them.

This publication does meet the threshold requirements for a new system and a report was submitted to the Office of Management and Budget (OMB), the Senate Committee on Homeland Security and Governmental Affairs, and the House Committee on Government Reform as instructed by Paragraph 4c of Appendix l to OMB Circular No. A–130, ''Federal Agencies Responsibilities for Maintaining Records About Individuals,'' July 25, 1994 (59 FR 37914).

Authority: 5 U.S.C. 552a; 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: September 19, 2014.

Rafael C. Diaz,

Chief Information Officer.

[Docket No. FR–5763–N–09]

SYSTEM OF RECORDS NO.:

OCIO/QN.01

SYSTEM NAME:

Digital Identity Access Management System (DIAMS)—P281

SYSTEM LOCATION:

U.S. Department of Housing and Urban Development, 451 Seventh Street SW., Washington DC 20410; Hewlett-Packard Enterprise Services, Building 6000, 2020 Union Carbide Drive, South Charleston, WV 25303. Backup, recovery, and archived digital media is stored in secure facilities located with Iron Mountain, 1545 Hansford St., Charleston, WV 25311. The DIAMS is accessible from all systems connected to the HUD Intranet nationwide at HUD Field and Regional offices. [1]

SECURITY CLASSIFICATION:

Most identity records are not classified. However, in some cases, records of a few individuals, or portions of some records, may potentially be classified in the interest of national security.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The following are covered by the DIAMS: all users of HUD information technology systems including HUD employees and supporting contractors, students, interns, volunteers; affiliates of, and users from, State and local governments, non-profit organizations, academia, and third party business partners. The system does not apply to occasional visitors or short-term guests to whom HUD will issue temporary identification and credentials.

CATEGORIES OF RECORDS IN THE SYSTEM:

DIAMS will collect and store the First Name, Last Name, Address, City, State, Country, Date of Birth, Social Security Number, Agency Rank, Agency, U.S. Citizen Status, User Principal Name (UPN), AD Identifier, Distinguished Name, Common Name, Display Name, User Password, Email Address and Unique User ID (e.g., H or C ID numbers).

[1] *http://portal.hud.gov/hudportal/HUD?src=/localoffices*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for maintenance of the system and authorizes the collection of information is the Federal Information Processing Standards, 201 Personal Identity Verification (PIV) of Federal Employees and Contractors (44 U.S.C. 3542(b)(2)). Other governing laws and regulations for managing and processing Federal credentials are as follows: 5 U.S.C. 301; Federal Information Security Act (P.L.104–106, sec. 5113); Electronic Government Act (P.L. 104–347, sec. 203); Paperwork Reduction Act of 1995 (44 U.S.C. 3501); Government Paperwork Elimination Act (P.L. 105–277, 44 U.S.C. 3504); Homeland Security Presidential Directive 12 (HSPD–12), Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004; and Federal Property and Administrative Act of 1949, as amended OMB Circular No. A–130, Management of Federal Information Resources (11/28/2000) and Federal Agency Responsibilities for Maintaining Records about Individuals, dated June 25, 1993 (58 FR 36075, July 2, 1993); OMB Memo M–05–24, Federal Information Systems Management Act of 2002; and Executive Order—Improving Critical Infrastructure Cyber Security (February 12, 2013).

PURPOSE(S):

DIAMS will provide centralized, automated functionality to manage the many digital identities that interact with HUD's information technology environment. DIAMS will provide a central repository and web-based portal that stores and allows central management of core digital identification, credential and access management (ICAM) data elements. DIAMS captures and stores information about persons and non-person entities that are granted access into HUD's business applications. DIAMS also provides HUD with a platform to centrally and actively manage the identity life-cycle of persons and non-person entities from account creation through account removal. DIAMS will integrate with HUD's authoritative data sources including HUD's human resource management system, physical access control system including USAccess operated by the General Services Administration, personnel clearance system, and multiple internal Directory Services to ensure synchronization of identities across HUD's digital landscape. DIAMS will use batch files and IdM's (Identity Management's) connector to synchronize data from and to authorized data sources. The connection pipe will be secured with Public Key Infrastructure exchange. A feed from HUD's Human Resource (HR) system for employees and Sponsor initiation of Contractors in IdM will start the on-boarding process for a HUD Identity. The on-boarding process will require notifications to the responsible manager or sponsor during all stages of the workflow. During employment, application access will be requested through the IdM application provisioning and de-provisioning functions by authorized HUD personnel. When personnel are off-boarded, HR and Sponsors will initiate off-boarding disabling accounts and removing privileges.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. Section 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside HUD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To HUD contractors, grantees, or volunteers who have been engaged to assist the agency in the performance of a contract service, grant, cooperative agreement with HUD, when necessary to accomplish an agency function or other activity related to this system of records, limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under this routine use is subject to the same Privacy Act requirements and limitations on disclosure as are applicable to HUD officers and employees;

2. To appropriate agencies, entities, and persons to the extent such disclosures are compatible with the purpose for which the records in this system were collected, as set forth by Appendix I [2]—HUD's Library of Routine Uses published in the **Federal Register** on (77 FR 41996, July 17, 2012);

3. To USAccess operated by the General Services Administration, personnel clearance system, and multiple internal Directory Services to ensure synchronization of identities across HUD's digital landscape. DIAMS will share UPN and Email with USAccess;

4. To appropriate agencies, entities, and persons when: a) HUD suspects or has confirmed that the security or confidentiality of information in a system of records has been compromised; b) HUD has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of systems or programs (whether maintained by HUD or another agency or entity) that rely upon the compromised information; and c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm for purposes of facilitating responses and remediation efforts in the event of a data breach;

5. To the National Archives and Records Administration (NARA) or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906; and

6. To other agencies to notify them when a PIV Card is no longer valid. The full system of records notice covering categories of DIAMS with complete description of other routine uses was published in the Federal Register: GSA GOVT–7, Federal Personal Identity Verification Identity Management System (PIV IDMS), 71 FR 56983 (September 28, 2006).

STORAGE:

All data are stored at a secured data center on the production DIAMS database servers. Backup, recovery and archived digital media is stored in secure facilities located with Iron Mountain. There are no hardcopy records produced that require additional storage.

RETRIEVABILITY:

Personnel information within the system is retrieved based on Name, Date of Birth and Social Security Numbers (SSNs), HUD Network ID, Home Address, U.S. Citizenship. There are no hardcopy records produced that require additional retrieval.

SAFEGUARDS:

The data in DIAMs records are backed up regularly in accordance with HUD policy 4.3.9 as documented in HUD Handbook 2400.25 Rev.3, August 2013. Strict access controls are governed for electronic records by the use of a user ID and password that require authentication before access is granted to DIAMS. Multi-factor authentication, once implementation is completed will require the use of PIV cards to access the system. Personnel who have access to the data are vetted by Personnel Security Division prior to being granted

[2] *http://portal.hud.gov/hudportal/documents/huddoc?id=append1.pdf*

access to systems where sensitive Personally Identifiable Information (PII) resides, are provided PII training, and have access to all policies regarding PII and its safeguarding requirements. All database systems are housed in a secure data center that is protected by security personnel. Accessing computer systems within the data center requires appropriate credentials to physically enter the facility and access the systems. All data is protected via encryption both at rest and in motion. There are no hardcopy records produced that require additional protections.

RETENTION AND DISPOSAL:

Records retention and disposal are per Policy in HUD Handbook 2225.6 Rev 1 HUD Records Disposition Schedules Handbook (2225.6) Under General Records Schedule 24, Information Technology Operations and Management Records, Section 6—User Identification, Profiles, Authorizations, and Password Files. Section 6 requires that files be destroyed/deleted 6 years after the user account is terminated or password is altered, or when no longer needed for investigative or security purposes, whichever is later. Backup and Recovery digital media will be destroyed or otherwise rendered irrecoverable per NIST SP 800–88 ''Guidelines for Media Sanitization'' (September 2006). This complies with all Federal regulations. There are no hardcopy records produced that require additional archival.

SYSTEM MANAGER(S) AND ADDRESS:

Joseph Milazzo, Deputy Chief Information Officer for IT Operations, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4178, Washington, DC 20410.

NOTIFICATION AND RECORD ACCESS PROCEDURES:

For Information, assistance, or inquiries about the existence of records, contact the Donna Robinson-Staton, Chief Privacy Officer, 451 Seventh Street SW. Washington, DC 20410 (Attention: Capitol View Building, 4th Floor), telephone number: (202) 402–8073. Verification of your identity must include original signature and be notarized. Written request must include the full name, Social Security Number, date of birth, current address, and telephone number of the individual making the request.

CONTESTING RECORD PROCEDURES

The Department's rules for contesting contents of records and appealing initial denials appear in 24 CFR Part 16. Additional assistance may be obtained by contacting: U.S. Department of Housing and Urban Development, Chief Privacy Officer, 451 Seventh Street SW., Washington, DC 20410 or the HUD Departmental Privacy Appeals Officers, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street SW., Washington DC 20410.

RECORD SOURCE CATEGORIES

The source of DIAMS records are Internal and External both. Internally sourced records come from HUD's Human Resource Systems, HUD's Physical Access Control System commonly referred to as Hirsch Velocity, HUD's systems maintaining personnel security records, and HUD's multiple Directory Services including Active Directory. Externally sourced records are from the General Service Administration's USAccess system.

SYSTEMS EXEMPTED FROM CERTAIN PROVIOSIONS OF THE ACT

None.

[FR Doc. 2014–23117 Filed 9–26–14; 8:45 a.m.]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[XXXD5198NI DS61100000 DNINR0000.000000 DX61104]

Exxon Valdez Oil Spill Public Advisory Committee

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of renewal.

SUMMARY: The U.S. Department of the Interior announces the charter renewal of the Exxon Valdez Oil Spill Public Advisory Committee.

SUPPLEMENTARY INFORMATION: The Court Order establishing the Exxon Valdez Oil Spill Trustee Council also requires a public advisory committee. The Public Advisory Committee was established to advise the Trustee Council, and began functioning in October 1992. The Public Advisory Committee consists of 10 members representing the following principal interests: aquaculturists/mariculturists, commercial fishers, commercial tourism, recreation users, conservationists/environmentalists, Native landowners, sport hunters/fishers, subsistence users, scientists/technologists, and public-at-large. In order to ensure that a broad range of public viewpoints continues to be available to the Trustee Council, and in keeping with the settlement agreement, the continuation of the Public Advisory Committee is recommended.

In order to ensure that a broad range of public viewpoints continues to be available to the *Exxon Valdez* Oil Spill Trustee Council, and in keeping with the settlement agreement, the continuation of the *Exxon Valdez* Public Advisory Committee is recommended.

In accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C., App. 2), following the recommendation and approval of the *Exxon Valdez* Oil Spill Trustee Council, and in consultation with the General Services Administration, the Secretary of the Interior hereby renews the charter for the *Exxon Valdez* Oil Spill public Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Philip Johnson, Department of the Interior, Office of Environmental Policy and Compliance, 1689 C Street, Suite 119, Anchorage, Alaska, 99501–5126, 907–271–5011.

Certification Statement: I hereby certify that the renewal of the Charter Of The Exxon Valdez Oil Spill Public Advisory Committee is necessary and in the public interest in connection with the performance of duties mandated by the settlement of *United States v. State of Alaska,* No. A91–081 CV, and is in accordance with the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended and supplemented.

Dated: September 23, 2014.

Sally Jewell,

Secretary of the Interior.

[FR Doc. 2014–23125 Filed 9–26–14; 8:45 am]

BILLING CODE 4310–RG–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–WSFR–2014–N205; FVWF58520900000]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Coastal Impact Assistance Program

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on September 30, 2014. We 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. However, under OMB

regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before October 29, 2014.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail), or *hope_grey@fws.gov* (email). Please include ''1018–0147'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey at *hope_grey@fws.gov* (email) or 703–358–2482 (telephone). You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

Information Collection Request

OMB Control Number: 1018–0147.

Title: Coastal Impact Assistance Program.

Service Form Number: None.

Type of Request: Revision of a currently approved collection.

Number of Respondents: 73.

Description of Respondents: 6 States (Alabama, Alaska, California, Louisiana, Mississippi, and Texas) and 67 coastal political subdivisions in these States.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for amendments/changes to a project and other requests; annually for reports; and ongoing for recordkeeping.

Activity	Number of responses	Completion time per response (hours)	Total annual burden hours
Submit annual reports	479	8	3,832
Notify FWS in case of delays, adverse conditions, etc., that impair ability to meet objectives of an award	60	8	480
Request termination and supporting information	45	6	270
Maintain records	756	0.5	378
Telephone followup discussion on financial capabilities	100	8	800
Develop language and individual signage at CIAP Sites	100	8	800
Submission of photographs/CDs of projects for tracking purpose	250	4	1,000
Request changes and/or amendments to a project	192	42	8,064
TOTALS	1,982		15,624

Abstract: Section 384 of the Energy Policy Act of 2005 (Pub. L. 109–58) established the Coastal Impact Assistance Program (CIAP). This program provides Federal grant funds derived from Federal offshore lease revenues to oil-producing States for:

- Conservation, protection, or restoration of coastal areas, including wetlands;
- Mitigation of damage to fish, wildlife, or natural resources;
- Planning assistance and the administrative costs of complying with these objectives;
- Implementation of a federally approved marine, coastal, or comprehensive conservation management plan; and
- Mitigation of the impact of Outer Continental Shelf activities through funding of onshore infrastructure projects and public service needs.

The States of Alabama, Alaska, California, Louisiana, Mississippi, and Texas are eligible for CIAP funding. Also eligible to receive CIAP funds are 67 coastal political subdivisions (CPS) in the 6 States. The affected States have prepared Statewide CIAP plans that include proposed projects. The federally approved CIAP plans have also been coordinated through a public review process.

Once a project is approved, we must monitor the project to determine that the CIAP funds are being used for appropriate expenses. The monitoring will be achieved through the grant regulations that require grantees to provide, at a minimum, an annual progress report and a financial status report.

Comments Received and Our Responses

On July 25, 2014, we published in the **Federal Register** (79 FR 43503) a notice of our intent to request that OMB approve the collection of information associated with CIAP. We solicited comments for 60 days, ending on September 23, 2014. We received no comments.

Request for Public Comments

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: September 24, 2014.

Tina A. Campbell,

Chief, Division of Policy and Directives Management, U.S. Fish and Wildlife Service.

[FR Doc. 2014–23100 Filed 9–26–14; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L14200000.BK0000.LXSILITS0000; 14XL1109AF]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on October 29, 2014.

DATES: Protests of the survey must be filed before October 29, 2014 to be considered.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Blaise Lodermeier, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5128 or (406) 896–5007, *bloderme@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed by the direction of the Chief Cadastral Surveyor for Montana in response to litigation against the United States Government for Quiet Title. The survey was needed to identify the boundaries of Federal Interest lands and to determine if a title conflict existed with Amended Certificate of Survey 37, on file in the Treasure County Courthouse, Hysham, MT.

The lands we surveyed are:

Principal Meridian, Montana

T. 6 N., R. 35 E.

The plat, in one sheet, representing the dependent resurvey of a portion of the subdivisional lines and the adjusted original meanders of the former left bank of the Yellowstone River, through section 28 and the survey of the meanders of the present left bank of the Yellowstone River, through section 28, Township 6 North, Range 35 East, Principal Meridian, Montana, was accepted September 16, 2014.

We will place a copy of the plat, in one sheet in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in one sheet, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in one sheet, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals.

Authority: 43 U.S.C. Chap. 3.

Joshua F. Alexander,

Chief, Branch of Cadastral Survey, Division of Energy, Minerals and Realty.

[FR Doc. 2014–23087 Filed 9–26–14; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNML00000 L14300000.EQ0000 14XL1109AF]

Notice of Temporary Closure of Public Land in Doña Ana County, NM

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: As authorized under the provisions of the Federal Land Policy and Management Act of 1976 and Bureau of Land Management (BLM) regulations, certain public land near Doña Ana International Jetport in Santa Teresa, New Mexico, will be temporarily closed to all public use to provide for public safety during the Amigo Airsho event to be held from October 29 through November 2, 2014.

DATES: The temporary closure period is October 29 through November 2, 2014.

FOR FURTHER INFORMATION CONTACT: David Wallace, Assistant District Manager, Multi-Resources Division, BLM Las Cruces District Office, 1800 Marquess Street, Las Cruces, New Mexico 88005; by telephone at 575–525–4393; or by email at *dwallace@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact Mr. Wallace during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question for Mr. Wallace. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This closure applies to all public use, including pedestrian use and vehicles on the affected public lands. The public lands affected by this closure are described as follows:

New Mexico Principal Meridian, New Mexico

T. 28 S., R. 2 E.,
Sec. 3, lot 1, SE¼NE¼, and SE¼;
Sec. 10, N½NE¼;
Sec. 11, NE¼, N½NW¼, E½SW¼NW¼, E½NW¼SW¼NW¼, E½SW¼SW¼NW¼, SE¼NW¼, NE¼NE¼SW¼, E½NW¼NE¼SW¼, NE¼SE¼, N½NW¼SE¼, and SE¼NW¼SE¼.

The area described aggregates 714.80 acres.

The closure notice and map of the closure area will be posted at the BLM Las Cruces District Office, 1800 Marquess Street, Las Cruces, New Mexico. Roads leading into the public land under the closure will be posted to notify the public of the closure. Under the authority of Section 303(a) of the Federal Lands Policy and Management Act of 1976 (43 U.S.C. 1733(a)), 43 CFR 8364.1 and 43 CFR 8360.0–7, the BLM will enforce the following use in the area described above: All public use, whether motorized, on foot, or otherwise, is prohibited.

Exceptions: Closure restrictions do not apply to event officials, medical and rescue personnel, law enforcement, and agency personnel monitoring the events.

Penalties: Any person not excepted who fails to comply with the closure order is subject to arrest and, upon conviction, may be fined not more than $1,000 and/or imprisonment for not more than 12 months under 43 CFR 8360.0–7. Violations may also be subject to the provisions of Title 18, U.S.C. sections 3571 and 3581.

Authority: 43 CFR 8364.1 and 8360.0–7.

Jesse J. Juen,

State Director.

[FR Doc. 2014–23072 Filed 9–26–14; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[XXXL8069TF LLUTC03000.L71220000.EU0000.LVTFJ0995850; UTU–90587]

Notice of Realty Action: Proposed Non-Competitive (Direct) Sale of Public Lands in Washington County, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: The Bureau of Land Management (BLM) is proposing a non-competitive (direct) sale of .44-acres in Washington County, Utah, at not less than the appraised value of $16,720 to the Ridgepointe Homeowners Association South, Inc., whose members own homes on the adjoining private land. The sale parcel will be offered pursuant to Section 203 and Section 209 of the Federal Land Policy and Management Act of 1976 and the applicable BLM land-sale regulations.

DATES: Interested parties may submit written comments regarding the proposed sale of public land until November 13, 2014. The public sale would not occur prior to November 28, 2014. Comments may be mailed, hand delivered, or faxed to 435–688–3252. Telephone calls and email will not be accepted.

ADDRESSES: Submit written comments to the BLM, St. George Field Office, Field Manager, 345 E. Riverside Drive, St. George, UT 84790.

FOR FURTHER INFORMATION CONTACT: Teresa Burke by email: *tsburke@blm.gov,* or by telephone: 435–688–3326. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to leave a message or question for the above individual. The FIRS is available 24 hours a day, 7 days a week. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM proposes to offer for direct sale the following described public land:

Salt Lake Meridian, Utah

T. 42 S., R. 15 W.,
Sec. 13, lots 6 and 7.
The area described aggregate .44-acres.

This direct sale is in conformance with the St. George Resource Management Plan (RMP), approved in March 1999. The parcel is identified for disposal in the RMP Record of Decision (decision LD–06), and is not needed for any other Federal purpose. The sale parcel was analyzed in a site-specific Environmental Analysis numbered DOI–BLM–UT–C030–2011–0005–EA. The parcel is being offered as a direct sale to Ridgepointe Homeowners Association South, Inc., in order to resolve inadvertent development by multiple homeowners on a 20-foot strip of public land that adjoins the Ridgepointe Subdivision. The BLM found the unauthorized use when preparing the adjoining BLM acreage for a competitive sale. The .44-acre parcel is the smallest legal subdivision that would wholly encompass the unauthorized improvements. 43 CFR 2711.3–3(a) provides for a direct sale to protect the existing equities or where there is a need to resolve an inadvertent unauthorized use or occupancy of the land. A mineral potential report concluded the parcel contains no known mineral values; therefore, the mineral interest would be conveyed with the surface. Revenue from the sale would be deposited in the Washington County Land Acquisition Account, pursuant to the Omnibus Public Land Management Act of 2009, Subtitle O.

The conveyance documents for the parcel identified above will contain the following reservations, terms, and conditions:

1. A right-of-way reservation for ditches or canals constructed by authority of the United States under the Act of August 30, 1890 (43 U.S.C. 945).
2. The conveyance will be subject to all valid existing rights of record.
3. An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy, or occupations on the patented land.

On publication of this notice and until completion of the sale, the BLM is no longer accepting land use applications affecting the parcel identified for sale. The parcel was segregated for a 2-year period from appropriation under the public land and mining laws on August 7, 2012 (77 FR 47090). Publication of this notice serves to extend the segregation period for an additional 2 years pursuant to 43 CFR 2711.1–2(d). On July 1, 2014, the State Director determined in writing that this extension is necessary in order to provide adequate time to complete the land sale process.

Information concerning the sale, including the appraisal, planning and environmental documents, and mineral report are available for review during business hours, 7:30 a.m. to 4:30 p.m., Mountain Time, Monday through Friday, at the BLM, St. George Field Office, except during Federal holidays.

Before including an address, phone number, email address, or other personal identifying information in any comment, be aware that your entire comment, including any personal identifying information may be made publicly available at any time. Requests to withhold personal identifying information from public review can be submitted, but the BLM cannot guarantee that it will be able to do so.

Any adverse comments regarding the proposed sale will be reviewed by the BLM Utah State Director or other authorized official of the Department of the Interior, who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, this realty action will become the final determination of the Department of the Interior.

Authority: 43 CFR 2710, 43 CFR 2711, and 43 CFR 2720.

Jenna Whitlock,
Associate State Director.

[FR Doc. 2014–23068 Filed 9–26–14; 8:45 am]
BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–IMR–LAMR–16172; PX.PD104097E.00.1]

Final Environmental Impact Statement for the General Management Plan, Lake Meredith National Recreation Area, Alibates Flint Quarries National Monument, Texas

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: The National Park Service announces the availability of the final environmental impact statement for the general management plan for Lake Meredith National Recreation Area and Alibates Flint Quarries National Monument. The general management plan will guide the management of the park units over the next 15 to 20 years.

DATES: The NPS will execute a record of decision no sooner than 30 days following publication by the Environmental Protection Agency of the notice of availability of the final environmental impact statement for the general management plan in the **Federal Register**.

ADDRESSES: Electronic copies of the final environmental impact statement and the draft environmental impact statement will be available online at *http://parkplanning.nps.gov/LAMR.* To request a hard copy, contact Superintendent Robert Maguire, 419 East Broadway, Fritch, Texas, 79036, (806) 857–0300.

FOR FURTHER INFORMATION CONTACT: Chief of Resources Arlene Wimer, P.O. Box 1460, Fritch, Texas, 79036; telephone (806) 857–0309.

SUPPLEMENTARY INFORMATION: We have prepared the final environmental impact statement for the general management plan (FEIS/GMP) and we are publishing this notice pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C). The final environmental impact statement for the

general management plan (FEIS/GMP) responds to and incorporates agency and public comments received on the draft EIS/plan, which was available for public review from March 29, 2013, through May 28, 2013. Two public meetings were held, one in Amarillo, Texas on April 30, 2013, and the other in Fritch, Texas on May 1, 2013, to gather input on the draft EIS/plan; 27 members of the public attended these meetings. We received approximately 25 comments during the public review period. Few of the comments were substantive and none required more than minor responses such as factual corrections. For this reason we have prepared an abbreviated final EIS that includes our response to comments and an errata sheet. This abbreviated FEIS/GMP and the text of the DEIS/GMP together constitute the Final EIS/GMP.

The FEIS/GMP evaluates three alternatives for managing Lake Meredith NRA and three alternatives for managing Alibates Flint Quarries NM. The NPS-preferred alternative for Lake Meredith NRA would promote both traditional and nontraditional uses, developing facilities and opportunities to address changing lake conditions and visitor uses. The national recreation area would become a destination for semi-primitive outdoor recreation opportunities and would strengthen partnerships to improve visitor experience.

The preferred alternative for Alibates Flint Quarries NM would provide a greater understanding and appreciation for archeological protection through enhanced educational opportunities and research. It also would accommodate a wider range of visitor uses and experiences by zoning part of the national monument for unrestricted visitor access by foot.

The responsible official for this FEIS/GMP is the Regional Director, NPS Intermountain Region, 12795 W Alameda Parkway, Lakewood, Colorado 80228.

Dated: September 11, 2014.

Sue E. Masica,

Regional Director, Intermountain Region, National Park Service.

[FR Doc. 2014–23038 Filed 9–26–14; 8:45 am]

BILLING CODE 4312–CB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–IMR–BITH–16171; PX.PD109246J.00.1]

Final Environmental Impact Statement for General Management Plan, Big Thicket National Preserve, Texas

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability.

SUMMARY: The National Park Service announces the availability of the Final Environmental Impact Statement for the general management plan for Big Thicket National Preserve. Consistent with NPS laws, regulations, and policies and the purpose of the parkway, the general management plan will guide the management of the park over the next 15–20 years.

DATES: The NPS will sign a Record of Decision no sooner than 30 days following publication of the Environmental Protection Agency of its Notice of Availability of the general management plan in the **Federal Register**.

ADDRESSES: Electronic copies of the general management plan will be available online at *http://parkplanning.nps.gov/BITH.* To request a copy, contact Superintendent Doug Neighbor, 6044 FM 420, Kountze, TX 77625, 409–951–6801, and at the following location: Fire Management Office, 860 CR 1040, Woodville, TX 75997.

FOR FURTHER INFORMATION CONTACT: Superintendent Doug Neighbor, Big Thicket National Preserve, 6044 FM 420, Kountze, TX 77625; telephone (409) 951–6801.

SUPPLEMENTARY INFORMATION: We have prepared the final environmental impact statement for the general management plan (FEIS/GMP) and we are publishing this notice pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C). The FEIS/GMP responds to, and incorporates, agency and public comments received on the draft EIS/plan, which was available for public review from May 3, 2013, through July 1, 2013. Three public meetings were held from May 14–16, 2013, to gather input on the draft EIS/plan. The meetings were held at the preserve visitor center in Kountze, Texas, and in Woodville and Beaumont, Texas. There were 16 pieces of correspondence received during the public review period. The NPS responses to substantive agency and public comments are provided in ''Chapter 5: Consultation and Coordination'' of the FEIS/GMP.

The FEIS/GMP evaluates four alternatives for managing use and development of the park. The preferred alternative (alternative 2) would expand opportunities for diverse, low-impact visitor activities by increasing the number of hiking and water-based trails and access points, especially on the newly acquired lands and linking existing trails to trails in the park. Natural resource management activities would focus on minimizing the effects of habitat fragmentation using a number of techniques including fire management, voluntary actions for oil and gas operations in the preserve, and land management agreements with partners. Partnerships are important for implementation of the preferred alternative including protection of natural flow regimes, preventing illegal dumping and other illegal activities as well as noncompatible land uses, and encouraging compatible resource management approaches. Infrastructure development is focused on providing access into the preserve and making existing facilities more sustainable. When approved, the plan will guide the management of the park over the next 15 to 20 years.

The responsible official for this FEIS/GMP is the Regional Director, NPS Intermountain Region, 12795 W Alameda Parkway, Lakewood, Colorado 80228.

Dated: September 11, 2014.

Sue E. Masica,

Regional Director, Intermountain Region, National Park Service.

[FR Doc. 2014–23039 Filed 9–26–14; 8:45 am]

BILLING CODE 4312–CB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–16712;PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before September 5, 2014. Pursuant to § 60.13 of 36 CFR Part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National

Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th Floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by October 14, 2014. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: September 17, 2014.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

CONNECTICUT

Hartford County

Hartford National Bank and Trust, 777 Main & 33 Asylum Sts., Hartford, 14000867

MINNESOTA

Houston County

Hokah Municipal Building, (Federal Relief Construction in Minnesota MPS AD) 57 Main St., Hokah, 14000868

Renville County

Sacred Heart Public School, 100 Elm St., Sacred Heart, 14000869

MISSOURI

Boone County

Sigma Alpha Epsilon Building, 24 E. Stewart Rd., Columbia, 14000870

Greene County

McDaniel Building, 316 Park Central E., Springfield, 14000871

Jasper County

Sarcoxie Public Square Historic District, Along 5th, 6th, Center & Cross Sts., Sarcoxie, 14000872

NEW YORK

Kings County

Nassau Brewing Company, 925–949 Bergan & 1024 Dean Sts., Brooklyn, 14000873

Richmond County

Building at One Pendleton Place, 1 Pendleton Pl., Staten Island, 14000874

OREGON

Multnomah County

Heathman Hotel, (Downtown Portland, Oregon MPS) 723 SW. Salmon St., Portland, 14000879

SOUTH CAROLINA

Richland County

Columbia Commercial Historic District, Portions of Main, Blanding, Taylor & Sumter Sts., Columbia, 14000875

WISCONSIN

La Crosse County

Funke, Joseph B., Company, 101 State St., La Crosse, 14000876

Manitowoc County

FLORETTA (canaller) Shipwreck, (Great Lakes Shipwreck Sites of Wisconsin MPS) 11 mi. SE. of Manitowac, Centerville, 14000877

Milwaukee County

Square D Company—Industrial Controller Division, 710 S. 3rd St., Milwaukee, 14000878

A request for removal has been received for the following properties:

INDIANA

Pulaski County

Pulaski County Bridge No. 31, Cty. Rd. 1175 W., Medaryville, 03000546

IOWA

Carroll County

Coon Rapids Bridge, (Highway Bridges of Iowa MPS) Sumpter Ave. over Middle Raccoon R., Coon Rapids, 98000745

Des Moines County

Flint River Bridge, (Highway Bridges of Iowa MPS) 155th St. over Flint R., Burlington, 98000792

Keokuk County

Hayesville Independent School, 231 Washington St., Hayesville, 90001195

Winneshiek County

Turkey River Bridge, (Highway Bridges of Iowa MPS) Little Church Rd. over Turkey R. Festina, 98000468

OREGON

Lincoln County

TRADEWINDS KINGFISHER (cruiser), Depoe Bay Boat Basin, Depoe Bay, 91001562

[FR Doc. 2014–23040 Filed 9–26–14; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–16668; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before August 30, 2014. Pursuant to § 60.13 of 36 CFR Part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th Floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by October 14, 2014. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: September 15, 2014.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

ARIZONA

Pima County

Tucson Community Center Landscape, 180–260 S. Church Ave., Tucson, 14000850

CALIFORNIA

Riverside County

Luiseno Ancestral Origin Landscape, Address Restricted, Temecula, 14000851

San Luis Obispo County

Morro Bay State Park Trailer and Tent Campground, (National-State Cooperative Program and the CCC in California State Parks MPS) 20 State Park Rd., Morro Bay, 14000852

COLORADO

Gilpin County

Winks Panorama (Boundary Increase), 213 Winks Way, Pinecliffe, 14000853

DISTRICT OF COLUMBIA

District of Columbia

Terminal Refrigerating and Warehouse Company, 300 D St. SW., Washington, 14000854

IOWA

Cerro Gordo County

East Park Historic District, Roughly bounded by the Winnebago R., N. Carolina, N. Kentucky & N. Virginia Aves., CPRR tracks, E. State St., Mason City, 14000855

Parker's Woods Park Historic District, N. Jackson Ave. between 1st & 4th Sts. NW., Mason City, 14000856

KANSAS

Gray County

Soule Canal—Gray County Segment 1, (Soule Canal MPS) Between US 400/50 & Soule Ave., Ingalls, 14000857

Soule Canal—Segment 2, (Soule Canal MPS) N. side of US 400/50, Ingalls, 14000858

NEW MEXICO

Bernalillo County

Atchison, Topeka and Santa Fe Railway Locomotive Shops, (Central Albuquerque MPS) Roughly bounded by BNSF RR, 1st & 2nd Sts., Albuquerque, 14000859

NEW YORK

Albany County

New York State Barge Canal, NYS Barge Canal, Waterford to Tonawanda, Whitehall, Oswego & Waterloo, Cohoes, 14000860

Franklin County

U.S. Inspection Station—Chateaugay, New York, (U.S. Border Inspection Stations MPS) NY 374, Chateaugay, 14000861

UTAH

Box Elder County

Anderson, George and Mabel, House, 63 N. 200 East, Brigham City, 14000862

Salt Lake County

Murray Hillside Historic District, (Murray City, Utah MPS) Roughly bounded by 5300 South, Kenwood Dr., 5600 South & 235 East, Murray, 14000863

Sanpete County

Shomaker, Ezra and Abigail, House, 194 W. 400 North, Manti, 14000864

VIRGINIA

Loudoun County

Ashburn Historic District, Ashburn Rd. between former African American School & Partlow Rd., Ashburn, 14000865

WISCONSIN

Manitowoc County

MAJOR ANDERSON (barkentine) Shipwreck, (Great Lakes Shipwreck Sites of Wisconsin MPS) Lake Michigan near mouth of Molash Cr., Two Rivers, 14000866

[FR Doc. 2014–23041 Filed 9–26–14; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–16518; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate a Cultural Item: U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior, Bureau of Indian Affairs, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, has determined that the cultural item listed in this notice meets the definition of unassociated funerary object. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request to the U.S. Department of the Interior, Bureau of Indian Affairs. If no additional claimants come forward, transfer of control of the cultural item to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to the U.S. Department of the Interior, Bureau of Indian Affairs at the address in this notice by October 29, 2014.

ADDRESSES: Anna Pardo, Museum Program Manager/NAGPRA Coordinator, U.S. Department of the Interior, Bureau of Indian Affairs, 12220 Sunrise Valley Drive, Room 6084, Reston, VA 20191, telephone (703) 390–6343, email *Anna.Pardo@bia.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate a cultural item under the control of the U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC that meets the definition of unassociated funerary object under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural item. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item

At an unknown date in the 1930s or 1940s, one cultural item was taken from a cemetery in the village of Sikort Chuapo in the Pozo Redondo Valley, Hickiwan District of the Tohono O'odham Nation in Pima County, AZ. The item was donated to the Organ Pipe Cactus National Monument at an unknown date in the 1950s. During a review of the inventory, National Park Service staff became aware that the item was removed from the exterior of park boundaries and control of the item rests with the Bureau of Indian Affairs. The one unassociated funerary object is a stone doll that was removed from a child's grave.

Sikort Chuapo has been an established Tohono O'odham village dating back to the 1870s and likely earlier. It was common practice to place such objects on the graves of both adults and children. Based on catalog record of the object, its geographic origin, and the description of traditional territory of the tribe, these objects are believed to be culturally affiliated with the Tohono O'odham Nation of Arizona.

Determinations Made by the U.S. Department of the Interior, Bureau of Indian Affairs

Officials of the U.S. Department of the Interior, Bureau of Indian Affairs have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the one cultural item described above is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and is believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary object and Tohono O'odham Nation of Arizona.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to Anna Pardo, Museum Program Manager/NAGPRA Coordinator, U.S. Department of the Interior, Bureau of Indian Affairs, 12220 Sunrise Valley Drive, Room 6084, Reston, VA 20191, telephone (703) 390–6343, email *Anna.Pardo@bia.gov,* by October 29, 2014. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary object to Tohono O'odham Nation of Arizona may proceed.

The U.S. Department of the Interior, Bureau of Indian Affairs is responsible for notifying the Tohono O'odham Nation of Arizona that this notice has been published.

Dated: September 12, 2014.

Melanie O'Brien,

Acting Manager, National NAGPRA Program.

[FR Doc. 2014–23082 Filed 9–26–14; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX066A000 67F 134S180110; S2D2S SS08011000 SX066A00 33F 13xs501520]

Notice of Proposed Information Collection; Request Comments for 1029–0107

AGENCY: Office of Surface Mining Reclamation and Enforcement, Department of the Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request approval for the collection of information for its Subsidence insurance program grants. This collection request has been forwarded to the Office of Management and Budget (OMB) for review and comment. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collections but may respond after 30 days. Therefore, public comments should be submitted to OMB by October 29, 2014, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Department of the Interior Desk Officer, by telefax at (202) 395–5806 or via email to *OIRA_Submission@omb.eop.gov.* Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please refer to OMB Control Number 1029–0107 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review this collection request by going to *http://www.reginfo.gov* (Information Collection Review, Currently Under Review, Agency is Department of the Interior, DOI–OSMRE).

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), 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)]. OSM has submitted a request to OMB to renew its approval of the collection of information contained in 30 CFR 887—Subsidence insurance program grants. OSM is requesting a 3-year term of approval for each information collection activity.

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 number for this collection is 1029–0107 and is codified at 30 CFR 887.10. Regulatory authorities are required to respond to this collection to obtain a benefit.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on June 24, 2014 (79 FR 35793). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR 887—Subsidence insurance program grants.

OMB Control Number: 1029–0107.

Summary: States and Indian tribes having an approved reclamation plan may establish, administer and operate self-sustaining State and Indian Tribe-administered programs to insure private property against damages caused by land subsidence resulting from underground mining. States and Indian tribes interested in requesting monies for their insurance programs would apply to the Director of OSM.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: States and Indian tribes with approved coal reclamation plans.

Total Annual Responses: 1.

Total Annual Burden Hours: 8.

Total Annual Non-Wage Costs: $0.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the addresses listed under **ADDRESSES**. Please refer to the appropriate OMB control number 1029–0107 in your correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: September 19, 2014.

Harry J. Payne,

Chief, Division of Regulatory Support.

[FR Doc. 2014–23167 Filed 9–26–14; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX066A000 67F 134S180110; S2D2S SS08011000 SX066A00 33F 13xs501520]

Notice of Proposed Information Collection; Request Comments for 1029–0054

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

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request approval for the collection of information for its Abandoned mine reclamation funds. This collection request has been forwarded to the Office of Management and Budget (OMB) for review and comment. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, public comments should be submitted to OMB by October 29, 2014, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Department of the Interior Desk Officer, by telefax at (202)

395–5806 or via email to *OIRA_Submission@omb.eop.gov.* Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203—SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please refer to OMB Control Number 1029–0054 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review this collection request by going to *http://www.reginfo.gov* (Information Collection Review, Currently Under Review, Agency is Department of the Interior, DOI–OSMRE).

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), 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)]. OSM has submitted a request to OMB to renew its approval of the collection of information contained in 30 CFR part 872—Abandoned mine reclamation funds. OSM is requesting a 3-year term of approval for each information collection activity.

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 number for this collection is 1029–0054 and is codified at 30 CFR 872.10. Regulatory authorities are required to respond to this collection to obtain a benefit.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on June 24, 2014 (79 FR 35794). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR 872—Abandoned mine reclamation funds.

OMB Control Number: 1029–0054.

Summary: 30 CFR 872 establishes a procedure whereby States and Indian tribes submit written statements announcing the State's/Tribe's decision not to submit reclamation plans and, therefore, not be granted AML funds.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: State and Tribal abandoned mine land reclamation agencies.

Total Annual Responses: 1.

Total Annual Burden Hours: 1.

Total Annual Non-Wage Costs: $0.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the addresses listed under **ADDRESSES**. Please refer to the appropriate OMB control number 1029–0054 in your correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: *September 19, 2014.*

Harry J. Payne,

Chief, Division of Regulatory Support.

[FR Doc. 2014–23169 Filed 9–26–14; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–931]

Certain Formatted Magnetic Data Storage Tapes and Cartridges Containing the Same Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on August 22, 2014, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Advanced Research Corporation of White Bear Lake, Minnesota. A supplement to the complaint was filed on September 8, 2014. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain formatted magnetic data storage tapes and cartridges containing the same by reason of infringement of certain claims of U.S. Patent No. 7,525,761 (''the '761 patent''); U.S. Patent No. 7,948,705 (''the '705 patent''); U.S. Patent No. 8,254,052 (''the '052 patent''); U.S. Patent No. 8,437,103 (''the '103 patent''); and U.S. Patent No. 8,542,457 (''the '457 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2014).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on September 23, 2014, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain formatted magnetic data storage tapes and cartridges containing the same by reason of infringement of one or more of claims 1–12 of the '761 patent; claims 1–5 and 9 of the '705 patent; claims 1, 2, 4–9,

11–15, 17, and 18 of the '052 patent; claims 1–6 of the '103 patent; and claims 1–6 and 10–12 of the '457 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Advanced Research Corporation, 4459 White Bear Parkway, White Bear Lake, MN 55110.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

International Business Machines Corp., New Orchard Road, Armonk, NY 10504.

Fujifilm Holdings Corporation, 7–3, Akasaka 9-chome, Minato-ku, Tokyo 107–0052, Japan.

Fujifilm Corporation, 7–3, Akasaka 9-chome, Minato-ku, Tokyo 107–0052, Japan.

Oracle Corporation, 500 Oracle Parkway, Redwood Shores, CA 94065.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: September 24, 2014.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2014–23094 Filed 9–26–14; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—The Open Group, L.L.C.

Notice is hereby given that, on September 8, 2014, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), The Open Group, L.L.C. ("TOG") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Specifically, Adservio, Paris, FRANCE; aicas GmbH, Karlsruhe, GERMANY; 24 Learning Beijing Hua Fang Ji Ye Technology Co., Ltd., Beijing, PEOPLE'S REPUBLIC OF CHINA; bitil.com, Avellino, ITALY; Central Bank of Republic of Turkey, Ankara, TURKEY; ECIS Consultants Limited, Oxford, UNITED KINGDOM; Enterprise Architects LTD, London, UNITED KINGDOM; Firebrand Training Limited, London, UNITED KINGDOM; Fujitsu Limited, Chiyoda-ku, JAPAN; Gelder Gringas and Associates, Ottawa, CANADA; Maryville Data Systems, Inc., St. Louis, MO; SE7Ti Serviços de Tecnologia da Informação, Rio de Janeiro, BRAZIL; Sierra Nevada Corporation, Sparks, NV; Silosmashers, Inc., Fairfax, VA, Technology Service Corporation, Turnbull, CT; Tonex, Inc., Dallas, TX; and Visual Paradigm, Kowloon, HONG KONG–CHINA, have been added as parties to this venture.

Also, 1Plug Corporation, Alameda, CA; Baker Hughes, Sugar Land, TX; Dirogsa, Lima, PERU; EA Fellows ApS, Dragor, DENMARK; Enterprise Architecture Consulting Ltd, Oxford, UNITED KINGDOM; Enterprise Architecture Solutions Ltd., London, UNITED KINGDOM; Gobuchi, Dubai, UNITED ARAB EMIRATES; Litmus Group (Pty) Ltd, Sydney, AUSTRALIA; Net Security Training Ltd, Wembley, UNITED KINGDOM; Novay, Enschede, THE NETHERLANDS; Raymond James, St. Petersburg, FL; Standard Insurance Company, Portland, OR; and VisioTech Solutions Pvt. Ltd., Bahawalpur, PAKISTAN, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and TOG intends to file additional written notifications disclosing all changes in membership.

On April 21, 1997, TOG filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 13, 1997 (62 FR 32371).

The last notification was filed with the Department on June 16, 2014. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 3, 2014 (79 FR 38071).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2014–23146 Filed 9–26–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance; Correction

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice; correction.

SUMMARY: The Employment and Training Administration (ETA) published in the **Federal Register** on Thursday, September 11, 2014, an announcement of investigation regarding eligibility to apply for workers adjustment assistance (Vol. 79, No. 176, page 54291, see *http://www.gpo.gov/fdsys/pkg/FR-2014-09-11/pdf/2014-*

21626.pdf). The announcement included Trade Adjustment Assistance petitions instituted between 8/11/14 and 8/15/14. This notice corrects the subject firm name and date of institution for Pixel Corporation, Woodland Hills, CA (TA–W–83,367) to read Pixel Playground and 04/23/2013.

No other corrections are made, and the remainder of the notice and appendix that published on September 11, 2014, remains the same.

DATES: This Notice is effective on September 11, 2014.

FOR FURTHER INFORMATION CONTACT: Please contact Mike Jaffe, Department of Labor, Employment and Training Administration, Office of Trade Adjustment Assistance, 200 Constitution Avenue NW., Room N–5428, Washington, DC 20210.

Signed at Washington, DC, this 23rd day of September 2014.

Michael W. Jaffe,

Certifying Officer, Office of the Trade Adjustment Assistance.

[FR Doc. 2014–23079 Filed 9–26–14; 8:45 am]

BILLING CODE 4510–FN–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting

DATE AND TIME: The Legal Services Corporation's Institutional Advancement Committee will meet telephonically on October 1, 2014. The meeting will commence at 5:00 p.m., ET, and will continue until the conclusion of the Committee's agenda.

LOCATION: John N. Erlenborn Conference Room, Legal Services Corporation Headquarters, 3333 K Street NW., Washington DC 20007.

PUBLIC OBSERVATION: Members of the public who are unable to attend in person but wish to listen to the public proceedings may do so by following the telephone call-in directions provided below.

CALL-IN DIRECTIONS FOR OPEN SESSIONS:

- Call toll-free number: 1–866–451–4981;
- When prompted, enter the following numeric pass code: 5907707348
- When connected to the call, please immediately ''MUTE'' your telephone. Members of the public are asked to keep their telephones muted to eliminate background noises. To avoid disrupting the meeting, please refrain from placing the call on hold if doing so will trigger recorded music or other sound. From time to time, the presiding Chair may solicit comments from the public.

STATUS OF MEETING: Open, except that, upon a vote of the Board of Directors, the meeting may be closed to the public for an update on the 40th anniversary conference. A verbatim transcript will be made of the closed session meeting of the Institutional Advancement Committee. The transcript of any portion of the closed session falling within the relevant provision of the Government in the Sunshine Act, 5 U.S.C. 552b(c), will not be available for public inspection. A copy of the General Counsel's Certification that, in his opinion, the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

Open

1. Consider and act on agenda
2. Wrap-up report on September 40th Anniversary Conference
3. Communications Subcommittee Report
   - Julie Reiskin, Chairman, Communications Subcommittee
   - Carl Rauscher, Director of Communications and Media Relations
4. Public Comment
5. Consider and act on other business

Closed

6. 40th Anniversary conference follow-up
7. Consider and act on adjournment of meeting

CONTACT PERSON FOR INFORMATION: Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1500. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

ACCESSIBILITY: LSC complies with the Americans with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals who need other accommodations due to disability in order to attend the meeting in person or telephonically should contact Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: September 24, 2014.

Katherine Ward,

Executive Assistant to the Vice President & General Counsel.

[FR Doc. 2014–23205 Filed 9–25–14; 11:15 am]

BILLING CODE 7050–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Notice of Meeting

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 2–4, 2014, 11545 Rockville Pike, Rockville, Maryland.

Thursday, October 2, 2014, Conference Room T2–B1, 11545 Rockville Pike, 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.–9:45 a.m.: Discussion of Topics for Meeting with the Commission (Open) Discussion of the following topics in preparation for the meeting with the Commission.

- Overview
- Human Reliability Analysis Models
- Biennial Review of the NRC Safety Research Program
- Proposed Revision to 10 CFR 50.55a and Digital Instrumentation and Control
- SECY–14–XXXX, ''Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses''

10:00 a.m.–12:00 p.m.: Meeting with the Commission, Commissioner's Conference Room, 1st Floor, One White Flint North (Open) Meeting with the Commission to discuss topics of mutual interest.

1:00 p.m.–3:00 p.m.: Callaway Plant, Unit 1, License Renewal Application (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff and Ameren regarding the final safety evaluation report associated with the Callaway Plant, Unit 1, license renewal application.

3:15 p.m.–6:00 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

Friday, October 3, 2014, Conference Room T2–B1, 11545 Rockville Pike, 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.–9:45 a.m.: Clarification of the Process for Addressing Reevaluated Flooding Hazards Identified from Japan

Lessons Learned Activities for Operating Nuclear Power Plants (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff regarding the clarification of the process for addressing reevaluated flooding hazards identified from Japan lessons learned activities for operating nuclear power plants.

10:00 a.m.–11:00 a.m.: Meeting with NRC Chairman, Allison M. Macfarlane (Open)—The Committee will meet with NRC Chairman, Allison M. Macfarlane, to discuss items of mutual interest.

11:15 a.m.–12:15 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS Meetings, and matters related to the conduct of ACRS business, including anticipated workload and member assignments. [**Note:** A portion of this meeting may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

12:15 p.m.–12:30 p.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

2:00 p.m.–3:00 p.m.: Assessment of the Quality of Selected NRC Research Programs—FY 2014 (Open)—The Committee will discuss the quality assessment of selected NRC research projects.

3:00 p.m.–6:00 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

Saturday, October 4, 2014, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–11:30 a.m.: Preparation of ACRS Reports (Open)—The Committee will continue its discussion of proposed ACRS reports.

11:30 a.m.–12:00 p.m.: Miscellaneous (Open)—The Committee will continue its discussion related to the conduct of Committee activities and specific issues that were not completed during previous meetings.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on November 8, 2013 (78 FR 67205–67206). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff (Telephone: 301–415–5844, Email: Quynh *Nguyen@nrc.gov*), five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. 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.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) Public Law 92–463, and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. 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. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr.resource@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/.*

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service 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 video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated: September 23, 2014.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 2014–23123 Filed 9–26–14; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2014–0001]

Sunshine Act Meeting Notice

DATE: Weeks of September 29, October 6, 13, 20, 27, November 3, 2014.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of September 29, 2014

Thursday, October 2, 2014

10:00 a.m. Meeting with the Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting); (Contact: Ed Hackett, 301–415–7360)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Friday, October 3, 2014

2:00 p.m. Discussion of International Activities (Closed—Ex. 9)

Week of October 6, 2014—Tentative

Tuesday, October 7, 2014

9:00 a.m. Briefing on the Status of Near-Term Task Force Recommendation 2 for Seismic Hazard Reevaluations (Public Meeting); (Contact: Nicholas DiFrancesco, 301–415–1115)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of October 13, 2014—Tentative

Wednesday, October 15, 2014

11:00 a.m. Discussion of Management and Personnel Issues (Closed—Ex. 2 and 6)

Week of October 20, 2014—Tentative

There are no meetings scheduled for the week of October 20, 2014.

Week of October 27, 2014—Tentative

Wednesday, October 29, 2014

9:00 a.m. Briefing on Security Issues (Closed—Ex. 1)

1:30 p.m. Briefing on Security Issues (Closed—Ex. 1)

Thursday, October 30, 2014

9:00 a.m. Briefing on Watts Bar Unit 2 License Application Review (Public Meeting) (Contact: Justin Poole, 301–415–2048)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of November 3, 2014—Tentative

There are no meetings scheduled for the week of November 3, 2014.

* * * * *

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Rochelle Bavol at (301) 415–1651 or via email at *Rochelle.Bavol@nrc.gov.*

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/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 Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an email to *Patricia.Jimenez@nrc.gov* or *Brenda.Akstulewicz@nrc.gov.*

Dated: September 25, 2014.

Rochelle C. Bavol,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2014–23284 Filed 9–25–14; 4:15 pm]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2014–47 and CP2014–83; Order No. 2192]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an addition of Priority Mail Contract 93 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 30, 2014.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 93 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2014–47 and CP2014–83 to consider the Request pertaining to the proposed Priority Mail Contract 93 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than September 30, 2014. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2014–47 and CP2014–83 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than September 30, 2014.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2014–23001 Filed 9–26–14; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail Contract 93 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, September 22, 2014 (Request).

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 22, 2014, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service To Add Priority Mail Contract 92 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2014–46, CP2014–82.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2014–23028 Filed 9–26–14; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 22, 2014, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service To Add Priority Mail Contract 91 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2014–45, CP2014–81.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2014–23030 Filed 9–26–14; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on September 22, 2014, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 93 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2014–47, CP2014–83.

Stanley F. Mires,

Attorney, Federal Requirements.

[FR Doc. 2014–23027 Filed 9–26–14; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73196; File No. SR–ISEGemini-2014–23]

Self-Regulatory Organizations; ISE Gemini Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Amendment of Its Limited Liability Company Agreement (''LLC Agreement'')

September 23, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 15, 2014, ISE Gemini Exchange, LLC (the ''Exchange'' or ''ISE Gemini'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change, as described in Items I, II and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its LLC Agreement to incorporate changes that were made as part of Amendment No.1 to its Form 1 Application, but then were inadvertently dropped from Amendment No. 3 to the Form 1 Application, such that the changes from Amendment No. 1 did not make it into the final version of the Exchange's LLC Agreement.

The text of the proposed rule change is available at the Commission's Public Reference Room and on the Exchange's Internet Web site at *http://www.ise.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend its LLC Agreement to incorporate changes that were made as part of Amendment No.1 to the Topaz Exchange Form 1 Application, but then were inadvertently dropped from Amendment No. 3 to Form 1 Application, such that the changes from Amendment No. 1 did not make it into the final version of the Exchange's LLC Agreement.[3]

Specifically, the Exchange is proposing to: (1) Incorporate the correct address of the Registered Agent in Section 1.5; (2) incorporate the correct provision of Section 3.3 to Article III, which states that: no distributions shall be made to the Sole LLC Member except: (i) Pursuant to Section 3.4 below; or (ii) upon liquidation of the Company. Notwithstanding any provision to the contrary contained in this LLC Agreement, (i) the Company shall not be required to make a distribution to the Sole LLC Member if such distribution would violate the Act or any other applicable law or is otherwise required to fulfill the regulatory functions or responsibilities of the Company, and (ii) Regulatory Funds shall be used to fund the legal, regulatory and surveillance operations of the Company and the Company shall not make any distribution to the Sole LLC Member using Regulatory Funds. For the purposes of this Section 3.3, ''Regulatory Funds'' means fees, fines or penalties derived from the regulatory operations of the Company, provided that Regulatory Funds shall not include revenues derived from listing fees,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 2 to the Form 1 Application did not touch on the LLC Agreement, but rather, consisted of amendments to Form 1 and Exhibits to update Exhibit C concerning (i) the Board of Directors of International Securities Exchange, LLC (''ISE'') and Corporate Governance Committee of ISE, as a result of interim changes thereto, and (ii) the inclusion of information regarding Longitude S.A., a newly incorporated affiliate of ISE Gemini, which information included the Articles of Incorporation of Longitude S.A. In addition, Exhibit D was updated to provide financials for Longitude S.A. and the Foreign Affiliate Exemption Request was amended to make certain corrections and clarifications to the organizational chart.

market data revenues, transaction revenues or any other aspect of the commercial operations of the Company or a facility of the Company, even if a portion of such revenues are used to pay costs associated with the regulatory operations of the Company.; (3) incorporate in Section 5.2 the correct provision that the Board of Directors shall consist of no less than eight (8) directors; and (4) to incorporate in Section 6.3(b) the correct provision stating that any exercise of voting rights in excess of twenty percent (20%) of the outstanding Exchange Rights by a holder of Exchange Rights, together with any affiliate, as such term is defined in the Constitution, shall be deemed null and void.

None of the foregoing changes are substantive.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange proposes to amend the LLC Agreement to reflect changes that the Exchange had incorporated into its Amendment No. 1 to the Form 1 Application, but had inadvertently dropped when the Exchange submitted its Amendment No. 3 to the Form 1 Application.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule changes are non-substantive in nature and do not implicate any burdens on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3) of the Act [4] and Rule 19b–4(f)(3) thereunder.[5] At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the 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 email to *rule-comments@sec.gov.* Please include File No. SR–ISEGemini–2014–23 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISEGemini–2014–23. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. 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–ISEGemini–2014–23 and should be submitted on or before October 20, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–23052 Filed 9–26–14; 8:45 am]

BILLING CODE 8011–01–P

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 19b–4(f)(3).

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73193; File No. SR–NASDAQ–2014–093]

Self-Regulatory Organizations; the NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change To Amend the Amended and Restated Certificate of Incorporation and By-Laws of the NASDAQ OMX Group, Inc.

September 23, 2014.

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 September 10, 2014, The NASDAQ Stock Market LLC (''NASDAQ'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing this proposed rule change with respect to amendments of the Amended and Restated Certificate of Incorporation (the ''Charter'') and By-Laws (the ''By-Laws'') of its parent corporation, The NASDAQ OMX Group, Inc. (''NASDAQ OMX'' or the ''Company''). The proposed amendments will be implemented on a date designated by NASDAQ OMX following approval by the Commission. The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ OMX is proposing to make certain amendments to its Charter and By-Laws.

(i) Background

Article Fourth, Paragraph C of NASDAQ OMX's Charter includes a voting limitation that generally prohibits a stockholder from voting shares beneficially owned, directly or indirectly, by such stockholder in excess of 5% of the then-outstanding shares of capital stock of NASDAQ OMX entitled to vote as of the record date in respect of any matter. Pursuant to Article Fourth, Paragraph C(6) of the Charter, NASDAQ OMX's Board may grant exemptions to this limitation prior to the time a stockholder beneficially owns more than 5% of the outstanding shares of stock entitled to vote on the election of a majority of directors at such time. NASDAQ OMX's Board has never granted an exemption to the 5% voting limitation and has no current plans to do so. However, in the event the Board decides to grant such an exemption in the future, Article Fourth, Paragraph C(6) of the Charter and Section 12.5 of the By-Laws limit the Board's authority to grant the exemption. These provisions, which are intended to be substantively identical, currently contain some language differences. Following discussions with the SEC staff,[3] NASDAQ OMX proposes the amendments described below to the Charter and By-Laws to conform these provisions and remove any ambiguity that may exist because of the current language differences.

(ii) Proposed Amendments to Charter

First, unlike the Charter, the By-Laws state that for so long as NASDAQ OMX shall control, directly or indirectly, any self-regulatory subsidiary, a resolution of the Board to approve an exemption for any person under Article Fourth, Paragraph C(6) of the Charter shall not be permitted to become effective until such resolution has been filed with and approved by the SEC under Section 19 of the Act. NASDAQ OMX proposes that this requirement be added to the Charter and that ''self-regulatory subsidiary,'' which is currently not a defined term in the Charter, be defined as any subsidiary of NASDAQ OMX that is a ''self-regulatory organization'' as defined under Section 3(a)(26) of the Act.[4] At present, this defined term would include NASDAQ, BX and Phlx, which are national securities exchanges, and BSECC and SCCP, which are registered clearing agencies that are both currently dormant.

Second, both the Charter and the By-Laws state that the Board may not approve an exemption to the 5% voting limitation for: (i) A registered broker or dealer or an affiliate thereof or (ii) an individual or entity that is subject to a statutory disqualification under Section 3(a)(39) of the Act. The By-Laws include a further proviso stating that, for these purposes, an ''affiliate'' shall not be deemed to include an entity that either owns 10% or less of the equity of a broker or dealer, or receives 1% or less of its consolidated gross revenues from a broker or dealer. This proviso, which is not currently included in the Charter, allows NASDAQ OMX's Board to grant exemptions to the 5% voting limitation for entities that either own 10% or less of the equity of a broker or dealer, or receive 1% or less of their consolidated gross revenues from a broker or dealer. NASDAQ OMX proposes that this proviso be added to the Charter to ensure consistency between the Charter and By-Laws.

Third, both the Charter and By-Laws require the Board to make certain determinations prior to granting an exemption to the 5% voting limitation. Regarding the first of these determinations, the Charter states that the Board must determine that granting such an exemption would not reasonably be expected to diminish the quality of, or public confidence in, NASDAQ OMX or The NASDAQ Stock Market LLC or the other operations of NASDAQ OMX and its subsidiaries, on the ability to prevent fraudulent and manipulative acts and practices and on investors and the public. The By-Laws include similar language, but state that the Board must make this determination with respect to NASDAQ OMX or its self-regulatory subsidiaries. Because the term ''self-regulatory subsidiary'' includes The NASDAQ Stock Market LLC but also includes other entities, NASDAQ OMX proposes that the provisions be made fully consistent by amending the Charter to refer to NASDAQ OMX or the self-regulatory subsidiaries, and to define the term ''self-regulatory subsidiary'' as described above.

Fourth, unlike the Charter, the By-Laws further provide that prior to granting an exemption from the 5% voting limitation, the Board must also determine that granting the exemption would promote the prompt and accurate clearance and settlement of securities transactions (and to the extent applicable, derivative agreements, contracts and transactions), assure the safeguarding of securities and funds in the custody or control of the self-regulatory subsidiaries that are clearing agencies or securities and funds for which they are responsible, foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions, and remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions. NASDAQ OMX proposes that this language be added to the Charter.

Finally, NASDAQ OMX proposes that Article Fourth, Paragraph C(6) of the Charter be amended to correct a cross-reference to subparagraph 6(b), which no longer exists.

(iii) Proposed Amendments to the By-Laws

NASDAQ OMX also proposes amendments to NASDAQ OMX's By-Laws to further conform the Charter and By-Law provisions discussed above. Specifically, the proposed amendment to Article I(s) revises the definition of ''self-regulatory subsidiary'' in the By-Laws to refer to any subsidiary of NASDAQ OMX that is a self-regulatory organization as defined under Section 3(a)(26) of the Act, rather than list specific subsidiaries that would fall within this category. This revised definition, which is the same definition of ''self-regulatory subsidiary'' proposed for purposes of the Charter as described above, will capture NASDAQ OMX's

[3] *See* Securities Exchange Act Release No. 71353 (January 17, 2014), 79 FR 4209 (January 24, 2014) (SR–BSECC–2013–001, SR–BX–2013–057, SR–NASDAQ–2013–148, SR–Phlx–2013–115, SR–SCCP–2013–01), at note 14.

[4] Under Section 3(a)(26) of the Act, a ''self-regulatory organization'' is ''any national securities exchange, registered securities association, or registered clearing agency . . . '' 15 U.S.C. 78c(a)(26).

current self-regulatory subsidiaries as well as any subsidiaries that in the future meet the definition of ''self-regulatory organization'' under the Act. Consequently, such future self-regulatory subsidiaries will automatically be subject to the By-Law provisions relating to these subsidiaries without NASDAQ OMX having to take formal action to amend the By-Laws to include them.

The proposed By-Law amendments also include the correction of a typographical error in Article I and minor edits to Section 12.5 to conform the language regarding the 5% voting limitation to the language in the analogous provision of the Charter.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

NASDAQ OMX is proposing changes to its Charter and By-Laws to conform the provisions in each document relating to the procedures by which NASDAQ OMX's Board may grant an exemption to the prohibition on any NASDAQ OMX stockholder voting shares in excess of 5% of the Company's then-outstanding shares of capital stock. The Exchange believes that the changes will protect investors and the public interest by eliminating confusion that may exist because of the current language differences between the two provisions. In addition, NASDAQ OMX is proposing to define ''self-regulatory subsidiary'' with reference to a definition in the Act. The Exchange believes that this will protect investors and the public interest by ensuring that any NASDAQ OMX subsidiary that meets the definition of ''self-regulatory organization'' in the Act will be subject to the Charter and By-Law provisions relating to self-regulatory subsidiaries. Finally, the remaining changes are clarifying in nature, and they enhance investor protection by making NASDAQ OMX's governance documents clearer and easier to understand.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of NASDAQ OMX and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 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 shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2014–093 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2014–093. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. 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–NASDAQ–2014–093, and should be submitted on or before October 20, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–23049 Filed 9–26–14; 8:45 am]

BILLING CODE 8011–01–P

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73192; File No. SR–FINRA–2014–025]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1, and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt a Supplementary Schedule for Inventory Positions Pursuant to FINRA Rule 4524 (Supplemental FOCUS Information)

September 23, 2014.

I. Introduction

On June 16, 2014, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt a supplementary schedule for inventory positions pursuant to FINRA Rule 4524 (Supplemental FOCUS Information). The proposed rule change was

[1] *See* 15 U.S.C. 78s(b)(1).

[2] *See* 17 CFR 240.19b–4.

published for comment in the **Federal Register** on June 26, 2014.[3] The Commission received three comment letters on the proposed rule change.[4] On September 22, 2014, FINRA filed Amendment No. 1 with the Commission to respond to the comment letters and to add clarifying instructions.[5] The Commission is publishing this notice and order to solicit comments on Amendment No. 1 and to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of Proposal

Pursuant to Exchange Act Rule 17a–5,[6] most firms are required to file with FINRA reports concerning their financial and operational status using the Financial and Operational Combined Uniform Single (FOCUS) Report.[7] In general, firms with a FOCUS filing requirement must either file a FOCUS Report Part II if they clear transactions or carry customer accounts[8] or file a FOCUS Report Part IIA if they do not.[9] Firms that are government securities broker-dealers registered under Section 15C of the Exchange Act[10] do not file a FOCUS Report and instead are required to file reports concerning their financial and operational status using the Report on Finances and Operations of Government Securities Brokers and Dealers (''FOGS Report'').[11] These firms are required to file a FOGS Report Part I and either a FOGS Report Part II if they clear transactions or carry customer accounts or FOGS Report Part IIA if they do not.[12]

FINRA Rule 4524 (Supplemental FOCUS Information) requires each firm, as FINRA shall designate, to file such additional financial or operational schedules or reports as FINRA may deem necessary or appropriate for the protection of investors or in the public interest as a supplement to the FOCUS Report.[13] Pursuant to FINRA Rule 4524, FINRA is proposing the adoption of a supplemental schedule to the FOCUS Report Part II, FOCUS Report Part IIA and the FOGS Report Part I that would provide more detailed information about inventory positions held by firms. The proposed Supplemental Inventory Schedule (''SIS'') would be due 20 business days after the end of a firm's FOCUS or FOGS reporting period.[14]

The proposal requires the SIS to be filed by firms that are required to file FOCUS Report Part II, FOCUS Report Part IIA or FOGS Report Part I with inventory positions as of the end of the FOCUS or FOGS reporting period with two exceptions. The first exception is for firms that have a minimum dollar net capital or liquid capital requirement[15] of less than $100,000. Such firms are not allowed to engage in dealer activities and are limited to 10 proprietary transactions per year. Further, such firms are not permitted to self-clear or carry customer accounts. The second exception is for firms that have inventory positions consisting only of money market mutual funds. Money market mutual funds limit their investments to short-term, high-quality debt securities and are permitted to sell and redeem shares at a stable price, typically at $1.00 per share, without regard to small variations in the value of the funds' underlying securities.[16] A firm with inventory positions consisting only of money market mutual funds would need to affirmatively indicate through functionality on the eFOCUS system that no SIS filing is required for the reporting period. FINRA believes that firms that meet either of these two criteria pose significantly less risk to customers and other market participants. These exceptions would not only minimize the burden on firms, but also would allow FINRA to focus its resources where the risk is most concerning.

The proposed SIS is intended to capture more details of a firm's long and short inventory positions than what is captured on the FOCUS Report Part II, FOCUS Report Part IIA and FOGS Report Part I. For example, FOCUS Report Part II, FOCUS Report Part IIA and FOGS Report Part I require total inventory of securities sold short to be reported in aggregate (Item 1620), providing no information on the types of securities sold short by firms. In addition, FOGS Report Part I requires that all long inventory be reported in aggregate (Item 850). Further, on FOCUS Report Part II and IIA, long inventory is reported in categories that aggregate securities with different market risk profiles (*e.g.,* the Corporate Obligations category on the FOCUS Report Part II (Item 400) and Debt Securities category on the FOCUS Report Part IIA (Item 419) include single name corporate bonds, private-label mortgage-backed securities and foreign issuer debt obligations). The proposed SIS would enhance FINRA's ongoing surveillance monitoring of firms' financial condition by providing greater transparency into the market risk posed by a firm's inventory positions and the potential impact to a firm's net capital or liquid capital, as well as related funding and liquidity needs. In addition, the information provided by the proposed SIS would enable FINRA staff to perform more targeted examinations of firms' market risk exposure.

The proposed rule change will be effective upon Commission approval. FINRA will announce the implementation date of the proposed supplemental schedule in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The due date for the first proposed schedule will be no later than 90 days following Commission approval of the proposed rule change.

III. Summary of Comment Letters, FINRA's Response, and Amendment No. 1

As stated above, the Commission received three comment letters in response to the proposed rule change.[17] One commenter opposed the definition of ''arbitrage'' in the instructions for the SIS and questioned why the definition was limited to firms that have a separate arbitrage trading desk.[18] The commenter stated that the SIS should take into account arbitrage strategies and

[3] *See* Exchange Act Release No. 72444 (June 20, 2014), 79 FR 36357 (June 26, 2014).

[4] *See* Letter from Holly H. Smith, Sutherland Asbill & Brennan LLP, to Elizabeth M. Murphy, Secretary, SEC, dated July 17, 2014 (''Sutherland''); Letter from Howard Spindel, Senior Managing Director, and Cassondra E. Joseph, Managing Director, Integrated Management Solutions USA LLC, to Elizabeth M. Murphy, Secretary, SEC, dated July 17, 2014 (''IMS''); Letter from Suzanne Shatto, dated September 7, 2014 (''Shatto'').

[5] *See* SEC File No. SR–FINRA–2014–025 Amendment No. 1, dated September 22, 2014 (''Amendment No. 1''). Amendment No. 1 is described below in Section III and the text of Amendment No. 1 is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA, and on the Commission's Web site at *http://www.sec.gov/rules/sro.shtml.*

[6] *See* 17 CFR 240.17a–5.

[7] *See* SEC Form X–17A–5.

[8] Firms that calculate net capital using Appendix E to Exchange Act Rule 15c3–1 file FOCUS Report Part II CSE, rather than FOCUS Report Part II.

[9] *See* 17 CFR 240.17a–5.

[10] *See* 15 U.S.C. 78o–5.

[11] *See* Department of the Treasury Form G–405.

[12] *See* 17 CFR 405.2; 17 CFR 240.17a–5.

[13] The reference to FOCUS Reports under FINRA Rule 4524 includes FOGS Reports required to be filed by government securities broker-dealers registered under Section 15C of the Exchange Act in lieu of FOCUS Reports.

[14] Firms that file FOCUS Report Part II CSE would not be subject to the proposed SIS. As part of FOCUS Report Part II CSE, the Aggregate Securities and OTC Derivative Positions schedule requires firms to provide information that is similar to the proposed SIS.

[15] Firms that file the FOCUS Report must comply with a minimum dollar net capital requirement, while firms that file the FOGS Report must comply with a minimum liquid capital requirement.

[16] *See* Securities Act Release No. 9408 (June 5, 2013), 78 FR 36834, 36835 (June 19, 2013) (Proposed Rule: Money Market Fund Reform; Amendments to Form PF).

[17] *See supra* note 4.

[18] *See* IMS.

recommended amending the SIS to allow firms ''to indicate how much of the gross market value reported in the long or short columns represented positions that were offsets or related to other positions, directly or indirectly.'' [19] In addition, the commenter recommended eliminating line 10 (Arbitrage) and the parenthetical description on line 9 (Stocks and Warrants (other than arbitrage positions)) on the SIS on the grounds that they would become redundant if the columns for offsets were added.[20] Finally, the commenter suggested the definition of ''arbitrage'' in the instructions ''be changed to indicate something to the effect that arbitrage is whatever the reporting firm thinks it is.'' [21]

In response to the commenter's concern regarding the definition of ''arbitrage,'' FINRA agrees that the definition should not be limited to firms that have a separate arbitrage trading desk and is proposing to amend the instructions to provide that firms would report the market value of all securities that are part of a ''bona fide arbitrage.'' For purposes of the SIS, a security would be considered part of a ''bona fide arbitrage'' if a security is convertible into or exchangeable for another security within a period of 90 days, subject to no conditions other than the payment of money, and the other securities into which such security is convertible or for which it is exchangeable, are short in the accounts of such broker or dealer. The definition of ''bona fide arbitrage'' is substantially similar to the provision in Exchange Act Rule 15c3–1(c)(2)(vi)(J)(*1*). With respect to the additional changes requested by the commenter, FINRA believes, at this time, that the proposed SIS captures the information that is needed to enable FINRA staff to assess the related market risk and impact on firms' liquidity and funding needs arising from inventory holdings.

Another commenter had concerns ''with FINRA's piecemeal approach to requesting supplemental financial and operational information'' and recommended ''that FINRA coordinate with the SEC to propose an amended FOCUS report that requests all of the information FINRA is collecting or plans to collect from firms via supplementary schedules or reports.'' [22] In addition, the commenter requested that FINRA: (1) ''define the term 'inventory' by reference to specific reporting lines of the FOCUS report, so that member firms know exactly what FOCUS line items are required to be disaggregated for the SIS''; (2) confirm that ''investments held by member firms for the purpose of funding employee benefit plans for a member firm's associated persons'' would not be considered inventory under the SIS; and (3) publish general directions for firms with nothing to report because they have no inventory.[23]

In response to the commenter's recommendation that FINRA coordinate with the SEC to propose an amended FOCUS Report, FINRA proposed the SIS pursuant to FINRA Rule 4524, which, subject to FINRA meeting the requirements of Section 19(b)(1) of the Exchange Act [24] and Rule 19b–4 thereunder,[25] provides an independent basis for FINRA to supplement information provided on FOCUS and FOGS Reports filed pursuant to Exchange Act Rule 17a–5 and FINRA Rule 2010.[26] In response to this commenter, FINRA further notes that Form X–17A–5 is an SEC form, and any changes to it must be proposed and adopted by the SEC. However, FINRA would support updates to Form X–17A–5 by the SEC that would incorporate more detailed reporting, and, if such updates were made, FINRA staff would seek to reduce accordingly the requirement for firms to file supplemental information. With respect to the term ''inventory,'' for purposes of the SIS, FINRA is proposing to define the term ''inventory positions'' to mean securities or commodities positions (long, short or both) which are required to be reported on the balance sheet pursuant to GAAP. Consequently, if ''investments held by member firms for the purpose of funding employee benefit plans for a member firm's associated persons'' fall within the term ''inventory positions,'' as defined in the proposed SIS, then such investments would be required to be reported. Finally, in regard to firms with nothing to report, the eFOCUS system would not require an affirmative indication from the firm that no filing is required for the reporting period.

A third commenter raised a number of issues that are outside the scope of the proposal.[27] This commenter, however, also suggested daily reporting for the proposed SIS.[28] FINRA believes daily reporting for the proposed SIS would be overly burdensome on firms without a concomitant benefit to FINRA regarding its understanding of a firm's market risk.

In addition to the changes proposed in response to some of the comments the SEC received, discussed above, FINRA is proposing to clarify that the capital exception for filing the proposed SIS is based on the minimum dollar net capital requirement or liquid capital requirement. Firms that have a minimum dollar net capital or liquid capital requirement, as applicable, of less than $100,000 would not have to file the proposed SIS.

IV. Commission's Findings

After careful consideration of the proposed rule change, as modified by Amendment No. 1, the comment letters received, and FINRA's response to the comment letters, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Exchange Act, and the rules and regulations thereunder that are applicable to a national securities association.[29] In particular, the Commission finds that the proposal, as modified by Amendment No. 1, is consistent with Section 15A(b)(6) of the Exchange Act,[30] which requires, among other things, that the rules of a national securities association be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission believes that FINRA adequately addressed the comments raised in response to FINRA's notice.

The proposed SIS should provide FINRA with the ability to obtain more specific information about the inventory of a member broker-dealer. Thus, the Commission believes that the proposed rule change, as modified by Amendment No. 1, is consistent with the provisions of the Exchange Act noted above in that the proposed SIS could provide FINRA with greater insights into the types of securities held in inventory by firms and the related market risk associated with such inventory positions. In addition, the proposed SIS would enable FINRA staff to review inventory

[19] *See* IMS.

[20] *See* IMS.

[21] *See* IMS.

[22] *See* Sutherland.

[23] *See* Sutherland.

[24] *See* 15 U.S.C. 78s(b)(1).

[25] *See* 17 CFR 240.19b–4.

[26] *See* Securities Exchange Act Release No. 66364 (Feb. 9, 2012), 77 FR 8938 (Feb. 15, 2012) (Order Granting Accelerated Approval of SR–FINRA–2011–064).

[27] *See* Shatto.

[28] *See* Shatto.

[29] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[30] *See* 15 U.S.C. 78*o*–3(b)(6).

trends and assess the related impact on firms' liquidity and funding needs. The information provided on the proposed SIS would be used by FINRA to monitor firms' financial condition and perform more targeted examinations of firms' market risk exposure.

The Commission believes that the proposed rule change, as modified by Amendment No. 1, works in conjunction with the existing Commission broker-dealer financial responsibility rules and will further FINRA's ability to oversee its members by, among other things, capturing trends in the securities held in broker-dealers' inventory.

The Commission does not believe that the proposed rule change, as modified by Amendment No. 1, will result in burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. As stated above, the Commission believes the proposed SIS will allow FINRA to better understand the potential impact of broker-dealers' inventory on net capital, leverage and liquidity, and ability to fulfill customer protection obligations. Ready access to the information in the proposed SIS is important for FINRA to efficiently monitor on an ongoing basis the financial condition of firms.

The Commission also believes FINRA has carefully crafted the proposed SIS to achieve its intended and necessary regulatory purpose while being cognizant of the burden on firms. The information required to complete the proposed SIS should be readily available to firms due to firms' obligations to maintain books and records and apply applicable capital charges to their inventory. Further, for smaller firms, the proposed SIS contains exceptions for firms that (1) have a minimum dollar net capital or liquid capital requirement, as applicable, of less than $100,000, or (2) have inventory positions consisting only of money market mutual funds.

V. Accelerated Approval

The Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act [31] for approving the proposal, as modified by Amendment No. 1, prior to the 30th day after publication of Amendment No. 1 in the **Federal Register**. The changes proposed in Amendment No. 1 are technical or clarifying changes and do not raise regulatory concerns.

Accordingly, the Commission finds that good cause exists to approve the proposal, as modified by Amendment No. 1, on an accelerated basis.

VI. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2014–025 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2014–025. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2014–025 and should be submitted on or before October 20, 2014.

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[32] that the proposed rule change (SR–FINRA–2014–025), as modified by Amendment No. 1, be and hereby is approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2014–23048 Filed 9–26–14; 8:45 am]

BILLING CODE 8011–01–P

[31] *See* 15 U.S.C. 78s(b)(2).

[32] *See* 15 U.S.C. 78s(b)(2).

[33] *See* 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73194; File No. SR–Phlx–2014–61)

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing of Proposed Rule Change To Amend the Amended and Restated Certificate of Incorporation and By-Laws of the NASDAQ OMX Group, Inc.

September 23, 2014.

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 September 10, 2014, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing this proposed rule change with respect to amendments of the Amended and Restated Certificate of Incorporation (the ''Charter'') and By-Laws (the ''By-Laws'') of its parent corporation, The NASDAQ OMX Group, Inc. (''NASDAQ OMX'' or the ''Company''). The proposed amendments will be implemented on a date designated by NASDAQ OMX following approval by the Commission. The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com,* at

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ OMX is proposing to make certain amendments to its Charter and By-Laws.

(i) Background

Article Fourth, Paragraph C of NASDAQ OMX's Charter includes a voting limitation that generally prohibits a stockholder from voting shares beneficially owned, directly or indirectly, by such stockholder in excess of 5% of the then-outstanding shares of capital stock of NASDAQ OMX entitled to vote as of the record date in respect of any matter. Pursuant to Article Fourth, Paragraph C(6) of the Charter, NASDAQ OMX's Board may grant exemptions to this limitation prior to the time a stockholder beneficially owns more than 5% of the outstanding shares of stock entitled to vote on the election of a majority of directors at such time. NASDAQ OMX's Board has never granted an exemption to the 5% voting limitation and has no current plans to do so. However, in the event the Board decides to grant such an exemption in the future, Article Fourth, Paragraph C(6) of the Charter and Section 12.5 of the By-Laws limit the Board's authority to grant the exemption. These provisions, which are intended to be substantively identical, currently contain some language differences. Following discussions with the SEC staff,[3] NASDAQ OMX proposes the amendments described below to the Charter and By-Laws to conform these provisions and remove any ambiguity that may exist because of the current language differences.

(ii) Proposed Amendments to Charter

First, unlike the Charter, the By-Laws state that for so long as NASDAQ OMX shall control, directly or indirectly, any self-regulatory subsidiary, a resolution of the Board to approve an exemption for any person under Article Fourth, Paragraph C(6) of the Charter shall not be permitted to become effective until such resolution has been filed with and approved by the SEC under Section 19 of the Act. NASDAQ OMX proposes that this requirement be added to the Charter and that ''self-regulatory subsidiary,'' which is currently not a defined term in the Charter, be defined as any subsidiary of NASDAQ OMX that is a ''self-regulatory organization'' as defined under Section 3(a)(26) of the Act.[4] At present, this defined term would include NASDAQ, BX and Phlx, which are national securities exchanges, and BSECC and SCCP, which are registered clearing agencies that are both currently dormant.

Second, both the Charter and the By-Laws state that the Board may not approve an exemption to the 5% voting limitation for: (i) A registered broker or dealer or an affiliate thereof or (ii) an individual or entity that is subject to a statutory disqualification under Section 3(a)(39) of the Act. The By-Laws include a further proviso stating that, for these purposes, an ''affiliate'' shall not be deemed to include an entity that either owns 10% or less of the equity of a broker or dealer, or receives 1% or less of its consolidated gross revenues from a broker or dealer. This proviso, which is not currently included in the Charter, allows NASDAQ OMX's Board to grant exemptions to the 5% voting limitation for entities that either own 10% or less of the equity of a broker or dealer, or receive 1% or less of their consolidated gross revenues from a broker or dealer. NASDAQ OMX proposes that this proviso be added to the Charter to ensure consistency between the Charter and By-Laws.

Third, both the Charter and By-Laws require the Board to make certain determinations prior to granting an exemption to the 5% voting limitation. Regarding the first of these determinations, the Charter states that the Board must determine that granting such an exemption would not reasonably be expected to diminish the quality of, or public confidence in, NASDAQ OMX or The NASDAQ Stock Market LLC or the other operations of NASDAQ OMX and its subsidiaries, on the ability to prevent fraudulent and manipulative acts and practices and on investors and the public. The By-Laws include similar language, but state that the Board must make this determination with respect to NASDAQ OMX or its self-regulatory subsidiaries. Because the term ''self-regulatory subsidiary'' includes The NASDAQ Stock Market LLC but also includes other entities, NASDAQ OMX proposes that the provisions be made fully consistent by amending the Charter to refer to NASDAQ OMX or the self-regulatory subsidiaries, and to define the term ''self-regulatory subsidiary'' as described above.

Fourth, unlike the Charter, the By-Laws further provide that prior to granting an exemption from the 5% voting limitation, the Board must also determine that granting the exemption would promote the prompt and accurate clearance and settlement of securities transactions (and to the extent applicable, derivative agreements, contracts and transactions), assure the safeguarding of securities and funds in the custody or control of the self-regulatory subsidiaries that are clearing agencies or securities and funds for which they are responsible, foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions, and remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions. NASDAQ OMX proposes that this language be added to the Charter.

Finally, NASDAQ OMX proposes that Article Fourth, Paragraph C(6) of the Charter be amended to correct a cross-reference to subparagraph 6(b), which no longer exists.

(iii) Proposed Amendments to the By-Laws

NASDAQ OMX also proposes amendments to NASDAQ OMX's By-Laws to further conform the Charter and By-Law provisions discussed above. Specifically, the proposed amendment to Article I(s) revises the definition of ''self-regulatory subsidiary'' in the By-Laws to refer to any subsidiary of NASDAQ OMX that is a self-regulatory organization as defined under Section 3(a)(26) of the Act, rather than list specific subsidiaries that would fall within this category. This revised definition, which is the same definition of ''self-regulatory subsidiary'' proposed

[3] *See* Securities Exchange Act Release No. 71353 (January 17, 2014), 79 FR 4209 (January 24, 2014) (SR–BSECC–2013–001, SR–BX–2013–057, SR–NASDAQ–2013–148, SR–Phlx–2013–115, SR–SCCP–2013–01), at note 14.

[4] Under Section 3(a)(26) of the Act, a ''self-regulatory organization'' is ''any national securities exchange, registered securities association, or registered clearing agency . . .'' 15 U.S.C. 78c(a)(26).

for purposes of the Charter as described above, will capture NASDAQ OMX's current self-regulatory subsidiaries as well as any subsidiaries that in the future meet the definition of ''self-regulatory organization'' under the Act. Consequently, such future self-regulatory subsidiaries will automatically be subject to the By-Law provisions relating to these subsidiaries without NASDAQ OMX having to take formal action to amend the By-Laws to include them. The proposed By-Law amendments also include the correction of a typographical error in Article I and minor edits to Section 12.5 to conform the language regarding the 5% voting limitation to the language in the analogous provision of the Charter.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

NASDAQ OMX is proposing changes to its Charter and By-Laws to conform the provisions in each document relating to the procedures by which NASDAQ OMX's Board may grant an exemption to the prohibition on any NASDAQ OMX stockholder voting shares in excess of 5% of the Company's then-outstanding shares of capital stock. The Exchange believes that the changes will protect investors and the public interest by eliminating confusion that may exist because of the current language differences between the two provisions. In addition, NASDAQ OMX is proposing to define ''self-regulatory subsidiary'' with reference to a definition in the Act. The Exchange believes that this will protect investors and the public interest by ensuring that any NASDAQ OMX subsidiary that meets the definition of ''self-regulatory organization'' in the Act will be subject to the Charter and By-Law provisions relating to self-regulatory subsidiaries. Finally, the remaining changes are clarifying in nature, and they enhance investor protection by making NASDAQ OMX's governance documents clearer and easier to understand.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of NASDAQ OMX and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 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 shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2014–61 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2014–61. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2014–61, and should be submitted on or before October 20, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–23050 Filed 9–26–14; 8:45 am]

BILLING CODE 8011–01–P

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73191; File No. SR–OC–2014–04]

Self-Regulatory Organizations; OneChicago, LLC; Notice of Filing of Proposed Rule Change to Update OCX's Rulebook To Remove References To the OCX.BETS and CBOEdirect Trading Platforms

September 23, 2014.

Pursuant to Section 19(b)(7) of the Securities Exchange Act of 1934 (the ''Act''),[1] notice is hereby given that on September 4, 2014, OneChicago, LLC (''OneChicago,'' ''OCX,'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. OneChicago has also filed this rule change with the Commodity Futures Trading Commission (''CFTC'').

[1] 15 U.S.C. 78s(b)(7).

OneChicago filed a written certification with the CFTC under Section 5c(c) of the Commodity Exchange Act (''CEA'') on September 4, 2014.

I. Self-Regulatory Organization's Description of the Proposed Rule Change

OCX is proposing to amend its Rulebook to remove references to the OCX.BETS and CBOE*direct* trading platforms. Currently, trading on OCX is bifurcated between these two platforms. OCX.BETS provides a marketplace for trading blocks and Exchange of Futures for Physicals (EFPs), whereas CBOE*direct* provides a central limit order book for traditional, low latency trading. Beginning on September 22, 2014, OCX will phase out its OCX.BETS platform, and replace it with its new trading platform, OCXdelta1. OCX will also replace CBOE*direct* with OCXdelta1 in early 2015. Accordingly, OCX is removing references to these two platforms in its Rulebook, and replacing them with references to the OneChicago System, a term that is already defined in the OCX Rulebook.

The text of the proposed rule change is attached as *Exhibit 4* to the filing submitted by the Exchange but is not attached to the published notice of the filing.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OneChicago included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of OneChicago's filing is to update the OCX Rulebook to remove references to the OCX.BETS and CBOE*direct* trading platforms, which OCX is phasing out and replacing. Currently, the OCX Rulebook mentions OCX.BETS and CBOE*direct* in various OCX Rules. This rule filing proposes to update the OCX Rulebook to refer to the OneChicago System, which is a defined term and broadly refers to any trading platform that OCX may utilize.

2. Statutory Basis

OneChicago believes that the proposed rule change is consistent with Section 6(b) of the Act,[2] in general, and furthers the objectives of Section 6(b)(5) of the Act,[3] in particular, in that it is designed to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and remove impediments to and perfect the mechanism of a free and open market and national market system. OneChicago believes that updating the Rulebook to remove references to trading platforms it will no longer support ensures that market participants are aware of the method by which trading is conducted on the Exchange. The proposed rule change also ensures that the OCX Rulebook is up to date and accurate.

B. Self-Regulatory Organization's Statement on Burden on Competition

OneChicago does not believe that the proposed rule changes will impose any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The rule change simply makes clerical changes to the OCX Rulebook. The rule change does not impose any new burdens on any market participants. The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because all of the amended rules apply equally to all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The rule change will become operative on September 22, 2014.

At any time within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule change and require that the proposed rule change be refiled in accordance with the provisions of Section 19(b)(1) of the Act.[4]

[2] 15 U.S.C. 78f(b).

[3] 15 U.S.C. 78(f)(b)(5).

[4] 15 U.S.C. 78s(b)(1).

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 email to *rule-comments@sec.gov.* Please include File Number SR–OC–2014–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OC–2014–04. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. 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–OC–2014–04, and should be submitted on or before October20, 2014.

[5] 17 CFR 200.30–3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[5]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–23047 Filed 9–26–14; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73195; File No. SR–BX–2014–045]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing of Proposed Rule Change To Amend the Amended and Restated Certificate of Incorporation and By-Laws of the NASDAQ OMX Group, Inc.

September 23, 2014.

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 September 10, 2014, NASDAQ OMX BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing this proposed rule change with respect to amendments of the Amended and Restated Certificate of Incorporation (the ''Charter'') and By-Laws (the ''By-Laws'') of its parent corporation, The NASDAQ OMX Group, Inc. (''NASDAQ OMX'' or the ''Company''). The proposed amendments will be implemented on a date designated by NASDAQ OMX following approval by the Commission. The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

NASDAQ OMX is proposing to make certain amendments to its Charter and By-Laws.

(i) Background

Article Fourth, Paragraph C of NASDAQ OMX's Charter includes a voting limitation that generally prohibits a stockholder from voting shares beneficially owned, directly or indirectly, by such stockholder in excess of 5% of the then-outstanding shares of capital stock of NASDAQ OMX entitled to vote as of the record date in respect of any matter. Pursuant to Article Fourth, Paragraph C(6) of the Charter, NASDAQ OMX's Board may grant exemptions to this limitation prior to the time a stockholder beneficially owns more than 5% of the outstanding shares of stock entitled to vote on the election of a majority of directors at such time. NASDAQ OMX's Board has never granted an exemption to the 5% voting limitation and has no current plans to do so. However, in the event the Board decides to grant such an exemption in the future, Article Fourth, Paragraph C(6) of the Charter and Section 12.5 of the By-Laws limit the Board's authority to grant the exemption. These provisions, which are intended to be substantively identical, currently contain some language differences. Following discussions with the SEC staff,[3] NASDAQ OMX proposes the amendments described below to the Charter and By-Laws to conform these provisions and remove any ambiguity that may exist because of the current language differences.

(ii) Proposed Amendments to Charter

First, unlike the Charter, the By-Laws state that for so long as NASDAQ OMX shall control, directly or indirectly, any self-regulatory subsidiary, a resolution of the Board to approve an exemption for any person under Article Fourth, Paragraph C(6) of the Charter shall not be permitted to become effective until such resolution has been filed with and approved by the SEC under Section 19 of the Act. NASDAQ OMX proposes that this requirement be added to the Charter and that ''self-regulatory subsidiary,'' which is currently not a defined term in the Charter, be defined as any subsidiary of NASDAQ OMX that is a ''self-regulatory organization'' as defined under Section 3(a)(26) of the Act.[4] At present, this defined term would include NASDAQ, BX and Phlx, which are national securities exchanges, and BSECC and SCCP, which are registered clearing agencies that are both currently dormant.

Second, both the Charter and the By-Laws state that the Board may not approve an exemption to the 5% voting limitation for: (i) A registered broker or dealer or an affiliate thereof or (ii) an individual or entity that is subject to a statutory disqualification under Section 3(a)(39) of the Act. The By-Laws include a further proviso stating that, for these purposes, an ''affiliate'' shall not be deemed to include an entity that either owns 10% or less of the equity of a broker or dealer, or receives 1% or less of its consolidated gross revenues from a broker or dealer. This proviso, which is not currently included in the Charter, allows NASDAQ OMX's Board to grant exemptions to the 5% voting limitation for entities that either own 10% or less of the equity of a broker or dealer, or receive 1% or less of their consolidated gross revenues from a broker or dealer. NASDAQ OMX proposes that this proviso be added to the Charter to ensure consistency between the Charter and By-Laws.

Third, both the Charter and By-Laws require the Board to make certain determinations prior to granting an exemption to the 5% voting limitation. Regarding the first of these determinations, the Charter states that the Board must determine that granting such an exemption would not reasonably be expected to diminish the quality of, or public confidence in, NASDAQ OMX or The NASDAQ Stock Market LLC or the other operations of NASDAQ OMX and its subsidiaries, on the ability to prevent fraudulent and manipulative acts and practices and on investors and the public. The By-Laws include similar language, but state that the Board must make this determination with respect to NASDAQ OMX or its self-regulatory-subsidiaries. Because the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 71353 (January 17, 2014), 79 FR 4209 (January 24, 2014) (SR–BSECC–2013–001, SR–BX–2013–057, SR–NASDAQ–2013–148, SR–Phlx–2013–115, SR–SCCP–2013–01), at note 14.

[4] Under Section 3(a)(26) of the Act, a ''self-regulatory organization'' is ''any national securities exchange, registered securities association, or registered clearing agency. . .'' 15 U.S.C. 78c(a)(26).

term ''self-regulatory subsidiary'' includes The NASDAQ Stock Market LLC but also includes other entities, NASDAQ OMX proposes that the provisions be made fully consistent by amending the Charter to refer to NASDAQ OMX or the self-regulatory subsidiaries, and to define the term ''self-regulatory subsidiary'' as described above.

Fourth, unlike the Charter, the By-Laws further provide that prior to granting an exemption from the 5% voting limitation, the Board must also determine that granting the exemption would promote the prompt and accurate clearance and settlement of securities transactions (and to the extent applicable, derivative agreements, contracts and transactions), assure the safeguarding of securities and funds in the custody or control of the self-regulatory subsidiaries that are clearing agencies or securities and funds for which they are responsible, foster cooperation and coordination with persons engaged in the clearance and settlement of securities transactions, and remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions. NASDAQ OMX proposes that this language be added to the Charter.

Finally, NASDAQ OMX proposes that Article Fourth, Paragraph C(6) of the Charter be amended to correct a cross-reference to subparagraph 6(b), which no longer exists.

(iii) Proposed Amendments to the By-Laws

NASDAQ OMX also proposes amendments to NASDAQ OMX's By-Laws to further conform the Charter and By-Law provisions discussed above. Specifically, the proposed amendment to Article I(s) revises the definition of ''self-regulatory subsidiary'' in the By-Laws to refer to any subsidiary of NASDAQ OMX that is a self-regulatory organization as defined under Section 3(a)(26) of the Act, rather than list specific subsidiaries that would fall within this category. This revised definition, which is the same definition of ''self-regulatory subsidiary'' proposed for purposes of the Charter as described above, will capture NASDAQ OMX's current self-regulatory subsidiaries as well as any subsidiaries that in the future meet the definition of ''self-regulatory organization'' under the Act. Consequently, such future self-regulatory subsidiaries will automatically be subject to the By-Law provisions relating to these subsidiaries without NASDAQ OMX having to take formal action to amend the By-Laws to include them. The proposed By-Law amendments also include the correction of a typographical error in Article I and minor edits to Section 12.5 to conform the language regarding the 5% voting limitation to the language in the analogous provision of the Charter.

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

NASDAQ OMX is proposing changes to its Charter and By-Laws to conform the provisions in each document relating to the procedures by which NASDAQ OMX's Board may grant an exemption to the prohibition on any NASDAQ OMX stockholder voting shares in excess of 5% of the Company's then-outstanding shares of capital stock. The Exchange believes that the changes will protect investors and the public interest by eliminating confusion that may exist because of the current language differences between the two provisions. In addition, NASDAQ OMX is proposing to define ''self-regulatory subsidiary'' with reference to a definition in the Act. The Exchange believes that this will protect investors and the public interest by ensuring that any NASDAQ OMX subsidiary that meets the definition of ''self-regulatory organization'' in the Act will be subject to the Charter and By-Law provisions relating to self-regulatory subsidiaries. Finally, the remaining changes are clarifying in nature, and they enhance investor protection by making NASDAQ OMX's governance documents clearer and easier to understand.

B. Self-Regulatory Organization's Statement on Burden on Competition

Because the proposed rule change relates to the governance of NASDAQ OMX and not to the operations of the Exchange, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 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 shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number *SR*-BX–2014–045 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2014–045. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for

inspection and copying at the principal offices of the Exchange. 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–BX–2014–045, and should be submitted on or before October 20, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–23051 Filed 9–26–14; 8:45 am]

BILLING CODE 8011–01–P

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of All Grade Mining, Inc., Bluforest, Inc., DHS Holding Co., Essential Innovations, Technology Corp., Global Green Inc., Inova Technology, Inc., mLight Tech, Inc., Solar Thin Films, Inc., Xumanii International, Holdings Corp.; Order of Suspension of Trading

September 25, 2014.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of the issuers listed below.

1. All Grade Mining, Inc. is a Colorado corporation based in New Jersey. Questions have arisen concerning the adequacy and accuracy of press releases concerning the company's revenues. The company is quoted on OTC Link operated by OTC Markets Group, Inc. (''OTC Link''), under the ticker symbol HYII.

2. Bluforest, Inc. is a Nevada corporation based in Quito, Ecuador. Questions have arisen concerning the adequacy of publicly available information about the company because it has not filed any periodic reports since the period ended September 30, 2013. The company is quoted on OTC Link under the ticker symbol BLUF.

3. DHS Holding Co. is a Nevada corporation based in Tennessee. Questions have arisen concerning the adequacy and accuracy of press releases concerning the company's revenues. The company is quoted on OTC Link under the ticker symbol DHSM.

4. Essential Innovations Technology Corp. is a Nevada corporation based in Washington state and Hong Kong. Questions have arisen concerning the adequacy and accuracy of press releases concerning the company's operations. The company is quoted on OTC Link under the ticker symbol ESIV.

5. Global Green Inc. is a Florida corporation based in Florida. Questions have arisen concerning the adequacy and accuracy of press releases concerning the company's operations. The company is quoted on OTC Link under the ticker symbol GOGC.

6. Inova Technology, Inc. is a Nevada corporation based in Nevada. Questions have arisen concerning the adequacy of publicly available information about the company because it has not filed any periodic reports since the period ended July 31, 2013. The company is quoted on OTC Link under the ticker symbol INVA.

7. mLight Tech, Inc. is a Florida corporation based in California. Questions have arisen concerning the adequacy and accuracy of press releases concerning the company's operations. The company is quoted on OTC Link under the ticker symbol MLGT.

8. Solar Thin Films, Inc. is a New York corporation based in New York. Questions have arisen concerning the adequacy and accuracy of press releases concerning the company's operations. The company is quoted on OTC Link under the ticker symbol SLTZ.

9. Xumanii International Holdings Corp. is a Nevada corporation based in Nevada. Questions have arisen concerning the adequacy and accuracy of press releases concerning the company's operations. The company is quoted on OTC Link under the ticker symbol XUII.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

THEREFORE, IT IS ORDERED, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT, on September 25, 2014 through 11:59 p.m. EDT, on October 8, 2014.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2014–23247 Filed 9–25–14; 4:15 pm]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day Notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before October 29, 2014.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: For financial assistance programs authorized by section 7(a) and (b) of the Small Business Act and Title V of the Small Business Investment Act of 1958, SBA regulations require any loan guarantor and individual owners of the small business applicant to submit a personal financial statement to provide information on their assets and liabilities. *See,* 13 CFR 120.191 and 13 CFR 123.6. The information is necessary for the Agency, the participating lender or CDC to make informed decisions concerning the applicant's repayment abilities or creditworthiness.

For the 8(a) Business Development (BD), Small Disadvantaged Business (SDB), and Women-Owned Small Business (WOSB) programs the information is necessary for SBA to determine if the applicant or participant meets the economic disadvantage requirements to participate in these programs. SBA regulations at 13 CFR

124.104, 124.112, 124.1002, and 13 CFR 127.203 require, among other things, that applicants and participants submit financial information to facilitate this determination.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collections

(1) *Title:* Personal Financial Statement.

Description of Respondents: Applicants and/or Participants in SBA's 7(a) loan program, 504 loan program, and disaster loan program, and 8(a) Business Development program, and the Women-Owned Small Business program.

Form Numbers: SBA Forms 413(7a), 413(D), 413(8(a)) and 413(WOSB)

Estimated Annual Respondents: 44,588

Estimated Annual Responses: 44,588

Estimated Annual Hour Burden: 66,882

Curtis B. Rich,

Management Analyst.

[FR Doc. 2014–23031 Filed 9–26–14; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day Notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before October 29, 2014.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer,* Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205–7030 *curtis.rich@sba.gov*

Copies: A copy of the Form OMB 83–1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: A small business determined to be non-responsible for award of a specific prime Government contract by a Government contracting office has the right to appeal that decision through the Small Business Administration (SBA). The information contained on this form, as well as, other information developed by SBA, is used in determining whether the decision by the Contracting Officer should be overturned.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collections

(1) *Title:* Small Business Administration Application for Certificate of Competency

Description of Respondents: Small Businesses

Form Number: SBA Form 1531

Estimated Annual Respondents: 300

Estimated Annual Responses: 300

Estimated Annual Hour Burden: 2,400

Curtis B. Rich,

Management Analyst.

[FR Doc. 2014–23033 Filed 9–26–14; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 8888]

60-Day Notice of Proposed Information Collection: Training/Internship Placement Plan

ACTION: Notice of request for public comments.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceded submission of the collection to OMB.

DATES: The Department will accept comments from the public up to November 28, 2014.

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

- *Web:* Persons with access to the Internet may use the Federal Docket Management System (FDMS) to comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Public Notice 8888'' in the Search bar. If necessary, use the Narrow by Agency filter option on the Results page.
- Email: *JExchanges@State.gov*.
- Mail (paper, disk, or CD–ROM submissions): U.S. Department of State, ECA/EC, SA–5, Floor 5, 2200 C Street NW., Washington, DC 20522–0505, ATTN: Federal Register Notice Response.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Robin J. Lerner, Deputy Assistant Secretary for Private Sector Exchange, ECA/EC, SA–5, Floor 5, Department of State, 2200 C Street NW., Washington, DC 20522–0505, who may be reached on 202–632–3206 or at *JExchanges@state.gov*.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Training/Internship Placement Plan.
- *OMB Control Number:* 1405–0170.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Educational and Cultural Affairs, ECA/EC.
- *Form Number:* Form DS–7002.
- *Respondents:* Entities designated by the Department of State as sponsors of exchange visitor programs in the trainee or intern categories and U.S. businesses that provide the training or internship opportunity.
- *Estimated Number of Respondents:* 120.

• *Estimated Number of Responses:* 30,000.

• *Average Hours Per Response:* 1.5 hours.

• *Total Estimated Burden:* 45,000 hours.

• *Frequency:* On occasion depending on the number of exchange participants annually.

• *Obligation to Respond:* Required to Obtain or Retain Benefits.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper performance of our functions.

• Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of technology.

Abstract of proposed collection:

The collection is the continuation of information collected and needed by the Bureau of Educational and Cultural Affairs in administering the Exchange Visitor Program (J-Visa) under the provisions of the Mutual Educational and Cultural Exchange Act of 1961, as amended. Trainee/Internship Placement Plans are to be completed by designated program sponsors. A Training/Internship Placement Plan is required for each trainee or intern participant. It will set forth the training or internship program to be followed, methods of supervision, the skills the trainee or intern will obtain, and trainee or intern remuneration. The plan must be signed by the trainee or intern, sponsor, and the third party placement organization, if a third party organization is used in the conduct of the training or internship. Upon request, trainees or interns must present a fully executed Trainee/Internship Placement Plan on Form DS–7002 to any Consular Official interviewing them in connection with the issuance of J–1 visas.

Dated: September 22, 2014.

Robin Lerner,

Deputy Assistant Secretary for Private Sector Exchange Bureau of Educational and Cultural Affairs, U.S. Department of State.

[FR Doc. 2014–23111 Filed 9–26–14; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8886]

Certification Related to Foreign Military Financing for Colombia under section 7045(A)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2014

Pursuant to the authority vested in the Secretary of State, including under section 7045(a)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2014 (Div. K, Pub. L. 113–76), I hereby certify and report that the Colombian Armed Forces and the Government of Colombia are meeting the conditions contained in section 7045 of the Joint Explanatory Statement accompanying the Act.

This Certification shall be published in the **Federal Register**, and copies shall be transmitted to the appropriate committees of Congress.

Dated: September 17, 2014.

John F. Kerry,

Secretary of State.

[FR Doc. 2014–23105 Filed 9–26–14; 8:45 am]

BILLING CODE 4710–29–P

DEPARTMENT OF STATE

[Public Notice: 8885]

Culturally Significant Objects Imported for Exhibition Determinations: ''Vodou: Sacred Powers of Haiti'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Vodou: Sacred Powers of Haiti,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Field Museum of Natural History, Chicago, IL, from on or about October 24, 2014, until on or about April 26, 2015, the Museum of Fine Arts, Boston, MA, from on or about April 3, 2016, until on or about June 17, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including lists of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: September 22, 2014.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2014–23107 Filed 9–26–14; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 8887]

Culturally Significant Objects Imported for Exhibition Determinations: ''Madame Cézanne'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Madame Cézanne,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, NY, from on or about November 19, 2014, until on or about March 15, 2015, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of

State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: September 23, 2014.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2014–23109 Filed 9–26–14; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0102]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice and Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before November 28, 2014.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA–2014–0102 using any of the following methods:

- *Electronic submissions:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility, M–30, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Instructions: Each submission must include the Agency name and the Docket number for this Notice. Note that all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: 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://dot.gov/privacy.html or http://Docketslnfo.dot.gov.*

FOR FURTHER INFORMATION CONTACT: For background documents, contact Gary R. Toth, Office of Data Acquisitions (NVS–410), Room W53–505, 1200 New Jersey Avenue SE., Washington, DC 20590. Mr. Toth's telephone number is (202) 366–5378.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5CFR 1320.8(d), an agency must ask for public comment on the following:

(i) 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) 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) how to enhance the quality, utility, and clarity of the information to be collected;

(iv) how 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.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collections of information:

Title: Crash Report Sampling System (CRSS).

Type of Request: New information collection.

OMB Control Number: None.

Requested Expiration Date of Approval: Five (5) years from the approval date.

Abstract: Under both the Highway Safety Act of 1966 and the National Traffic and Motor Vehicle Safety Act of 1966, the National Highway Traffic Safety Administration (NHTSA) has the responsibility to collect crash data that support the establishment and enforcement of motor vehicle regulations and highway safety programs. These regulations and programs are developed to reduce the severity of injury and the property damage associated with motor vehicle crashes. In the late 1970s, NHTSA's National Center for Statistics and Analysis (NCSA) devised a multidisciplinary approach to meet the data needs of our end users that utilized an efficient combination of census, sample-based, and existing State files to provide information on traffic crashes on a timely basis. NCSA operates data programs consisting of records-based systems that include the Fatality Analysis Reporting System (FARS) and the National Automotive Sampling System General Estimates System (NASS–GES); and detailed crash investigation-based systems which include the National Automotive Sampling System Crashworthiness Data System (NASS–CDS) and the Special Crash Investigations (SCI) program. NASS–CDS focused on the crashworthiness of passenger cars, light trucks, and vans involved in crashes that were damaged enough to be towed. NASS–GES, on the other hand, collected limited data on all level of severities of highway crashes involving all types of motor vehicles in order to produce general estimates.

Recognizing the importance as well as the limitations of the current National Automotive Sampling System, NHTSA is undertaking a modernization effort to upgrade our data systems by improving the information technology infrastructure, updating the data we collect and reexamining the sample sites. The goal of this overall modernization effort is to develop new crash data systems that meet current and future data needs. These data acquisition systems will be designed to collect record-based information and investigation-based information. The redesigned records-based acquisition process will identify highway safety problem areas and provide general data trends. The system will be referred to as the Crash Report Sampling System (CRSS).

CRSS will obtain data from a nationally representative probability

sample selected from police reported motor vehicle traffic crashes. Specifically, crashes involving at least one motor vehicle in transport on a trafficway that result in property damage, injury or a fatality will be included in the CRSS sample. The crash reports sampled will be chosen from selected areas that reflect the geography, population, miles driven, and the number of crashes in the United States. No additional data beyond the selected crash reports will be collected. Once the crash reports are received they will be coded and the data will be entered into the CRSS database.

CRSS will acquire national information on fatalities, injuries and property damage directly from existing State police crash reports. The user population includes Federal and State agencies, automobile manufacturers, insurance companies, and the private sector. Annual changes in the sample parameters are minor in terms of operation and method of data collection, and do not affect the reporting burden of the respondent. CRSS data coders will utilize existing State crash files.

Estimated Annual Burden: 34,944 hours.

Number of Respondents: 630.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for the agency's performance of its functions; (b) the accuracy of the estimated burden; (c) ways for the agency to enhance the quality, utility and clarity of the information to be collected; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize your comments and the agency's responses in the request for OMB clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. chap. 35; 49 U.S.C. 30181–83.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95.

Terry T. Shelton,

Associate Administrator, National Center for Statistics and Analysis.

[FR Doc. 2014–23113 Filed 9–26–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

September 23, 2014.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before October 29, 2014 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request may be found at *www.reginfo.gov.*

Community Development Financial Institutions (CDFI) Fund

OMB Number: 1559–0044.

Type of Review: Revision of a currently approved collection.

Title: Bond Guarantee Program.

Abstract: The purpose of the Community Development Financial Institutions (CDFI) Bond Guarantee Program (BG Program) is to support CDFI lending by providing Guarantees for Bonds issued by Qualified Issuers as part of a Bond Issue for Eligible Community or Economic Development Purposes.

Affected Public: Private Sector: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Annual Responses: 570.

Estimated Annual Burden Hours: 9,100.

Reason for Change: The CDFI Fund has developed two new information collection instruments to support the collection of financial and impact data from borrowers under the Bond Guarantee (BG) Program. The information collected is crucial for adequately managing and monitoring the total portfolio of outstanding Bond Loans.

The *Financial Condition Monitoring (FCM) Report* is a quarterly report submission, allowing for the BG Program to monitor and compare eligible CDFIs' balance sheets, income statements and cash flows, and portfolio quality in a standard format.

The *Pledged Loan Monitoring (PLM) Report* is a monthly report submission, allowing the BG Program to monitor the terms, payment performance and value of the underlying collateral (i.e., pledged loan receivables) for the Bond Loans on a real-time basis.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2014–23046 Filed 9–26–14; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

September 23, 2014.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before October 29, 2014 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by emailing *PRA@treasury.gov,* calling (202) 927–5331, or viewing the entire information collection request at *www.reginfo.gov.*

Bureau of the Fiscal Service

OMB Number: 1535–0059.

Type of Review: Revision of a currently approved collection.

Title: Special Form of Assignment for U.S. Registered Definitive Securities and U.S. Bearer Securities for Conversion to BECCS or CUBES.

Form: PD F 1832.

Abstract: PD F 1832 is completed by the owner (or authorized representative) of registered securities to convert the definitive (paper) registered securities to an account in TreasuryDirect®; convert the definitive (paper) registered securities to a book-entry account with a commercial financial institution, or

allow matured or called definitive (paper) registered securities to be paid to another party.

Affected Public: Individuals or households.

Estimated Annual Burden Hours: 400.

OMB Number: 1535–0113.

Type of Review: Revision of a currently approved collection.

Title: Disclaimer and Consent with Respect to United States Savings Bond/Notes.

Form: PD F 1849.

Abstract: Used to obtain a disclaimer and consent as the result of an error in registration or otherwise the payment, refund of the purchase price, or reissue as requested by one person would appear to affect the right, title or interest of some other person.

Affected Public: Individuals or households.

Estimated Annual Burden Hours: 300.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2014–23053 Filed 9–26–14; 8:45 am]

BILLING CODE 4810–39–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Funding Opportunity Title: Notice of Funds Availability (NOFA) Inviting Applications for Financial Assistance (FA) Awards or Technical Assistance (TA) Grants Under the Community Development Financial Institutions Program (CDFI Program) FY 2015 Funding Round

Announcement Type: Announcement of funding opportunity.

Funding Opportunity Number: CDFI–2015–FATA

Catalog Of Federal Domestic Assistance (CFDA) Number: 21.020

KEY DATES:

TABLE 1—FY 2015 CDFI PROGRAM FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (Eastern daylight time-EDT)	Submission method
CDFI Certification Applications	October 24, 2014	5:00 p.m. EDT	MyCDFI Fund.
Last day to contact CDFI Program staff	November 20, 2014	5:00 p.m. EDT	CDFI Fund Helpdesk: 202–653–0421 or *cdfihelp@cdfi.treas.gov*.
CDFI Program Application for Financial Assistance (FA) or Technical Assistance (TA).	November 24, 2014	11:59 p.m. EDT	Electronically via Grants.gov.

Executive Summary: Through the CDFI Program, the CDFI Fund provides (i) FA awards of up to $2 million to Certified Community Development Financial Institutions (CDFIs) to build their financial capacity to lend to their Target Markets, and (ii) TA grants of up to $125,000 to build Certified, Certifiable, and Emerging CDFIs' organizational capacity to serve their Target Markets. All awards provided through this NOFA are subject to funding availability.

I. Program Description

A. *History:* The CDFI Fund was established by the Riegle Community Development Banking and Financial Institutions Act of 1994 to promote economic revitalization and community development through investment in and assistance to CDFIs. Since its creation in 1994, the CDFI Fund has awarded over $1.9 billion to CDFIs, community development organizations, and financial institutions through the Community Development Financial Institutions Program (CDFI Program), the Native American CDFI Assistance Program (NACA Program), the Bank Enterprise Award Program (BEA Program), the Capital Magnet Fund, and the Financial Education and Counseling Pilot Program. In addition, the CDFI Fund has allocated $40 billion in tax credit allocation authority through the New Markets Tax Credit Program (NMTC Program) and has obligated $325 million in bond guarantees to Eligible CDFIs through the CDFI Bond Guarantee Program.

B. *Priorities:* Through the CDFI Program's FA awards and TA grants, the CDFI Fund invests in and builds the capacity of for-profit and non-profit community based lending organizations known as Community Development Financial Institutions, or CDFIs. These organizations, Certified as CDFIs by the CDFI Fund, serve rural and urban low-income people and communities across the nation that lack adequate access to affordable financial products and services.

C. *Authorizing Statutes and Regulations:* The CDFI Program is authorized by the Riegle Community Development Banking and Financial Institutions Act of 1994 (Pub. L. 103–325, 12 U.S.C. 4701 *et seq.*). The regulations governing the CDFI Program are found at 12 CFR Parts 1805 and 1815 (the Regulations) and set forth evaluation criteria and other program requirements. The CDFI Fund encourages Applicants to review the Regulations, this NOFA, the Application, and the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Part 200; 78 FR 78590) (Uniform Federal Award Requirements) for a complete understanding of the program; capitalized terms in this NOFA are defined in the authorizing statute, the Regulations, this NOFA, the Application, and the Uniform Federal Award Requirements. Details regarding Application content requirements are found in the Application and related materials.

D. *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Part 200):* In December 2013, the Office of Management and Budget (OMB) published a final rule that provides a government-wide framework for grants management, with the goal of combining several OMB guidance circulars, reducing administrative burden for Recipients, and reducing the risk of waste, fraud and abuse of Federal financial assistance. The Uniform Federal Award Requirements codifies financial, administrative, procurement, and program management standards that Federal award agencies must

follow. When evaluating award applications, awarding agencies must evaluate the risks to the program posed by each applicant, and each applicant's merits and eligibility. These requirements are designed to ensure that applicants for Federal assistance receive a fair and consistent review prior to an award decision. This review will assess items such as the Applicant's financial stability, quality of management systems, history of performance, and single audit findings. In addition, the Uniform Federal Award Requirements includes guidance on audit requirements and other award requirements that award Recipients must comply with.

E. *Funding limitations:* The CDFI Fund reserves the right to fund, in whole or in part, any, all, or none of the Applications submitted in response to this NOFA. The CDFI Fund also reserves the right to reallocate funds from the amount that is anticipated to be available through this NOFA to other CDFI Fund programs, particularly if the CDFI Fund determines that the number of awards made through this NOFA is fewer than projected.

II. Federal Award Information

A. *Funding Availability:*

1. *FY 2015 Funding Round:* Subject to funding availability, the CDFI Fund expects to award, through this NOFA, approximately $186 million as indicated in the following table:

TABLE 2—FY 2015 FUNDING ROUND ANTICIPATED CATEGORY AMOUNTS

Funding categories (See definition in Table 7)	Estimated total amount to be awarded (millions)	Award amount		Estimated number of awards	Average amount awarded in FY 2013
		Minimum	Maximum		
FA: Category I/Small and/or Emerging CDFI Assistance (SECA)	$19	$100,000	$700,000	40	$400,000
FA: Category II/Core	128	100,000	2,000,000	110	1,250,000
TA	4	10,000	125,000	40	67,500
Healthy Food Financing Initiative—Financial Assistance (HFFI–FA) *	35	500,000	5,000,000	13	2,750,000
Total	186			203	

* HFFI–FA appropriation will be allocated in one competitive round between the NACA and CDFI Program NOFAs.

The CDFI Fund reserves the right to award more or less than the amounts cited above in each category, based upon available funding and other factors, as appropriate.

2. *Funding Availability for the FY 2015 Funding Round:* Funds for the FY 2015 Funding Round have not yet been appropriated; if Congress does not appropriate funds for the CDFI Program, there will not be a FY 2015 Funding Round. If funds are appropriated, the amount of such funds may be greater or less than the amounts set forth above. In the event that funds are not appropriated for the NACA Program, CDFIs that qualify for NACA Program awards are encouraged to apply for CDFI Program awards through this NOFA. The CDFI Fund reserves the right to contact applicants to seek additional information in the event that the final FY 2015 appropriations for the CDFI Program change any of the requirements in this NOFA.

3. *Anticipated Start Date and Period of Performance:* The CDFI Fund anticipates the period of performance for the FY 2015 Funding Round will begin in the fall of calendar year 2015. Specifically, the period of performance for TA grants begins with the date of the notice of the award and includes an award Recipient's two full consecutive fiscal years after the date of the notice of the award, during which the Recipient must meet the performance goals set forth in the Assistance Agreement. The period of performance for FA awards includes an award Recipient's three full consecutive fiscal years after the date of the notice of the award, during which time the Recipient must meet its performance goals.

B. *Types of Awards:* Through the CDFI Program, the CDFI Fund provides two types of awards: Financial Assistance (FA) and Technical Assistance (TA) awards. An Applicant may submit an Application for a TA grant or an FA award, but not both.

1. *FA Awards:* FA awards can be in the form of loans, grants, Equity Investments, and deposits and credit union shares. The form of the FA award is based on the form of the matching funds that the Applicant includes in its Application, unless Congress waives the matching funds requirement. Matching funds are required for FA awards, must be from non-Federal sources, and cannot have been used as matching funds for any other Federal award. The CDFI Fund reserves the right, in its sole discretion, to provide an FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

2. *Healthy Food Financing Initiative—Financial Assistance (HFFI–FA) Awards:* HFFI–FA awards will be provided as a supplement to FA awards; therefore, only those Applicants that have been selected to receive an FA award through the CDFI Program FY 2015 Funding Round will be eligible to receive an HFFI–FA award. HFFI–FA awards can be in the form of loans, grants, Equity Investments, and deposits and credit union shares. The form of the HFFI–FA award is based on the form of the matching funds that the Applicant includes in its Application, unless Congress waives the matching funds requirement. Matching funds are required for HFFI–FA awards, must be from non-Federal sources, and cannot have been used as matching funds for any other Federal award. The CDFI Fund reserves the right, in its sole discretion, to provide an HFFI–FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

3. *TA Grants:* TA is provided in the form of grants. The CDFI Fund reserves the right, in its sole discretion, to provide a TA grant in an amount other than which the Applicant requests; however, the TA grant amount will not exceed the Applicant's request as stated in its Application and the applicable budget chart.

C. *Eligible Activities:*

1. *FA Awards:*

FA and HFFI–FA award funds can be expended for activities in the following five categories: (i) Financial Products; (ii) Financial Services; (iii) Loan Loss Reserves; (iv) Development Services;

and (v) Capital Reserves. Each of the allowable activity categories will be eligible for indirect costs and an associated indirect cost rate. Indirect cost rates will be determined as part of the terms and conditions of the award. For purposes of this NOFA, the five activity categories are defined as follows:

TABLE 3—FA AND HFFI–FA ELIGIBLE ACTIVITY CATEGORIES

FA Activity	FA Activity definition	Eligible CDFI Institution types
i. Financial Products	FA expended as loans, Equity Investments and similar financing activities (as determined by the CDFI Fund) including the purchase of loans originated by Certified CDFIs and the provision of loan guarantees; in the case of CDFI Intermediaries, grants to CDFIs and/or emerging CDFIs and deposits in Insured Credit Union CDFIs, emerging Insured Credit Union CDFIs, and/or State-Insured Credit Union CDFIs.	All.
ii. Financial Services	FA expended for the provision of checking and savings accounts, certified checks, automated teller machines services, deposit taking, remittances, safe deposit box services, and other similar services.	Insured Depository Institutions only.
iii. Loan Loss Reserves	FA set aside in the form of cash reserves, or through accounting-based accrual reserves, to cover losses on loans, accounts, and notes receivable made in the Applicant's Target Market, or for related purposes that the CDFI Fund deems appropriate.	All.
iv. Development Services	FA expended for activities that promote community development and are integral to the Applicant's provision of Financial Products and Financial Services. Such services that shall prepare or assist current or potential borrowers or investees to utilize the Financial Products or Financial Services of the Applicant.	All.
v. Capital Reserves	FA set aside as reserves to support the Applicant's ability to leverage other capital, for such purposes as increasing its net assets or serving the financing needs of its Target Market, or for related purposes as the CDFI Fund deems appropriate.	Insured Depository Institutions only.

2. *TA Grants:*

TA grant funds can be expended for the following seven eligible activity categories: (i) Compensation—personal services; (ii) Compensation—fringe benefits; (iii) Professional Service Costs; (iv) Travel Costs; (v) Training and Education Costs; (vi) Equipment and other capital expenditures; and (vii) Supplies. Each of the allowable activity categories will be eligible for indirect costs and an associated indirect cost rate. Indirect cost rates will be determined as part of the terms and conditions of the award. For purposes of this NOFA, the seven activity categories are defined as follows:

TABLE 4—TA ELIGIBLE ACTIVITY CATEGORIES

(i) Compensation—personal services	TA paid to cover salaries of the Applicant's personnel that are paid currently or accrued by the Applicant for work performed directly related to carrying out the purpose of the TA grant (including activities related to becoming certified as a CDFI), subject to the applicable provisions of the Uniform Federal Award Requirements.
(ii) Compensation—fringe benefits	TA paid to cover costs of the Applicant's personnel employment (other than the employees' salaries income) in proportion to the salary charged to the TA grant, to the extent that such payments are made under formally established and consistently applied organizational policies, subject to the applicable provisions of the Uniform Federal Award Requirements.
(iii) Professional service costs	TA used to pay for professional and consultant services rendered by persons who are members of a particular profession or possess a special skill, and who are not officers or employees of the Recipient, subject to the applicable provisions of the Uniform Federal Award Requirements. Payment for a consultant's services may not exceed the daily equivalent of the current maximum rate paid to an Executive Schedule Level IV Federal employee.
(iv) Travel costs	TA used to pay expenses for transportation, lodging, subsistence, and related items incurred by the Applicant's personnel who are on travel status on business related to the TA grant, subject to the applicable provisions of the Uniform Federal Award Requirements.
(v) Training and education costs	TA used to pay the cost of training and education provided for employee development, subject to the applicable provisions of the Uniform Federal Award Requirements.
(vi) Equipment	TA used to pay for tangible personal property, having a useful life of more than one year and a per-unit acquisition cost of at least $5,000 and subject to the applicable provisions of the Uniform Federal Award Requirements. Examples include office equipment, furnishings, and information technology equipment and systems.
(vii) Supplies	TA used to pay for tangible personal property with a per unit acquisition of less than $5,000 and subject to the applicable provisions of the Uniform Federal Award Requirements.

III. Eligibility Information

A. *Eligible Applicants:* For the purposes of this NOFA, the following tables set forth the eligibility criteria to receive an award from the CDFI Fund, along with certain definitions of terms. There are four categories of Applicant eligibility criteria: (1) CDFI certification criteria (Table 5); (2) requirements that apply to all Applicants (Table 6); (3) requirements that apply to TA Applicants (Table 7); and (4) requirements that apply to FA Applicants (Table 8).

TABLE 5—CDFI CERTIFICATION CRITERIA DEFINITIONS

Certified CDFI	• An entity that the CDFI Fund has officially notified that it meets all CDFI certification requirements.
Certifiable CDFI	• An entity that has submitted a CDFI Certification Application to the CDFI Fund demonstrating that it meets the CDFI certification requirements but which has not yet been officially certified. • The CDFI Fund will not enter into an Assistance Agreement or disburse FA award funds unless and until an Applicant is Certified CDFI.
Emerging CDFI	• A non-Certified entity that has not submitted a CDFI Certification Application but demonstrates to the CDFI Fund that it has an acceptable plan to meet certification requirements by the end of its period of performance, or another date that the CDFI Fund selects. • An Emerging CDFI that has prior award(s) will be held to the CDFI certification performance goal and measure(s) stated in its prior Assistance Agreement(s). • Emerging CDFIs may only apply for TA grants; they are not eligible to apply for FA awards. • Each Emerging CDFI selected to receive a TA grant will be required to become a Certified CDFI by a date specified in the Assistance Agreement.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS

Applicant	• Only the entity that will carry out the proposed award activities should apply for an award (e.g., the intended award Recipient). • An Applicant that applies on behalf of another organization will be rejected without further consideration, except for Depository Institution Holding Companies (see below).
Application type and submission overview.	• The CDFI Fund will only accept Applications that use the official Word Narrative and Excel Workbook templates provided on the Grants.gov and CDFI Fund Web sites. • Applications submitted with alternative or altered templates will not be considered. • Only Applications submitted via the Grants.gov Web site will be accepted for review.
Microsoft Word Narrative Template	• Each Applicant must submit a completed Microsoft Word Narrative Template. • An Applicant that does not submit a completed Narrative Template will be rejected without further consideration.
Microsoft Excel Workbook	• Each Applicant must submit a completed Microsoft Excel Workbook template. • An Applicant that does not submit a completed Microsoft Excel Workbook template will be rejected without further consideration.
Employer Identification Number (EIN)	• An Applicant must provide an electronic copy of the letter from the IRS as evidence that the Applicant has been assigned its own unique EIN. • The CDFI Fund will reject an Application submitted with the EIN of a parent or Affiliate organization. • The CDFI Fund will deem an Application incomplete if it does not include an IRS document that verifies the Applicant's EIN (a tax return is not an acceptable form of IRS documentation). The CDFI Fund will allow an Applicant two business days upon request by the CDFI Fund to submit the appropriate documentation before the Application will be rejected without further consideration due to missing documentation of the Applicant's EIN.
DUNS number	• Pursuant to OMB guidance (68 FR 38402), an Applicant must apply using its unique DUNS number in Grants.gov. • The CDFI Fund will reject an Application submitted with the DUNS number of a parent or Affiliate organization.
MyCDFI Fund account	• Each Applicant must register as an organization in MyCDFI Fund by the Application deadline. • The Authorized Representative and/or Application point of contact must be included as ''users'' in the Applicant's MyCDFI Fund account. • An Applicant that fails to properly register and update its MyCDFI Fund account may miss important communication from the CDFI Fund that could impact its Application. • The CDFI Fund will allow an Applicant two business days upon request by the CDFI Fund to create or update its MyCDFI Fund account before the Application will be rejected without further consideration.
501(c)(4) status	• Pursuant to 2 U.S.C. 1611, a 501(c)(4) any organization that engages in lobbying activities is not eligible for the receipt of a CDFI or NACA Program award.
Compliance with Federal civil rights requirements.	• An Applicant may not be eligible to receive an award if proceedings have been instituted against it in, by, or before any court, governmental agency, or administrative body, and a final determination within the last three years indicates the Applicant has violated any of the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975, (42 U.S.C. 6101–6107), and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.
Depository Institution Holding Company Applicant.	• In the case where a CDFI Depository Institution Holding Company Applicant intends to carry out the activities of an award through its CDFI Subsidiary Insured Depository Institution, the Application must be submitted by the CDFI Depository Institution Holding Company and reflect the consolidated activities and financial performance of the CDFI Subsidiary Insured Depository Institution.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS—Continued

	• Authorized representatives of both the Depository Institution Holding Company and the CDFI Subsidiary Insured Depository Institution must certify that the information included in the Application represents that of the CDFI Subsidiary Insured Depository Institution and that the award funds will be used to support the CDFI Subsidiary Insured Depository Institution for the eligible activities outlined in the Application.
Insured CDFI—Insured Credit Union and Insured Depository Institution.	• To be eligible for an award, each Insured Depository Institution Applicant must have a CAMELS/CAMEL (rating for banks and credit unions, respectively), by its Federal regulator of at least "4." • Organizations with CAMELS/CAMEL ratings of "5" will not be eligible for awards.
Use of award	• All awards made through this NOFA must be used to support the Applicant's approved FA or TA eligible activities (see Section II.C). • Awards cannot be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others (except Depository Institution Holding Company Applicants.)
Requested award amount for eligible activities.	• An Applicant must state its requested award amount and proposed eligible activities in the "Award Request Table" (Tab 4—Purpose) in the Excel Workbook. • An Applicant that does not fully complete the "Award Request Table" will be rejected without further consideration.
Pending resolution of noncompliance	• The CDFI Fund will consider an Application submitted by an Applicant that has pending noncompliance issues if the CDFI Fund has not yet made a final determination as to whether the Applicant is in default of any of its previously executed award agreement(s).
Default status	• The CDFI Fund will not consider an Application submitted by an Applicant that has been notified by the CDFI Fund in writing that it is in default of a previously executed award agreement under any CDFI Fund program, at the time of the Application deadline. • The CDFI Fund will not consider any Applicant that has defaulted on a CDFI Program loan within five years of the Application deadline.
Undisbursed award funds and calculations (general).	• An Applicant that has funds from a prior award that have not been disbursed, as defined in (a)–(d) below, as of the Application deadline will not be eligible for an award. (a) The CDFI Fund will include the combined undisbursed award funds of the Applicant and its Affiliates. (b) Balances on undisbursed award funds cannot exceed five percent of the combined BEA Program awards made to the Applicant in FYs 2011, 2012, and 2013. (c) Balances on undisbursed award funds cannot exceed five percent of the combined CDFI/NACA Program awards made to the Applicant in FYs 2011, 2012, and 2013. (d) The undisbursed award funds calculation does not include award funds for: (i) Which the Recipient has submitted a full and complete disbursement request before the Application deadline; (ii) an award that has been terminated or de-obligated; or (iii) an award that does not have a fully executed award agreement; and (iv) the tax credit allocation authority made available through the NMTC Program.

TABLE 7—ELIGIBILITY REQUIREMENTS FOR TA APPLICANTS

CDFI certification status	(1) Certifiable or Emerging CDFIs (see definitions in Table 5), or (2) Certified CDFIs (see Table 5) that meet the SECA criteria (see Table 8).
Matching funds	• Matching funds documentation is not required for TA awards.

TABLE 8—ELIGIBILITY REQUIREMENTS FOR FA APPLICANTS

CDFI certification status	• Each FA Applicant must be a Certified CDFI prior to the announcement of award decisions. • An Applicant that is in a cure period to remedy CDFI recertification deficiencies at the time of award announcements will not be eligible for an FA award under this NOFA.
Matching funds documentation	• All Applicants must submit acceptable documentation that they have received or will receive matching funds. Applications that do not submit acceptable matching funds documentation will not be evaluated. • Award size will be limited to no more than two times the amount of In-Hand or Committed matching funds documentation provided at the time of Application, but actual award size may be less than this amount. Awards will be obligated in like form to the matching funds provided. • Award payments from the CDFI Fund will require eligible dollar-for-dollar In-Hand matching funds for the total payment amount. • Any award Recipient that is not able to demonstrate dollar-for-dollar matching funds by the end of the Matching Funds Window will have its award amount reduced and the corresponding funds will be de-obligated.
$5 Million funding cap	• The CDFI Fund is prohibited from obligating more than $5 million in CDFI and NACA Program awards, in the aggregate, to any one organization and its Subsidiaries and Affiliates during any three-year period. • The CDFI Fund will make FY 2015 funding round award announcements on or after August 7, 2015; the CDFI Fund will include awards in the cap calculation that were provided to an Applicant (and its Subsidiaries and Affiliates) under the FY 2013 and 2014 funding rounds, as well as the requested FY 2015 award, excluding HFFI–FA awards.
FA Category I (SECA)	• To be an eligible SECA Applicant, an Applicant must meet the following criteria: (1) Be a Certified or Certifiable CDFI; (2) Request $700,000 or less in FA funds; and either

TABLE 8—ELIGIBILITY REQUIREMENTS FOR FA APPLICANTS—Continued

	(3) Have total assets * as of the end of the Applicant's most recent fiscal year end in the following amounts: • Insured Depository Institutions and Depository Institution Holding Companies: up to $250 million • Insured Credit Unions: up to $10 million • Venture capital funds: up to $10 million • Other CDFIs: up to $5 million OR (4) Have begun operations ** on or after January 1, 2011 * "Total assets" is defined as the Total Assets of Fiscal Year End Date field stated in the CDFI Program Applicant Intake Form. ** "Have begun operations" is defined as the financing activity start date indicated in the Applicant's MyCDFI Fund account.
FA Category II (Core)	• A Core Applicant must be either a Certified or Certifiable CDFI as defined in Table 5. • An Applicant that meets the SECA requirements stated above, that requests more than $700,000 in award funds is categorized as an FA Category II (Core) Applicant, regardless of its total assets and/or years in operation.
HFFI–FA	• All HFFI–FA Applicants must: ○ Apply for an FA Core or SECA award; ○ Meet all FA award eligibility requirements; and ○ Complete and submit a CDFI/NACA Program Financial Assistance Application along with an HFFI–FA Narrative Template at the time of Application.

B. *Matching Funds Requirements:* In order to receive an FA award, an Applicant must provide documentation of eligible dollar-for-dollar matching funds. The CDFI Fund will review all matching funds documentation prior to award disbursement and will disburse funds based upon eligible In-Hand matching funds (see Table 9 for the definition of In-Hand). The CDFI Fund encourages Applicants to review the Regulations at 12 CFR 1805.500, the Uniform Federal Award Requirements, and the matching funds guidance materials in the Excel Workbook, which is available on the CDFI Fund's Web site and Grants.gov. Table 9 provides a summary of the matching funds requirements; additional details are set forth in the Application materials.

TABLE 9—MATCHING FUNDS REQUIREMENTS

Matching funds requirements by application type.	The following Applicants must provide documentation of acceptable matching funds: • Category 1/SECA FA Applicants, • Category II/Core FA Applicants; and • HFFI–FA Applicants. (upon request) * TA Applicants are not required to provide matching funds. * The matching funds requirement for HFFI–FA applicants was waived in the appropriations bill for FY 2014 and final FY 2015 appropriations are still pending. HFFI–FA applicants are not required to submit matching funds for their HFFI–FA award request at the time of application. However, the CDFI Fund reserves the right to request matching funds from HFFI–FA applicants if matching funds are not waived in the final FY 2015 CDFI Program appropriation.
Amount of required match	Applicants must submit documentation of eligible In-Hand dollar-for-dollar non-Federal matching funds for every FA award dollar to be disbursed by the CDFI Fund.
Determination of award form	FA awards will be made in comparable form and value to the eligible In-Hand or Committed matching funds documentation submitted by the Applicant. • For example, if an FA Applicant provides documentation of eligible loan matching funds for $200,000 and $400,000 of its matching funds in the form of grant, the CDFI Fund will obligate $200,000 of the FA award as a loan and $400,000 as a grant.
Matching Funds Window definition	• The Applicant must receive eligible In-Hand matching funds between January 1, 2013 and January 15, 2016. • An award Recipient must provide the CDFI Fund with all documentation demonstrating the receipt of matching funds by January 31, 2016.
Matching funds and form of award	• Recipients will be approved for a maximum award size of two times the total amount of eligible In-Hand or Committed matching funds documentation included in the Application, so long as they do not exceed the award amount limit. • The form of the matching funds documented in the Application determines the form of the award.
In-Hand matching funds definition	• Matching funds are eligible and In-Hand when the Applicant actually receives disbursement of the matching funds and includes acceptable documentation in the Application, showing the source, form (e.g., grant, loan, deposit, and Equity Investment), and amount of the matching funds. • The following documentation, depending on the type of award being requested, must be included in the Application: i. loan—the loan agreement and/or promissory note; ii. grant—the grant letter or agreement for all grants of $50,000 or more; iii. Equity Investment—the stock certificate and shareholder agreement; iv. retained earnings—audits or call reports from regulating entity; and v. third party in-kind contribution—evidence of receipt of contribution and valuation; and vi. clearly legible documentation that demonstrates receipt of the matching funds including the date of the transaction and the amount, such as a copy of a check or a wire transfer statement. • The CDFI Fund will only disburse FA awards that have eligible In-Hand matching funds, as determined by the CDFI Fund.

TABLE 9—MATCHING FUNDS REQUIREMENTS—Continued

Committed matching funds definition	• Matching funds are Committed when the Applicant has entered into or received a legally binding commitment from the matching funds source showing the matching funds will be disbursed to the Applicant at a future date. • The Applicant must provide to the CDFI Fund acceptable written documentation showing the source, form, and amount of the Committed matching funds (including, in the case of a loan, the terms thereof), as well as the anticipated disbursement date of the Committed funds.
Limitations on matching funds	• Matching funds must be from non-Federal sources. • Applicants cannot proffer matching funds that were accepted as matching funds for a prior FA award under the CDFI Program or under another Federal grant or award program. • Matching funds must comply with Regulations at 12 CFR 1805.500 et seq. • The CDFI Fund will not consider any FA Application that does not include any In-Hand or Committed matching funds documentation as of the Application deadline. • Matching funds must be attributable to at least one of the five eligible activities (see Section II.C).
Rights of the CDFI Fund	• The CDFI Fund reserves the right to contact the matching funds source to discuss the matching funds and the documentation that the Applicant has provided. • The CDFI Fund may grant an extension of the Matching Funds Window (defined in Table 9), on a case-by-case basis, if the CDFI Fund deems it appropriate. • The CDFI Fund reserves the right to rescind all or a portion of an FA award and re-allocate the rescinded award amount to other qualified Applicant(s), if an award Recipient fails to obtain In-Hand 100 percent of the required Matching Funds during the Matching Funds Window.
Matching funds in the form of third-party in-kind contributions.	• Third party in-kind contributions are the value of non-cash contributions (i.e., property or services) provided by non-Federal third parties. • Third party in-kind contributions will be considered to be in the form of a grant. • Third party in-kind contributions may be in the form of real property, equipment, supplies, and other expendable property, and the value of goods and services directly benefiting the eligible activities. • For third-party in-kind contributions, the fair market value of goods and services must be documented. • Applicants will be responsible for documenting the value of all in-kind contributions as described in the Uniform Federal Award Requirements.
Matching funds in the form of a loan	• An FA award made in the form of a loan will have the following standardized terms: • A 13-year term with semi-annual interest-only payments due in years 1 through 10, and fully amortizing payments due each year in years 11 through 13; and • A fixed interest rate of 2.5 percent, which was calculated by the CDFI Fund based on the U.S. Department of the Treasury's 10-year Treasury note. • The Applicant's matching funds loan(s) must: i. have a minimum of a 3-year term. Loans presented as matching funds with less than a 3-year term will not qualify as eligible match; and ii. not be from a Federal source.
Ineligible matching funds	• If the CDFI Fund determines that any portion of the Applicant's matching funds is ineligible, the CDFI Fund will permit the Applicant to offer documentation of alternative matching funds as a substitute for the ineligible matching funds. • In such instances: i. the Applicant must provide acceptable alternative matching funds documentation within the period of time specified by the CDFI Fund, and ii. the alternative matching funds documentation will not increase the total amount of FA requested.
Use of matching funds from a prior CDFI Program Recipient.	If an Applicant offers matching funds documentation from an organization that was a prior Recipient under the CDFI Program, the Applicant must prove to the CDFI Fund's satisfaction that such funds do not consist, in whole or in part, of CDFI Program funds or other Federal funds.
Matching funds in the form of retained earnings.	• Retained earnings are eligible for use as matching funds when the CDFI Fund calculates an amount equal to: i. the increase in retained earnings that occurred over any one of the Applicant's fiscal years within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and matching funds previously used for an award; or ii. the annual average of such increases that occurred over any three consecutive fiscal years of the Applicant with at least one of the fiscal years occurring within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and matching funds previously used for an award; or iii. any combination of (i) and (ii) above that does not include matching funds previously used for an award. • Retained earnings will be matched in the form of a grant.
Special rule for Insured Credit Unions	• An Insured Credit Union's retained earnings are eligible for use as matching funds when the CDFI Fund calculates an amount equal to: i. the increase in retained earnings that occurred over any one of the Applicant's fiscal years within the Matching Funds Window, adjusted to remove revenue from Federal sources and matching funds previously used for an award; or ii. the annual average of such increases that occurred over any three consecutive fiscal years of the Applicant with at least one of the fiscal years occurring within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and matching funds previously used for an award; or iii. the entire retained earnings that have been accumulated since the inception of the Applicant, as provided in the Regulations. • If option (iii) is used, the Applicant must increase its member and/or non-member shares and/or total loans outstanding by an amount equal to the amount of retained earnings committed as matching funds.

TABLE 9—MATCHING FUNDS REQUIREMENTS—Continued

	• This increase will be measured from March 31, 2015 and must occur by the end of the Recipient's Year 1 of Performance Period, as set forth in its Assistance Agreement, and will be based on amounts reported in the Applicant's National Credit Union Administration (NCUA) form 5300 Call Report. • The CDFI Fund will assess the likelihood of this increase during the Application review process. • An award will not be made to any Applicant that has not demonstrated in the relevant financial statements or NCUA form 5300 Call Report that it has increased shares and/or loans by at least 25 percent of the requested FA award amount between December 31, 2013, and December 31, 2014. • The matching funds are not In-Hand until the Recipient has increased its member and/or non-member shares or total loans outstanding within the time period specified.

IV. Application and Submission Information

A. *Address to Request an Application Package:* Application materials can be found on Grants.gov and the CDFI Fund's Web site at *www.cdfifund.gov/cdfi.* Applicants may request a paper version of any Application material by contacting the CDFI Fund Help Desk at *cdfihelp@cdfi.treas.gov.*

B. *Content and Form of Application Submission:*

All Applications must be prepared using the English language and calculations must be made in U.S. dollars. The following table lists the required Application documents for the FY 2015 Funding Round. The CDFI Fund reserves the right to request and review other pertinent or public information that has not been specifically requested in this NOFA or the Application. Information submitted by the Applicant that the CDFI Fund has not specifically been requested will not be reviewed or considered as part of the Application.

TABLE 10—REQUIRED APPLICATION DOCUMENTS

Application documents	Applicant type	Submission format
Applicant Intake Form	All Applicants	Fillable PDF
SF–424	All Applicants	Fillable PDF.
IRS Documentation of Organization's EIN	New Applicants only	PDF.
Application Excel Workbook Tab 3—Input Sheet	All Applicants	Excel.
Application Excel Workbook Tab 4—Purpose	All Applicants	Excel.
Application Excel Workbook Tab 5—Products	All Applicants	Excel.
Application Excel Workbook Tab 6—Policies	All Applicants	Excel.
Application Excel Workbook Tab 7—People	All Applicants	Excel.
Application Excel Workbook Tab 8—Partnerships	All Applicants	Excel.
Application Excel Workbook Tab 9—Performance	All Applicants	Excel.
Application Excel Workbook Tab 10—Projections	All Applicants	Excel.
Application Excel Workbook Tab 13—Matching Funds Breakout Table	FA Applicants	Excel.
Application Excel Workbook Tab 14—Matching Funds Grants under $50,000.	FA Applicants, if applicable	Excel.
Matching Funds Documentation	FA Applicants	PDF.
Narrative Template	All Applicants	Word document.
HFFI–FA Narrative Template	HFFI–FA Applicants	Word document.
Policies and Procedures	FA Applicants	PDF.
Key Staff Resumes	All Applicants	PDF or Word document.
Organizational Chart	All Applicants	PDF.
Community Partnership Agreement	All Applicants, if applicable	PDF or Word document.
Audited Financial Statements, September 30, 2014 Quarter End Financial Statements, and Call Reports (Insured Depository Institutions only).	FA Applicants	PDF.
Financial Statements, September 30, 2014 Quarter End Financial Statements, and Call Reports (Insured Depository Institutions only).	TA Applicants	PDF.

C. *Application Submission:* All Application documents must be submitted through the Grants.gov electronic system. The CDFI Fund will not accept Applications via MyCDFI Fund accounts, email, mail, facsimile, or other forms of communication, except in extremely rare circumstances that have been pre-approved by the CDFI Fund.

The CDFI Fund strongly encourages Applicants to start the Grants.gov registration process as soon as possible (refer to the following link: *http://www.grants.gov/web/grants/register.html*) as it may take several weeks to complete. An Applicant that has previously registered with Grants.gov must verify that its registration is current and active. Applicants should contact Grants.gov directly with questions related to the registration or submittal process as the CDFI Fund does not maintain the Grants.gov system.

D. *Dun & Bradstreet Universal Numbering System (DUNS):* Pursuant to the Uniform Federal Award Requirements, each Applicant must provide as part of its Application submission, a Dun and Bradstreet Universal Numbering System (DUNS) number. Applicants without a DUNS number will not be able to register and submit an Application in the Grants.gov system. Please allow sufficient time for Dun & Bradstreet to respond to inquiries and/or requests for DUNS numbers.

E. *System for Award Management (SAM):* Any entity applying for Federal grants or other forms of Federal financial assistance through Grants.gov must be registered in SAM before submitting its Application. The SAM registration process can take several weeks to complete. Applicants that have previously completed the SAM registration process must verify that

their SAM accounts are current and active. Each Applicant must continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an Application under consideration by a Federal awarding agency. The CDFI Fund will not consider any Applicant that fails to properly register or activate its SAM account and, as a result, is unable to submit its Application by the Application deadline. Applicants must contact SAM directly with questions related to registration or SAM account changes as the CDFI Fund does not maintain this system. For more information about SAM, please visit *https://www.sam.gov.*

F. *Submission Dates and Times:*

1. *Submission Deadlines:* The following table provides the critical deadlines for the FY 2015 Funding Round.

TABLE 11—FY 2015 FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (EDT)	Submission method
CDFI Certification Applications	October 24, 2014	5:00 p.m.	MyCDFI Fund: *https://www.cdfifund.gov/myCDFI.*
Last day to contact CDFI Program staff	November 20, 2014	5:00 p.m.	CDFI Fund Helpdesk: 202–653–0421 or *cdfihelp@cdfi.treas.gov.*
CDFI Program Application for Financial Assistance (FA) or Technical Assistance (TA).	November 24, 2014	11:59 p.m.	Electronically via Grants.gov.

2. *Confirmation of Application Submission:* Each Applicant will receive an email from Grants.gov immediately after Application submission confirming that the submission has entered the Grants.gov system. This email will contain a tracking number for the submitted Application package. Within 48 hours, the Applicant will receive a second email which will indicate if the submitted Application package was either successfully validated or rejected with errors. However, Applicants should not rely on the email notification from Grants.gov to confirm that their Applications were validated. Applicants are strongly encouraged to use the tracking number provided in the first email to closely monitor the status of their Application package by contacting the helpdesk at Grants.gov directly. The Application package is not officially accepted by the CDFI Fund until Grants.gov has validated the Application.

3. *Multiple Application Submissions:* If an Applicant submits multiple Applications, the CDFI Fund will only review the last Application submitted in Grants.gov.

4. *Late Submission:* The CDFI Fund will not accept an Application submitted after the Application deadline except where the submission delay was a direct result of a Federal government administrative or technological error. In such case, the Applicant must submit a request for acceptance of late Application submission and include documentation of the error no later than two business days after the Application deadline. The CDFI Fund will not respond to request for acceptance of late Application submissions after that time period. Applicants must submit late Application submission requests to the CDFI Helpdesk at *cdfihelp@cdfi.treas.gov* with a subject line of ''Late Application Submission Request.''

G. *Funding Restrictions:* FA, HFFI–FA and TA awards are limited by the following:

1. *FA awards:*

(a) An award Recipient shall use FA funds only for the eligible activities described in Section II. Award Description (C)(1) of this NOFA and its Assistance Agreement.

(b) A Recipient may not distribute FA funds to an Affiliate, Subsidiary, or any other entity, without the CDFI Fund's prior written approval.

(c) FA funds shall only be disbursed to the Recipient.

(d) The CDFI Fund, in its sole discretion, may disburse FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

2. *HFFI–FA awards:*

(a) An award Recipient shall use HFFI–FA funds only for the eligible activities described in Section II. Award Description (C)(1) of this NOFA and its Assistance Agreement.

(b) A Recipient may not distribute FA funds to an Affiliate, Subsidiary, or any other entity, without the CDFI Fund's prior written approval.

(c) HFFI–FA funds shall only be disbursed to the Recipient.

(d) The CDFI Fund, in its sole discretion, may disburse HFFI–FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

3. *TA grants:*

(a) An award Recipient shall use TA funds only for the eligible activities described in Section II. Award Description (C)(2) of this NOFA and its Assistance Agreement.

(b) A Recipient may not distribute TA funds to an Affiliate, Subsidiary or any other entity, without the CDFI Fund's prior written consent.

(c) TA funds shall only be disbursed to the Recipient.

(d) The CDFI Fund, in its sole discretion, may disburse TA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

V. Application Review Information

1. *Criteria:* If the Applicant has submitted a complete and eligible Application, the CDFI Fund will conduct a substantive review in accordance with the criteria and procedures described in the Regulations, this NOFA, the Application guidance, and the Uniform Federal Award Requirements. The CDFI Fund reserves the right to contact the Applicant by telephone, email, or mail for the sole purpose of clarifying or confirming Application information. If contacted, the Applicant must respond within the time period communicated by the CDFI Fund or run the risk that its Application will be rejected.

(a) *Application Scoring and Award Selection (FA, HFFI–FA, and TA):* The CDFI Fund will evaluate each Application using the FA and TA Application Scoring Criteria described in the Application. An Applicant must receive a minimum 50 percent of the total score for the FA, HFFI–FA, and TA components in order to be considered for an award. An Applicant that is an Emerging CDFI and has not received a previous TA award will be rated, among other elements, on its plan to meet the requirements of a Certified CDFI within two years of the beginning of the period of performance. In addition, an Emerging CDFI Applicant that is a prior

TA Recipient will be rated, among other elements, on its plan to meet the CDFI certification goal specified in its previous Assistance Agreement.

The CDFI Fund will score each part as indicated in Table 12 and 13.

TABLE 12—FA & TA APPLICATION SCORING CRITERIA

FA & TA narrative sections	FA Applicants (points)	TA Applicants (points)
Executive Summary	Not Scored	Not Scored
Purpose/Proposal	10	15
Products	10	10
Policies	10	10
People	10	15
Partnerships	10	5
Performance	40	30
Projections	10	15
Total Points	100	100

TABLE 13—HFFI–FA APPLICATION SCORING CRITERIA

HFFI–FA Narrative sections	HFFI–FA Applicants (points)
H1. HFFI Target Market Profile	4
H2. Healthy Food Financial Products	5
H3. Healthy Food Development Services	2
H4. Projected HFFI–FA Activities	7
H5, H6, and H7. HFFI Track Record, Management Capacity for Providing Healthy Food Financing, Healthy Food Financing Outcomes	7
Total Points	25

The CDFI Fund will deduct points, in accordance with the following table, from Applicants that have received prior awards under any CDFI Fund program:

TABLE 14—POINT DEDUCTIONS

Issues	Descriptions
Failure to meet Agreement requirements	The CDFI Fund will deduct points from any Applicant that has not met requirements in any previously executed CDFI Fund award agreement(s) including compliance reports due 24 months prior to the Application deadline.
Failure to provide timely loan payments	The CDFI Fund will deduct points from any Applicant that has failed to submit one or more timely loan payments to the CDFI Fund within the 24 months prior to the Application deadline.
Incurred de-obligations	The CDFI Fund will deduct points from any Applicant if any CDFI Fund award funds were de-obligated within the 12 months prior to the Application deadline for any reason other than insufficient matching funds. Points will not be deducted for any de-obligations that resulted from a Recipient's inability to provide eligible matching funds within the specified time frame.

2. *Review and Selection Process.* All Applications will be initially evaluated by external non-Federal reviewers who are selected based on criteria that includes: A professional background in community and economic development finance; experience reviewing financial statements of all CDFI institution types; and experience performing underwriting of community and economic development projects. Reviewers must complete the CDFI Fund's conflict of interest process and be approved by the CDFI Fund. The CDFI Fund's application reader conflict of interest policy is located on the CDFI Fund's Web site.

TA Applications will be evaluated by one external reviewer; FA and HFFI–FA Applications will be evaluated by three external reviewers. All Applications will be reviewed in accordance with reviewer evaluation materials. Applications will be ranked based on Application scores, from highest to lowest. In the case of tied scores, Applicants will be ranked first according to each Performance score, then the Purpose section. TA Applicants, Category I, Category II, and HFFI–FA Applicants will be grouped and ranked separately.

3. *Programmatic and Financial Risk Analysis.* The CDFI Fund conducts three additional levels of due diligence for Applications that are in scoring contention for an award. This due diligence includes an analysis of programmatic and financial risk factors including, but not limited to: Financial stability; quality of management systems and ability to meet award management standards; history of performance in managing Federal awards (including timeliness of reporting and compliance); reports and findings from audits; and

the Applicant's ability to effectively implement Federal requirements. Award amounts may be reduced as a result of this analysis. In addition, for FA awards, the CDFI Fund may reduce awards sizes from requested amounts based on certain variables, including an Applicant's loan disbursement activity, total portfolio outstanding, and similar factors. Lastly, the CDFI Fund may consider the institutional diversity of Applicants when making its funding decisions.

4. *Insured Depository Institutions:* The CDFI Fund will consider safety and soundness information from the Appropriate Federal or State Banking Agency. If the Applicant is a CDFI Depository Institution Holding Company, the CDFI Fund will consider information provided by the Appropriate Federal or State Banking Agencies on the CDFI Depository Institution Holding Company and the CDFI Certified Insured Depository Institution that will expend and carry out the award. If the Appropriate Federal Banking Agency or Appropriate State Agency identifies safety and soundness concerns, the CDFI Fund will assess whether the concerns cause or will cause the Applicant to be incapable of undertaking the activities for which funding has been requested.

5. *Non-Regulated Institutions:* In accordance with the CDFI Program's authorizing statute and regulations, the CDFI Fund must ensure, to the maximum extent practicable, that recipients that are non-regulated CDFIs are financially and managerially sound and maintain appropriate internal controls (12 U.S.C. 4707(f)(1)(A) and 12 CFR 1805.800(b)). Further, the CDFI Fund must determine that an Applicant's capacity to operate as a CDFI will not be dependent upon assistance from the CDFI Fund for continued viability (12 U.S.C. 4704(b)(2)(A)). If it is determined the Applicant is incapable of meeting these requirements, the CDFI Fund reserves the right to deem the Applicant ineligible or terminate the award.

6. *Anticipated Award Announcement:* The CDFI Fund anticipates making CDFI Program award announcements by September 30, 2015.

7. *Application Rejection:* The CDFI Fund reserves the right to reject an Application if information (including administrative error) comes to the CDFI Fund's attention that either: Adversely affects an Applicant's eligibility for an award; adversely affects the Recipient's certification as a CDFI (to the extent that the award is conditional upon CDFI certification); adversely affects the CDFI Fund's evaluation or scoring of an Application; or indicates fraud or mismanagement on the Applicant's part. If the CDFI Fund determines any portion of the Application is incorrect in a material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the Application. The CDFI Fund reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If the changes materially affect the CDFI Fund's award decisions, the CDFI Fund will provide information about the changes through its Web site. The CDFI Fund's award decisions are final and there is no right to appeal the decisions.

VI. Federal Award Administration Information

A. *Award Notification:* Each successful Applicant will receive an email ''notice of award'' notification from the CDFI Fund stating that its Application has been approved for an award. Each Applicant not selected for an award will receive an email stating that a debriefing notice has been provided in its MyCDFI Fund account.

B. *Assistance Agreement:* Each Applicant selected to receive an award must enter into an Assistance Agreement with the CDFI Fund in order to receive a disbursement(s). The Assistance Agreement will set forth the award's terms and conditions, including but not be limited to the: (i) Award amount; (ii) award type; (iii) award uses; (iv) Target Market(s) or activities; (v) performance goals and measures; and (vi) reporting requirements. FA Assistance Agreements have three-year periods of performance; TA Assistance Agreements have two-year periods of performance.

1. *Certificate of Good Standing:* All FA and TA Recipients that are not Insured Depository Institutions will be required to provide the CDFI Fund with a certificate of good standing from the secretary of state for the Recipient's State of incorporation prior to closing. This certificate can often be acquired online on the secretary of state Web site for the Recipient's State of incorporation and must generally be dated within 270 days before the date the Recipient executes the Assistance Agreement. Due to potential backlogs in State government offices, Applicants are advised to submit requests for certificates of good standing no later than 60 days after they submit their Applications.

2. *Closing:* Pursuant to the Assistance Agreement, there will be an initial closing at which point the Assistance Agreement and related documents will be properly executed and delivered, and an initial payment of FA or TA may be made. The CDFI Fund will minimize the time between the Recipient incurring costs for eligible activities and award payment based on what is administratively feasible. The advanced payments for eligible activities will occur no more than one year in advance of the Recipient incurring costs for the eligible activities. Following the initial closing, there may be subsequent closings involving additional award payments. Any documents in addition to the Assistant Agreement that are connected with such subsequent closings and payments shall be properly executed and timely delivered by the Recipient to the CDFI Fund.

3. *Requirements Prior To Entering Into an Assistance Agreement:* If, prior to entering into an Assistance Agreement, information (including administrative error) comes to the CDFI Fund's attention that: Adversely affects the Recipient's eligibility for an award; the Recipient's certification as a CDFI (to the extent that the award is conditional upon CDFI certification); the CDFI Fund's evaluation of the Application evaluation; the Recipient is not in compliance with any requirement listed the Uniform Federal Award Requirements; or indicates fraud or mismanagement on the Recipient's part, the CDFI Fund may, in its discretion and without advance notice to the Recipient, terminate the award or take such other actions as it deems appropriate. The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient fails to return the Assistance Agreement, signed by the authorized representative of the Recipient, and/or provide the CDFI Fund with any other requested documentation, within the CDFI Fund's deadlines.

In addition, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Assistance Agreement and the award made under this NOFA pending the criteria described in the following table:

TABLE 15—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT

Requirement	Criteria
Failure to meet reporting requirements	• If a Recipient received a prior award under any CDFI Fund program and is not current with the reporting requirements in the previously executed agreement(s), the CDFI Fund can delay entering into an Assistance Agreement or disbursing an award until reporting requirements are met. • If such a Recipient is unable to meet the requirement within the timeframe specified, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA. • The automated systems the CDFI Fund uses only acknowledge a report's receipt, not a determination of meeting reporting requirements.
Failure to maintain CDFI Certification	• An FA Recipient must be a Certified CDFI prior to entering into an Assistance Agreement. • If an FA Recipient fails to maintain CDFI Certification, the CDFI Fund will terminate and rescind the Assistance Agreement and the award made under this NOFA.
Pending resolution of noncompliance	• The CDFI Fund will delay entering into an Assistance Agreement with a Recipient that has pending noncompliance issues if the CDFI Fund has not yet made a final determination as to whether the Recipient is in default of its previously executed award agreement(s). • If the Recipient is unable to satisfactorily resolve the compliance issues, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Default status	• If, at any time prior to entering into an Assistance Agreement, the CDFI Fund determines that an Recipient is in default of a previously executed agreement with the CDFI Fund and the Recipient has been provided written notification of such determination, the CDFI Fund can delay entering into an Assistance Agreement, until the Recipient has cured the default by taking actions the CDFI Fund has specified within the specified timeframe. • If the Recipient is unable to meet the cure requirement within the specified timeframe, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Final Default and sanctions	If the CDFI Fund has found the Recipient in final default of a prior executed agreement and provided notification of sanctions, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA within the time period specified in such notification.
Compliance with Federal civil rights requirements.	If prior to entering into an Assistance Agreement under this NOFA, the Recipient receives a final determination, made within the last three years, in any proceeding instituted against the Recipient in, by, or before any court, governmental, or administrative body or agency, declaring that the Recipient has violated the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975, (42 U.S.C. 6101–6107), and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency, the CDFI Fund will terminate and rescind the Assistance Agreement and the award made under this NOFA.
Do Not Pay	• The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government. • The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient is identified as an ineligible recipient on the Do Not Pay database.
Safety and soundness	• If it is determined the Recipient is or will be incapable of meeting its award obligations, the CDFI Fund will deem the Recipient to be ineligible or require it to improve safety and soundness conditions prior to entering into an Assistance Agreement.

C. *Reporting:*

1. *Reporting requirements:* On an annual basis for the period of performance, the CDFI Fund may collect information from each Recipient including, but not limited to, an Annual Report with the following components:

TABLE 16—ANNUAL REPORTING REQUIREMENTS

Single Audit Narrative Report (or like report).	The Recipient must submit, via MyCDFI Fund, a Single Audit Narrative Report for each year of its period of performance notifying the CDFI Fund whether it is required to have a single audit pursuant to OMB Single Audit requirements.
Single Audit (if applicable) (or similar report).	If a Recipient is required to complete a Single Audit Report, it should be submitted to the Federal Audit Clearinghouse see 2 CFR Subpart F-Audit Requirements in the Uniform Federal Award Requirements. For-profit Recipients will be required to complete and submit a similar report directly to the CDFI Fund.
Institution Level Report (ILR)	The ILR is a report used to collect compliance and performance data from CDFI Fund award Recipients. The ILR is submitted through the Community Investment Impact System (CIIS) and captures organizational information, financial position, lending and investing activities, community development outputs, and development services.
Transaction Level Report (TLR)	The TLR is a report used to collect compliance and performance data from CDFI Fund award Recipients. The TLR is submitted through the CIIS and captures data on each individual loan and investment in the award Recipient's portfolio. • For CDFI Depository Institution Holding Company award Recipients, the TLR captures data on the individual loans and investments by its CDFI Subsidiary Insured Depository Institution's portfolio. • TLR is not required for TA Recipients.
Federal Financial Report/OMB Standard Form 425.	If the Recipient receives a TA award, it must submit the Federal Financial Report/*OMB Standard Form 425* via MyCDFI Fund.

TABLE 16—ANNUAL REPORTING REQUIREMENTS—Continued

Uses of Financial Assistance Report	If the Recipient receives an FA award, it must submit the Uses of Financial Assistance Report via MyCDFI Fund.
Explanation of Noncompliance (as applicable) or successor report.	If the Recipient fails to meet a Performance Goal, it must submit the Explanation of Noncompliance via MyCDFI Fund.
Uses of Technical Assistance Report	If the Recipient receives a TA award, it must submit the Uses of Technical Assistance Report via MyCDFI Fund.

Each Recipient is responsible for the timely and complete submission of the Annual Reporting requirements. The CDFI Fund reserves the right to contact the Recipient and additional entities or signatories to the Assistance Agreement to request additional information and documentation. The CDFI Fund will use such information to monitor each Recipient's compliance with the requirements in the Assistance Agreement and to assess the impact of the CDFI Program. The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after notice to Recipients.

2. *Financial Management and Accounting:* The CDFI Fund will require Recipients to maintain financial management and accounting systems that comply with Federal statutes, regulations, and the terms and conditions of the Federal award. These systems must be sufficient to permit the preparation of reports required by general and program specific terms and conditions, including the tracing of funds to a level of expenditures adequate to establish that such funds have been used according to the Federal statutes, regulations, and the terms and conditions of the Federal award.

The cost principles used by Recipients must be consistent with Federal cost principles and support the accumulation of costs as required by the principles, and must provide for adequate documentation to support costs charged to the CDFI Program award. In addition, the CDFI Fund will require Recipients to: Maintain effective internal controls; comply with applicable statutes, regulations, and the Assistance Agreement; evaluate and monitor compliance; take action when not in compliance; and safeguard personally identifiable information.

VII. Agency Contacts

A. The CDFI Fund will respond to questions concerning this NOFA and the Application between the hours of 9:00 a.m. and 5:00 p.m. Eastern Time, starting on the date that the NOFA is published through the date listed in Table 1 and Table 11. The CDFI Fund will post on its Web site responses to reoccurring questions received about this Application. Other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's Web site at *http://www.cdfifund.gov.* Table 17 lists CDFI Fund contact information:

TABLE 17—CONTACT INFORMATION

Type of question	Telephone number (not toll free)	Email addresses
CDFI Program	202–653–0421, option 1	*cdfihelp@cdfi.treas.gov.*
Certification, Compliance Monitoring, and Evaluation	202–653–0423	*ccme@cdfi.treas.gov.*
MyCDFI Fund—IT Help Desk	202–653–0422	*IThelpdesk@cdfi.treas.gov.*

B. *Information Technology Support:* People who have visual or mobility impairments that prevent them from using the CDFI Fund's Web site should call (202) 653–0422 for assistance (this is not a toll free number).

C. *Communication with the CDFI Fund:* The CDFI Fund will use contact information in MyCDFI Fund to communicate with Applicants and Recipients. It is imperative, therefore, that Applicants, Recipients, Subsidiaries, Affiliates, and signatories maintain accurate contact information in their accounts. This includes information such as contact names (especially for the authorized representative) listed in this NOFA's application materials, email addresses, fax and phone numbers, and office locations.

D. *Civil Rights and Diversity:* Any person who is eligible to receive benefits or services from CDFI Fund or Recipients under any of its programs is entitled to those benefits or services without being subject to prohibited discrimination. The Department of the Treasury's Office of Civil Rights and Diversity enforces various Federal statutes and regulations that prohibit discrimination in financially assisted and conducted programs and activities of the CDFI Fund. If a person believes that s/he has been subjected to discrimination and/or reprisal because of membership in a protected group, s/he may file a complaint with: Associate Chief Human Capital Officer, Office of Civil Rights, and Diversity, 1500 Pennsylvania Ave. NW., Washington, DC 20220 or (202) 622–1160 (not a toll-free number).

VIII. Other Information

A. *Paperwork Reduction Act:* Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. If applicable, the CDFI Fund may inform Applicants that they do not need to provide certain Application information otherwise required. Pursuant to the Paperwork Reduction Act, the CDFI Program, and NACA Program Application has been assigned the following control number: 1559–0021.

B. *Application Information Sessions:* The CDFI Fund may conduct webinars or host information sessions for organizations that are considering applying to, or are interested in learning about, the CDFI Fund's programs. For further information, please visit the CDFI Fund's Web site at *http://www.cdfifund.gov.*

Authority: 12 U.S.C. 4701, et seq; 12 CFR parts 1805 and 1815; 2 CFR part 200.

Dated: September 23, 2014.

Dennis Nolan,

Deputy Director, Community Development Financial Institutions Fund.

[FR Doc. 2014–23060 Filed 9–26–14; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Funding Opportunity Title: Notice of Funds Availability (NOFA) inviting Applications for Financial Assistance (FA) awards or Technical Assistance (TA) grants under the Native American CDFI Assistance Program (NACA Program) FY 2015 Funding Round.

Announcement Type: Announcement of funding opportunity.

Funding Opportunity Number: CDFI–2015–NACA.

Catalog of Federal Domestic Assistance (CFDA) Number: 21.020.

KEY DATES:

TABLE 1—FY 2015 NACA PROGRAM FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (eastern daylight time—EDT)	Submission method
CDFI Certification Applications	October 24, 2014	5:00 p.m. EDT	MyCDFI Fund.
Last day to contact NACA Program staff	November 20, 2014	5:00 p.m. EDT	CDFI Fund Helpdesk: 202–653–0421 or *cdfihelp@cdfi.treas.gov.*
NACA Program Application for Financial Assistance (FA) *and/or* Technical Assistance (TA).	November 24, 2014	11:59 p.m. EDT	Electronically via *Grants.gov.*

Executive Summary: Through the CDFI Program, the CDFI Fund provides (i) FA awards of up to $1 million to Certified Community Development Financial Institutions (CDFIs) serving Native American, Alaska Native, or Native Hawaiian populations or Native American areas defined as Federally-designated reservations, Hawaiian homelands, Alaska Native Villages and U.S. Census Bureau-designated Tribal Statistical Areas (collectively, ''Native Communities'') to build their financial capacity to lend to their Target Markets, and (ii) TA grants of up to $150,000 to build Certified, Certifiable, and Emerging CDFIs' organizational capacity to serve their Target Markets and Sponsoring Entities ability to create Certified CDFIs that serve Native Communities. All awards provided through this NOFA are subject to funding availability.

I. Program Description

A. *History:* The CDFI Fund was established by the Riegle Community Development Banking and Financial Institutions Act of 1994 to promote economic revitalization and community development through investment in and assistance to CDFIs. Since its creation in 1994, the CDFI Fund has awarded over $1.9 billion to CDFIs, community development organizations, and financial institutions through the Community Development Financial Institutions Program (CDFI Program), the NACA Program, the Bank Enterprise Award Program (BEA Program), the Capital Magnet Fund, and the Financial Education and Counseling Pilot Program. In addition, the CDFI Fund has allocated $40 billion in tax credit allocation authority through the New Markets Tax Credit Program (NMTC Program) and has obligated $325 million in bond guarantees to Eligible CDFIs through the CDFI Bond Guarantee Program.

B. *Priorities:* Through the NACA Program's FA awards and TA grants, the CDFI Fund invests in and builds the capacity of for-profit and non-profit community based lending organizations known as Community Development Financial Institutions, or CDFIs. These organizations, Certified as CDFIs by the CDFI Fund, serve Native Communities.

C. *Program Regulations:* The regulations governing the NACA Program are found at 12 CFR Parts 1805 and 1815 (the Regulations) and set forth evaluation criteria and other program requirements. The CDFI Fund encourages Applicants to review the Regulations, this NOFA, the Application, and the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR 200; 78 **Federal Register** 78590) (Uniform Federal Award Requirements) for a complete understanding of the program; capitalized terms in this NOFA are defined in the Regulations, this NOFA, the Application, and the Uniform Federal Award Requirements. Details regarding Application content requirements are found in the Application and related materials.

D. *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR 200):* In December 2013, the Office of Management and Budget (OMB) published a final rule that provides a government-wide framework for grants management, with the goal of combining several OMB guidance circulars, reducing administrative burden for Recipients, and reducing the risk of waste, fraud and abuse of Federal financial assistance. The Uniform Federal Award Requirements codifies financial, administrative, procurement, and program management standards that Federal award agencies must follow. When evaluating award applications, awarding agencies must evaluate the risks to the program posed by each applicant, and each applicant's merits and eligibility. These requirements are designed to ensure that applicants for Federal assistance receive a fair and consistent review prior to an award decision. This review will assess items such as the Applicant's financial stability, quality of management systems, history of performance, and single audit findings. In addition, the Uniform Federal Award Requirements includes guidance on audit requirements and other award requirements that award Recipients must comply with.

E. *Funding limitations:* The CDFI Fund reserves the right to fund, in whole or in part, any, all, or none of the Applications submitted in response to this NOFA. The CDFI Fund also reserves the right to reallocate funds from the amount that is anticipated to be available through this NOFA to other CDFI Fund initiatives that are designed to benefit Native American, Native Hawaiian, and Alaskan Native communities, particularly if the CDFI Fund determines that the number of awards made through this NOFA is fewer than projected.

II. Federal Award Information

A. Funding Availability

1. *FY 2015 Funding Round:* Subject to funding availability, the CDFI Fund expects to award, through this NOFA, approximately $15 million as indicated in the following table:

TABLE 2—FY 2015 FUNDING ROUND ANTICIPATED CATEGORY AMOUNTS

Funding categories (see definition in table 7)	Estimated total amount to be awarded (millions)	Award amount		Estimated number of awards	Average amount awarded in FY 2013
		Minimum	Maximum		
FA	$12	$100,000	$1,000,000	20	$555,000
TA	3	10,000	150,000	30	141,000
Total	15			50	
Healthy Food Financing Initiative—Financial Assistance (HFFI–FA)*	35	500,000	5,000,000	13	2,750,000

* HFFI–FA appropriation will be allocated in one competitive round between the NACA and CDFI Program NOFAs.

The CDFI Fund reserves the right to award more or less than the amounts cited above in each category, based upon available funding and other factors, as appropriate.

2. *Funding Availability for the FY 2015 Funding Round:* Funds for the FY 2015 Funding Round have not yet been appropriated; if Congress does not appropriate funds for the NACA Program, there will not be a FY 2015 Funding Round. If funds are appropriated, the amount of such funds may be greater or less than the amounts set forth above. In the event that funds are not appropriated for the NACA Program, CDFIs that might otherwise qualify for NACA Program awards are encouraged to apply for CDFI Program awards through the CDFI Program NOFA. The CDFI Fund reserves the right to contact applicants to seek additional information in the event that the final FY 2015 appropriations for the CDFI Program change any of the requirements in this NOFA.

3. *Anticipated Start Date and Period of Performance:* The CDFI Fund anticipates the period of performance for the FY 2015 Funding Round will begin in the fall of calendar year 2015. Specifically, the period of performance for TA grants begins with the date of the notice of the award and includes either (i) an Emerging or Certified CDFI award Recipient's two full consecutive fiscal years after the date of the notice of the award or (ii) a Sponsoring Entity award Recipient's four full consecutive fiscal years after the date of the notice of the award, during which the Recipient must meet the performance goals set forth in the Assistance Agreement. The period of performance for FA awards includes an award Recipient's three full consecutive fiscal years after the date of the notice of the award, during which time the Recipient must meet its performance goals.

B. Types of Awards

Through the NACA Program, the CDFI Fund provides two types of awards: Financial Assistance (FA) and Technical Assistance (TA) awards. *An Applicant may submit an Application for a TA grant or an FA award, but not both.*

1. *FA Awards:* FA awards can be in the form of loans, grants, Equity Investments, and deposits and credit union shares. The form of the FA award is based on the form of the matching funds that the Applicant includes in its Application, unless Congress waives the matching funds requirement. Matching funds are required for FA awards, must be from non-Federal sources, and cannot have been used as matching funds for any other Federal award. The CDFI Fund reserves the right, in its sole discretion, to provide an FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

2. *Healthy Food Financing Initiative—Financial Assistance (HFFI–FA) Awards:* HFFI–FA awards will be provided as a supplement to FA awards; therefore, only those Applicants that have been selected to receive an FA award through the NACA Program FY 2015 Funding Round will be eligible to receive an HFFI–FA award. HFFI–FA awards can be in the form of loans, grants, Equity Investments, and deposits and credit union shares. The form of the HFFI–FA award is based on the form of the matching funds that the Applicant includes in its Application, unless Congress waives the matching funds requirement. Matching funds are required for HFFI–FA awards, must be from non-Federal sources, and cannot have been used as matching funds for any other Federal award. The CDFI Fund reserves the right, in its sole discretion, to provide an HFFI–FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

3. *TA Grants:* TA is provided in the form of grants. The CDFI Fund reserves the right, in its sole discretion, to provide a TA grant in an amount other than which the Applicant requests; however, the TA grant amount will not exceed the Applicant's request as stated in its Application and the applicable budget chart.

C. Eligible Activities

1. FA Awards

FA and HFFI–FA award funds can be expended for activities in the following five categories: (i) Financial Products; (ii) Financial Services; (iii) Loan Loss Reserves; (iv) Development Services; and (v) Capital Reserves. Each of the allowable activity categories will be eligible for indirect costs and an associated indirect cost rate. Indirect cost rates will be determined as part of the terms and conditions of the award. For purposes of this NOFA, the five activity categories are defined as follows:

TABLE 3—FA AND HFFI–FA ELIGIBLE ACTIVITY CATEGORIES

FA activity	FA activity definition	Eligible CDFI institution types
i. Financial Products	FA expended as loans, Equity Investments and similar financing activities (as determined by the CDFI Fund) including the purchase of loans originated by Certified CDFIs and the provision of loan guarantees; in the case of CDFI Intermediaries, grants to CDFIs and/or emerging CDFIs and deposits in Insured Credit Union CDFIs, emerging Insured Credit Union CDFIs, and/or State-Insured Credit Union CDFIs.	All.
ii. Financial Services	FA expended for the provision of checking and savings accounts, certified checks, automated teller machines services, deposit taking, remittances, safe deposit box services, and other similar services.	Insured Depository Institutions only.
iii. Loan Loss Reserves	FA set aside in the form of cash reserves, or through accounting-based accrual reserves, to cover losses on loans, accounts, and notes receivable made in the Applicant's Target Market, or for related purposes that the CDFI Fund deems appropriate.	All.
iv. Development Services	FA expended for activities that promote community development and are integral to the Applicant's provision of Financial Products and Financial Services. Such services that shall prepare or assist current or potential borrowers or investees to utilize the Financial Products or Financial Services of the Applicant.	All.
v. Capital Reserves	FA set aside as reserves to support the Applicant's ability to leverage other capital, for such purposes as increasing its net assets or serving the financing needs of its Target Market, or for related purposes as the CDFI Fund deems appropriate.	Insured Depository Institutions only.

2. TA Grants

TA grant funds can be expended for the following seven eligible activity categories: (i) Compensation—personal services; (ii) Compensation—fringe benefits; (iii) Professional Service Costs; (iv) Travel Costs; (v) Training and Education Costs; (vi) Equipment and other capital expenditures; and (vii) Supplies. Each of the allowable activity categories will be eligible for indirect costs and an associated indirect cost rate. Indirect cost rates will be determined as part of the terms and conditions of the award. For purposes of this NOFA, the seven activity categories are defined as follows:

TABLE 4—TA ELIGIBLE ACTIVITY CATEGORIES

(i) Compensation—personal services.	TA paid to cover salaries of the Applicant's personnel that are paid currently or accrued by the Applicant for work performed directly related to carrying out the purpose of the TA grant (including activities related to becoming certified as a CDFI), subject to the applicable provisions of the Uniform Federal Award Requirements.
(ii) Compensation—fringe benefits	TA paid to cover costs of the Applicant's personnel employment (other than the employees' salaries income) in proportion to the salary charged to the TA grant, to the extent that such payments are made under formally established and consistently applied organizational policies, subject to the applicable provisions of the Uniform Federal Award Requirements.
(iii) Professional service costs	TA used to pay for professional and consultant services rendered by persons who are members of a particular profession or possess a special skill, and who are not officers or employees of the Recipient, subject to the applicable provisions of the Uniform Federal Award Requirements. Payment for a consultant's services may not exceed the daily equivalent of the current maximum rate paid to an Executive Schedule Level IV Federal employee.
(iv) Travel costs	TA used to pay expenses for transportation, lodging, subsistence, and related items incurred by the Applicant's personnel who are on travel status on business related to the TA grant, subject to the applicable provisions of the Uniform Federal Award Requirements.
(v) Training and education costs	TA used to pay the cost of training and education provided for employee development, subject to the applicable provisions of the Uniform Federal Award Requirements.
(vi) Equipment	TA used to pay for tangible personal property, having a useful life of more than one year and a per-unit acquisition cost of at least $5,000 and subject to the applicable provisions of the Uniform Federal Award Requirements. Examples include office equipment, furnishings, and information technology equipment and systems.
(vii) Supplies	TA used to pay for tangible personal property with a per unit acquisition of less than $5,000 and subject to the applicable provisions of the Uniform Federal Award Requirements.

III. Eligibility Information

A. *Eligible Applicants:* For the purposes of this NOFA, the following tables set forth the eligibility criteria to receive an award from the CDFI Fund, along with certain definitions of terms. There are four categories of Applicant eligibility criteria: (1) CDFI certification criteria (Table 5); (2) requirements that apply to all Applicants (Table 6); (3) requirements that apply to TA Applicants (Table 7); and (4) requirements that apply to FA Applicants (Table 8).

TABLE 5—CDFI CERTIFICATION CRITERIA DEFINITIONS

Certified CDFI	• An entity that the CDFI Fund has officially notified that it meets all CDFI certification requirements.

TABLE 5—CDFI CERTIFICATION CRITERIA DEFINITIONS—Continued

Certifiable CDFI	• An entity that has submitted a CDFI Certification Application to the CDFI Fund demonstrating that it meets the CDFI certification requirements but which has not yet been officially certified. • The CDFI Fund will not enter into an Assistance Agreement or disburse FA award funds unless and until an Applicant is Certified CDFI.
Emerging CDFI	• A non-Certified entity that has not submitted a CDFI Certification Application but demonstrates to the CDFI Fund that it has an acceptable plan to meet certification requirements by the end of its period of performance, or another date that the CDFI Fund selects. • An Emerging CDFI that has prior award(s) will be held to the CDFI certification performance goal and measure(s) stated in its prior Assistance Agreement(s). • Emerging CDFIs may only apply for TA grants; they are not eligible to apply for FA awards. • Each Emerging CDFI selected to receive a TA grant will be required to become a Certified CDFI by a date specified in the Assistance Agreement.
Sponsoring Entity	• Sponsoring Entities include any legal organization that primarily serves Native Community with ''primary'' meaning, at least 50 percent of its activities are directed toward the Native Community. • An eligible organization that proposes to create a separate legal organization that will become a Certified CDFI serving Native Communities. • Sponsoring Entities may only apply for TA grants; they are not eligible to apply for FA awards. • Each Sponsoring Entity selected to receive a TA grant will be required to create and certify an Emerging CDFI by the dates specified in the Assistance Agreement.
Definition of Native Other Targeted Population as Target Market.	The CDFI Fund uses the following definitions, set forth in the Office of Management and Budget (OMB) Notice, Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (October 30, 1997), as amended and supplemented: a) American Indian, Native American, or Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment; and b) Native Hawaiian (living in Hawaii): A person having origins in any of the original peoples of Hawaii.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS

Applicant	• Only the entity that will carry out the proposed award activities should apply for an award (e.g., the intended award Recipient). • An Applicant that applies on behalf of another organization will be rejected without further consideration, except for Depository Institution Holding Companies (see below).
Application type and submission overview.	• The CDFI Fund will only accept Applications that use the official Word Narrative and Excel Workbook templates provided on the Grants.gov and CDFI Fund websites. • Applications submitted with alternative or altered templates will not be considered. • Only Applications submitted via the Grants.gov Web site will be accepted for review.
Microsoft Word Narrative Template	• Each Applicant must submit a completed Microsoft Word Narrative Template. • An Applicant that does not submit a completed Narrative Template will be rejected without further consideration.
Microsoft Excel Workbook	• Each Applicant must submit a completed Microsoft Excel Workbook template. • An Applicant that does not submit a completed Microsoft Excel Workbook template will be rejected without further consideration.
Employer Identification Number (EIN).	• An Applicant must provide an electronic copy of the letter from the IRS as evidence that the Applicant has been assigned its own unique EIN. • The CDFI Fund will reject an Application submitted with the EIN of a parent or Affiliate organization. • The CDFI Fund will deem an Application incomplete if it does not include an IRS document that verifies the Applicant's EIN (a tax return is not an acceptable form of IRS documentation). The CDFI Fund will allow an Applicant two business days upon request by the CDFI Fund to submit the appropriate documentation before the Application will be rejected without further consideration due to missing documentation of the Applicant's EIN.
DUNS number	• Pursuant to OMB guidance (68 FR 38402), an Applicant must apply using its unique DUNS number in Grants.gov. • The CDFI Fund will reject an Application submitted with the DUNS number of a parent or Affiliate organization.
MyCDFI Fund account	• Each Applicant must register as an organization in MyCDFI Fund by the Application deadline. • The Authorized Representative and/or Application point of contact must be included as ''users'' in the Applicant's MyCDFI Fund account. • An Applicant that fails to properly register and update its MyCDFI Fund account may miss important communication from the CDFI Fund that could impact its Application. • The CDFI Fund will allow an Applicant two business days upon request by the CDFI Fund to create or update its MyCDFI Fund account before the Application will be rejected without further consideration.
501(c)(4) status	• Pursuant to 2 U.S.C. 1611, a 501(c)(4) any organization that engages in lobbying activities is not eligible for the receipt of a CDFI or NACA Program award.
Compliance with Federal civil rights requirements.	• An Applicant may not be eligible to receive an award if proceedings have been instituted against it in, by, or before any court, governmental agency, or administrative body, and a final determination within the last three years indicates the Applicant has violated any of the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975, (42 U.S.C. 6101–6107), and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS—Continued

Depository Institution Holding Company Applicant.	• In the case where a CDFI Depository Institution Holding Company Applicant intends to carry out the activities of an award through its CDFI Subsidiary Insured Depository Institution, the Application must be submitted by the CDFI Depository Institution Holding Company and reflect the consolidated activities and financial performance of the CDFI Subsidiary Insured Depository Institution. • Authorized representatives of both the Depository Institution Holding Company and the CDFI Subsidiary Insured Depository Institution must certify that the information included in the Application represents that of the CDFI Subsidiary Insured Depository Institution and that the award funds will be used to support the CDFI Subsidiary Insured Depository Institution for the eligible activities outlined in the Application.
Insured CDFI—Insured Credit Union and Insured Depository Institution.	• To be eligible for an award, each Insured Depository Institution Applicant must have a CAMELS/CAMEL (rating for banks and credit unions, respectively), by its Federal regulator of at least "4." • Organizations with CAMELS/CAMEL ratings of "5" will not be eligible for awards.
Use of award	• All awards made through this NOFA must be used to support the Applicant's approved FA or TA eligible activities (see Section II.C). • Awards cannot be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others (except Depository Institution Holding Company Applicants.)
Requested award amount for eligible activities.	• An Applicant must state its requested award amount and proposed eligible activities in the "Award Request Table" (Tab 4—Purpose) in the Excel Workbook. • An Applicant that does not fully complete the "Award Request Table" will be rejected without further consideration.
Pending resolution of noncompliance.	• The CDFI Fund will consider an Application submitted by an Applicant that has pending noncompliance issues if the CDFI Fund has not yet made a final determination as to whether the Applicant is in default of any of its previously executed award agreement(s).
Default status	• The CDFI Fund will not consider an Application submitted by an Applicant that has been notified by the CDFI Fund in writing that it is in default of a previously executed award agreement under any CDFI Fund program, at the time of the Application deadline. • The CDFI Fund will not consider any Applicant that has defaulted on a CDFI Program loan within five years of the Application deadline.
Undisbursed award funds and calculations (general).	• An Applicant that has funds from a prior award that have not been disbursed, as defined in (a)–(d) below, as of the Application deadline will not be eligible for an award. (a) The CDFI Fund will include the combined undisbursed award funds of the Applicant and its Affiliates. (b) Balances on undisbursed award funds cannot exceed five percent of the combined BEA Program awards made to the Applicant in FYs 2011, 2012, and 2013. (c) Balances on undisbursed award funds cannot exceed five percent of the combined CDFI/NACA Program awards made to the Applicant in FYs 2011, 2012, and 2013. (d) The undisbursed award funds calculation does not include award funds for: (i) which the Recipient has submitted a full and complete disbursement request before the Application deadline; (ii) an award that has been terminated or de-obligated; or (iii) an award that does not have a fully executed award agreement; and (iv) the tax credit allocation authority made available through the NMTC Program.

TABLE 7—ELIGIBILITY REQUIREMENTS FOR TA APPLICANTS

CDFI certification status	• Certified, Certifiable, Emerging CDFIs, or Sponsoring Entities (see definitions in Table 5).
Matching funds	• Matching funds documentation is not required for TA awards.
Limitation on Awards	• An Emerging CDFI serving Native Communities will be allowed to receive no more than three TA awards as an uncertified CDFI. • A Sponsoring Entity is only eligible to apply for an award if (i) it does not have an active prior award or (ii) the certification goal in its active award's Assistance Agreement has been satisfied and it proposes to create another CDFI that will serve one or more Native Communities.
Target Market	• TA Applicants must demonstrate that the Certified, Certifiable, Emerging CDFI, or the CDFI to be created by the Sponsoring Entity will primarily serve one or more Native Community as its Target Market.

TABLE 8—ELIGIBILITY REQUIREMENTS FOR FA APPLICANTS

CDFI certification status	• Each FA Applicant must be a Certified CDFI prior to the announcement of award decisions. • An Applicant that is in a cure period to remedy CDFI recertification deficiencies at the time of award announcements will not be eligible for an FA award under this NOFA.
Activities in Native Communities	• For consideration under this NOFA, each FA Applicant must: ○ demonstrate that at least 50 percent of its past activities were in one or more Native Communities; and ○ describe how it will target its lending/investing activities to more or more Native Communities.
Target Market	• For consideration under this NOFA, an FA Applicant's certification Target Market must have one or more of the following characteristics: ○ For qualifying with an *investment area* Target Market, the Applicant must demonstrate that the investment area approved for certification is *also* a geographic area of Federally-designated reservations, Hawaiian homelands, Alaska Native Villages and U.S. Census Bureau designated Tribal Statistical Areas; and/or ○ For qualifying with an *Other Targeted Population (OTP)* Target Market, the applicant's Target Market approved for certification must be an OTP of Native Americans or American Indians, including Alaska Natives living in Alaska and Native Hawaiians living in Hawaii. • Any FA Applicant whose certification Target Market does not meet either of the conditions above will not be eligible for an FA award under this NOFA.

TABLE 8—ELIGIBILITY REQUIREMENTS FOR FA APPLICANTS—Continued

Community Partnership	• All FA Applicants must demonstrate strong Community Partnerships with Native Communities.
Matching funds documentation	• All Applicants must submit acceptable documentation that they have received or will receive matching funds. Applications that do not submit acceptable matching funds documentation will not be evaluated. • Award size will be limited to no more than two times the amount of In-Hand or Committed matching funds documentation provided at the time of Application, but actual award size may be less than this amount. Awards will be obligated in like form to the matching funds provided. • Award payments from the CDFI Fund will require eligible dollar-for-dollar In-Hand matching funds for the total payment amount. • Any award Recipient that is not able to demonstrate dollar-for-dollar matching funds by the end of the Matching Funds Window will have its award amount reduced and the corresponding funds will be de-obligated.
$5 Million funding cap	• The CDFI Fund is prohibited from obligating more than $5 million in CDFI and NACA Program awards, in the aggregate, to any one organization and its Subsidiaries and Affiliates during any three-year period. • The CDFI Fund will make FY 2015 funding round award announcements on or after August 7, 2015; the CDFI Fund will include awards in the cap calculation that were provided to an Applicant (and its Subsidiaries and Affiliates) under the FY 2013 and 2014 funding rounds, as well as the requested FY 2015 award, excluding HFFI–FA awards.
HFFI–FA	• All HFFI–FA Applicants must: (a) Apply for an FA award; (b) Meet all FA award eligibility requirements; and (c) Complete and submit a NACA Program Financial Assistance Application along with an HFFI–FA Narrative Template at the time of Application

B. *Matching Funds Requirements:* In order to receive an FA award, an Applicant must provide documentation of eligible dollar-for-dollar matching funds. The CDFI Fund will review all matching funds documentation prior to award disbursement and will disburse funds based upon eligible In-Hand matching funds (see Table 9 for the definition of In-Hand). The CDFI Fund encourages Applicants to review the Regulations at 12 CFR 1805.500, the Uniform Federal Award Requirements, and the matching funds guidance materials in the Excel Workbook, which is available on the CDFI Fund's Web site and Grants.gov. Table 9 provides a summary of the matching funds requirements; additional details are set forth in the Application materials.

TABLE 9—MATCHING FUNDS REQUIREMENTS

Matching funds requirements by application type.	The following Applicants must provide documentation of acceptable matching funds: • FA Applicants; and • HFFI–FA Applicants. (upon request) * TA Applicants are not required to provide matching funds. * The matching funds requirement for HFFI–FA applicants was waived in the appropriations bill for FY 2014 and final FY 2015 appropriations are still pending. HFFI–FA applicants are not required to submit matching funds for their HFFI–FA award request at the time of application. However, the CDFI Fund reserves the right to request matching funds from HFFI–FA applicants if matching funds are not waived in the final FY 2015 CDFI Program appropriation.
Amount of required match	Applicants must submit documentation of eligible In-Hand dollar-for-dollar non-Federal matching funds for every FA award dollar to be disbursed by the CDFI Fund.
Determination of award form	FA awards will be made in comparable form and value to the eligible In-Hand or Committed matching funds documentation submitted by the Applicant. • For example, if an FA Applicant provides documentation of eligible loan matching funds for $200,000 and $400,000 of its matching funds in the form of grant, the CDFI Fund will obligate $200,000 of the FA award as a loan and $400,000 as a grant.
Matching Funds Window definition	• The Applicant must receive eligible In-Hand matching funds between January 1, 2013 and January 15, 2016. • An award Recipient must provide the CDFI Fund with all documentation demonstrating the receipt of matching funds by January 31, 2016.
Matching funds and form of award	• Recipients will be approved for a maximum award size of two times the total amount of eligible In-Hand or Committed matching funds documentation included in the Application, so long as they do not exceed the award amount limit. • The form of the matching funds documented in the Application determines the form of the award.

TABLE 9—MATCHING FUNDS REQUIREMENTS—Continued

In-Hand matching funds definition ..	• Matching funds are eligible and In-Hand when the Applicant actually receives disbursement of the matching funds and includes acceptable documentation in the Application, showing the source, form (e.g., grant, loan, deposit, and Equity Investment), and amount of the matching funds. • The following documentation, depending on the type of award being requested, must be included in the Application: i. loan—the loan agreement and/or promissory note; ii. grant—the grant letter or agreement for all grants of $50,000 or more; iii. Equity Investment—the stock certificate and shareholder agreement; iv. retained earnings—audits or call reports from regulating entity; and v. third party in-kind contribution—evidence of receipt of contribution and valuation; AND vi. clearly legible documentation that demonstrates receipt of the matching funds including the date of the transaction and the amount, such as a copy of a check or a wire transfer statement. • The CDFI Fund will only disburse FA awards that have eligible In-Hand matching funds, as determined by the CDFI Fund.
Committed matching funds definition.	• Matching funds are Committed when the Applicant has entered into or received a legally binding commitment from the matching funds source showing the matching funds will be disbursed to the Applicant at a future date. • The Applicant must provide to the CDFI Fund acceptable written documentation showing the source, form, and amount of the Committed matching funds (including, in the case of a loan, the terms thereof), as well as the anticipated disbursement date of the Committed funds.
Limitations on matching funds	• Matching funds must be from non-Federal sources. • Applicants cannot proffer matching funds that were accepted as matching funds for a prior FA award under the CDFI Program or under another Federal grant or award program. • Matching funds must comply with Regulations at 12 CFR 1805.500 et seq. • The CDFI Fund will not consider any FA Application that does not include any In-Hand or Committed matching funds documentation as of the Application deadline. • Matching funds must be attributable to at least one of the five eligible activities (see Section II.C).
Rights of the CDFI Fund	• The CDFI Fund reserves the right to contact the matching funds source to discuss the matching funds and the documentation that the Applicant has provided. • The CDFI Fund may grant an extension of the Matching Funds Window (defined in Table 9), on a case-by-case basis, if the CDFI Fund deems it appropriate. • The CDFI Fund reserves the right to rescind all or a portion of an FA award and re-allocate the rescinded award amount to other qualified Applicant(s), if an award Recipient fails to obtain In-Hand 100 percent of the required Matching Funds during the Matching Funds Window.
Matching funds in the form of third-party in-kind contributions.	• Third party in-kind contributions are the value of non-cash contributions (i.e., property or services) provided by non-Federal third parties. • Third party in-kind contributions will be considered to be in the form of a grant. • Third party in-kind contributions may be in the form of real property, equipment, supplies, and other expendable property, and the value of goods and services directly benefiting the eligible activities. • For third-party in-kind contributions, the fair market value of goods and services must be documented. • Applicants will be responsible for documenting the value of all in-kind contributions as described in the Uniform Federal Award Requirements.
Matching funds in the form of a loan.	• An FA award made in the form of a loan will have the following standardized terms: • A 13-year term with semi-annual interest-only payments due in years 1 through 10, and fully amortizing payments due each year in years 11 through 13; and • A fixed interest rate of 2.5 percent, which was calculated by the CDFI Fund based on the U.S. Department of the Treasury's 10-year Treasury note. • The Applicant's matching funds loan(s) must: i. have a minimum of a 3-year term. Loans presented as matching funds with less than a 3-year term will not qualify as eligible match; and ii. not be from a Federal source.
Ineligible matching funds	• If the CDFI Fund determines that any portion of the Applicant's matching funds is ineligible, the CDFI Fund will permit the Applicant to offer documentation of alternative matching funds as a substitute for the ineligible matching funds. • In such instances: i. the Applicant must provide acceptable alternative matching funds documentation within the period of time specified by the CDFI Fund, and ii. the alternative matching funds documentation will not increase the total amount of FA requested.
Use of matching funds from a prior CDFI Program Recipient.	If an Applicant offers matching funds documentation from an organization that was a prior Recipient under the CDFI Program, the Applicant must prove to the CDFI Fund's satisfaction that such funds do not consist, in whole or in part, of CDFI Program funds or other Federal funds.
Matching funds in the form of retained earnings.	• Retained earnings are eligible for use as matching funds when the CDFI Fund calculates an amount equal to: i. the increase in retained earnings that occurred over any one of the Applicant's fiscal years within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and matching funds previously used for an award; or ii. the annual average of such increases that occurred over any three consecutive fiscal years of the Applicant with at least one of the fiscal years occurring within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and matching funds previously used for an award; or iii. any combination of (i) and (ii) above that does not include matching funds previously used for an award. • Retained earnings will be matched in the form of a grant.

TABLE 9—MATCHING FUNDS REQUIREMENTS—Continued

Special rule for Insured Credit Unions.	• An Insured Credit Union's retained earnings are eligible for use as matching funds when the CDFI Fund calculates an amount equal to: i. the increase in retained earnings that occurred over any one of the Applicant's fiscal years within the Matching Funds Window, adjusted to remove revenue from Federal sources and matching funds previously used for an award; or ii. the annual average of such increases that occurred over any three consecutive fiscal years of the Applicant with at least one of the fiscal years occurring within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and matching funds previously used for an award; or iii. the entire retained earnings that have been accumulated since the inception of the Applicant, as provided in the Regulations. • If option (iii) is used, the Applicant must increase its member and/or non-member shares and/or total loans outstanding by an amount equal to the amount of retained earnings committed as matching funds. • This increase will be measured from March 31, 2015 and must occur by the end of the Recipient's Year 1 of Performance Period, as set forth in its Assistance Agreement, and will be based on amounts reported in the Applicant's National Credit Union Administration (NCUA) form 5300 Call Report. • The CDFI Fund will assess the likelihood of this increase during the Application review process. • An award will not be made to any Applicant that has not demonstrated in the relevant financial statements or NCUA form 5300 Call Report that it has increased shares and/or loans by at least 25 percent of the requested FA award amount between December 31, 2013, and December 31, 2014. • The matching funds are not In-Hand until the Recipient has increased its member and/or non-member shares or total loans outstanding within the time period specified.

IV. Application and Submission Information

A. Address To Request an Application Package

Application materials can be found on *Grants.gov* and the CDFI Fund's Web site at *www.cdfifund.gov/native.* Applicants may request a paper version of any Application material by contacting the CDFI Fund Help Desk at *cdfihelp@cdfi.treas.gov.*

B. Content and Form of Application Submission

All Applications must be prepared using the English language and calculations must be made in U.S. dollars. The following table lists the required Application documents for the FY 2015 Funding Round. The CDFI Fund reserves the right to request and review other pertinent or public information that has not been specifically requested in this NOFA or the Application. Information submitted by the Applicant that the CDFI Fund has not specifically been requested will not be reviewed or considered as part of the Application.

TABLE 10—REQUIRED APPLICATION DOCUMENTS

Application documents	Applicant type	Submission format
Applicant Intake Form	All Applicants	Fillable PDF.
SF–424	All Applicants	Fillable PDF.
IRS Documentation of Organization's EIN	New Applicants only	PDF.
Application Excel Workbook Tab 3a—NACA Eligibility Form	All Applicants	Excel.
Application Excel Workbook Tab 3—Input Sheet	All Applicants	Excel.
Application Excel Workbook Tab 4—Purpose	All Applicants	Excel.
Application Excel Workbook Tab 5—Products	All Applicants	Excel.
Application Excel Workbook Tab 6—Policies	All Applicants	Excel.
Application Excel Workbook Tab 7—People	All Applicants	Excel.
Application Excel Workbook Tab 8—Partnerships	All Applicants	Excel.
Application Excel Workbook Tab 9—Performance	All Applicants	Excel.
Application Excel Workbook Tab 10—Projections	All Applicants	Excel.
Application Excel Workbook Tab 13—Matching Funds Breakout Table	FA Applicants	Excel.
Application Excel Workbook Tab 14—Matching Funds Grants under $50,000.	FA Applicants, if applicable	Excel.
Matching Funds Documentation	FA Applicants	PDF.
Narrative Template	All Applicants	Word document.
HFFI–FA Narrative Template	HFFI–FA Applicants	Word document.
Policies and Procedures	FA Applicants	PDF.
Key Staff Resumes	All Applicants	PDF or Word document.
Organizational Chart	All Applicants	PDF.
Community Partnership Agreement	All Applicants, if applicable	PDF or Word document.
Audited Financial Statements, September 30, 2014 Quarter End Financial Statements, and Call Reports (Insured Depository Institutions only).	FA Applicants	PDF.
Financial Statements, September 30, 2014 Quarter End Financial Statements, and Call Reports (Insured Depository Institutions only).	TA Applicants	PDF.

C. Application Submission

All Application documents must be submitted through the *Grants.gov* electronic system. The CDFI Fund will not accept Applications via MyCDFI Fund accounts, email, mail, facsimile, or other forms of communication, except in extremely rare circumstances that have been pre-approved by the CDFI Fund.

The CDFI Fund strongly encourages Applicants to start the *Grants.gov* registration process as soon as possible (refer to the following link: *http://www.grants.gov/web/grants/register.html*) as it may take several weeks to complete. An Applicant that has previously registered with *Grants.gov* must verify that its registration is current and active. Applicants should contact *Grants.gov* directly with questions related to the registration or submittal process as the CDFI Fund does not maintain the *Grants.gov* system.

D. Dun & Bradstreet Universal Numbering System (DUNS)

Pursuant to the Uniform Federal Award Requirements, each Applicant must provide as part of its Application submission, a Dun and Bradstreet Universal Numbering System (DUNS) number. Applicants without a DUNS number will not be able to register and submit an Application in the *Grants.gov* system. Please allow sufficient time for Dun & Bradstreet to respond to inquiries and/or requests for DUNS numbers.

E. System for Award Management (SAM)

Any entity applying for Federal grants or other forms of Federal financial assistance through *Grants.gov* must be registered in SAM before submitting its Application. The SAM registration process can take several weeks to complete. Applicants that have previously completed the SAM registration process must verify that their SAM accounts are current and active. Each Applicant must continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an Application under consideration by a Federal awarding agency. The CDFI Fund will not consider any Applicant that fails to properly register or activate its SAM account and, as a result, is unable to submit its Application by the Application deadline. Applicants must contact SAM directly with questions related to registration or SAM account changes as the CDFI Fund does not maintain this system. For more information about SAM, please visit *https://www.sam.gov.*

F. Submission Dates and Times

1. *Submission Deadlines:* The following table provides the critical deadlines for the FY 2015 Funding Round.

TABLE 11—FY 2015 FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (EDT)	Submission method
CDFI Certification Applications	October 24, 2014	5:00 p.m. EDT	MyCDFI Fund: *https://www.cdfifund.gov/myCDFI.*
Last day to contact NACA Program staff	November 20, 2014	5:00 p.m. EDT	CDFI Fund Helpdesk: 202–653–0421 or *cdfihelp@cdfi.treas.gov.*
NACA Program Application for Financial Assistance (FA) *or* Technical Assistance (TA).	November 24, 2014	11:59 p.m. EDT	Electronically via *Grants.gov.*

2. *Confirmation of Application Submission:* Each Applicant will receive an email from *Grants.gov* immediately after Application submission confirming that the submission has entered the *Grants.gov* system. This email will contain a tracking number for the submitted Application package. Within 48 hours, the Applicant will receive a second email which will indicate if the submitted Application package was either successfully validated or rejected with errors. However, Applicants should not rely on the email notification from *Grants.gov* to confirm that their Applications were validated. Applicants are strongly encouraged to use the tracking number provided in the first email to closely monitor the status of their Application package by contacting the helpdesk at *Grants.gov* directly. The Application package is not officially accepted by the CDFI Fund until *Grants.gov* has validated the Application.

3. *Multiple Application Submissions:* If an Applicant submits multiple Applications, the CDFI Fund will only review the last Application submitted in *Grants.gov*.

4. *Late Submission:* The CDFI Fund will not accept an Application submitted after the Application deadline except where the submission delay was a direct result of a Federal government administrative or technological error. In such case, the Applicant must submit a request for acceptance of late Application submission and include documentation of the error no later than two business days after the Application deadline. The CDFI Fund will not respond to request for acceptance of late Application submissions after that time period. Applicants must submit late Application submission requests to the CDFI Helpdesk at *cdfihelp@cdfi.treas.gov* with a subject line of ''Late Application Submission Request.''

G. Funding Restrictions

FA, HFFI–FA and TA awards are limited by the following:

1. FA Awards

(a) An award Recipient shall use FA funds only for the eligible activities described in Section II. Award Description (C)(1) of this NOFA and its Assistance Agreement.

(b) A Recipient may not distribute FA funds to an Affiliate, Subsidiary, or any other entity, without the CDFI Fund's prior written approval.

(c) FA funds shall only be disbursed to the Recipient.

(d) The CDFI Fund, in its sole discretion, may disburse FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

2. HFFI–FA Awards

(a) An award Recipient shall use HFFI–FA funds only for the eligible activities described in Section II. Award Description (C)(1) of this NOFA and its Assistance Agreement.

(b) A Recipient may not distribute FA funds to an Affiliate, Subsidiary, or any other entity, without the CDFI Fund's prior written approval.

(c) HFFI–FA funds shall only be disbursed to the Recipient.

(d) The CDFI Fund, in its sole discretion, may disburse HFFI–FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

3. TA Grants

(a) An award Recipient shall use TA funds only for the eligible activities described in Section II. Award Description (C)(2) of this NOFA and its Assistance Agreement.

(b) A Sponsoring Entity award Recipient must create, as a legal entity, the Emerging CDFI no later than the end of the first year of the period of performance, whereupon the Sponsoring Entity must request the CDFI Fund to amend the Assistance Agreement and add the Emerging CDFI as a co-awardee thereto, with the Sponsoring Entity, thereby transferring any and all remaining balances and/or assets derived from the TA award to the Emerging CDFI.

(c) An Emerging CDFI or Certified CDFI award Recipient may not distribute TA funds to an Affiliate, Subsidiary or any other entity, without the CDFI Fund's prior written consent.

(d) TA funds shall only be disbursed to the Recipient.

(e) The CDFI Fund, in its sole discretion, may disburse TA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

V. Application Review Information

1. *Criteria:* If the Applicant has submitted a complete and eligible Application, the CDFI Fund will conduct a substantive review in accordance with the criteria and procedures described in the Regulations, this NOFA, the Application guidance, and the Uniform Federal Award Requirements. The CDFI Fund reserves the right to contact the Applicant by telephone, email, or mail for the sole purpose of clarifying or confirming Application information. If contacted, the Applicant must respond within the time period communicated by the CDFI Fund or run the risk that its Application will be rejected.

(a) *Application Scoring and Award Selection (FA, HFFI–FA, and TA):* The CDFI Fund will evaluate each Application using the FA and TA Application Scoring Criteria described in the Application. An Applicant must receive a minimum 40 percent of the total score for the FA, HFFI–FA, and TA components in order to be considered for an award. An Applicant that is an Emerging CDFI and has not received a previous TA award will be rated, among other elements, on its plan to meet the requirements of a Certified CDFI within two years of the beginning of the period of performance. In addition, an Emerging CDFI Applicant that is a prior TA Recipient will be rated, among other elements, on its plan to meet the CDFI certification goal specified in its previous Assistance Agreement. A Sponsoring Entity Applicant will be rated, among other elements, on its plan to create an Emerging CDFI by the end of the first year of the performance period and comply with CDFI Certification requirements within four years of the beginning of the period of performance.

The CDFI Fund will score each part as indicated in Table 12 and 13.

TABLE 12—FA & TA APPLICATION SCORING CRITERIA

FA & TA Narrative sections	FA Applicants	TA Applicants
Executive Summary	Not Scored	Not Scored.
Purpose/Proposal	10 points	15 points.
Products	10 points	10 points.
Policies	10 points	10 points.
People	10 points	15 points.
Partnerships	10 points	5 points.
Performance	40 points	30 points.
Projections	10 points	15 points.
Total Points	100 points	100 points.

TABLE 13—HFFI–FA APPLICATION SCORING CRITERIA

HFFI–FA Narrative sections	HFFI–FA Applicants
H1. HFFI Target Market Profile	4 points.
H2. Healthy Food Financial Products	5 points.
H3. Healthy Food Development Services	2 points.
H4. Projected HFFI–FA Activities	7 points.
H5, H6, and H7. HFFI Track Record, Management Capacity for Providing Healthy Food Financing, Healthy Food Financing Outcomes.	7 points.
Total Points	25 points.

The CDFI Fund will deduct points, in accordance with the following table, from Applicants that have received prior awards under any CDFI Fund program:

TABLE 14—POINT DEDUCTIONS

Issues	Descriptions
Failure to meet Agreement requirements.	The CDFI Fund will deduct points from any Applicant that has not met requirements in any previously executed CDFI Fund award agreement(s) including compliance reports due 24 months prior to the Application deadline.
Failure to provide timely loan payments.	The CDFI Fund will deduct points from any Applicant that has failed to submit one or more timely loan payments to the CDFI Fund within the 24 months prior to the Application deadline.

TABLE 14—POINT DEDUCTIONS—Continued

Issues	Descriptions
Incurred de-obligations	The CDFI Fund will deduct points from any Applicant if any CDFI Fund award funds were de-obligated within the 12 months prior to the Application deadline for any reason other than insufficient matching funds. Points will not be deducted for any de-obligations that resulted from a Recipient's inability to provide eligible matching funds within the specified time frame.

2. *Review and Selection Process.* All Applications will be initially evaluated by external non-Federal reviewers who are selected based on criteria that includes: A professional background in community and economic development finance; understanding of community and economic development in Native Communities; experience reviewing financial statements of all CDFI institution types; and experience performing underwriting of community and economic development projects. Reviewers must complete the CDFI Fund's conflict of interest process and be approved by the CDFI Fund. The CDFI Fund's application reader conflict of interest policy is located on the CDFI Fund's Web site.

TA Applications will be evaluated by one external reviewer; FA and HFFI–FA Applications will be evaluated by three external reviewers. All Applications will be reviewed in accordance with reviewer evaluation materials. Applications will be ranked based on Application scores, from highest to lowest. In the case of tied scores, Applicants will be ranked first according to each Performance score, then the Purpose section. TA Applicants, FA Applicants, and HFFI–FA Applicants will be grouped and ranked separately.

3. *Programmatic and Financial Risk Analysis.* The CDFI Fund conducts three additional levels of due diligence for Applications that are in scoring contention for an award. This due diligence includes an analysis of programmatic and financial risk factors including, but not limited to: Financial stability; quality of management systems and ability to meet award management standards; history of performance in managing Federal awards (including timeliness of reporting and compliance); reports and findings from audits; and the Applicant's ability to effectively implement Federal requirements. Award amounts may be reduced as a result of this analysis. In addition, for FA awards, the CDFI Fund may reduce awards sizes from requested amounts based on certain variables, including an Applicant's loan disbursement activity, total portfolio outstanding, and similar factors. Lastly, the CDFI Fund may consider the institutional diversity of Applicants when making its funding decisions.

4. *Insured Depository Institutions:* The CDFI Fund will consider safety and soundness information from the Appropriate Federal or State Banking Agency. If the Applicant is a CDFI Depository Institution Holding Company, the CDFI Fund will consider information provided by the Appropriate Federal or State Banking Agencies on the CDFI Depository Institution Holding Company and the CDFI Certified Insured Depository Institution that will expend and carry out the award. If the Appropriate Federal Banking Agency or Appropriate State Agency identifies safety and soundness concerns, the CDFI Fund will assess whether the concerns cause or will cause the Applicant to be incapable of undertaking the activities for which funding has been requested.

5. *Non-Regulated Institutions:* In accordance with the NACA Program's authorizing statute and regulations, the CDFI Fund must ensure, to the maximum extent practicable, that recipients that are non-regulated CDFIs are financially and managerially sound and maintain appropriate internal controls (12 U.S.C. 4707(f)(1)(A) and 12 CFR 1805.800(b)). Further, the CDFI Fund must determine that a Certified, Emerging, or Certifiable CDFI Applicant's capacity to operate as a CDFI will not be dependent upon assistance from the CDFI Fund for continued viability (12 U.S.C. 4704(b)(2)(A)). If it is determined the Certified, Emerging, or Certifiable CDFI Applicant is incapable of meeting these requirements, the CDFI Fund reserves the right to deem the Applicant ineligible or terminate the award.

6. *Anticipated Award Announcement:* The CDFI Fund anticipates making CDFI Program award announcements by September 30, 2015.

7. *Application Rejection:* The CDFI Fund reserves the right to reject an Application if information (including administrative error) comes to the CDFI Fund's attention that either: Adversely affects an Applicant's eligibility for an award; adversely affects the Recipient's certification as a CDFI (to the extent that the award is conditional upon CDFI certification); adversely affects the CDFI Fund's evaluation or scoring of an Application; or indicates fraud or mismanagement on the Applicant's part. If the CDFI Fund determines any portion of the Application is incorrect in a material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the Application. The CDFI Fund reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If the changes materially affect the CDFI Fund's award decisions, the CDFI Fund will provide information about the changes through its Web site. The CDFI Fund's award decisions are final and there is no right to appeal the decisions.

VI. Federal Award Administration Information

A. Award Notification

Each successful Applicant will receive an email ''notice of award'' notification from the CDFI Fund stating that its Application has been approved for an award. Each Applicant not selected for an award will receive an email stating that a debriefing notice has been provided in its MyCDFI Fund account.

B. Assistance Agreement

Each Applicant selected to receive an award must enter into an Assistance Agreement with the CDFI Fund in order to receive a disbursement(s). The Assistance Agreement will set forth the award's terms and conditions, including but not be limited to the: (i) Award amount; (ii) award type; (iii) award uses; (iv) Target Market(s) or activities; (v) performance goals and measures; and (vi) reporting requirements. FA Assistance Agreements have three-year periods of performance; TA Assistance Agreements have two-year periods of performance for Emerging and Certified CDFI TA Recipients and four-year periods of performance for Sponsoring Entity TA Recipients. Upon creation of the Emerging CDFI, the Sponsoring Entity will request the CDFI Fund to amend the Assistance Agreement and add the Emerging CDFI as a party thereto; the Emerging CDFI, as co-

awardee, must comply with all of the requirements in the Assistance Agreement, including all program goals and measures.

1. *Certificate of Good Standing:* All FA and TA Recipients that are not Insured Depository Institutions will be required to provide the CDFI Fund with a certificate of good standing from the secretary of state for the Recipient's State of incorporation prior to closing. This certificate can often be acquired online on the secretary of state Web site for the Recipient's State of incorporation and must generally be dated within 270 days before the date the Recipient executes the Assistance Agreement. Due to potential backlogs in State government offices, Applicants are advised to submit requests for certificates of good standing no later than 60 days after they submit their Applications.

2. *Closing:* Pursuant to the Assistance Agreement, there will be an initial closing at which point the Assistance Agreement and related documents will be properly executed and delivered, and an initial payment of FA or TA may be made. The CDFI Fund will minimize the time between the Recipient incurring costs for eligible activities and award payment based on what is administratively feasible. The advanced payments for eligible activities will occur no more than one year in advance of the Recipient incurring costs for the eligible activities. Following the initial closing, there may be subsequent closings involving additional award payments. Any documents in addition to the Assistant Agreement that are connected with such subsequent closings and payments shall be properly executed and timely delivered by the Recipient to the CDFI Fund.

3. *Requirements Prior to Entering into an Assistance Agreement:* If, prior to entering into an Assistance Agreement, information (including administrative error) comes to the CDFI Fund's attention that: Adversely affects the Recipient's eligibility for an award; the Recipient's certification as a CDFI (to the extent that the award is conditional upon CDFI certification); the CDFI Fund's evaluation of the Application evaluation; the Recipient is not in compliance with any requirement listed the Uniform Federal Award Requirements; or indicates fraud or mismanagement on the Recipient's part, the CDFI Fund may, in its discretion and without advance notice to the Recipient, terminate the award or take such other actions as it deems appropriate. The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient fails to return the Assistance Agreement, signed by the authorized representative of the Recipient, and/or provide the CDFI Fund with any other requested documentation, within the CDFI Fund's deadlines.

In addition, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Assistance Agreement and the award made under this NOFA pending the criteria described in the following table:

TABLE 15—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT

Requirement	Criteria
Failure to meet reporting requirements.	• If a Recipient received a prior award under any CDFI Fund program and is not current with the reporting requirements in the previously executed agreement(s), the CDFI Fund can delay entering into an Assistance Agreement or disbursing an award until reporting requirements are met. • If such a Recipient is unable to meet the requirement within the timeframe specified, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA. • The automated systems the CDFI Fund uses only acknowledge a report's receipt, not a determination of meeting reporting requirements.
Failure to maintain CDFI Certification.	• An FA Recipient must be a Certified CDFI prior to entering into an Assistance Agreement. • If an FA Recipient fails to maintain CDFI Certification, the CDFI Fund will terminate and rescind the Assistance Agreement and the award made under this NOFA.
Pending resolution of noncompliance.	• The CDFI Fund will delay entering into an Assistance Agreement with a Recipient that has pending noncompliance issues if the CDFI Fund has not yet made a final determination as to whether the Recipient is in default of its previously executed award agreement(s). • If the Recipient is unable to satisfactorily resolve the compliance issues, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Default status	• If, at any time prior to entering into an Assistance Agreement, the CDFI Fund determines that an Recipient is in default of a previously executed agreement with the CDFI Fund and the Recipient has been provided written notification of such determination, the CDFI Fund can delay entering into an Assistance Agreement, until the Recipient has cured the default by taking actions the CDFI Fund has specified within the specified timeframe. • If the Recipient is unable to meet the cure requirement within the specified timeframe, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Final Default and sanctions	If the CDFI Fund has found the Recipient in final default of a prior executed agreement and provided notification of sanctions, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA within the time period specified in such notification.
Compliance with Federal civil rights requirements.	If prior to entering into an Assistance Agreement under this NOFA, the Recipient receives a final determination, made within the last three years, in any proceeding instituted against the Recipient in, by, or before any court, governmental, or administrative body or agency, declaring that the Recipient has violated the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. § 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794); the Age Discrimination Act of 1975, (42 U.S.C. § 6101–6107), and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency, the CDFI Fund will terminate and rescind the Assistance Agreement and the award made under this NOFA.
Do Not Pay	• The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government. • The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient is identified as an ineligible recipient on the Do Not Pay database.
Safety and soundness	• If it is determined the Recipient is or will be incapable of meeting its award obligations, the CDFI Fund will deem the Recipient to be ineligible or require it to improve safety and soundness conditions prior to entering into an Assistance Agreement.

C. Reporting

1. *Reporting requirements:* On an annual basis for the period of performance, the CDFI Fund may collect information from each Recipient including, but not limited to, an Annual Report with the following components:

TABLE 16—ANNUAL REPORTING REQUIREMENTS

Single Audit Narrative Report (or like report).	The Recipient must submit, via MyCDFI Fund, a Single Audit Narrative Report for each year of its period of performance notifying the CDFI Fund whether it is required to have a single audit pursuant to OMB Single Audit requirements.
Single Audit (if applicable) (or similar report).	If a Recipient is required to complete a Single Audit Report, it should be submitted to the Federal Audit Clearinghouse see 2 CFR Subpart F-Audit Requirements in the Uniform Federal Award Requirements. For-profit Recipients will be required to complete and submit a similar report directly to the CDFI Fund.
Institution Level Report (ILR)	The ILR is a report used to collect compliance and performance data from CDFI Fund award Recipients. The ILR is submitted through the Community Investment Impact System (CIIS) and captures organizational information, financial position, lending and investing activities, community development outputs, and development services.
Transaction Level Report (TLR)	The TLR is a report used to collect compliance and performance data from CDFI Fund award Recipients. The TLR is submitted through the CIIS and captures data on each individual loan and investment in the award Recipient's portfolio. • For CDFI Depository Institution Holding Company award Recipients, the TLR captures data on the individual loans and investments by its CDFI Subsidiary Insured Depository Institution's portfolio. • TLR is not required for TA Recipients.
Federal Financial Report/OMB Standard Form 425.	If the Recipient receives a TA award, it must submit the Federal Financial Report/*OMB Standard Form 425* via MyCDFI Fund.
Uses of Financial Assistance Report.	If the Recipient receives an FA award, it must submit the Uses of Financial Assistance Report via MyCDFI Fund.
Explanation of Noncompliance (as applicable) or successor report.	If the Recipient fails to meet a Performance Goal, it must submit the Explanation of Noncompliance via MyCDFI Fund.
Uses of Technical Assistance Report.	If the Recipient receives a TA award, it must submit the Uses of Technical Assistance Report via MyCDFI Fund.

Each Recipient is responsible for the timely and complete submission of the Annual Reporting requirements. Sponsoring Entities with co-awardees will be informed of any reporting shifts at the time the Emerging CDFI is adjoined to the Agreement. The CDFI Fund reserves the right to contact the Recipient and additional entities or signatories to the Assistance Agreement to request additional information and documentation. The CDFI Fund will use such information to monitor each Recipient's compliance with the requirements in the Assistance Agreement and to assess the impact of the NACA Program. The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after notice to Recipients.

2. *Financial Management and Accounting:* The CDFI Fund will require Recipients to maintain financial management and accounting systems that comply with Federal statutes, regulations, and the terms and conditions of the Federal award. These systems must be sufficient to permit the preparation of reports required by general and program specific terms and conditions, including the tracing of funds to a level of expenditures adequate to establish that such funds have been used according to the Federal statutes, regulations, and the terms and conditions of the Federal award.

The cost principles used by Recipients must be consistent with Federal cost principles and support the accumulation of costs as required by the principles, and must provide for adequate documentation to support costs charged to the NACA Program award. In addition, the CDFI Fund will require Recipients to: Maintain effective internal controls; comply with applicable statutes, regulations, and the Assistance Agreement; evaluate and monitor compliance; take action when not in compliance; and safeguard personally identifiable information.

VII. Agency Contacts

A. The CDFI Fund will respond to questions concerning this NOFA and the Application between the hours of 9:00 a.m. and 5:00 p.m. Eastern Time, starting on the date that the NOFA is published through the date listed in Table 1 and Table 11. The CDFI Fund will post on its Web site responses to reoccurring questions received about this Application. Other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's Web site at *http://www.cdfifund.gov.* Table 17 lists CDFI Fund contact information:

TABLE 17—CONTACT INFORMATION

Type of question	Telephone No. (not toll free)	Email addresses
NACA Program	202–653–0421, option 1	*cdfihelp@cdfi.treas.gov.*
Certification, Compliance Monitoring, and Evaluation	202–653–0423	*ccme@cdfi.treas.gov.*
MyCDFI Fund—IT Help Desk	202–653–0422	*IThelpdesk@cdfi.treas.gov.*

B. *Information Technology Support:* People who have visual or mobility impairments that prevent them from using the CDFI Fund's Web site should call (202) 653–0422 for assistance (this is not a toll free number).

C. *Communication with the CDFI Fund:* The CDFI Fund will use contact information in MyCDFI Fund to

communicate with Applicants and Recipients. It is imperative, therefore, that Applicants, Recipients, Subsidiaries, Affiliates, and signatories maintain accurate contact information in their accounts. This includes information such as contact names (especially for the authorized representative) listed in this NOFA's application materials, email addresses, fax and phone numbers, and office locations.

D. *Civil Rights and Diversity:* Any person who is eligible to receive benefits or services from CDFI Fund or Recipients under any of its programs is entitled to those benefits or services without being subject to prohibited discrimination. The Department of the Treasury's Office of Civil Rights and Diversity enforces various Federal statutes and regulations that prohibit discrimination in financially assisted and conducted programs and activities of the CDFI Fund. If a person believes that s/he has been subjected to discrimination and/or reprisal because of membership in a protected group, s/he may file a complaint with: Associate Chief Human Capital Officer, Office of Civil Rights, and Diversity, 1500 Pennsylvania Ave. NW., Washington, DC 20220 or (202) 622–1160 (not a toll-free number).

VIII. Other Information

A. *Paperwork Reduction Act:* Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. If applicable, the CDFI Fund may inform Applicants that they do not need to provide certain Application information otherwise required. Pursuant to the Paperwork Reduction Act, the CDFI Program, and NACA Program Application has been assigned the following control number: 1559–0021.

B. *Application Information Sessions:* The CDFI Fund may conduct webinars or host information sessions for organizations that are considering applying to, or are interested in learning about, the CDFI Fund's programs. For further information, please visit the CDFI Fund's Web site at *http://www.cdfifund.gov.*

Authority: 12 CFR parts 1805 and 1815; 2 CFR 200.

Dated: September 23, 2014.

Dennis Nolan,

Deputy Director, Community Development Financial Institutions Fund.

[FR Doc. 2014–23062 Filed 9–26–14; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8858 and Sch. M

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8858, Information Return of U.S. Persons With Respect To Foreign Disregarded Entities, and Schedule M, Transaction Between Foreign Disregarded Entity of a Foreign Tax Owner and the Filer on Other Related Entities.

DATES: Written comments should be received on or before November 28, 2014 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms and instructions should be directed to R. Joseph Durbala, (202) 317–5746, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Information Return of U.S. Persons With Respect To Foreign Disregarded Entities (Form 8858), and Transaction Between Foreign Disregarded Entity of a Foreign Tax Owner and the Filer on Other Related Entities (Schedule M).

OMB Number: 1545–1910.

Form Number: Form 8858 and Schedule M.

Abstract: Form 8858 and Schedule M are used by certain U.S. persons that own a foreign disregarded entity (FDE) directly or, in certain circumstances, indirectly or constructively.

Current Actions: There are no changes being made to the burden at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other-for-profit organizations, and individuals or households.

Estimated Number of Respondents: 50,000.

Estimated Time per Respondent: 51 hours, 30 minutes.

Estimated Total Annual Burden Hours: 1,832,500.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 8, 2014.

Christie Preston,

IRS, Reports Clearance Officer.

[FR Doc. 2014–23164 Filed 9–26–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8804–C, Certificate of Partner-Level Items to Reduce Section 1446 Withholding, and Special Rules to Reduce Section 1446 Withholding.

DATES: Written comments should be received on or before November 28, 2014 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to R. Joseph Durbala, (202) 317–5746, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certificate of Partner-Level Items to Reduce Section 1446 Withholding.

OMB Number: 1545–1934.

Form Number: Form 8804–C.

Abstract: Form 8804–C will be a form a foreign partner would voluntary submit to the partnership if it chooses to provide a certification that could reduce or eliminate the partnership's need to withhold 1446 tax.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Individuals or Households, and Not-for-Profit Organizations.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 18 hour 42 minutes.

Estimated Total Annual Burden Hours: 18,700.

Title: Special Rules to Reduce Section 1446 Withholding.

OMB Number: 1545–1934.

Form Number: TD 9394.

Abstract: This document contains final regulations regarding when a partnership may consider certain deductions and losses of a foreign partner to reduce or eliminate the partnership's obligation to pay withholding tax under section 1446 on effectively connected taxable income allocable under section 704 to such partner.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Individuals or Households, and Not-for-Profit Organizations.

Estimated Number of Respondents: 1.

Estimated Time per Respondent: 1 Hour.

Estimated Total Annual Burden Hours: 1.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 15, 2014.

Christie Preston,

IRS Reports Clearance Officer.

[FR Doc. 2014–23162 Filed 9–26–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Biomedical Laboratory Research and Development Service, Special Emphasis Panel—Gulf War Veterans' Illnesses Biorepository, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App., that the Special Emphasis Panel—Gulf War Veterans' Illnesses Biorepository will meet on November 4, 2014, from 9:00 a.m. until 3:30 p.m. at the AAAE Conference Center, 601 Madison Street, Suite 400, Alexandria, VA. The panel meeting will be open to the public for approximately one-half hour at the start of the meeting to discuss the general status of the project. The remaining portion of the meeting will be closed to the public for the review, discussion, and evaluation of the research project to be performed for VA. The closed portion of the meeting involves discussion, examination, reference to staff and consultant critiques of the research proposal. As provided by subsection 10(d) of Public Law 92–463, as amended, closing portions of a panel meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

The purpose of this Special Emphasis Panel is to review the Veterans Affairs Gulf War Veterans' Illnesses Biorepository for its continued funding. The Gulf War Veterans' Illnesses Biorepository is a project of high programmatic importance to VA. The Special Emphasis Panel will review activities related to the Gulf War Veterans' Illnesses Biorepository including the significance of the biorepository, along with some other key areas such as innovation, environment, feasibility, and protection of human subjects.

No time will be allocated at this meeting for receiving oral presentations from the public. Those who plan to attend or would like to obtain a copy of minutes of the panel meeting and roster of the participants of the panel should contact Dr. Victor Kalasinsky, Designated Federal Officer, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC, or by email at *victor.kalasinsky@va.gov.* Any member of the public wishing to attend the meeting or seeking additional information should contact Dr. Kalasinsky at (202) 443–5682.

Dated: September 24, 2014.

Rebecca Schiller,

Committee Management Officer.

[FR Doc. 2014–23160 Filed 9–26–14; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 79 Monday,

No. 188 September 29, 2014

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 112

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA–2011–N–0921]

RIN 0910–AG35

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend certain specific provisions of the proposed rule, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' We are taking this action because the extensive information received in public comments has led to significant changes in our current thinking on certain key provisions of the proposed rule. We are reopening the comment period only with respect to the specific issues identified in this document.

DATES: Submit either electronic or written comments on the proposed rule by December 15, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 15, 2014 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA–2011–N–0921) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, 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.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
Purpose of the Supplemental Notice of Proposed Rulemaking
Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking
Costs and Benefits
I. Background
II. Amendments to the Previously Published Proposed Rule
A. Proposed Subpart A—General Provisions
B. Proposed Subpart E—Standards Directed to Agricultural Water
C. Proposed Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste
D. Proposed Subpart I—Standards Directed to Domesticated and Wild Animals
E. Proposed Subpart R—Withdrawal of Qualified Exemption
III. Preliminary Regulatory Impact Analysis
A. Overview
B. Regulatory Flexibility Analysis
C. Unfunded Mandates
D. Small Business Regulatory Enforcement Fairness Act
IV. Paperwork Reduction Act of 1995
V. Analysis of Environmental Impact
VI. Comments
VII. References

Executive Summary

Purpose of the Supplemental Notice of Proposed Rulemaking

To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, FDA published the proposed rule entitled, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,'' which would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, January 16, 2013). FDA proposed these standards to implement section 105 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). The comment period for the proposed rule closed on November 22, 2013.

Taking into account information we heard at public meetings, and based on a preliminary review of written comments submitted to the docket, currently available information, and our subsequent analysis of the proposed provisions in light of this information, we are proposing certain new provisions and certain amendments to our previously proposed provisions.

Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking

We are reopening the comment period to seek public comment on the specific issues and amended and new proposed provisions that are discussed in this document, which include the following: (1) Proposed amendments to paragraph (a) of proposed 21 CFR 112.4 to exclude from coverage of the Produce Safety proposed rule those farms or farm mixed-type facilities with an average annual monetary value of produce (as ''produce'' is defined in § 112.3(c)) sold during the previous 3-year period of $25,000 or less (on a rolling basis); and corresponding revisions to the definitions of ''very small business'' and ''small business'' in proposed § 112.3(b) to apply the monetary value thresholds based on sales of produce; (2) proposed amendments to the definitions of ''farm'' in proposed § 112.3(c) responding to comments about overlap between the produce and preventive control rules, such that establishments that pack or hold produce that is grown or harvested on another farm would now be subject to the produce safety standards of proposed part 112 regardless of whether or not that farm is under the same ownership; and corresponding revisions to the definitions of ''covered activity,'' ''harvesting,'' ''holding,'' and ''packing'' in proposed § 112.3(c); (3) proposed amendments to § 112.44(c) to update the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method in a way that is consistent with the U.S. Environmental Protection Agency's (EPA) current recreational water standard, *i.e.,* a geometric mean of samples not to exceed 126 colony forming units (CFU) of generic *Escherichia. coli (E. coli)* per 100 milliliters (mL) of water and (when applicable) a statistical threshold value of samples not to exceed 410 CFU of generic *E. coli* per 100 mL of water; (4) new proposed provisions within

§ 112.44(c) to incorporate additional flexibility and provide means to achieve the proposed microbial quality standard for agricultural water used for direct application during growing, *i.e.,* by either applying a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (proposed § 112.44(c)(1)); and/or applying a time interval (in days) between harvest and end of storage (including during activities such as commercial washing) using appropriate microbial die-off or removal rates, provided there is adequate supporting scientific data and information (proposed § 112.44(c)(2)); in addition, a new proposed provision to provide for an alternative microbial die-off rate between last irrigation and harvest in accordance with § 112.12; (5) proposed amendments to § 112.45(b) and new proposed provisions §§ 112.45(c) and (d) to provide tiered-approaches for specific testing frequency requirements to test untreated surface water as well as untreated ground water, which would enable testing at a reduced frequency than that proposed in the previously published proposed rule; (6) a new proposed provision § 112.45(e) to provide that a farm may meet the requirements related to agricultural water testing using the farm's own test results or data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represents the farm's agricultural water source(s) and all other applicable requirements are met; (7) proposed removal of the 9-month minimum application interval for use of raw manure in proposed § 112.56(a)(1)(i). FDA defers its decision on an appropriate time interval until FDA pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with the U.S. Department of Agriculture (USDA) and other stakeholders. At this time, we do not intend to take exception to the continuation of adherence to the National Organic Program (NOP) standard; (8) proposed amendments to § 112.56(a)(4)(i)) to establish that if the biological soil amendment of animal origin is treated by a composting process and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.,* time between application and harvest) is 0 days; (9) new proposed provision § 112.84 to explicitly state that part 112 would not authorize or require covered farms to take actions that would constitute the ''taking'' of threatened or endangered species in violation of the Endangered Species Act, or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages; (10) new proposed provision § 112.201(b)(1) to establish that, before FDA issues an order to withdraw a qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction; (11) new proposed provisions §§ 112.201(b)(2) and 112.201(b)(3) to establish that, before FDA issues an order to withdraw a qualified exemption, FDA must notify the farm of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the farm to respond to FDA's notification; and that FDA must consider actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption; and (12) new proposed provision § 112.213 to list the circumstances under which FDA would reinstate a farm's qualified exemption that is withdrawn.

We are seeking comment on the issues discussed in this document by December 15, 2014. The previously published proposed rule (78 FR 3504; January 16, 2013) and the proposed amendments and new provisions published in this document, taken together, constitute the entirety of the proposed rule on ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' At this time, we are not seeking comment on any other provisions of the previously published proposed rule that are not identified for public comment in this document. We will complete our review of public comments received thus far, and take into account comments received in response to this document, in issuing a final rule.

Costs and Benefits

We performed additional analyses to examine the impacts of the amended and new proposed provisions described in this document. We estimate the costs of the proposed rule as currently amended to be $386.23 million annually for domestic farms, $143.39 million annually for foreign farms covered by the rule (for a grand total of $529.62 million annually), resulting in $400.37 million annually in estimated potential net benefits.

SUMMARY OF COSTS AND BENEFITS OF THE PROPOSED RULE AS CURRENTLY AMENDED

Prevented foodborne illnesses (in millions)	Total benefits (in millions)	Total domestic costs (in millions)	Total foreign costs (in millions)	Total costs (domestic + foreign)	Net benefits (in millions)
1.57	$930.00	$386.23	$143.39	$529.62	$400.37

Compared to the previously published proposed rule, in total, this represents a cost savings of $73.33 ($459.56 − $386.23) million for domestic produce farms, and a decrease in overall net benefits of $7.19 ($400.37 − $407.56) million.

I. Background

To minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, FDA published the proposed rule, ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (hereafter referred to as ''the Produce Safety proposed rule'' or ''the previously published proposed rule''), which would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption (78 FR 3504, January 16, 2013). We later issued a notice to correct technical errors and errors in reference numbers cited in the proposed rule (78 FR 17155, March 20, 2013).

In the same issue of the **Federal Register** in which the Produce Safety proposed rule was published, FDA published another proposed rule entitled, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food'' that would apply to human food and require domestic and foreign facilities that are required to register

under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, monitor results, and act to correct problems that arise (hereafter referred to as ''the Preventive Controls for Human Food proposed rule'') (78 FR 3646, January 16, 2013). These proposed rules help form the foundation of, and a central framework for, a new food safety system in the United States.

We requested comments on the Produce Safety proposed rule by May 16, 2013. We extended the comment period for the proposed rule and its information collection provisions (which are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (78 FR 11611, February 19, 2013; 78 FR 24692, April 26, 2013; 78 FR 48637, August 9, 2013; 78 FR 69605, November 20, 2013). The comment period for the proposed rule closed on November 22, 2013.

Since publication of the Produce Safety proposed rule in January 2013, we conducted numerous outreach activities. For example, we held three public meetings to solicit oral stakeholder and public comments on the proposed rule, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the proposed rule (78 FR 6762, January 31, 2013, and 78 FR 10107, February 13, 2013). We also traveled across the country and around the world to discuss the Produce Safety proposed rule, as well as the other foundational FSMA proposed rules (Refs. 1, 2, and 3).

II. Amendments to the Previously Published Proposed Rule

In December 2013, FDA issued a public statement reiterating our goal of ensuring produce safety, and indicating that, based on the extensive input we have received from produce farmers, consumers, and others in the agricultural sector, significant changes will be needed in key provisions of the Produce Safety proposed rule, including those related to water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms (Ref. 4). We also announced our intent to propose revised regulatory requirements and request comment on them, allowing the public the opportunity to provide input on our current thinking. In this document, FDA is providing our current thinking on certain issues discussed in the Produce Safety proposed rule that we previously published, including certain amended and new proposed provisions, for public comment. In addition, published elsewhere in this issue of the **Federal Register**, we are also providing our current thinking on certain issues discussed in the Preventive Controls for Human Food proposed rule that we previously published, and seeking public comment on those issues.

To date, over 15,000 electronically submitted comments have been received in the docket in response to the previously published proposed rule. We are continuing to review all electronic and paper submissions of comments to the docket. Taking into account information received at public meetings, and based on a preliminary review of written comments submitted to the docket, currently available information, and our subsequent analysis of the proposed provisions in light of this information, we are reopening the comment period to seek public comment on certain specific issues described in this section.

Importantly, the amended and new proposed provisions we have included in the regulatory text are based on a preliminary review of the comments. We will complete our review of comments previously submitted and consider the comments responsive to this document in developing the final rule.

The previously published proposed rule and the proposed amendments and new provisions published in this document, taken together, constitute the entirety of the proposed rule on ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.'' Throughout this document, we discuss amendments and additions to the previously proposed part 112 and, in the codified section of this document, we list each of the amended and new proposed provisions of proposed part 112. For the convenience of readers and ease of reference, we prepared a separate document to identify the changes to the previously published codified provisions and provide the complete proposed part 112, as amended through this document (Ref. 5).

A. Proposed Subpart A—General Provisions

In the previously published proposed rule, under subpart A of proposed part 112, we proposed various provisions to establish the scope of, and definitions applicable to, the Produce Safety regulation, and to identify who would be subject to the requirements of part 112. Proposed subpart A also described the proposed modified requirements and procedures governing qualified exemptions from the regulations. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3534 through 3551).

We are reopening the comment period to solicit public comment on our current thinking on two specific issues related to the general provisions in subpart A: (1) Farm sizes based on monetary value of total food sales to determine those farms that are not covered by the rule and those that would qualify for extended compliance periods and (2) definition of ''farm''. We describe our current thinking on these two issues in this section.

1. Farms Sizes Based on Monetary Value of Total Food Sales

In the previously published proposed rule, we proposed to apply the Produce Safety regulation only to farms and farm mixed-type facilities with an average annual monetary value of food (as defined under the FD&C Act and including seeds and beans used to grow sprouts) sold during the previous 3-year period of more than $25,000 on a rolling basis (proposed § 112.4). We explained that farms below this $25,000 limit collectively account for only 1.5 percent of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. Based on a tentative conclusion that such businesses do not contribute significantly to the produce market and, therefore, to the volume of production that could become contaminated, we tentatively concluded that imposing the proposed requirements of part 112 on these businesses is not warranted because it would have little measurable public health impact. We also noted that such farms are and would continue to be subject to the applicable provisions of the FD&C Act and applicable implementing regulations, irrespective of whether they are included within the scope of the Produce Safety proposed rule (78 FR 3504 at 3518 and 3549).

In addition, we proposed to apply certain monetary value thresholds based on total food sales to define those very small and small businesses that would be eligible for our proposed extended time periods to comply with the Produce Safety regulation. In proposed § 112.3(b)(1), we proposed to define ''very small business'' to mean a business that is subject to proposed part 112 and for which, on a rolling basis, the average annual monetary value of food (as defined under the FD&C Act and including seeds and beans used to

grow sprouts) sold during the previous 3-year period is no more than $250,000. In addition, under proposed § 112.3(b)(2), we proposed to define ''small business'' to mean a business that is subject to proposed part 112 and for which, on a rolling basis, the average annual monetary value of food (as defined under the FD&C Act and including seeds and beans used to grow sprouts) sold during the previous 3-year period is no more than $500,000, and which farm is not a ''very small business.''

a. Relevant comments. We received several comments opposing our tentative decision to identify farm sizes based on total food sales either for coverage by the rule or for extended compliance periods. Commenters recommended that farm sizes should be based on the sale of ''covered produce'' or ''regulated'' produce, rather than on the sale of all food. Some of these commenters noted that the proposed coverage of farms based on their total food sales would make it difficult for midsize farms to diversify their operations. Other commenters maintained that covering farms based on their total food sales would have an adverse impact on diversified farms that primarily raise food grains or dairy cattle (and produce dairy products) by forcing them to comply with produce safety standards. Some commenters that recommended identifying farm sizes (both those that would not be covered and those that would be covered and considered as ''small businesses'' or ''very small businesses'') based on monetary value of sales of ''covered produce'' also recommended similarly applying the qualified exemptions provided under proposed § 112.5 to farms based on an average annual monetary value of $500,000 or less of sales of covered produce, rather than on sales of all food.

b. FDA's consideration of comments. In response to comments received, we considered what, if any, revisions are needed to the proposed $25,000 limit as the threshold above which farms would be subject to the Produce Safety regulation.

As noted in the previously published proposed rule, farms with an average annual monetary value of food sold of $25,000 or less collectively account for 1.5 percent of covered produce acres, suggesting that they contribute little exposure to the overall produce consumption. Applying the $25,000 limit to an average annual monetary value of produce (rather than food) sold would account for an estimated total of 4 percent of covered produce acres and about 3.1 percent of all produce acres in the United States. The amended proposal would remove farms with produce sales of $25,000 or less from coverage, resulting in removal of an additional 2.1 percent of produce acres from coverage (after removal of acres as a result of the provisions related to the qualified exemption, produce that is rarely consumed raw, and produce destined for commercial processing that eliminates pathogens of concern). Under this scenario, as with the previous proposed approach, such businesses would not contribute significantly to the volume of produce in the marketplace that could become contaminated and, therefore, would have little measurable public health impact. We believe that applying the $25,000 limit to *produce* sales would accommodate the concerns expressed by some comments without adversely affecting the level of public health protection, envisioned under our previous proposal.

We also considered applying the $25,000 limit to average annual monetary value of ''covered produce'' sold, as requested by some commenters. This scenario presented a number of challenges, including the difficulty of determining the scope and public health impact of excluding farms based on the sales of covered produce, particularly considering the likely variability in produce commodities grown year to year; variability resulting from provisions under which certain commodities would not be considered ''covered produce'' (for example, produce that is rarely consumed raw); changes in the amount of produce that is used for personal consumption or for consumption on the farm or another farm under the same ownership; and whether and how to account for produce that would be eligible for exemption under certain conditions, which may be inherently variable based on market conditions (for example, produce that is destined for commercial processing). Given these confounding factors and based on available data, at this time, we are unable to determine the extent to which businesses with an average annual monetary value of ''covered produce'' sold of more than $25,000 would contribute to the overall produce market or the public health impact of not covering such businesses under part 112. In addition, the likely frequent change to a farm's covered or non-covered status may also be challenging for compliance and enforcement purposes.

For these reasons, we are proposing to amend paragraph (a) of proposed § 112.4 to establish that if you are a farm or farm mixed-type facility with an average annual monetary value of produce (as ''produce'' is defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a ''covered farm'' subject to this part, and that if you are a ''covered farm'' subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on ''covered produce.''

In addition, we are proposing corresponding revisions to the definitions of ''very small business'' and ''small business'' to apply the monetary thresholds consistently across three size-based categories of businesses that we proposed in the previously published proposed rule. As revised, a very small business defined under proposed § 112.3(b)(1) would mean a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce (as defined in proposed § 112.3(c)) sold during the previous 3-year period is no more than $250,000. As revised, a small business defined under proposed § 112.3(b)(2) would mean a farm that is subject to part 112 and, on a rolling basis, the average annual monetary value of produce (as defined in proposed § 112.3(c)) sold during the previous 3-year period is no more than $500,000; and the farm is not a very small business. Applying the monetary value limits for very small and small businesses to produce rather than to food, as previously proposed, would not alter the coverage of these businesses under the Produce Safety regulation, although we expect that a greater number of farms would likely fit within the revised definitions of very small business and small business and, therefore, qualify for the extended compliance periods we proposed for these businesses in the previously published proposed rule. See Table 1 for summary of these three proposed size-based categories, as revised.

We seek comment on our current proposal to cover farms with an average annual monetary value of ''produce'' sold of more than $25,000, and the corresponding revisions to apply the relevant monetary thresholds to the sales of produce to define small businesses and very small businesses that would be subject to this regulation for the purpose of establishing extended compliance periods. We also seek comment on whether and how these monetary thresholds may be applied to covered produce only.

TABLE 1—SUMMARY OF PROPOSED QUALIFICATIONS

[On a rolling basis, average annual monetary value of produce (as defined in proposed § 112.3(c)) sold during the previous 3-year period]

Above $250,000 and no more than $500,000.	Small Business.
Above $25,000 and no more than $250,000.	Very Small Business.
$25,000 or less	Not covered.

We also considered applying the monetary value limit to covered produce sales, rather than to total food sales, in the criteria applicable to farms that would be eligible for a qualified exemption under proposed § 112.5. In the previously published proposed rule, we proposed that a farm would be eligible for a qualified exemption and associated modified requirements in a calendar year if: (1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in proposed § 112.3(c)) you sold directly to qualified end-users (as defined in proposed § 112.3(c)) during such period exceeded the average annual monetary value of the food you sold to all other buyers during that period; and (2) the average annual monetary value of all food (as defined in proposed § 112.3(c)) you sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation (proposed § 112.5(a)). As explained in the proposed rule, proposed § 112.5(a) establishes the criteria for eligibility for a qualified exemption and associated special requirements based on average monetary value of all food sold and direct farm marketing, as mandated by section 419(f) of the FD&C Act (21 U.S.C 350h(f)). The criteria established in proposed § 112.5(a), including the requirement that ''all food'' be considered in calculating sales, are derived from section 419(f) of the FD&C Act. We, therefore, as a result of the statutory language, cannot apply the monetary value limit to covered produce sales, but instead must apply it to total or ''all'' food sales. Therefore, we are not able to make any change to the provision that the average annual monetary value of all food (as defined in proposed § 112.3(c)) sold during the 3-year period preceding the applicable calendar year must be less than $500,000, as proposed in § 112.5(a)(2)).

2. Definition of ''Farm'' (and ''Covered Activity,'' ''Harvesting,'' ''Holding,'' and ''Packing'')

In the previously published proposed rule, under subpart A of proposed part 112, we proposed definitions for various terms used in part 112. In proposed § 112.3(c), we proposed to define ''farm'' to mean to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. As proposed, the term '' farm'' included: (1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and (2) facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. We also proposed definitions for ''farm mixed-type facility'' and related activities, such as ''manufacturing/processing,'' ''packing,'' and ''holding.'' In developing these definitions, we considered the interrelationship between farms and facilities, and articulated five organizing principles to explain the basis for the proposed definitions that would classify activities on-farm and off-farm for the purpose of the Produce Safety regulation. See the discussion of this issue in the previously published proposed rule (78 FR 3504 at 3539 through 3544).

a. Relevant Comments. We received numerous comments regarding the proposed definition of a ''farm,'' including concerns related to packing or holding activities that routinely take place on a farm that commenters believed should be considered under the farm definition but would be instead covered under the proposed definition of a ''mixed-type facility.'' In particular, commenters noted that, as proposed, packing or holding of produce would be subject to either the Preventive Controls for Human Food regulation or the Produce Safety regulation, depending on whether or not the produce was grown on a farm under the same ownership. Commenters expressed various concerns with this proposed approach, including that: (1) This divergence in requirements does not have a public health basis given that the activities of packing or holding would present similar food safety risks regardless of the ownership of the farm on which the produce was grown; (2) subjecting a farm to the requirements of two different food safety regulations would be burdensome and is arbitrary; (3) it is common practice for a farm to buy and resell produce from other farms in order to fill out the necessary scale of supply (for example, when supplied to restaurants, retail establishments, or large wholesale markets), to pack produce for a neighbor who lacks a packing house, hold produce with a long shelf-life for a neighboring farm with limited storage space, or to pack or hold produce grown on farms of different ownership given costs associated with packing or holding activities; and (4) some farms sell their produce through ''Community Supported Agriculture'' arrangements and such deliveries often include produce grown by other farms not under the same ownership. We also received another comment that opposed broadening the proposed ''farm'' definition due to concerns that such changes could undermine the public health objectives of the rule.

b. FDA's Consideration of Comments. We tentatively concur with commenters who stated that packing or holding of produce presents similar reasonably foreseeable hazards regardless of whether the produce is grown and harvested on farms under the same or different ownership, and that such hazards associated with packing or holding activities would best be addressed through the standards established under the Produce Safety regulation.

In response to the comments described above and similar public comments received on the Preventive Controls for Human Food proposed rule, elsewhere in this issue of the **Federal Register**, we are issuing a notice to reopen the docket and seek public comment on certain specific issues related to that proposed rule (referred to as ''amendments to the Preventive Controls for Human Food proposed rule''). In that document, we are proposing a revised definition of ''farm'' to mean an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. As revised, the term ''farm'' would include establishments that, in addition to these activities: (1) Pack or hold raw agricultural commodities (RACs); (2) pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in subparagraph (3)(ii)(A) of the ''farm'' definition; and (3) manufacture/process food, provided that: (i) All food used in such activities is consumed on that farm or another farm under the same ownership; or (ii) Any manufacturing/processing of food

that is not consumed on that farm or another farm under the same ownership consists only of: (A) Drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and (B) Packaging and labeling RACs, when these activities do not involve additional manufacturing/processing. Under this amended proposed definition of ''farm,'' farms that pack or hold produce RACs that are grown on a farm that is under a different ownership would no longer necessarily be ''farm mixed-type facilities'' subject to the requirements of the Preventive Controls for Human Food regulation. Rather, packing or holding others' produce RACs on a covered farm would now be subject to the Produce Safety standards of proposed part 112 (unless the produce is not covered by part 112, as described in proposed § 112.2). Similarly, we are proposing in that document to amend the definitions of ''harvesting,'' ''holding,'' and ''packing,'' consistent with this amendment to the farm definition and in response to other issues discussed in that document. We refer you to the discussion of this issue in section V of that document.

Consistent with our proposed amendments to the definition of ''farm'' as it applies to proposed 21 CFR part 117, we are proposing to amend the definition of ''farm'' as it applies to proposed part 112 to include within that definition establishments that pack or hold RACs that are grown or raised on another farm, whether or not under the same ownership. In addition, we are proposing corresponding revisions to the proposed definitions of ''covered activity,'' ''harvesting,'' ''holding,'' and ''packing'' in proposed § 112.3(c) to remove the previous proposed restriction to encompass only RACs grown on farms under the same ownership. As revised, ''covered activity,'' ''harvesting,'' ''holding,'' and ''packing'' would encompass relevant activities regardless of the ownership of the farm where the RACs are grown.

In the amendments to the Preventive Controls for Human Food proposed rule, we are also proposing certain other amendments to the definitions of ''farm,'' ''holding,'' and ''packing,'' taking into account comments received. For example, as amended, the proposed definition of ''farm'' also includes establishments that manufacture/process food by drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing. The amended proposed definition of ''farm'' also includes manufacturing/processing food by packaging and labeling RACs, when these activities do not involve additional manufacturing/processing. In addition, the amended proposed definition of farm would refer to ''establishments'' rather than to ''facilities,'' a term used in the previous proposed definition. In addition, as a conforming change relevant to this substitution, we are adding to the ''farm'' definition the criterion that the establishment is ''under one ownership,'' to retain that aspect of the current ''farm'' definition in the revised definition. As amended, the proposed definition of ''holding'' also includes activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same RAC and breaking down pallets)). Finally, as amended, the proposed definition of ''packing'' also includes activities performed incidental to packing a food (*e.g.,* activities performed for the safe or effective packing of that food (such as sorting, culling and grading)). We refer you to the discussion of these issues in section V of that document. Consistent with our proposed amendments to these definitions as they apply to proposed part 117, we are proposing to amend the definitions of ''farm,'' ''holding,'' and ''packing'' as they apply to proposed part 112.

Taken together, we are proposing to amend the definition of ''farm'' in proposed § 112.3(c) to mean an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' would include establishments that, in addition to these activities: (i) Pack or hold RACs; (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in subparagraph (iii)(B)(1) of the ''farm'' definition; and (iii) Manufacture/process food, provided that: (A) All food used in such activities is consumed on that farm or another farm under the same ownership; or (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of: (1) Drying/dehydrating RACs to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and (2) Packaging and labeling RACs, when these activities do not involve additional manufacturing/processing.

As amended, ''harvesting'' would apply to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on RACs on a farm. Harvesting does not include activities that transform an RAC, as defined in section 201(r) of the FD&C Act (21 U.S.C. 321(r)), into a processed food as defined in section 201(gg) of the FD&C Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling RACs grown on a farm are examples of harvesting.

In addition, as amended, ''holding'' would mean storage of food and also includes activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same RACs and breaking down pallets)), but does not include activities that transform an RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Finally, as amended, ''packing'' would mean placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (*e.g.,* activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform an RAC, as defined in section 201(r) of the FD&C Act, into a processed food as defined in section 201(gg) of the FD&C Act. (For reference, we previously proposed to define ''packaging'' (when used as a verb) to mean placing food into a container that directly contacts the food and that the consumer receives.)

The defined term ''covered activity,'' which establishes what activities are subject to proposed part 112, is directly related to and affected by the scope of the definitions of ''farm,'' ''harvesting,'' ''packing,'' ''holding,'' and ''manufacturing/processing.'' We are proposing to amend the definition of ''covered activity'' to mean growing, harvesting, packing, or holding covered produce on a farm. ''Covered activity''

includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on RACs and only to the extent that such activities are within the meaning of ''farm'' as defined in this chapter. This part does not apply to activities of a facility that are subject to 21 CFR Part 110 of this chapter.

We are proposing these changes to the definition of ''covered activity'' to reflect the changes we are proposing to the definitions of ''farm'' and related terms. First, we have removed the limitation ''provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership'' to reflect our proposed expansion of the farm definition to include packing and holding of others' produce RACs. Second, because we are proposing to add some additional, limited types of ''manufacturing/processing'' to the definition of ''farm,'' (and to reclassify some activities from ''packing'' to ''manufacturing/processing'') those activities should be subject to proposed part 112 when they are performed on a covered farm on covered produce. For example, because the proposed definitions would now provide that packaging RACs would be manufacturing/processing (rather than ''packing''), and would be within the farm definition if the packaging does not include additional manufacturing/processing, that activity should be covered by proposed part 112 when performed on a covered farm on covered produce. For example, a covered farm placing strawberries in a plastic ''clamshell'' package should be considered a ''covered activity''.

We seek comment on the amended definition of ''farm,'' and the corresponding changes to the definitions of ''harvesting,'' ''holding,'' ''packing,'' and ''covered activity.'' In addition, we seek comment on whether the phrase ''in one general physical location'' should be included in the farm definition in the final rule. We are aware that numerous produce farms own and grow crops in non-contiguous parcels of land in various geographical locations, such as in multiple States or even in more than one country. If finalized as proposed, how should we interpret ''in one general physical location'' for the purposes of enforcing this regulation? For example, farms that are in separate geographical locations, although under the same ownership, could be considered as different ''farms'' under this proposed definition and, therefore, such businesses might qualify for extended compliance periods that we proposed for ''small business'' and ''very small business'' farms.

In addition, we seek comment on whether to include in the final rule a requirement that a farm supplying produce to another farm that will pack or hold that produce should provide to the farm that receives the produce its name, complete business address, and description of the produce in any individual shipment. Under these circumstances, is it appropriate to also require the farm that receives the shipment to maintain such record of information and, if so, for what specified period of time? Farms that pack or hold produce that is grown and harvested on farms under a different ownership and that are currently subject to the recordkeeping requirements of Subpart J of 21 CFR Part 1 may no longer be required to establish or maintain such records, if they fit within the amended proposed ''farm'' definition. Information about where the produce was grown or harvested may be important to trace contaminated product during an illness outbreak or other adverse event related to that produce and, therefore, we seek comment on whether we should require such farms to continue to be subject to recordkeeping requirements.

Finally, we seek comment on whether on-farm packinghouses under cooperative ownership by multiple growers should be considered under the same ownership as any or all of the growers' farms, for the purposes of this regulation.

3. Summary of FDA's Revisions and Request for Comment

We are proposing to: (1) Revise paragraph (a) of proposed § 112.4 to so that farms or farm mixed-type facilities with an average annual monetary value of produce (as ''produce'' is defined in § 112.3(c)) sold during the previous 3-year period of $25,000 or less (on a rolling basis) would not be covered by the Produce Safety regulation; and to make corresponding revisions to the definitions of ''very small business'' and ''small business'' in proposed § 112.3(b) to apply the monetary value thresholds based on sales of produce; (2) revise the definition of ''farm'' in proposed § 112.3(c) such that establishments that pack or hold produce RACs that are grown or harvested on another farm would now be subject to the Produce Safety standards of proposed part 112 regardless of whether or not that farm is under the same ownership; and corresponding revisions to the definitions of ''covered activity,'' ''harvesting,'' ''holding,'' and ''packing'' in proposed § 112.3(c); and (3) revise the definitions of ''farm,'' ''holding,'' and ''packing'' as they apply to proposed part 112, consistent with the proposed amendments as these terms apply to proposed part 117.

We seek comment on our amended proposed provisions, including our current proposal not to cover farms with an average annual monetary value of ''produce'' sold of $25,000 or less and whether (and, if so, how), as an alternative, we should apply this monetary threshold to covered produce only. We also seek comment on the amended proposed definitions of ''farm,'' ''harvesting,'' ''packing,'' ''holding,'' and ''covered activity,'' and whether the phrase ''in one general physical location'' should be included in the farm definition in the final rule. In addition, we seek comment on whether, in instances where a farm supplies its produce to another farm to pack, hold, or store the produce, the farms involved should be subject to a requirement to establish and maintain a record of such produce shipment for tracking purposes in the event of an illness outbreak. We also seek comment on whether on-farm packinghouses under cooperative ownership by multiple growers should be considered under the same ownership as any or all of the growers' farms for the purposes of this regulation.

B. Proposed Subpart E—Standards Directed to Agricultural Water

Under subpart E of proposed part 112, we proposed science-based minimum standards directed to agricultural water. Specifically, we proposed various measures regarding agricultural water sources and distribution systems (proposed §§ 112.41 and 112.42); requirements for treating agricultural water (proposed § 112.43); requirements for testing agricultural water (proposed § 112.44) and at certain specified frequencies (proposed § 112.45); requirements for water used in harvesting, packing, and holding activities (proposed § 112.46); and certain record-keeping requirements (proposed § 112.50). We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3559–3573).

We are reopening the comment period to solicit public comment on our current thinking on three specific issues related to the provisions for agricultural water: (1) Microbial quality standard for agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method; (2) frequency of testing agricultural water; and (3) use of third party agricultural water testing

data. We describe our current thinking on these three issues in this section.

1. Microbial Quality Standard for Agricultural Water Used During Growing Activities for Covered Produce (Other Than Sprouts) Using a Direct Water Application Method

In the previously published proposed rule, under proposed § 112.44(c), we proposed to require that when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N. We also proposed that if you find that there is more than 235 CFU (or most probable number (MPN), as appropriate) generic *E. coli* per 100 mL for any single sample or a rolling geometric mean (n = 5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in proposed § 112.44(c). Moreover, before you may use the water source and/or distribution system again for the uses described in proposed § 112.44(c), we proposed that you must either reinspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of proposed § 112.43.

As explained in the proposed rule, our review of available scientific literature led us to tentatively conclude that the above described standards, which are consistent with the EPA recreational water standards, provide an appropriate basis to establish the microbial quality standard for agricultural water that is applied to produce using a direct application method. We explained our rationale and acknowledged the challenges related to identifying an appropriate microbial quality standard for such use of agricultural water where the water is intended to, or is likely to, contact covered produce or food-contact surfaces during use of the water. For example, we acknowledged that these EPA standards were developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers rather than to consumption of produce. These epidemiological studies were performed in beach areas subject to point source fecal contamination rather than non-point sources (*e.g.,* birds, agricultural and livestock runoff), which may impact agricultural water. We also noted that risks of adverse health outcomes resulting from full-body contact in contaminated water may be different than risks associated with consuming produce irrigated with contaminated water, given the differences in the expected routes of infection and pathogen mortality rates in the different environments (bodies of water for the EPA recreational water standards; soil, plants, and produce for this proposed rule). We considered other options, including proposing a standard based on the EPA drinking water standard or proposing a second lower microbial quality criteria for water used in growing, but where the water used for direct application is not reasonably likely to contact the edible portion of the covered produce. However, we did not find sufficient scientific support for such options. Moreover, we noted that we are aware that some industry groups have adopted the generic *E. coli* component of the EPA recreational water standards in the absence of sufficient information to support a pathogen-based microbiological standard for water used in the production of produce (78 FR 3504 at 3563 and 3569).

Therefore, we tentatively concluded that the above described generic *E. coli* criteria would serve to minimize risk of known or reasonably foreseeable hazards when used as a standard for agricultural water used on produce (other than sprouts) during growing in a direct water application method. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3563 and 3569).

a. Relevant Comments. We received an extensive number of comments on this issue, and a majority of them either questioned the scientific rationale for the proposed microbial quality standard, emphasized the burden placed on growers due to the stringency of this standard, and/or urged us to consider other factors that would allow the safe use of agricultural water that does not meet the proposed microbial water quality standard in direct application during growing activities. Commenters identified various concerns with the proposed microbial quality standard for agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method, including the following: (1) The lack of adequate data to inform a complete and thorough understanding of produce contamination resulting from irrigation water. Some commenters noted that there are relatively few confirmed cases of irrigation water as a source of pathogens in any food borne illness outbreaks, while other commenters thought that the proposed microbial quality standard appeared to address risks that are unidentified and unsubstantiated, without sufficient or meaningful underlying scientific rationale; (2) concerns with using the water quality standards developed for *recreational* water to determine acceptable levels of indicator organisms in *agricultural* water. Commenters opposed using the EPA standards and argued that it is not scientifically sound to apply the recreational water standards that are developed based on epidemiological data to irrigation water. Commenters also noted other limitations to this approach, including that using a recreational standard for water quality does not take into account the rapid die-off rate that occurs post irrigation and prior to harvest; (3) the need for education, guidance, and training to ensure growers understand the elements embedded in the proposed requirement and know how to properly sample, test, and make the necessary calculations to then determine whether or not their water meets the proposed microbial quality standard. Commenters also recommended simplifying the standard to eliminate the requirement for a rolling geometric mean (n = 5) of no more than 126 CFU (or MPN, as appropriate) per 100 mL of water, such that the single sample limit would then be maintained as the requirement. One commenter suggested that this proposed requirement would create an opportunity for confusion and noncompliance due to miscalculation or misunderstanding of the complex equation; (4) concerns that the proposed water quality threshold is either more stringent than or differs from other national or international best practices, recommendations, or guidelines. Commenters noted that the FDA proposed standard is more stringent than the World Health Organization (WHO) thresholds and urged us to amend the provisions to be more in line with WHO quality thresholds. Other commenters recommended following the Codex Alimentarius Commission's global standard (1,000 *E. coli* CFU/mL), the more stringent Canadian standard (77 *E. coli* CFU/100mL), or other thresholds established in the European Union; (5) concern that current science is inadequate to justify a fixed, generally applicable test organism, quantitative

microbial quality threshold, or testing requirements. For example, one commenter asserted that a different microbial standard should be considered for overhead irrigation water that is applied prior to fruit set or more than 14 days before harvest because, under field conditions, water that does not meet recreational water quality standards would be quite safe for such use. Another commenter cited the lack of adequate scientific information to develop a generally applicable microbial quality standard, and recommended that FDA employ the generic *E. coli* standard as a voluntary measure until such time that more scientific information is generated and FDA develops an appropriate standard. Still others urged us to delay the use of a quantitative standard to allow for new scientific information to evolve in the future that would enable identifying microbial quality thresholds specific to different regions and types of water; (6) concern with the use of generic *E. coli* as an indicator to test safety of agricultural water, including water used in direct application. One commenter suggested including *E. coli* O157:H7, non-O157 Shiga toxin *E-coli, Listeria monocytogenes,* and *Salmonella spp.* as pathogens to be tested in water quality tests. Another commenter noted that researchers have found that levels of *E. coli* present in water used for crop sprays do not represent the microbial load on the surface of tomatoes at harvest. This commenter also pointed out that tests conducted by a major U.S. grower have demonstrated that the generic *E. coli* standard can be exceeded without human pathogens being present, and it can be met when human pathogens are actually present in high quantities, thus, bringing into question the reliability of generic *E. coli* as an appropriate indicator. Another commenter urged FDA to provide for flexibility to allow alternative indicators of water safety. This commenter pointed out that several States have replaced water testing programs with a risk based computer modeling approach to address recreational water safety, and instead of using test results to determine if recreational water is safe, computer modeling programs that calculate the risks of a given source are designed to accurately predict when water will be outside acceptable ranges. The commenter recommended that the final rule should allow flexibility within the agricultural water section to allow this approach when an appropriate model has been designed; and (7) concern that, in identifying the microbial standard for direct application, FDA failed to consider certain significant factors that affect whether and how the microbial standard is applied to irrigation water used in different regions of the country and for different types of crops. For example, it was noted that farms in Maine use a wide variety of water sources, from city water to wells to open water sources. Even with open water sources there is a wide variety including rivers, ponds, streams and some water bodies affected by ocean tides, which require site-specific timing for water use. Another commenter stated that, in the Treasure Valley, irrigation systems mix clean water with runoff water, and such inter-mixing results in high counts of *E. coli* in irrigation water throughout large parts of the water distribution systems during the growing season. We also received a comment stating that surface water in some regions or watersheds may regularly fail the generic *E. coli* test, and that 30 percent of the samples of water collected at 22 surface water sites in the southeastern Vermont region in 2012 had generic *E. coli* levels that exceeded 235 CFU per 100 mL. The commenter further explained that, without a real scientific justification, the rule would remove an important source of agricultural irrigation to farmers in that region at critical periods throughout the growing season. Yet another commenter pointed out that, in eastern Oregon, growers downstream will inherently have higher microbiological contaminant loads than those upstream, due to runoff reuse systems and other water conservation measures, and as proposed, the Produce Safety regulation will undoubtedly injure downstream growers by preventing them from utilizing their water for the use stated on their water permit or certificate. Finally, we also received a comment that asserted that, in some parts of the western United States where farmers do not control the water, it would be extremely burdensome for FDA to require testing and mitigation for unidentified and unsubstantiated risks that may not, in fact, exist.

We also received several other comments in relation to the proposed requirement for testing water used for direct application. A commenter pointed out that the scientifically observed rates of microbial decline reported by some authors are vastly greater than the rates assumed in FDA's assessment of risks. The commenter disagreed with FDA's proposed microbial quality standard, and argued that FDA has chosen to regulate all directly applied agricultural water over the entire production season even though its own analysis supports regulating agricultural water only within a short window of a few days before harvest, thereby substantially increasing the costs associated with water quality testing with little substantiated benefit. Another commenter urged FDA to explicitly permit growers to use water testing data compiled by other entities. According to the commenter, municipalities in New Hampshire routinely test *E. coli* levels for recreational purposes, and it would be unnecessary to require growers to test the same water source for the same pathogens separately.

In contrast, some other comments generally agreed with the use of a numerical standard for testing water quality. These commenters suggested that a numerical standard is necessary, particularly where the effectiveness of individual control measures, such as to protect the source of agricultural water from contamination, are either not properly implemented or not fully known. In such cases, a numerical standard would serve as an objective tool to monitor the water quality on a specified schedule and trigger corrective actions, where necessary.

b. FDA's Consideration of Comments. As explained in the previously published proposed rule, based on a qualitative assessment of risk, we identified agricultural water as one of the most likely sources of produce contamination. Our tentative conclusions included: (1) There is a significant likelihood that surface waters may contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources; (2) susceptibility to runoff significantly increases the variability of surface water quality; (3) water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce; (4) timing of water application in produce production before consumption is an important factor in determining likelihood of contamination; and (5) microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices (78 FR 3504 at 3522, 3523). Consequently, our proposed standards for agricultural water including those for microbial quality of water and testing frequencies for ground water and surface water, address these potential contributing factors.

We do not believe that FDA should reconsider the use of generic *E. coli* as an indicator to test safety of agricultural water, including water used in direct application. As discussed in the previously published proposed rule, we proposed to use generic *E. coli* as an indicator of fecal contamination. We acknowledge that the presence of generic *E. coli* will not always correlate to the presence of pathogens in water. However, the presence of fecal contamination, especially as indicated by high levels of generic *E. coli,* may increase the likelihood of pathogen contamination in water (Refs. 6, 7, and 8). Therefore, the intent is to manage the presence of fecal contamination as a proxy for potential pathogen contamination, similar to use of fecal contamination as an indicator for the quality of water at swimming beaches and waters for harvesting molluscan shellfish (Refs. 9 and 10). In addition, several commenters noted that generic *E. coli* is an appropriate organism to use to characterize water quality and agreed with our proposal to require such characterization; these commenters expressed that generic *E. coli* provides the best and most practicable quantitative criterion at this time. Further, testing for pathogens to determine the appropriateness of the water would be more costly than testing for generic *E. coli* because of the need to test for multiple pathogens.

We also acknowledge the limitations of a general requirement for agricultural water for growing using direct application that is based on a single microbial indicator and associated quantitative microbial quality threshold, in that it may not adequately account for differences in risk associated with irrigation practices used for different commodities. Although we are proposing to retain a single microbial quality requirement that would apply to all agricultural water for growing using direct application, our proposed new provisions in §§ 112.44(c)(1) and 112.44(c)(2) provide for flexibility in order to address comments that requested us to account for the wide range of irrigation water sources, irrigation practices in different regions of the country, and different types of crops. We also tentatively determined that a quantitative microbial standard that is enforceable and facilitates necessary action by industry to ensure the safe use of water when used for direct application would be more appropriate than a qualitative water quality standard.

Taking into account comments received, currently available information, and upon further analysis, we are proposing amendments to proposed §§ 112.44(c), 112.44(d), and 112.50(b) that, collectively, result in the following changes: (1) Update the quantitative microbial quality requirements in a way that is consistent with the 2012 recreational water quality criteria (RWQC); (2) provide an allowance for microbial die-off between irrigation and harvest using a specified microbial die-off rate; (3) provide an allowance for microbial reduction between irrigation and end of storage; and (4) allow the use of an alternative in lieu of our specified microbial die-off rate between irrigation and harvest.

The scheme outlined above, each element of which is discussed in more detail in the sections immediately below, is consistent with the construct of the standard recommended by the WHO, although less restrictive than that standard. The WHO approach rests on a multistep process to achieve incremental microbial reductions to meet the overall necessary scheme, yielding a tolerable disease burden due to raw produce consumption that is no greater than that adopted for drinking water (non-detectable *E. coli* per 100 mL) (Refs. 11a and 11b). The initial step of the multibarrier process begins with wastewater treatment, which is followed by subsequent preventive measures to achieve the final health-based target of $\leq 10^{-6}$ DALY (disability-adjusted life year) per person, per year. Two specific examples of the multi-barrier process discussed in the guidelines are water qualities of 10^4 or 10^3 CFU *E. coli* per 100 mL, post-wastewater treatment, for use on surface and root crops, respectively, followed by subsequent mitigation strategies (Ref. 11a). According to the WHO analysis, using water of this microbial quality is dependent upon a 2-log reduction due to die-off between last irrigation and consumption (includes die-off in the field and during distribution) and a 1-log reduction attributed to washing prior to consumption. The WHO analysis recognizes the variable nature of die-off values, ranging from 0.5 to 2.0 log per day. FDA's previously proposed standard of 235 CFU generic *E. coli* per 100 mL for any single sample (or a rolling geometric mean of no more than 126 CFU per 100 mL) defined a microbial level for agricultural water used during growing activities using a direct water application method that would minimize the risk of serious adverse health consequences or death throughout the diversity of agricultural conditions, in addition to which alternatives could be developed to provide for the reductions assumed in the WHO standard for die-off in the field and during distribution and from activities such as washing. In response to comments asking for consideration of die-off and greater flexibility and to align with international recommendations from WHO and also Codex, we are again proposing a generally applicable microbial level for all agricultural water, but now allowing a standard reduction due to die-off in the field before harvest and consideration of additional die-off from activities such as storage or commercial washing. As described in the sections immediately below, these reductions would provide additional means to achieve our proposed microbial quality standard for agricultural water used in a direct application method of a statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water or a geometric mean (GM) of 126 or less CFU of generic *E. coli* per 100 mL of water, where known microbial reduction occurs after application. We believe that this approach is strongly supported by comprehensive risk management frameworks and associated recommendations for managing health risks in recycled wastewater use in agriculture (Refs. 11a and 12).

As will be discussed in detail in section II.B.2., we are also proposing certain amendments to proposed §§ 112.45 that, collectively, result in a proposed tiered approach to testing untreated surface water and untreated groundwater. The proposed approach would allow farms to make decisions about safe use of available water sources prior to the beginning of the next growing season; adjust testing frequencies dependent on long-term test results; and ultimately reduce the required frequency of testing.

i. Updating the quantitative microbial quality requirements. We continue to find that the EPA generic *E. coli* criteria for recreational water quality provides a quantitative microbial standard that is generally applicable to minimize the risk of known or reasonably foreseeable hazards associated with the use of agricultural water on produce other than sprouts during growing in a direct water application method. Further, the EPA analysis supporting the RWQC, while not perfect for our purposes, was developed using the necessary scientific rigor and describes illness rates due to incidental ingestion that can be generalized across different bodies of water (Ref. 13).

In addition, while commenters objected to the use of RWQC to establish microbial quality requirements for agricultural water for growing using

direct application, there is no consensus among commenters as to other appropriate alternative criteria or methodology. A majority of the concerns with using the RWQC appeared to center around the need to account for circumstances that are unique to produce growing and irrigation, such as die-off after application, which are factors that would not have been accounted for in formulating water quality requirements for recreational water purposes. We acknowledge these shortcomings, but we also believe that our complete set of amendments to proposed § 112.44(c), including new provisions in paragraphs (c)(1) and (c)(2), address these concerns.

Therefore, we continue to see the value in using the EPA RWQC as the starting point for a quantitative microbial water quality standard for water that is used for growing of produce (other than sprouts) in a direct application method in proposed § 112.44(c) (with additional provisions in proposed §§ 112.44(c)(1) and (c)(2), as explained in sections II.B.1.b.ii. and II.B.1.b.iii.). In the previously published proposed rule, we proposed to use the EPA recreational water criteria that were published in 1986 for this purpose. In November 2012, EPA recommended new RWQC to update their 1986 criteria (Ref. 14) (hereafter referred to as ''the 2012 RWQC''). Unlike the previous criteria, the 2012 RWQC specify a STV in conjunction with a recommended GM to describe the magnitude of the relevant bacterial indicators. The STV approximates the 90th percentile of the water quality distribution and is intended to be a value that should not be exceeded by more than 10 percent of the samples taken. The 2012 RWQC recommend a culturable *E. coli* level of a GM of 126 CFU per 100 mL of water and an STV of 410 CFU per 100 mL of water.

The 2012 RWQC are based on several recent health studies and use a broader definition of illness to recognize that symptoms may occur without a fever, including a number of stomach ailments. Among other evidence, EPA considered the latest research that demonstrates a link between fecal contamination in recreational waters and illness, and designed the criteria to protect primary contact recreation where immersion and ingestion are likely. We refer you to EPA's 2012 RWQC and accompanying documents for a full description of the new criteria and the underlying scientific rationale (ibid.).

Consistent with this new analysis, we are proposing to amend the microbial water quality standard in § 112.44(c) to reflect *E. coli* levels that are consistent with the recommendations in both the GM and STV values specified in the 2012 RWQC. As amended, proposed § 112.44(c) would require you to develop and verify the water quality profile of the water source as described in § 112.45(b)(1), and using your water quality profile as described in § 112.45(b)(1), take certain actions if you find that (when applicable) the estimate of the STV of samples exceeds 410 CFU of generic *E. coli* per 100 mL of water, or if you find that the GM of samples exceeds 126 CFU of generic *E. coli* per 100 mL of water, in order for you to use this water for direct application during growing of covered produce (other than sprouts).

As amended, proposed § 112.44(c) would no longer include a maximum threshold of *E. coli* in a single sample of 235 CFU per 100 mL. Rather, a STV of water quality distribution of 410 CFU per 100 mL would be used when there are sufficient numbers of samples to calculate it, in conjunction with the GM in all cases. This standard would be similar to the 2012 RWQC in that regard. Adoption of the STV, which approximates the 90th percentile of the water quality distribution, as a criterion acknowledges the inherent variability of *E. coli* measurements in water systems, while continuing to be sufficiently protective of public health. In addition, use of the STV does not establish a single value that, if exceeded, would require immediate corrective action. Instead, any value above 410 CFU per 100 mL may be acceptable, as long as those values (each corresponding to a water sample) do not result in a calculation of STV that exceeds 410 CFU per 100 mL. For example, a water source found to contain 2,100 CFU generic *E. coli* per 100 mL in one of 10 samples analyzed may be appropriate to use in direct application during growing, if the remaining 9 samples are such that the STV (based on all 10 samples) is 410 CFU or less of generic *E. coli* per 100 mL of water.

We seek comments on the absence of such a maximum level of generic *E. coli,* particularly in light of evidence that suggests that pathogen levels can increase at higher levels of generic *E. coli* or other indicators (Refs. 6, 7, and 8). In providing comments, we ask that you take into account that pathogens can survive for months in the soil and in crop tissue if they permeate that tissue, that soil or fecal material on the surface of produce may permeate cut tissues and create conditions to enhance the probability of growth of pathogens and other microorganisms, and that colonization and biofilm development may result in conditions that are protective for pathogens (Refs. 15 and 16).

Some public comments, too, recommended that we consider the WHO recommended levels of 1,000 CFU per 100 mL and 10,000 CFU per 100 mL for root crops and surface crops, respectively, as adequate maximum *E. coli* levels. Note, however, that the WHO values are better explained as illustrations of how specific health protection measures could be used together after treatment (*e.g.,* treatment, die-off, and washing or treatment and drip irrigation) to achieve the additional log reductions recommended for waste water reuse. As such, those values are not to be viewed as absolute end point or maximum permitted levels. Rather, under new proposed provisions §§ 112.44(c)(1) and 112.44(c)(1), we are proposing to provide for a WHO-type scheme that could be used to satisfy the proposed requirements for microbial quality of water. For example, under this proposed approach, there would be no maximum threshold for a baseline of generic *E. coli* above which the agricultural water would be precluded from use in direct application during growing such that you would not be able to apply an appropriate time interval between last irrigation and harvest or between harvest and end of storage. We seek comment on whether we should establish a maximum level of *E. coli* (GM and/or STV) above which the water should not be permitted for use in direct application (until specific followup actions are taken to ensure it meets the recommended microbial quality requirements) and, if so, what would be an appropriate maximum level.

As amended, proposed § 112.44(c) would continue to include a GM value of no more than 126 CFU per 100 mL of water, which is intended to be used in conjunction with the proposed STV explained above, consistent with the 2012 RWQC. However, we are removing the previously proposed requirement for a ''rolling geometric mean (n = 5)'' based on the sampling criteria we proposed in amended § 112.45(b), which is discussed in section II.B.2.b.

According to the 2012 RWQC, the waterbody GM should not be greater than 126 CFU per 100 mL during any 30-day interval, and there should not be greater than a 10 percent excursion frequency of 410 CFU per 100 mL based on the calculated STV during the same 30-day period (Ref. 14). We considered whether to apply the 30-day interval of the 2012 RWQC as a sampling frequency, and tentatively conclude that this criterion would be difficult to apply

in the context of our proposed sampling scheme. Instead, we are proposing amendments to proposed § 112.45 (see section II.B.2.) that would establish specific sampling frequencies ranging from 2 years for baseline characterization of water quality to annual verification of water quality.

We agree with comments that cited the need for education to ensure that growers and other relevant staff are appropriately informed and trained to properly test and perform the necessary calculations to determine how best to use their water, particularly when it does not meet the proposed microbial quality requirements. We have tentatively determined that both the GM and STV values (when there are sufficient samples to calculate STV), which reflect the central tendency (*i.e.,* the extent to which statistical values fall around a middle value) of the water and its variability, respectively, are necessary parameters to properly characterize the water. We expect to issue guidance document(s) to assist with education and training to help farmers understand and implement any final requirements in § 112.44(c).

We seek comment on our proposed amendments, including our decision to retain general microbial quality requirements and update them consistent with the 2012 RWQC; the use of GM and STV values to establish general microbial quality requirements; and the absence of a maximum generic *E. coli* threshold.

ii. Allowance for microbial die-off between irrigation and harvest. In the previously published proposed rule, we acknowledged that in specific circumstances an alternative standard (*e.g.,* a standard that applies a time between application and harvest in place of the proposed § 112.44(c) standard, but is specific to a specific commodity or commodity group and region) may be appropriate if the alternative standard is shown to provide the same level of public health protection as the standard in proposed § 112.44(c) and not to increase the likelihood that the covered produce will be adulterated. Accordingly, under proposed § 112.44(d), we provided for the use of alternatives to the requirements in proposed § 112.44(c). We also noted that we are working with stakeholders to facilitate research into application intervals that would be commodity- and region-specific, such that water not meeting the proposed § 112.44(c) standard could be used in a direct water application method for growing covered produce other than sprouts as long as it was applied before the start of the scientifically established application interval (*i.e.,* at a certain number of days before harvest or earlier) (78 FR 3504 at 3553).

Comments, however, included concerns from growers that buyers would demand that the grower meet the standard established in the Produce Safety regulation rather than meet an alternative that had not been explicitly sanctioned by FDA. A number of commenters that opposed our previously proposed microbial quality requirements also cited the lack of allowance for microbial reduction due to natural die-off in the field after application and prior to harvesting of the crop. On further consideration of this issue and relevant available scientific information, we are proposing to add a new provision under proposed § 112.44(c) to explicitly provide for use of water that meets the proposed microbial quality standard after accounting for microbial die-off, if applicable to your crop and practices on your farm. We discuss new proposed provision § 112.44(c)(1) in this section.

Proposed § 112.44(c)(1) would provide one option by which you would be able to achieve the microbial quality requirements for agricultural water specified in § 112.44(c). Under this option, you must apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your GM of generic *E. coli* level to 126 CFU or less per 100 mL and of your STV to 410 CFU or less per 100 mL of water. Examples of 0.5 log per day calculations follow this discussion.

Based on a review of currently available scientific literature, we tentatively determined that it would be appropriate to provide an allowance for microbial die-off between last irrigation and harvest using a proposed die-off rate of 0.5 log per day (Ref. 17). Survival of pathogens and other microorganisms on produce commodities is dependent upon several environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Generally, pathogens and other microbes die-off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool, and wet conditions. The impact of these variables results in a range of microbial die-off rates of 0.5 to 2.0 log per day (Refs. 11a and 12). We have evaluated the relevant studies and acknowledge that die-off rates below 0.5 log per day have been reported in the literature for particular crop and pathogen types, but we conclude that a rate of 0.5 log per day provides a reasonable estimate of die-off under a broad range of variables to include pathogen characteristics, environmental conditions, crop type, and watering frequency.

FDA is currently engaged in research activities in this area. In an effort to support scientific research in the area of agricultural water, one of FDA's Centers of Excellence, the Western Center for Food Safety at University of California, Davis, partnered with the Center for Produce Safety to provide seed money through a competitive grants program to fund produce safety projects focused on agricultural water issues that are topical and/or region specific. Research areas that have received funding through this process include transfer and survival of organisms on produce after exposure from contaminated surface irrigation water, application of biocide technology on manure-contaminated irrigation water, the potential role of overhead sprinkler irrigation systems in the contamination of produce, and the survival of pathogens during the growing, harvesting, and storage of dry bulb onions after exposure with contaminated water.

We seek comment on the appropriateness of the proposed 0.5 log per day die-off rate. Note also that the proposed provisions in § 112.44(d) would allow you to establish and use an alternative microbial die-off rate between last irrigation and harvest (in lieu of the proposed rate of 0.5 log per day), provided you satisfy the requirements of proposed § 112.12.

When applying a microbial die-off rate of 0.5 log per day, as proposed, the time interval (*i.e.,* number of days) you apply between last irrigation and harvest are the days necessary to achieve the reductions in both the GM and STV values of generic *E. coli* to levels at or below those expected on produce if it were irrigated with agricultural water that satisfied the microbial quality requirements proposed in § 112.44(c). We tentatively conclude that use of such a time interval would provide the same level of public health protection as the standard in proposed § 112.44(c) and not increase the likelihood that the covered produce will be adulterated.

This provision assumes that, for any given crop, the microbial levels found on produce after accounting for die-off when it is irrigated with water under the provisions of § 112.44(c)(1) would be approximately equal to or below the levels found if the crop were, instead, irrigated with water of higher quality (*i.e.,* that met our proposed microbial quality criteria). Reductions to achieve

both GM and, when applicable, STV criteria are necessary to ensure that risk thresholds determined in the 2012 RWQC are not exceeded.

For example, if you determined (using the procedures described in proposed §§ 112.45(b) or 112.45(c), as applicable), that your agricultural water which is to be used for the purposes described in § 112.44(c) has generic *E. coli* levels with a GM value of 241 CFU per 100 mL and a STV value of 576 CFU per 100 mL, your water would not meet the microbial quality specified in § 112.44(c), in that your values exceed both the GM value of 126 CFU per 100 mL and STV value of 410 CFU or less per 100 mL. Under proposed § 112.44(c)(1), you would be able to use this water by applying a calculated time interval of 1 day between your last irrigation event (by direct application method) and harvest of the crop. Using a microbial reduction rate of 0.5 log per day, a 1-day time interval would be sufficient to meet the microbial quality requirements specified in § 112.44(c) because it would reduce your GM and STV values to 76 CFU per 100 mL and 182 CFU per 100 mL, respectively.

As another example, if you determined that your agricultural water has generic *E. coli* levels with a GM value of 241 CFU per 100 mL and a STV value of 4,600 CFU per 100 mL, your water would not meet the microbial quality requirements specified in proposed § 112.44(c). Under proposed § 112.44(c)(1), you would be able to use this water by applying a calculated time interval of 3 days between your last irrigation event (by direct application method) and harvest of the crop. Using a microbial reduction rate of 0.5 log per day, 3 days between irrigation and harvest would be sufficient to achieve a 1.5 log total reduction and reduce your GM and STV to 8 CFU per 100 mL and 145 CFU per 100 mL, respectively.

We agree with comments that cited the need for education to ensure growers understand the elements embedded in our proposed requirements for agricultural water during growing using direct application. Relevant staff would need to be appropriately trained to properly sample, test, and make the necessary calculations to determine how best to use their water. We expect to work with the Produce Safety Alliance, and will also plan to issue guidance document(s), as needed, to further clarify our provisions and assist with such education and training, if these proposed provisions in § 112.44(c) are finalized, as proposed. In addition, there are resources available that would enable simply entering sample data into a form and automatically deriving the GM and STV values and/or calculating the appropriate time interval between irrigation and harvest, such that a farmer would not need to perform the necessary calculations. We plan to identify and provide such resources, if this proposal is finalized.

We seek comment on our proposed approach and tentative conclusions, including the appropriateness of permitting an adequate time interval between last irrigation and harvest as a means to achieve the specified microbial quality requirements, and the appropriateness of using a microbial reduction rate of 0.5 log per day. In addition, we seek comment on whether we should require farms to establish and maintain any documentation in relation to the option to apply an adequate time interval between last irrigation and harvest, as provided in proposed § 112.44(c)(1). For example, should we require that farms must keep records that identify the time interval applied, how the time interval is calculated, and/or the dates of last irrigation and harvest corresponding to that time interval?

iii. Allowance for microbial reduction between harvest and end of storage. A number of comments that opposed our previously proposed microbial quality requirements also cited the lack of allowance for microbial reduction due to natural die-off during storage and/or due to pathogen removal during certain post-harvest activities, such as commercial washing, prior to consumption. On further consideration of these issues and relevant available scientific information, we are proposing to add another new provision under proposed § 112.44(c). We discuss the new proposed provision § 112.44(c)(2) in this section.

Proposed § 112.44(c)(2) would provide a second option by which you would be able to achieve the microbial quality requirements specified in § 112.44(c). Under this option, you must apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of your GM of generic *E. coli* level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL, provided you have adequate supporting scientific data and information. You may apply this time interval in addition to the time interval in accordance with 112.44(c)(1). This provision would allow you to apply appropriate microbial die-off or reduction rates post harvest (*i.e.,* between harvest and end of storage, and during activities such as commercial washing), provided you have adequate supporting scientific information. As discussed in the section immediately above, we expected that farms would consider such factors as microbial die-off or microbial reduction post irrigation and prior to consumption, as they are applicable to their commodity and/or practices on the farm, and apply appropriate scientifically-supported alternatives (such as time intervals) under the provisions we proposed in § 112.44(d). However, based on comments, we are proposing new provision § 112.44(c)(2) to incorporate additional flexibility into our agricultural water quality standards, and provide farms with yet another means by which to safely use agricultural water by achieving our proposed microbial quality requirements, without compromising the safety of produce that comes into contact with such water. As previously noted, the WHO study attributed a 1-log reduction in microbial load to washing (Ref. 11a). In addition, it is reasonable to expect some die-off during post-harvest storage, though the rate would be highly dependent upon the conditions of storage. Farms would be able to more narrowly define die-off rates associated with their specific production practices and apply a time interval (in days) between harvest and end of storage, calculated using microbial die-off rate(s) for the period between harvest and end of storage, including any microbial removal rate(s) as a result of commercial washing, as applicable to their commodity. Regardless of the microbial rates applied, the total log reduction necessary and the time interval required would need to be calculated based on a comparison of the GM and (when applicable) STV values of your agricultural water with the proposed microbial quality requirements (GM of 126 CFU or less per 100 mL and STV of 410 CFU or less per 100 mL) in § 112.44(c).

At this time, we are not proposing to establish a specific microbial die-off rate(s) between harvest and end of storage or a specific microbial removal rate(s) during post-harvest activities such as commercial washing that can be broadly applied to calculate an adequate time interval between harvest and end of storage. We do not have sufficient information to support the derivation of an appropriate broadly applicable microbial reduction rate(s) between harvest and end of storage, or during activities such as commercial washing. However, under this option, you would

be able to establish and apply an adequate time interval using a microbial die-off rate(s) that is relevant to your covered produce and dependent on practices and conditions on your farm, provided you have adequate scientific data or information to support your conclusions.

As we noted in the previously published proposed rule, we are working with our stakeholders to facilitate research into application intervals that would be commodity- and region-specific, such that water not meeting the proposed § 112.44(c) standard could be used in a direct water application method for growing covered produce (other than sprouts) as long as it was applied before the start of the scientifically established application interval (*i.e.,* at a certain number of days before harvest or earlier). We will disseminate the results of these investigations, when available, and issue commodity- and region-specific guidance as appropriate, such that farmers would be able to consider our recommendations and apply the new scientific information to their current use of agricultural water, as appropriate.

In addition, we are proposing to add a new provision, *i.e.,* proposed § 112.50(b)(8), to require you to establish and keep records of such scientific data or information you rely on to support the microbial die-off or removal rate(s) that is used to determine the time interval (in days) between harvest and end of storage and/or other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *E. coli* in accordance with the provision in § 112.44(c)(2). This record-keeping requirement would enable us to verify the scientific basis for your time interval, should you choose to employ the approach permitted in § 112.44(c)(2). As in the case of alternatives permitted under § 112.12, we are not proposing to require farms to submit scientific data or information relied on to support the microbial die-off or removal rate applied in accordance with § 112.44(c)(2) to us for review or approval prior to marketing produce grown under those conditions. However, we would require that farms maintain a record of any such scientific data or information, including any analytical information, and make such data and information available to us to evaluate upon request.

We seek comment on this proposed provision, including on whether there is a specific microbial die-off rate(s) or microbial removal rate(s) that we should establish within this provision. We also seek comment on whether and, if so, how we should introduce additional flexibility.

iv. Provision for use of an alternative microbial die-off rate. As explained in section II.B.1.b., we are proposing to add a new provision § 112.44(c)(1) related to agricultural water used in a direct application method to permit the use of an adequate time interval between last irrigation and harvest, based on a microbial die-off rate of 0.5 log per day, to achieve water quality that meets the proposed microbial standard.

We acknowledge that practices and conditions on a farm and circumstances unique to a specific commodity or types of commodities could result in higher die-off rates, especially under conditions of high ultraviolet radiation, high temperature exposures or low humidity, coupled with little precipitation. To account for such variability, we are proposing a new provision, i.e., proposed § 112.44(d)(2), to specify that you may establish and use an alternative microbial die-off rate (in lieu of the 0.5 log per day microbial rate that we proposed under § 112.44(c)(1)), to determine the time interval (in days) between last irrigation and harvest, provided you satisfy the requirements of § 112.12. Among other requirements, the use of an alternative microbial die-off rate would necessitate you to have adequate scientific data and information to support your conclusions. We refer to section V.B of the previously published proposed rule for a discussion of the requirements of § 112.12.

Finally, as amended, proposed § 112.44(c) would continue to retain the previously proposed option to discontinue the use of water that does not meet the proposed microbial quality requirements and take corrective actions, prior to using that water for the same purposes. Proposed § 112.44(c)(3) would establish a third option, in lieu of following the procedures in §§ 112.44(c)(1) or 112.44(c)(2), where if water does not meet the proposed microbial quality requirements, you would immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in § 112.44(c). Before you may use the water source and/or distribution system again for those uses, you would be required to either reinspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

2. Frequency of Testing Agricultural Water

In the previously published proposed rule, under proposed § 112.45, we proposed to establish requirements related to frequency of testing agricultural water that is subject to the requirements of proposed § 112.44. Specifically, proposed § 112.45(a) would require that you test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every 3 months thereafter during the growing season, except that there would be no requirement to test water that meets certain conditions specified in proposed § 112.45(a)(1) to (a)(3) (i.e., treated water and water from a public water system).

As explained in the previously published proposed rule, water testing frequencies recommended by various industry documents vary widely, in part, because there is a lack of publicly available information pertaining to the quality of agricultural waters. Recommendations range from monthly testing to once each year, for sources with a history of compliance with commodity specific recommendations. Even for sources considered reliable (*e.g.,* well water), a 1-year period between testing may not minimize the risk of known or reasonably foreseeable hazards because microbiological water quality is often too variable for this frequency of testing to be protective (*e.g.,* effects of flooding, runoff). Alternatively, we tentatively concluded testing well water more frequently than every 3 months would not significantly improve the accuracy of your assessment of ground water quality and would therefore be unnecessary. We also considered proposing testing frequencies as a function of commodity, irrigation method (*e.g.,* furrow, seep, subsurface drip, foliar), and timing of application (days prior to harvest), and concluded that the most effective approach is to test at a frequency related to the reliability of the agricultural water sources. We requested comments on whether we should allow for adjustment of ground water testing frequencies dependent on historical test results, for example, testing ground water sources every 3 months for 1 year and yearly after that if the ground water consistently met the standard. We also requested public comments on any other alternative testing frequencies that can be supported by water quality data (78 FR 3504 at 3570).

In addition, under proposed § 112.45(b), we proposed to establish testing frequency requirements for the use of untreated surface water for purposes that are subject to the requirements of proposed § 112.44. As proposed, if the untreated surface water is from any source where a significant quantity of runoff is likely to drain into the source (for example, a river or natural lake), then you must test the water at least every 7 days during the growing season (proposed § 112.45(b)(1)). If the untreated surface water is from any source where underground aquifer water is transferred to a surface water containment constructed and maintained in a manner that minimizes runoff drainage into the containment (for example, an on-farm manmade water reservoir), then you must test the water at least once each month during the growing season (proposed § 112.45(b)(2)).

In proposing these testing frequencies, we tentatively divided untreated surface water into two categories based upon their potential to be adversely affected by runoff and the degree to which you reasonably could be expected to exercise protection and control over them. We tentatively concluded that runoff is the most important variable among the various environmental factors that may affect the microbial quality of surface water, because it has the potential to increase the number of pathogens in the water column if its origins include human, livestock or wildlife feces and because it has the potential to increase the amount of suspended sediments, which are likely to harbor pathogens. We also considered other factors, such as precipitation and its effects (*e.g.,* discharge and flow rate) along with temperature, which are common factors reported to affect the microbial quality of watersheds with agricultural land inputs. However, we did not propose a surface water testing frequency based on these factors because such an approach would require full characterization of its effects on the quality of surface water sources that are not likely to be generally useful across all farms, States, or regions (78 FR 3504 at 3571).

We also noted that our approach to testing untreated surface water was to propose practical intervals of testing both because they are likely to capture transient events that may degrade quality and because they are useful regardless of geographic location. The sampling and testing frequencies we proposed in § 112.45(b) are the minimum that we tentatively concluded provide sufficient information concerning your source surface water quality for you to use in determining the method of application for which the water is safe and of adequate sanitary quality. We asked for public comments on our proposed testing frequencies, including any alternative approaches and examples where testing should be more or less frequent based on your experience or observation, and specifically if you believe that surface waters can be thoroughly characterized when tested at frequency less than that proposed in § 112.45 (78 FR 3504 at 3571).

a. Relevant Comments. We received a number of comments on our proposed requirements for frequency of water testing, many of which voiced concerns and requested that FDA reduce the required testing frequencies and apply a flexible approach that considers the specific risks associated with the particular source of water and its use. Comments related to the frequency of water testing highlighted various issues, including the following: (1) Commenters recommended that FDA should employ and allow the use of risk-based testing strategies that account for the variability in risk associated with the specific source of water and its use. For example, commenters noted that the proposed testing frequencies do not consider the wide range of sources of agricultural water, which include municipal water to rural rain water catchment. Commenters also noted that frequent testing is either not necessary or does not provide meaningful information where there is inherently high variability in water quality due to rainfall or other natural events. Commenters stated that microbial growth and survival varies significantly by region and water source, and some open water sources have sufficient microbiological stability that weekly testing is unnecessary. In addition, commenters argued that the testing frequency requirements should recognize the reduced risk (and consequently, less frequent need for testing) associated with proper design and maintenance of the water source to encourage growers to implement preventive measures; (2) commenters stated that there is a need to incorporate flexibility into the testing frequency requirements so growers can determine appropriate frequencies, considering factors specific to their source of water and its use. For example, commenters asserted that testing frequencies should be tailored for farms using short-term or intermittent irrigation. In addition, some commenters stated that an assessment of risks associated with ground water should be farm-based because not all ground water is equal or merits the proposed testing frequency, and that FDA must permit alternative practices for water testing based on sound science; (3) commenters suggested that appropriate testing frequencies should be determined depending on historical test results. Commenters maintained that a more effective approach than the one proposed by FDA would be to take baseline samples to determine water quality and then schedule routine future testing based on the results of the baseline testing; (4) commenters argued that scientific data to support the proposed testing frequencies are lacking. For example, commenters opposed the specific requirements related to testing of untreated surface water in proposed § 112.45(b), and asserted that general water testing requirement in proposed § 112.45(a) to test agricultural water at the beginning of the growing and every 3 months thereafter during the growing season, coupled with the requirements in proposed § 112.42 to regularly inspect and maintain agricultural water systems, is adequate. Commenters who opposed the weekly testing requirement in proposed § 112.45(b)(1) pointed out that, although they acknowledge the need to test surface water sources more frequently than ground water sources, there is no basis for the proposed weekly testing of untreated surface water. One commenter also pointed out that a WHO analysis of tolerable risk for irrigation water determined that harvesting 5 days after last irrigation has a significant reduction in contamination. Other commenters argued that human pathogens do not survive well on produce in the field and, therefore, contamination that occurs early in a growing season may not survive to harvesting, such that a requirement to test at the beginning of each growing season would be of no value. Some commenters requested more clarity regarding the frequency of testing water that is used in harvest and post-harvest activities, and the data that FDA used to determine the adequate testing frequency for such use of water. Commenters also urged FDA to revisit the scientific data supporting the testing intervals and validate the quality of those data. Still other commenters encouraged FDA to create a separate rule or guidance on testing frequency requirements after further research is completed; and (5) commenters argued that the proposed testing frequencies would pose an undue financial burden without providing clear public health benefits. Commenters strongly opposed the weekly testing frequency, in

particular, and stated that farms do not have the necessary resources or facilities to accommodate such frequent testing, and some growers would have to ship their water samples to testing laboratories. Some commenters also noted that many growers use more than one pond for irrigation and using up to four ponds is not uncommon, such that costs of testing could become prohibitively expensive. One commenter estimated that the total cost associated with water testing requirements could amount to about $11,550 annually (including costs of labor and laboratory testing). Another commenter urged FDA to explicitly permit growers to use water testing data compiled by other entities. According to the commenter, municipalities in New Hampshire routinely test *E. coli* levels for recreational purposes, and it would be unnecessary to require growers to test the same water source for the same pathogens separately.

Commenters also recommended specific alternative testing frequencies in lieu of our proposed provisions. Some commenters mentioned that a more prudent testing requirement would be within a timeframe closer to harvest, while others suggested that it would be beneficial to require water testing at the outset for a new operation or when a new water source is first brought into use. Other notable suggestions included seasonal water sampling, or using the current USDA's Good Agricultural Practices requirements for testing surface waters at the beginning and the peak of the growing season and at harvest time.

Conversely, a few commenters agreed with the testing frequencies that we proposed, stating that the proposed schedule of water testing ensures the safety of water initially and during growing, harvesting, and post-harvest activities.

Overall, a majority of the concerns with the proposed testing frequencies centered on the financial burden imposed on farms, in particular, under a weekly testing requirement; that FDA did not provide scientific data in support of the proposed testing frequencies; and the need for a more flexible approach accounting for the variability in water quality associated with various water sources and the particular use of the water during growing, harvesting, or post-harvest activities.

b. FDA's Consideration of Comments. As noted above, a key objective of our proposed approach to water testing was to establish a testing frequency sufficient to adequately characterize the quality of the agricultural water such that the information could lead farms to make informed and appropriate decisions about its use and/or the need for any appropriate corrective actions, prior to such use. Commenters generally agreed with our intent to characterize the quality of the water source, but argued that the frequency intervals proposed were too short; and, as a consequence, would require more tests (and associated costs) than necessary to accomplish the desired outcome, without a commensurate gain in public health benefit. In view of comments received, we reviewed our previous proposed frequencies to characterize the quality of untreated surface water and untreated ground water sources.

Taking into account comments received, currently available information, and upon further analysis, we are proposing certain amendments to proposed §§ 112.45 that, collectively, result in a proposed tiered approach to testing untreated surface water and untreated groundwater. The proposed approach would allow farms to make decisions about safe use of available water sources prior to the beginning of the next growing season; adjust testing frequencies dependent on long-term test results; and ultimately reduce the required frequency of testing.

In the case of both untreated surface water and untreated ground water, we are proposing to more narrowly focus the period of characterization of water quality to those when the risk is greatest, *i.e.,* during periods when agricultural water is used immediately prior to harvest. Currently available information indicates that the risk to consumers is greater in relative terms when produce contamination via agricultural water occurs closest to consumption. That is, agricultural water used early in the growing season (*e.g.,* seeding, plant establishment) generally has less inherent risk associated with its use than water used in harvest (*e.g.,* field wash) or post-harvest activities (*e.g.,* washing, cooling). Requiring that water characterization focus on periods when the risk is greatest reconciles public comments with the scientific literature on the relative risks associated with the timing of use of agricultural water. This approach is supported by the discussion above concerning die-off rates between application of water and harvest. With die-off rates of 0.5 log or greater per day the impact of water quality more than a couple of weeks prior to harvest is minimal. We expect this time period (*i.e.,* immediately prior to harvest) to be variable and dependent on the crop and length of time harvest activities are performed. It is reasonable to conclude that it would include periods immediately prior to active harvest of one commodity or variety, even though another continues to mature but is not yet ready for harvest. To permit farms to tailor their sampling of water to the unique circumstances relevant to their crop(s) and practices and conditions on their farm, we are proposing as a requirement that the samples required to be collected include those ''collected during a time period(s) as close as practical to harvest.'' We recognize that the timing of the use of agricultural water using a direct application method varies by crop, region, season, and/or from year to year. By using the term ''practical,'' we intend to convey that agricultural water should be collected for analysis when, during the characterization or verification period, agricultural water is applied to covered produce, and not that samples would be collected from the source water when it is not being applied to the crop. Timing of the samples should be such that the last applications of agricultural water prior to harvest are targeted, again recognizing that in some circumstances such applications may not be preplanned (*e.g.,* early frost or unusually hot, dry weather). Further, timing of sample collection should occur in the time period during growing and near harvest, and be designed to represent events that can reasonably be expected to both impact water quality (*e.g.,* rainfall, high river stage, wildlife and domesticated animal movement through upstream water systems) and occur in the time period during growing and/or near harvest.

At this time, we are not proposing to further specify an appropriate time period prior to harvest for sampling. We seek comment on whether it would be practical to require sample collection during a certain time period(s) such that the test results based on such samples would be available in sufficient time to determine any changes to water quality and, if necessary, adjust harvesting times accordingly or take other corrective actions.

i. Tiered approach to testing untreated surface water. We are proposing to amend proposed § 112.45(b) to establish a new proposed tiered approach to testing untreated surface water that is used for the growing of produce (other than sprouts) using a direct application method. As amended, proposed § 112.45(b) would establish that if you use untreated surface water for purposes that are subject to the requirements of proposed § 112.44(c), you must take the following steps for each source of the untreated surface water: (1) Conduct a baseline survey to develop a water quality profile

of the agricultural water source. (i) You must conduct a baseline survey in order to initially develop the water quality profile of your water source. You must determine the appropriate way(s) in which the water may be used based on your water quality profile in accordance with § 112.44(c)(1) through 112.44(c)(3). (ii) The baseline survey must be conducted over a minimum period of 2 years by calculating the GM and the STV of generic *E. coli* (CFU per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. The water quality profile initially consists of the GM and STV of generic *E. coli* calculated using this data set. (iii) You must develop a new water quality profile: (A) At least once every 10 years by recalculating the GM and STV values using a minimum total of 20 samples collected during your most recent annual surveys (which are required under paragraph (b)(2) of this section); and (B) when required under paragraphs (b)(2) and (b)(3) of this section. (2) Conduct an annual survey to verify the water quality profile of your agricultural water source. (i) After the baseline survey described in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, you must test the water annually to verify your existing water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze a minimum number of five samples per year, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. (ii) If the GM and/or STV values of the annual survey samples do not support your water quality profile and therefore your existing water use as specified in § 112.44(c), you must develop a new water quality profile and, as appropriate, modify your water use based on the new water quality profile in accordance with § 112.44(c)(1) through (3) as soon as practical and no later than the following year. To develop a new water quality profile, you must calculate new GM and STV values using either: (A) Your current annual survey data, combined with your most recent baseline or annual survey data from prior years, to make up a data set of at least 20 samples; or (B) your current annual survey data, combined with new data, to make up a data set of at least 20 samples; and (3) if you know or have reason to believe that your water quality profile no longer represents the quality of your water for reasons other than those in paragraph (b)(2) of this section (for example, if there are significant changes in adjacent land use, erosion, or other impacts to water outside your control that are reasonably likely to adversely affect the quality of your water source), you must develop a new water quality profile. To develop a new water quality profile, you must calculate new GM and STV values using your current annual survey data, combined with new data, to make up a data set of at least 20 samples. Then, as required by § 112.44(c)(1) through (3), you must modify your water use based on the new water quality profile as soon as practical and no later than the following year.

The approach proposed in § 112.45(b) is responsive to comments that requested us to establish a risk-based, flexible testing approach that accounts for variability in water quality from different sources, considers the specific use of water from a particular water source, and contemplates the reduced likelihood of contamination from well-designed and adequately maintained water systems. In addition, this approach also provides for use of longer-term ''good'' results as a basis to support a reduced frequency of testing (compared to that previously proposed) resulting in overall reduced economic burden associated with testing of water. We also acknowledge comments that requested us to consider how best to ensure that growers understand and are able to implement our proposed requirements. We plan to provide guidance regarding the proposed water testing requirements, if finalized.

Proposed § 112.45(b) would apply only to untreated surface water that is used for the purposes specified in § 112.44(c), *i.e.,* for the growing of produce (other than sprouts) using a direct application method. As proposed, the tiered approach for testing of such agricultural water consists of three major elements.

First, you must conduct a baseline survey over a minimum period of 2 years to develop a water quality profile of your water source, based on which you would be able to determine whether the water meets the microbial quality requirements established in § 112.44(c). If it does not satisfy those requirements, then you must consider and implement any one of the options provided in §§ 112.44(c)(1), (c)(2), and (c)(3), as appropriate for your commodity and practices and conditions on your farm, if you wanted to continue to use the water source for the growing of produce (other than sprouts) using a direct water application method.

Second, every year after this initial baseline survey, you must conduct an annual survey to verify your water quality profile and ensure that the way in which you are using the water continues to be in accordance with § 112.44(c). If your annual survey verifies your water quality profile is still likely to be representative of the quality of your water source, no additional steps would be necessary in that year. If, however, the annual survey results are sufficiently different from your existing water quality profile to suggest that the profile is no longer representative of the quality of your water source, you would be required to develop a new water quality profile and make adjustments to the way in which you are using the water in accordance with § 112.44(c), as necessary. When developing a new water quality profile for this purpose, you would be allowed to rely on existing test results.

Third, you would be required to develop a new water quality profile on a regular, 10-year schedule and as needed when you know or have reason to believe that your water profile no longer represents the quality of your water source (for reasons other than your annual survey results). In both cases you would also be required to make corresponding adjustments to the way you use the water, as necessary. In the former case, you would be allowed to rely on existing test results when developing your new water quality profile. In the latter case, you would be required to use new test results to develop your new water quality profile.

The steps identified in proposed § 112.45(b) (*i.e.,* the baseline survey, annual verification testing and, as needed, development of new water quality profiles) would be required to be performed separately for each untreated surface water source used for direct water application to covered produce (other than sprouts) during growing. For example, if you have a surface water impoundment on your farm that stores groundwater to be used for this purpose, but you also sourced water from a river for the same purpose, you would need to evaluate both bodies of water individually in compliance with the requirements of proposed § 112.45(b), as each delivers water that is distinctly different in origin and likely to differ in overall composition and characteristics.

We are proposing that the water quality profile of untreated surface water sources include both a GM and a STV value, as reflected in the proposed baseline survey and annual surveys used for verification. This proposed

requirement is intended to serve two purposes. First, requiring both GM and STV values would correspond to the microbial quality requirements we proposed in § 112.44(c) and, thus, allow a comparison of the values derived from your surveys to the proposed microbial quality standard. Second, using both GM and STV values would provide a profile of the quality of your water source that reflects both its central tendency (the GM) and the variation in its quality (the STV). This information could be used to understand the effects of factors, such as precipitation, flow rate, and changes in adjacent land use on water quality, especially if characterization data are analyzed over additional years.

To increase the accuracy of the water quality profile and the annual survey data, samples should be collected at intervals over the period immediately preceding harvest and under a variety of environmental conditions (*e.g.,* after precipitation), as appropriate. We expect farms to determine the appropriate time period for sampling to meet our proposed requirement that samples be collected during a time period(s) as close as practical to harvest, while recognizing that samples of water taken more than a few weeks prior to harvest are unlikely to be relevant to the safety of the crop. In addition, we would not consider samples collected in a single day solely to satisfy the minimum sample number to provide adequate variation as the distribution estimates resulting from such a sampling plan would defeat the purpose of the survey.

We do not intend to limit data sharing among farms if, by inspection, the characteristics of the shared water source are found to be similar and no significant source of contamination is identified between sampling sites of the different farms. In fact, we encourage such sharing when appropriate. We have included a new proposed provision (§ 112.45(e)) that would explicitly allow data sharing under certain circumstances.

Similarly, we do not expect farms to incur additional sampling costs to satisfy the baseline survey requirement proposed in § 112.45(b)(1), if they already possess sufficient water quality data (consisting of the minimum required number of samples) collected during the required time period.

a. Baseline Survey—For the baseline survey described in § 112.45(b)(1)(i) and (ii), we are proposing that the survey must be conducted over a minimum period of 2 years, by calculating the GM and STV values of generic *E. coli* (CFU per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. You would be required to test these samples for generic E. coli in accordance with one of the appropriate analytical methods in subpart N, and to develop a water quality profile consisting of the GM and statistical threshold value STV of generic *E. coli* calculated using this dataset. We tentatively conclude that sampling an untreated surface water source over a period of 2 years is the minimum necessary to provide an adequate representation of its quality to enable informed decisions about its use in a direct application method. We also tentatively determined 20 samples to be the minimum necessary for the purposes of conducting such a baseline survey. We incorporated a certain degree of flexibility in this proposed requirement to allow farms to independently determine the appropriate number of samples required to characterize an untreated surface water source based on their knowledge of the water system, its inherent variability, and the vulnerability of their water source to contamination. We seek comment on these tentative conclusions.

Our analysis suggests that a minimum number of samples required in ''average'' surface water sources would be 20 samples. We based our determinations of the minimum necessary sample size for the baseline survey on an assessment of the relative precision of estimation of the GM and STV (approximation of the 90th percentile) afforded by different sample sizes when generic *E. coli* levels are log-normally distributed (Refs. 18, 19, and 20). The precision of estimation of GM and STV (approximation of the 90th percentile) of log-normally distributed data depends upon the variation (*i.e.,* standard deviation), which is likely to be different for different sources of water and uncertain with respect to any particular source of water. Precision of estimation will be lower when variability is higher. However, for the purpose of determining an appropriate sample size for ''average'' surface water sources a standard deviation of 0.4 (of log abundance of *E. coli*) was assumed based on estimates of variability of measurements of culturable *E. coli* in samples of recreational waters as determined by EPA in the 2012 RWQC. Based on this assessment of precision, we propose a minimum of 20 samples for the baseline survey in order to adequately characterize the water in a manner that provides initial estimates of GM and STV of *E. coli* distribution of sufficient precision to allow for a determination of the appropriate use (or conditions of use) of an untreated surface water source (Ref. 21). We would encourage farmers to sample more than the minimum required 20 samples to build a robust baseline characterization.

b. Annual Verification Survey—For the annual verification survey described in § 112.45(b)(2), we are proposing that the survey must be conducted by calculating the GM and STV values of generic *E. coli* (CFU per 100 mL) using a minimum number of five samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method. The purpose of the annual verification survey is to verify the water quality profile described in § 112.45(b)(1) and to confirm that the way(s) in which the water is used continues to be in accordance with § 112.44(c). If your annual verification survey detects a change in water quality that is no longer consistent with current water use, you would be required to develop a new water quality profile. As described in § 112.45(b)(2)(ii), to develop a new water quality profile, you would calculate new GM and STV values using either: (A) Your current annual survey data, combined with your most recent baseline or annual survey data from prior years, to make up a data set of at least 20 samples; or (B) your current annual survey data, combined with new data, to make up a data set of at least 20 samples. Then, as required by § 112.44(c)(1) through (3), you would be required to modify your water use based on the new water quality profile as soon as practical and no later than the following year.

We have tentatively determined five samples to be the minimum number necessary to calculate a GM and STV value appropriate for annual verification purpose. Although the precision of estimation afforded by five samples for annual verification is less than that afforded by the 20 samples proposed for the baseline survey, our assessment indicates that five samples would be sufficient to provide adequate probability of detecting large and substantial deviations in the GM (*e.g.,* 0.5 log or greater change from that of the baseline survey) for ''average'' water sources characterized by a standard deviation of 0.4 (of log abundance of *E. coli*). Consequently, a sample size of five is judged to be sufficient for annual verification of the water quality profile and that the way(s) in which the water

is used, based on that profile, continues to be appropriate (Ref. 21).

Where the outcome of annual sampling provides a GM or STV value that is inconsistent (*e.g.,* 0.5 log or greater change) with the current water quality profile GM or STV values, we expect the annual verification to be used, in combination with previously or subsequently conducted test result data to develop a new water quality profile, and for farms to alter their current water use practices as necessary during the current harvesting season if practical, and if not, to modify practices for the following year. The new water quality profile could be developed by combining the current year's annual survey data (of a minimum of test results from five samples) with data obtained by either collecting (and testing) additional, new samples (as described in § 112.45(b)(2)(ii)(B)), or using the test results from the most recent previous years' annual or baseline surveys (as described in § 112.45(b)(2)(ii)(A)), in either case the data set must contain at least 20 samples. For such revisions to the GM or STV values, we may consider stipulating a time period beyond which the data would not be appropriate to use because they would not be expected to provide a current representative profile of the water quality. For example, should we specify that when revising the baseline GM or STV values based on annual survey results, the annual verification data may be used, in combination with previously or subsequently collected baseline or annual survey data, but not including data sampled beyond the previous 3 years?

For example, in Year 1, Farm A conducts a baseline survey by taking 20 samples of its water source and testing them for generic *E. coli,* as described under § 112.45(b)(1)(i) and (ii), which indicates a GM of 125 CFU/100 mL and STV of 400 CFU/100 mL. This is the farm's initial water quality profile for this water source. The farm's GM and STV are below the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). Thus, based on this water quality profile, the farm would not be required to and does not implement any of the mitigation measures specified in §§ 112.44(c)(1) through (c)(3) in Year 1. In Year 2, Farm A conducts an annual survey by taking five samples of its water source and testing them for generic *E. coli,* as described in § 112.45(b)(2), and determines that the GM and STV values based on these five samples are 500 CFU/100 mL and 1600 CFU/100 mL, respectively. The farm finds that these Year 2 values are not consistent with the existing water quality profile because there is greater than a 0.5-log difference between the annual survey values and the water quality profile values. Therefore, as required by § 112.45(b)(2)(ii), the farm develops a new water quality profile. To do this, the farm uses its 5 test results from Year 2's annual survey, combined with 15 test results representing the most recently collected samples from the farm's earlier baseline data set to make up a data set of 20 samples, as described in § 112.45(b)(2)(ii)(A). The farm uses these 20 test results to develop a new water quality profile. The farm's new water quality profile GM and STV values are 200 CFU/100 mL and 600 CFU/100 mL, respectively. The farm's water quality profile GM and STV are now above the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). As a result, as required by §§ 112.45(b)(2)(ii) and 112.44(c), the farm must either apply a time interval as a mitigation measure (§ 112.44(c)(1) or (2)) or discontinue using the water for direct water application during growing covered produce until the water meets the water quality standard (§ 112.44(c)(3)). A 1-day time interval between last water application and harvest (under § 112.44(c)(1)) would be sufficient to meet the microbial quality requirements specified in proposed § 112.44(c) because it results in calculated GM and STV values of 63 CFU/100 mL and 190 CFU/100 mL, respectively. The timing of the Year 2 crop cycle is such that the farm is able to develop its new water quality profile and take action prior to the end of the current harvesting season, and the farm chooses to apply a 1-day interval between last water application and harvest.

As another example, all of the circumstances for Farm B are the same for Farm A, except that Farm B's Year 2 annual survey test results are not available prior to the end of the current harvesting season. In this example, the farm would modify its practices in Year 3 based on the new water quality profile values developed in Year 2. Farm B chooses to apply a 1-day interval between last water application and harvest, as required under § 112.44(c)(1), during Year 3.

As another example, Farm C conducts a baseline survey by taking 20 samples of its water source and testing them for generic *E. coli,* as described under § 112.45(b)(1)(i) and (ii). Using these test results, the farm calculates a GM of 241 CFU/100 mL and STV of 576 CFU/100 mL. This is the farm's initial water quality profile for this water source. The farm's GM and STV are above the GM and STV of the water quality standard in § 112.44(c) (GM of 126 CFU/100 mL, STV of 410 CFU/100 mL). As a result, as required by §§ 112.45(b)(2)(ii) and 112.44(c), the farm must either apply a time interval as a mitigation measure (§ 112.44(c)(1) or (2)) or discontinue using the water for direct water application during growing of covered produce until the water meets the water quality standard (§ 112.44(c)(3)). The farm chooses to apply a one-day interval between last water application and harvest. In Year 2, Farm C conducts an annual survey by taking five samples of its water source and testing them for generic *E. coli,* as described in § 112.45(b)(2). The farm calculates that the GM and STV values based on these five samples are 3000 CFU/100 mL and 5800 CFU/100 mL, respectively. The farm finds that these Year 2 values are not consistent with the existing water quality profile because there is greater than 1-log difference between the annual values and the water quality profile values. Therefore, as required by § 112.45(b)(2)(ii), the farm develops a new water quality profile. To do this, the farm uses its 5 test results from Year 2's annual survey, combined with 15 test results representing the most recently collected samples from the farm's earlier baseline data set to make up a data set of 20 samples, as described in § 112.45(b)(2)(ii)(A). The farm uses these 20 test results to develop a new water quality profile. The farm's new water quality profile GM and STV values are 475 CFU/100 mL and 1050 CFU/100 mL, respectively. These values are different from the ones the farm used in Year 1 to calculate its time interval under § 112.44(c)(1). The farm must now use the Year 2 new water quality profile GM and STV values to reconsider and implement one of the mitigation measures specified in §§ 112.44(c)(1) through (c)(3). A 2-day time interval between last water application and harvest would be sufficient to meet the microbial quality requirements specified in proposed § 112.44(c) because, using the Year 2 water quality profile values, a 2-day interval would result in calculated GM and STV values of 48 CFU/100 mL and 105 CFU/100 mL, respectively. The farm is able to modify its practices during the current season and applies a 2-day interval between last water application and harvest.

c. Other Requirements to Update Water Quality Profiles—Under proposed § 112.45(b)(1)(iii)(A), we are proposing to require farms to develop a new water

quality profile every 10 years. We tentatively conclude that re-establishing the GM and STV values at least once every 10 years is necessary to reevaluate your agricultural water source and its use in light of potential changes over time of your farm's practices and conditions and changes in the watershed from which you source your water, even if the farm's annual survey data in any single year of the 10 years does not reveal a substantial deviation from the values in the farm's then-current water quality profile. As proposed, a farm would be able to use the test results obtained from annual verification testing to develop the new water quality profile, so this provision would not require any additional testing. For example, a farm that conducts annual verification survey using five samples a year would be able to use these data gathered over the previous 4 years to make up the minimum number of 20 samples. All that would be required is for the farm to use these 20 test results to calculate a new GM and STV value, which would then represent the farm's water quality profile. The farm would then use the new water quality profile to determine what water use is appropriate under § 112.44(c), including whether any steps need to be taken under §§ 112.44(c)(1) through (3). We expect this proposed provision would serve to guide water management decisions with minimal additional cost or resources expended.

Proposed § 112.45(b)(3) would require you to develop a new water quality profile if you know or have reason to believe that your water quality profile no longer represents the quality of your water for reasons other than those in § 112.45(b)(2) (*i.e.,* reasons not based on annual survey test results). Then, as necessary and required by § 112.44(c)(1) through (3), you would be required to modify your water use based on the new water quality profile as soon as practical and no later than the following year.

For example, if you know or have reason to believe that there are significant changes in adjacent land use, erosion, or other impacts to water outside your control that are reasonably likely to adversely affect the water quality profile, you would be required to develop a new water quality profile under this section. In this provision, we listed some examples of events (such as land erosion) that may degrade the quality of surface water sources such that the development of a new water quality profile may become necessary, but we do not intend this list to be all-inclusive. Alternatively, there may be circumstances that lead to water quality improvements (for example, changes in upstream water management practices) that result in a higher water quality and may permit its wider use or use without specific time intervals. We limited the application of this provision, which *requires* development of a new water quality profile, to changes reasonably likely to have adverse effects on water quality. We note that a farm may become aware of a change likely to have a positive effect on water quality and choose to voluntarily develop a new water quality profile to evaluate whether the change has indeed improved the water quality to an extent that could justify changes in water use practices under § 112.44(c).

When developing a new water quality profile under proposed § 112.45(b)(3), you would be required to calculate new GM and STV values using your current annual survey data, combined with new data, to make up a data set of at least 20 samples. This is an important difference from all the other circumstances in proposed § 112.45 in which a farm would be required to develop a new water quality profile, because in this circumstance, the farm would not be allowed to use existing test results predating the current annual survey test results for this purpose. The farm would be required to conduct some new sampling and testing to make up its new data set of at least 20 test results (unless it opted to exceed the minimum annual survey requirements and already conducted at least 20 tests as part of its current annual survey).

d. Requests for Comment on Proposed § 112.45(b)—We ask for comment on our proposed approach, described in amended provision § 112.45(b), to testing untreated surface water that is used for the growing of produce (other than sprouts) using a direct application method. In particular, we seek comment on our tentative conclusions related to the tiered approach (including the baseline survey, annual verification testing, and requirements to develop new water quality profiles), sampling requirements (including minimum sample sizes, minimum sampling periods), and our determination that such an approach would provide for a reduced required frequency of testing while ensuring the quality and safe use of untreated surface water.

We acknowledge that there are certain limitations to our proposed approach, particularly regarding whether and how annual verification data (which can be based on as few as 5 data points, as proposed) may be used to identify the need for changes to water use practices in the current season and/or the need for a new water quality profile. We request comment on whether there are scenarios that should warrant the development of a new water quality profile using 15 new test results (in addition to the 5 annual survey test results to meet the minimum number of 20 samples), such as where the magnitude of the deviation from the existing water quality profile GM and STV values that formed the basis for the manner in which the water is currently used suggests that those prior sample values are no longer representative of the current agricultural water. For example, is there a threshold based on magnitude of deviation indicated in an annual survey (*e.g.,* a 1 to 2-log change in the GM or STV value compared to the GM or STV of the existing water quality profile) that would suggest that the existing water quality profile is no longer representative of the current water quality such that none of the sample data from that existing water quality profile should be used to determine the current quality of the agricultural water?

We plan to provide guidance to assist farmers to implement the water testing requirements, if finalized. Among other guidance, we expect to develop a tool(s) that you can use to derive the GM and STV values based on your input of water testing data. We recognize that there are different ways to determine STV values, including through sample-based empirical estimation and model-based calculation. We request comment on whether there is a specific statistical method(s) that we should either require or recommend be used for the derivation of GM and/or STV values.

We also request comment on whether we should require farms to alter practices in the current season based solely on the annual survey data under certain circumstances, such as where the annual survey test results suggest a public health concern that must be addressed in a timely manner. This would be different from what we are proposing, which is to use the annual survey data set (which may be as small as 5 test results) solely for verification purposes, which may lead to development of a new water quality profile (using at least 20 test results), upon which farms would determine the need for changes to their water use practices. If there are circumstances in which farms should be required to change water use practices based solely on the smaller annual survey data set, what results obtained in an annual survey should require such immediate changes? For example, should a substantial deviation in the GM or STV value indicated in an annual survey (*e.g.,* a 1 to 2-log change in the GM or STV value compared to the GM or STV

in the existing water quality profile) require farms to institute immediate corrections to current water use practices (such as application of a time interval between irrigation and harvest) based solely on the annual survey results? Note that under our proposed approach, an annual survey can be based on a minimum number of five samples. Should annual surveys be required to include more than five samples? Should annual survey data based on greater than five samples be used to support immediate changes to current practices?

We request comment on whether there are scenarios that might appropriately trigger both of the potential requirements discussed immediately above (*i.e.,* development of a new water quality profile using new test results and, in the interim, immediate changes to water use practices based solely on annual survey test results).

In our analysis related to the number of samples needed in annual verification surveys of untreated surface water, we used an estimate of average standard deviation of $\log_{10}$ *E. coli* abundance measurements in surface waters of 0.4 to characterize the variability of an average water source (Ref. 21). We request comment on whether, for a highly variable water source (*e.g.,* moving water body), we should require more than a five-sample annual verification survey. For example, should we require that you establish a new water quality profile annually using a minimum of 20 samples made up of the annual survey data combined with data from the previous survey(s)?

We also seek comment on whether there are other data sources that can be used in conjunction with water testing data to determine the need for immediate changes to current practices. For example, would data obtained through sanitary surveys conducted by farms be useful to identify the need for immediate changes to current use of the agricultural water?

In addition, we request comment on whether we should stipulate a time period beyond which data would not be appropriate to use in a water quality profile because the test results would not be expected to provide a currently representative profile of the water quality. For example, should we specify that whenever a farm is required to develop a water quality profile under this proposed rule, the data relied upon may only include samples collected within the last three calendar years?

As previously noted, in certain cases, such as where multiple crops are grown in a single year, harvesting will likely occur while the total required five samples for annual verification are collected such that it may be impractical to rely on the results of this verification to determine the appropriate use of that agricultural water for any one or more of those crops for the current harvesting season. We seek comment on this issue, including whether there is an alternative sampling scheme (in lieu of the one we proposed) that would be more responsive to crop cycles and facilitate the use of annual survey testing to make any necessary adjustments to water use during the current harvesting season.

Although we proposed a tiered approach that is based on a baseline survey, annual verification and, as necessary, developing new water quality profiles, we acknowledge that there may be alternative schemes to sampling and testing water quality. We seek comment on any such alternative schemes we should consider.

e. Testing Untreated Surface Water for Other Purposes—New § 112.45(d) would provide that if you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard and that you must have adequate scientific data or information to support your testing frequency. As described in the previously published proposed rule, the uses of agricultural water listed in proposed § 112.44(a) are agricultural water that is: (1) Used as sprout irrigation water; (2) applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities; (3) used to make a treated agricultural tea; (4) used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; and (5) used for washing hands during and after harvest activities.

As proposed, the testing requirements in § 112.45(b) apply when the untreated surface water is used during growing for purposes of direct application as specified in § 112.44(c) only. We anticipate that the primary use of untreated surface water would be in growing activities (*e.g.,* irrigation, crop protection sprays) although we are not restricting it solely for those activities. For example, we are not specifically prohibiting a farm from using untreated surface water for any purpose described in § 112.44(a), provided it meets the water quality requirements for those purposes, as described in that section. Although, in accordance with proposed § 112.44(a), untreated surface water that is used for any purpose described in § 112.44(a) would be required to meet the water quality parameters established in that provision, at this time, we are not proposing, in amended § 112.45, specific testing frequency requirements applicable to untreated surface water when used for the purposes described in § 112.44(a). Instead, we are proposing to include new § 112.45(d), which would provide that if you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard and that you must have adequate scientific data or information to support your testing frequency. We are also proposing to require records of your supporting data in new § 112.50(b)(9).

We seek comment on the prevalence of use of untreated surface water for those purposes listed under § 112.44(a), and on an appropriate approach(es) to sampling and testing of untreated surface water intended for such uses. Further, we acknowledge the challenge associated with designing a sampling scheme that would provide sufficient confidence that a source of untreated surface water, given its inherent variability, will consistently meet the water quality standard in proposed § 112.44(a).

Under the Surface Water Treatment Rule (40 CFR 141.70–141.75), EPA requires public water systems to treat surface water or ground water sources under the direct influence of surface water to meet the requirements of the Safe Drinking Water Act (SDWA) (42 U.S.C. 300f *et seq.*). We seek public comment on whether we should likewise require treatment of surface water sources used for the purposes specified in § 112.44(a), rather than provide for a testing scheme, if the latter is not practical.

ii. Tiered approach to testing untreated ground water. Similar to the tiered approach for testing untreated surface water for direct application during growing, we are proposing a tiered approach to testing ground water that is used for any of the purposes established in § 112.44. New proposed § 112.45(c) would establish that if you use untreated ground water for purposes that are subject to the requirements of

§ 112.44, you must test the quality of each source of the water at least four times during the growing season or over a period of 1 year, using a minimum total of 4 samples collected during a time period(s) as close as practical to harvest. If the samples tested meet the applicable microbial standard in § 112.44 (i.e., no detectable generic *E. coli* per 100 mL under 112.44(a) or a GM of generic *E. coli* of 126 CFU or less per 100 mL under 112.44(c), as applicable), you may test once annually thereafter, using a minimum of one sample collected during a time period as close as practical to harvest. You must resume testing at least four times per growing season or year if any annual test fails to meet the applicable microbial standard in § 112.44. We are not proposing that the STV component of the standard under § 112.44(c) be applied in the case of ground water because the minimum number of samples that we are proposing for collection would not be sufficient for a reliable calculation of that value. However, we expect you to apply the STV component of the standard in § 112.44(c) if the number of samples you collect allow for its calculation.

Under this approach, each ground water source would be required to be tested initially by sampling a minimum of four times during the growing season or over a period of 1 year using a total of at least four samples (i.e., a minimum of one sample collected at each sampling occasion). If the results of this initial testing show that the samples meet the microbial quality requirements for their intended use (i.e., either § 112.44(a) or § 112.44(c), as appropriate), then subsequent testing can be conducted only once per year using a minimum of one sample. However, the failure of any annual test to meet the appropriate requirement would result in resumption of the four times per growing season or year testing frequency. We tentatively conclude that our proposed testing frequency and sampling plan is the minimum necessary to ensure the quality of ground water sources for their intended use. We would encourage farmers to sample more than the minimum required four samples to build a robust baseline characterization. With this approach, we are responding to public recommendation for less frequent ground water testing based upon historically satisfactory test results in light of other requirements, most notably the inspection requirements of proposed § 112.42(b).

We seek comment on our proposed approach. We also request comment on whether, similar to § 112.45(b)(3) for untreated surface water, we should require the development of a new water quality profile if you know or have reason to believe that the existing water quality profile no longer represents the quality of your untreated ground water. For example, a compromised well seal, well casing or back flow prevention device may lead to a rapid decline in well water quality.

iii. Sharing of water testing data. Under new proposed provision § 112.45(e), we are proposing that you may meet the requirements related to testing of agricultural water that is required under § 112.45(b), (c), or (d) using test results from your agricultural water source(s) performed either by you or by someone else acting on your behalf; or, alternatively, you may use data collected by a third party or parties provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of part 112 are met. This provision would provide flexibility for you to determine the appropriate means by which to meet the proposed testing requirements in proposed § 112.45. You may conduct the necessary tests on your water source(s) or have those tests conducted for you by an appropriate person, group, or organization. Alternatively, you may use data collected by a third party or parties, such as water distribution districts or cooperatives, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water and all other applicable requirements of the proposed rule are met.

A water source sampled by a third party would adequately represent your water source if the third party takes its samples from the same water source you use (*e.g.,* the same canal, stream, or reservoir) and there is no reasonably identifiable source of likely microbiological contamination (*e.g.,* an untreated sewage discharge point, a source of significant amounts of untreated animal feces such as a livestock farm) between the point(s) at which the third party collects its samples and the point(s) at which you draw the water. Thus, under this provision, farms that share a water source may share testing data from that water source to meet the proposed testing requirements if there is no reasonably identifiable source of likely microbiological contamination between the sampling site(s) and the farm(s) involved. For example, where there is water that is held in a reservoir, and multiple farms draw from the reservoir, those farms are using the same water source. The farms drawing from the reservoir may share their testing data as long as there is no reasonably identifiable source of likely microbiological contamination between the points at which the farms sample and draw the reservoir water as agricultural water. We seek comment on whether and what specific conditions we should establish in this provision to identify circumstances where a third party's data would not adequately represent your agricultural water source and to preclude reliance on shared water testing data in such cases.

Under this proposed provision, farms using data collected by a third party or parties must still satisfy all applicable requirements of the proposed rule related to agricultural water testing. For example, the proposed rule includes requirements related to the timing of collection of samples and the number of samples collected (see proposed §§ 112.45(b), (c), and (d)), and recordkeeping (see proposed § 112.50). The proposed rule also includes other applicable requirements such as specified analytical method(s) to be used for testing (see proposed § 112.151). For example, covered farms sourcing water from a water distribution district may consider using water testing data from the district sampling program. A covered farm considering the district sampling program data would need to determine whether the water source(s) sampled adequately represent the covered farm's agricultural water. The covered farm would also need to consider whether the district's data set includes samples collected during a time period(s) as close as practical to the covered farm's harvest time; whether the district's data set satisfies the minimum number of samples the farm is required to have under the rule; and whether the district's data were obtained using appropriate test methods, as described in proposed subpart N of part 112. In addition, the covered farm would need to get and keep records of the district's testing that satisfy the rule's recordkeeping requirements.

We seek comment on this provision and on additional means FDA could consider to provide flexibility for covered farms to meet the proposed agricultural water testing requirements.

iv. Removal of general testing provision. Finally, with the proposed tiered approaches described above for testing untreated surface water used for the purposes of § 112.44(c) and for testing ground water used more broadly for purposes of § 112.44, we find our previous proposed general provision for testing of agricultural water in proposed

§ 112.45(a) to be unnecessary. Therefore, under proposed § 112.45(a), we are proposing to remove the previous proposed provision that stated ''You must test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every 3 months thereafter during the growing season,'' and to simply retain the exceptions to that provision that we previously proposed. As amended, proposed 112.45(a) would establish that there is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when: (1) You receive water from a public water system, as defined under the SDWA regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; (2) you receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or (3) you treat water in accordance with the requirements of § 112.43. We refer you to a discussion of these circumstances under which testing would not be required in section V.E.3.d of the previously published proposed rule (78 FR 3504 at 3571).

3. Summary of FDA's Revisions and Request for Comment

With respect to the microbial quality standard for water that is used during growing of produce (other than sprouts) using a direct application method, we are proposing to: (1) Amend proposed provision § 112.44(c) to update the microbial quality standard in a way that coincides with the current EPA recreational water standard, *i.e.,* a GM of samples not to exceed 126 CFU of generic *E. coli* per 100 mL of water and (when applicable) a STV of samples, as an approximation of the 90th percentile, not to exceed 410 CFU of generic *E. coli* per 100 mL of water; (2) add two new provisions within proposed § 112.44(c) to incorporate additional flexibility for the use of agricultural water for direct application during growing, i.e., either apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your GM of generic *E. coli* level to 126 CFU or less per 100 mL and of your STV to 410 CFU or less per 100 mL (proposed § 112.44(c)(1)); and/or apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of your GM of generic *E. coli* level to 126 CFU or less per 100 mL and of your STV to 410 CFU or less per 100 mL, provided you have adequate supporting scientific data and information (proposed § 112.44(c)(2)); and (3) provide for the use of alternatives to the microbial quality standard in proposed § 112.44(c) and the microbial die-off rate in proposed § 112.44(c)(1).

With respect to frequency of testing agricultural water, we are proposing to amend proposed § 112.45(b) and add new provision § 112.45(c) to provide for a tiered-approach to testing that would enable testing at a reduced frequency than that proposed in the previously published proposed rule. Specifically, we are proposing in amended proposed § 112.45(b) that if you use untreated surface water during growing of produce (other than sprouts) using a direct application method, you must conduct a baseline survey to develop the water quality profile of your agricultural water source(s); conduct an annual survey to verify the water quality profile of the water; and develop a new water quality profile at least once every 10 years (using data collected during the annual surveys) or sooner, if you know or have reason to believe that your existing water quality profile no longer represents the quality of the water. In addition, we are proposing to add a new provision, *i.e.,* proposed § 112.45(c), to require testing of ground water used as agricultural water at least four times during the growing season or over a period of 1 year, and if the samples tested meet the requirements of proposed § 112.44, testing may be done once annually thereafter. Testing frequency must return to at least four times per growing season or year if any annual test fails to meet the requirements of proposed § 112.44. We are proposing to add new provision § 112.45(d), which would require that, if you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard, and that you must have adequate scientific data or information to support your testing frequency. Finally, in proposed § 112.45(e), we are proposing that you may conduct the necessary tests on your water source(s) or have those tests conducted for you by an appropriate person, group, or organization, or alternatively, you may use data collected by a third party or parties, such as water distribution districts or cooperatives, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water and all other applicable requirements of the proposed rule are met.

We seek comment on our amended and new proposed provisions. With respect to the amended microbial quality standard, we seek comment on our decision to retain the general microbial quality requirements and update them based on the 2012 RWQC; the use of GM and STV values to establish general microbial quality requirements; and the absence of a maximum generic *E. coli* threshold. We also request comment on the appropriateness of permitting an adequate time interval between last irrigation and harvest using a microbial reduction rate of 0.5 log per day as a means to achieve the specified microbial quality requirements. In addition, we seek comment on whether there is a specific microbial die-off rate(s) or microbial removal rate(s) that we should establish for applying an appropriate time interval between harvest and end of storage. Finally, we request comment on whether there are other provisions that we should consider to introduce additional flexibility, for example, to allow alternative indicators of water safety.

With respect to the use of untreated surface water for the purposes listed under § 112.44(a), we seek comment on the prevalence of use of untreated surface water for those purposes, and on an appropriate approach(es) to sampling and testing of untreated surface water intended for such uses. We seek public comment on whether we should require treatment of surface water sources used for the purposes specified in § 112.44(a), rather than provide for a testing scheme, if the latter is not practical.

With respect to the specific frequencies we have proposed for water testing, we seek comment on our proposed tiered approach for testing untreated surface water and ground water, including sampling requirements, and our determination that such an approach would provide for a reduced required frequency of testing while ensuring the quality of agricultural water. We list a number of specific, detailed requests for comment on issues related to testing frequencies for untreated surface water in section

II.B.2.b.i. These include questions regarding whether there are scenarios that should warrant the development of a new water quality profile using 15 new test results (in addition to the 5 annual survey test results to meet the minimum number of 20 samples); whether we should require farms to alter practices in the current season based solely on the annual survey data under certain circumstances; whether annual surveys be required to include more than five samples; whether there are scenarios that might appropriately trigger both development of a new water quality profile using new test results and, in the interim, immediate changes to water use practices based solely on annual survey test results; whether we should require more than a five-sample annual verification survey for highly variable water sources; whether there are other data sources that can be used in conjunction with water testing data to determine the need for immediate changes to current practices; whether we should stipulate a time period beyond which data would not be appropriate to use in a water quality profile because the test results would not be expected to provide a currently representative profile of the water quality; whether there is an alternative sampling scheme that would be more responsive to crop cycles and facilitate the use of annual survey testing to make any necessary adjustments to water use during the current harvesting season; and identification of any alternative schemes we should consider.

We also request: (1) Data or information gathered from scientific studies and/or surveys on the prevalence and population levels of generic *E. coli* in untreated surface water sources of agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method; (2) data or information gathered from scientific studies and/or surveys regarding the regional- and/or commodity-specific microbial die-off rates of generic *E. coli* between last irrigation and harvest of covered produce; (3) data or information gathered from scientific studies and/or surveys regarding the regional- and/or commodity-specific microbial reduction rates of generic *E. coli* due to natural die-off during storage and/or due to pathogen removal during certain post-harvest activities, such as commercial washing; (4) information related to specific protocols for testing, and reliability of specific methods for testing generic *E. coli* in agricultural water; (5) information on seasonal water use of agricultural water during the growing and harvest of covered produce; and (6) information on current concerns based on the revised proposed provisions on the microbial quality standard for agricultural water used during growing activities for covered produce (other than sprouts) using a direct water application method and frequency of testing agricultural water.

C. Proposed Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

In the previously published proposed rule, under subpart F of proposed part 112, we proposed to establish various standards related to the use of biological soil amendments of animal origin. Specifically, we proposed to establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing (proposed §§ 112.51 and 112.52); prohibit the use of human waste for growing covered produce except in compliance with EPA regulations for such uses or equivalent regulatory requirements (proposed § 112.53); establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that satisfy certain specific microbial standards (proposed §§ 112.54 and 112.55), and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (proposed § 112.56), and provide for alternative requirements for certain provisions under certain conditions (proposed § 112.12); and require certain records, including documentation of application and harvest dates relevant to application intervals, documentation from suppliers of treated biological soil amendments of animal origin, periodic test results, and scientific data or information relied on to support any permitted alternatives to requirements (proposed § 112.60). We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3573 through 3585).

We are reopening the comment period to solicit public comment on our current thinking related to two issues: (1) The minimum application interval for the use of an untreated biological soil amendment of animal origin when it is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application; and (2) the minimum application interval for the use of a biological soil amendment of animal origin that is treated by a composting process when it is applied in a manner that minimizes the potential for contact with covered produce during and after application. We describe our current thinking on these issues in this section.

1. Minimum Application Interval for Untreated Biological Soil Amendment of Animal Origin

In the previously published proposed rule, we proposed that, if the biological soil amendment of animal origin is untreated and is applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, then the minimum application interval (*i.e.,* time between application and harvest) must be 9 months (proposed § 112.56(a)(1)(i)). As described in the proposed rule and in the conclusions of the Qualitative Assessment of Risk, soil amendments can be a source of contamination to produce and biological soil amendments of animal origin have a greater likelihood of containing human pathogens than do chemical or physical soil amendments or those that do not contain animal waste. We also noted that human pathogens in untreated or composted biological soil amendments, once introduced to the growing environment, will eventually die off, but the rate of die-off is dependent upon a number of environmental, regional, and other agro-ecological factors (78 FR 3504 at 3523).

As described in the proposed rule, we evaluated current scientific evidence to determine an appropriate minimum application interval for the use of untreated biological soil amendments of animal origin in a manner where there is a reasonable possibility that it will contact covered produce after application of the amendment (despite the fact that application must be made in a way to minimize the potential for such contact). We investigated the potential for survival of many enteric pathogens of public health concern and determined that across various pathogens and their potential environments, pathogen survival and die-off time in soils amended with raw manures are extremely varied. One consistency across many trials was an observed rapid early die-off of many pathogens, followed by a prolonged survival of the remaining low populations. It is unclear in the existing literature at what point the population is low enough to minimize the potential

for contamination of covered produce, and it is reasonable to suggest that once pathogen populations fall below detection limits, their risks are minimized.

Some of the longest survival times involved organisms present at very high initial populations (*e.g., E. coli* O157:H7 in sheep manure surviving for 21 months) or involved certain pathogens such as encysting parasites (*Cryptosporidium parvum* cysts surviving for over a year or the eggs of parasitic flatworms (*Ascaris* ova) surviving for over 15 years). Some enteric pathogens are reported to be more resilient to deleterious effects of the environment than others (most notably, *Salmonella* seems better attuned for survival outside of a host than does *E. coli* O157:H7); those microorganisms that produce spores are especially hardy. We noted that basing all manure application standards on these extreme cases (*i.e.,* spore-formers) would be unnecessary. The majority of survival studies showed that most enteric pathogens of public health importance, under the most common conditions, would not survive in the soil past 1 year. Further, organisms most commonly associated with produce outbreaks (such as *E. coli, Salmonella,* and *Listeria*) are unlikely to survive at detectable population levels in soil past 270 days. Therefore, we tentatively concluded that utilizing a 9-month waiting period between the application of an untreated biological soil amendment of animal origin and the harvest of covered produce would be protective for the preponderance of environments in situations where covered produce is reasonably likely to contact the soil after application of untreated biological soil amendments of animal origin. We further noted that this time interval, although somewhat less restrictive, would not be inconsistent with the 12-month restriction used by some segments of the produce industry (78 FR 3504 at 3582).

Moreover, as described in the previously published proposed rule, we tentatively concluded that, under certain circumstances, the application interval of 9 months may be more than what is necessary for minimizing the likelihood that covered produce that is grown in soils amended with an untreated biological soil amendment, and is reasonably likely to contact the soil after application, pose to the public health. Under certain circumstances, an alternative standard may be appropriate if it is shown to provide the same level of public health protection as the 9-month minimum application interval requirement in proposed § 112.56(a)(1)(i), and not to increase the likelihood that the covered produce will be adulterated. For example, alternatives to the proposed 9-month minimum application interval could take into account specific characteristics of the locality, crop and the agro-ecological environment. Such alternatives could consider differences in soil amendment feedstock, application methods, and treatment methods, especially given the potential for new innovations in such methods. Therefore, under proposed § 112.12(a)(3), we proposed that you may establish an alternative to the requirement for a minimum application interval of 9 months, provided you have adequate scientific data and information and satisfy other requirements established in proposed § 112.12 (78 FR 3504 at 3553 and 3584).

a. Relevant Comments. We received an extensive number of comments on this issue, a large majority of which expressed strong concerns with the proposed 9-month minimum application interval. Key concerns noted by commenters included the following: (1) There is no conclusive scientific evidence to support a 9-month minimum application interval requirement, and in developing this proposed application interval, FDA relied on the findings of a small number of published studies whose methods and designs do not include the range and variety of important factors and variables (*e.g.,* climates, soils, management practices) that can dramatically affect the viability of pathogens that may be present in these materials; furthermore, FDA used certain scenarios to assess pathogen risk from manure resulting in a cautious approach based on selective science, which is inconsistent with FDA's mandate to develop science-based produce safety rules; (2) a 9-month application interval is not appropriate as a general requirement applicable to all commodities, regions, and agro-ecological conditions; for example, such an extended time period between application and harvest is either not necessary or not practical in certain regions, such as the northeastern and northwestern regions, of the United States considering their climatic conditions and shorter growing seasons; (3) farmers currently comply with the standards established under the USDA's NOP, which specify a minimum application interval of 120 days for crops in contact with the soil and 90 days for crops not in contact with the soil, and the proposed 9-month application interval would be excessively burdensome, *i.e.,* a 9-month application interval could interfere with full compliance with the USDA organic regulations by impeding soil fertility and crop nutrient management practices and crop rotation practices (see 7 CFR 205.203 and 205.205); (4) a 9-month application interval requirement would have a negative impact on farmers' ability to rely on raw manure as a primary source of nitrogen for growing of crops; (5) a 9-month application interval requirement would disrupt current crop rotation cycles and is likely to limit the production of produce to only one cropping cycle per season; (6) raw manure has a long history of use and the proposed requirement to apply a 9-month application interval would pose severe economic and practical burdens on farmers; (7) the infrastructure necessary to make the transition from raw manure to compost is either lacking or not widely established; and (8) a 9-month application interval could mean that manure is handled in a less sustainable manner, could also result in greater use of chemical fertilizer, and would run counter to the Natural Resources Conservation Service's (NRCS) national campaign to dramatically increase soil health in part by reintroducing manure into farming systems. Commenters urged FDA to engage in a discussion of the growing body of research regarding the importance of biologically active soils in promoting pathogen die-off, and the harmful effects of soil sterilization through chemical-intensive fertilization and pest management practices. Some commenters also requested us to consider allowing raw manure that has been tested to a known safety standard to be held to lesser application restrictions.

In contrast, a few other commenters emphasized the public health concerns associated with the improper use of manure as a fertilizer, and supported FDA's proposed minimum application intervals, including the 9-month interval for use of untreated biological soil amendments in a manner where the crop is reasonably likely to contact the soil after application, urging us to maintain this waiting period to protect public health. One of these commenters, however, also noted that FDA must acknowledge that manure—raw and composted—plays an important role in sustainable agriculture by returning nutrients to the soil and reducing the need for chemical fertilizers.

Overall, there was widespread concern among commenters that the proposed 9-month minimum application interval would be impractical and/or unnecessarily

burdensome. Commenters urged FDA to evaluate and address concerns identified for each specific commodity sector and region, and develop and enforce a rule that sets a minimum standard for food safety that would be appropriate nationwide. In addition, a majority of commenters agreed that FDA should establish a process to engage the wider produce community in discussions about currently available scientific evidence on this issue; gaps in current scientific understanding; and the need for concerted efforts among various stakeholder groups to not only fill the research gaps but also build the necessary infrastructure to support and promote practical and effective produce safety strategies. Several commenters also urged FDA to publish a second set of revised proposed provisions and provide an additional opportunity for public input prior to finalizing the produce safety regulation.

b. FDA's Consideration of Comments. We considered the comments that objected to the 9-month interval on the basis that it is not scientifically sound. As described in the previously published proposed rule, FDA relied on currently available scientific evidence to identify the 9-month application interval as a general requirement broadly applicable for all crops, soils, types of manure, and growing regions. Our review of existing literature indicated a pattern of rapid early die-off of pathogens, followed by a prolonged period of survival of the remaining low populations. However, current data do not allow for a determination of the point at which pathogen populations would be considered too low to affect the potential for contamination of covered produce. Nevertheless, it is reasonable to expect that the likelihood of contamination is minimized when pathogen populations are below detection limits and, therefore, we considered this in identifying a minimum application interval. As explained in the previously published proposed rule, the majority of survival studies indicate that most enteric pathogens of public health importance, under the most common conditions, would not survive in the soil past 1 year. Moreover, organisms most commonly associated with produce outbreaks (such as *E. coli O157:H7, Salmonella,* and *Listeria monocytogenes*) are unlikely to survive at detectable population levels in soil past 270 days. Consequently, we proposed 9 months as the minimum application interval.

We also acknowledged that shorter waiting periods may be appropriate for some specific commodities and/or agro-ecological conditions, although conclusive evidence is lacking. Recognizing the limitations of available data, we provided for alternative application intervals to be used where there is adequate scientific data and information to support such alternative time intervals. Furthermore, recognizing the time and resources necessary to conduct the scientific investigations and/or gather the necessary data, we provided for compliance periods of 2 to 4 years, depending on the size of the farm.

We considered comments that recommended using the application intervals for raw manure established under the NOP. Under 7 CFR 205.203(c)(1), raw animal manure must be composted unless it is: (i) Applied to land used for a crop not intended for human consumption; (ii) incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or (iii) incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles. The restriction on the application of raw manure is in addition to the USDA organic requirements in § 205.203(c), which states in part that organic producers are required to ''manage plant and animal materials . . . in a manner that does not contribute to contamination of crops, soil, or water by . . . pathogenic organisms.'' In establishing this regulation, the Agricultural Marketing Service (AMS) acknowledged that this raw manure standard is based on organic crop production practices and noted the scarcity of scientific data on the regulation of raw manure use and food safety. Specifically, in the final rule that established this regulation, AMS noted the following: ''Although public health officials and others have identified the use of raw manure as a potential food safety concern, at the present time, there is no science-based, agreed-upon standard for regulating the use of raw manure in crop production. The standard in this [NOP] rule is not a public health standard. The determination of food safety demands a complex risk assessment methodology, involving extensive research, peer review, and field testing for validation of results.'' This statement was provided by AMS in response to comments on a broader discussion about the application of raw manure under NOP requirements. The AMS also stated that it ''does not have a . . . capacity with which to undertake a comprehensive risk assessment of the safety of applying raw manure to human food crops'' and that ''the standard in this rule is a reflection of AMS' view and of the public comments that this standard is reasonable and consistent with current organic industry practices and the NOSB [National Organic Standards Board] recommendations for organic food crop production.'' Finally, AMS noted that ''should additional research or Federal regulation regarding food safety requirements for applying raw manure emerge, AMS will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard'' (65 FR 80548 at 80567; December 21, 2000). Therefore, we believe that the current NOP application intervals for raw manure are not intended as science-based minimum standards for the safe production and harvesting of produce or measures reasonably necessary to minimize the risk of serious adverse health consequences or death, which is the underlying basis for the standards we proposed under part 112. Moreover, peer-reviewed literature suggests that a 90-day or 120-day interval, as required under the NOP regulations, does not sufficiently minimize the likelihood of contamination in all circumstances (Refs. 22 and 23).

Some of the comments expressed concerns about field crops that rely on the use of raw manure as a means of land-applied disposal of waste raw manures produced through animal husbandry. We believe crops used in such disposal of raw manure primarily include food grains such as dent or flint corn, wheat, and rye. As proposed in the previously published proposed rule, produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, cotton seed, and soybeans (see definition of ''Produce'' under proposed § 112.3). Some non-food crops, such as cotton, may also be used for disposal of raw manure, but non-food crops are outside of the scope of this rule. Therefore, we do not expect the current practice of use of raw manure in the growing of food grains or non-food crops to be affected by the produce safety regulation.

We also considered comments that opposed the 9-month application

interval citing limitations related to the use of raw manure as a source of nutrients. We recognize that nitrogen release from raw manure is highest immediately following application of the manure to the soil, and that nitrogen may be rapidly lost by volatilization (particularly if surface applied) or leaching (when rainfall or irrigation follow application) (Refs. 24, 25, and 26). Further, we recognize that many covered produce crops have a shorter than 9-month growing period, which complicates the synchronization of crop demand with nutrient availability from manure application. We note however, that soil amended with manure continues to benefit from manure applications after the initial nitrogen release, both by slow release of nitrogen as organic sources of nitrogen are mineralized, and by numerous benefits associated with the enhancement of soil microbial community structures and improvement of many soil physical and chemical properties, including an increase in nutrient cycling (Refs. 27, 28, and 29). A waiting period (either our previously proposed 9-month period, that imposed by the NOP, or another waiting period) may affect the benefit of raw manure as a nutrient supplement, but it is not expected that these waiting periods will completely negate the value of raw manure as a soil amendment. In addition, composted manure has stabilized forms of nitrogen, which are less susceptible to leaching or runoff (Ref. 30), but also retains many other key values of manure, including supply of carbon to support diverse and abundant soil microbial communities, which serve critically important functions in nutrient cycling, conditioning of soil physical and chemical properties (Ref. 31) and, in some cases, provide crop protection from phytopathogenic diseases (Ref. 32). We recognize that some loss of nitrogen during the composting process is likely and that adjustments to fertility management will be necessary when either allowing for a waiting period after applying raw manure or shifting to use of composted manure (Refs. 31 and 33). We believe increased use of composted manure offers significant food safety benefits and retains much of the agronomic value of manure as a resource for farmers, particularly those with animal components in their farm operations. Overall, no new studies have been published since the issuance of the previously published proposed rule that would refute the scientific basis for our proposed 9-month waiting period. Nevertheless, we recognize the limited body of scientific evidence, the limitations associated with the studies we relied on, the use of a no detectable pathogen level as the basis for identifying a minimum application interval, and the need for additional research in this area. The use of raw manure at a time close to harvest, during organic or conventional production, presents a significant likelihood of contamination of covered produce if produce is reasonably likely to contact the soil. We continue to believe that a science-based minimum standard to address this potential for contamination by such use of raw manure must include an appropriate quantitative minimum application interval. As noted in the previously published proposed rule, we are currently working with USDA and other stakeholders to conduct research on application intervals necessary to ensure the safety of covered produce when raw manure is applied to a growing area and covered produce is reasonably likely to contact the soil. We expect such research will help fill the current gaps in science, and enable us to identify specific agro-ecological or commodity-specific conditions that would support alternative minimum application intervals.

FDA also believes that progress toward its food safety goal can be achieved by facilitating the transition of farming practices, to the extent feasible, toward the safer option of using composted manure rather than raw manure. Our review of the scientific literature suggests that, regardless of the source, composting that is properly conducted (including proper turning of feedstock) can minimize the expected pathogen load and subsequent likelihood of produce contamination. Compost use can also result in a variety of environmental benefits, including that compost enriches soils, helps cleanup (remediate) contaminated soil, and helps prevent pollution (*e.g.,* by reducing the potential for nutrient rich run off as compared to raw manure use), and also offers economic benefits (*e.g.,* reduces the amount of irrigation water, fertilizers, and pesticides needed, and acts as an alternative to routing organic materials to landfills) (Ref. 34). A transition of farming practices from raw manure to composted manure use would require a concerted effort by the regulatory agencies, agricultural marketing agencies, academia, and the regulated community. We acknowledge the various concerns—*e.g.,* economic, scientific, and practical—that we heard from stakeholders across the country and foreign trading partners. We are also fully cognizant of not only the need for additional scientific information but also resources to build the necessary infrastructure to facilitate the use of appropriate composting treatments.

Considering the strong concerns expressed by stakeholders, our ongoing effort to build the scientific knowledge and infrastructure in this area, and our overall commitment to adopt practical and effective produce safety strategies, we have tentatively concluded that the appropriate approach is to remove the 9-month minimum application interval for use of raw manure that is specified in proposed § 112.56(a)(1)(i) and defer our decision on an appropriate minimum application interval until such time as necessary for us to pursue the following actions.

First, we will conduct a risk assessment on the safe use of raw manures in covered produce fields. Variables that may be considered in such a risk assessment include the source and type of manure (for example, animal type and animal diet); method of application (for example, broadcast, incorporated, and subsurface incorporation); climatic conditions (for example, temperature, days of sunlight, sunlight intensity, and expected rainfall); type of commodity; and the characteristics of the soil (for example, pH and moisture holding capacity). We will also work with USDA and other stakeholders to develop and implement a robust research strategy that will allow us to supplement the science currently available on this issue, and further develop our risk assessment model. As we explained in the previously published proposed rule, we are currently working with USDA and other stakeholders to conduct research on application intervals necessary to ensure the safety of covered produce when raw manure is applied to a growing area and covered produce is reasonably likely to contact the soil. Our research will address various issues, including and, in particular, whether and how application intervals can be tailored for specific commodities, types of commodities, growing environment and any other agro-ecological conditions. We encourage the farming community and others to partner with us on this effort, including by participating with academia, industry, and government on necessary research activities.

Second, we will work with USDA and other stakeholders to encourage the transition of the produce grower community to the use of compost rather than raw manure. As noted above, use of compost is a safer practice from a public health standpoint, and is also considered to be a more sustainable

environmental practice. We encourage the farming community and others to partner with us on this effort.

Third, although there will be no minimum application interval requirement in § 112.56(a)(1)(i) while we pursue the avenues of scientific research and infrastructure development identified above, we continue to believe that a quantitative application interval standard, established in the produce safety regulation, is necessary to minimize the likelihood of contamination of produce resulting from the use of raw manure in a manner that contacts the crop. Our view remains that a quantitative standard rather than a qualitative one (suggested by some commenters) is the more effective and enforceable public health standard. We are committed to revisiting this issue and identifying an appropriate minimum application interval(s) for such use of raw manure taking into account new information gathered from our ongoing risk assessment and research efforts. We anticipate that these efforts will take 5 to 10 years to complete. Following the completion of the risk assessment and research work, we expect to: (1) Provide stakeholders with data and information gathered from scientific investigations and risk assessment; (2) consider such new data and information to develop tentative scientific conclusions; (3) provide an opportunity for public comment on our tentative decisions; and (4) consider public input to establish an appropriate minimum application interval(s).

We acknowledge the comments that pointed out that many growers currently employ the NOP standard of 90 days or 120 days, as specified in 7 CFR 205.203(c)(1), and we recognize that such growers will likely continue their current practice to use this standard in organic crop production, in the absence of an FDA regulation that establishes a food safety standard for minimum application intervals associated with the use of raw manure. Given that the scientific literature demonstrates that the probability of pathogen survival decreases as the length of time between application of raw manure and harvest increases, and that more rapid die-off occurs during the months immediately following application (*e.g.,* 3 to 4 months) as compared to subsequent months (followed by prolonged survival of pathogens at low levels), we believe adherence to the NOP standard to be a prudent step toward minimizing the likelihood of contamination while the above described research program is ongoing. At this time, we do not intend to take exception to the continuation of this practice.

We request comment on our current thinking described above. In addition, we seek: (1) Data or information gathered from scientific studies on the persistence of human pathogens in raw manure in an open environment (published or unpublished data) under various agro-ecological conditions and the expected transfer of pathogens to various commodities grown in soils amended with raw manures; (2) information related to specific protocols for testing, and reliability of specific methods for testing pathogens in manure; (3) information on nitrogen availability and the costs associated with various fertilizer options currently available to produce farms; (4) information on the methods of use and prevalence of use of raw manure, including practices by small farms; and (5) information on current barriers that will need to be addressed to enable transition from use of raw manure to use of compost.

2. Minimum Application Interval for Biological Soil Amendment of Animal Origin Treated by a Composting Process

In the previously published proposed rule, we proposed that, if the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements we proposed in § 112.54(c) to meet the microbial standard we proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.,* time between application and harvest) must be 45 days (proposed § 112.56(a)(4)(i)).

As explained in the previously published proposed rule, we tentatively concluded that process controls for composting can be expected to be more prone to failure than process controls during chemical or physical treatments and, therefore, proposed to apply a minimum application interval of 45 days as part of a multiple hurdle approach. For example, heat treatments are often conducted in enclosed heat-treatment chambers (*i.e.,* ovens), often with various means of agitation (such as stirring rods, etc.), that can be accurately monitored and controlled to reach the required treatment conditions throughout the material being treated. Conversely, composting usually occurs outdoors, is exposed to fluctuating environmental pressures and wildlife activity, and is not homogeneous in nature and prone to having ''cold-spots'' that are not completely treated (even with proper turning). In general, during composting, there is a higher likelihood of having a systems failure, which is also more likely to go undetected, should it occur. Composting may result in a treated biological soil amendment of animal origin that may continue to harbor human pathogens of food safety concern, although any such pathogens that may be present can be expected to be present at low populations and unlikely to survive for extended periods under normal environmental conditions after application. Therefore, we proposed to impose an additional mitigation measure in situations where covered produce is reasonably likely to contact the soil after application of biological soil amendments of animal origin treated by composting by requiring a minimum application interval of 45 days. This time period has been shown to be effective when the population of the pathogen is minimal, as can be expected of a fully composted biological soil amendment of animal origin (78 FR 3504 at 3583).

a. Relevant Comments. We received a number of comments on this issue, many of which objected to the proposed 45-day minimum application interval. Comments also included relevant data and factual information. Concerns noted by commenters included the following: (1) Farmers currently comply with the standards established under the NOP for the use of composted animal manures to build organic matter in production fields, in part, to avoid use of synthetic fertilizers, and the NOP does not require any minimum application interval for composted manures; (2) the proposed 45-day application interval would be excessively burdensome; (3) there is a lack of scientific basis for the 45-day interval for compost and FDA has failed to show how the literature supports this conclusion; (4) farmers who use compost would be severely limited by the proposed 45-day interval in their ability to utilize crop rotations for short-season crops and/or to maintain or increase biodiversity, and in their use of compost during the growing season for side-dressing; and (5) the burden on farms from using a 45-day wait period for compost is unscientific, especially considering the wealth of data showing that soil treated with compost is more suppressive of human pathogens than soil not treated with compost. In addition, commenters recommended eliminating the 45-day minimum application interval for fully composted manures where the soil has no contact with the crop, and where the soil amendment is handled in accordance with the proposed time, temperature, holding, and microbial testing requirements. Some other commenters recommended retaining the 45-day

waiting period only where the soil has contact with the crop and where there is no testing conducted to confirm that the composting process was properly implemented.

In contrast, some commenters suggested that FDA would do much more for food safety if it required composting of all raw manure, or if it required raw manure to be tested for pathogens and then be composted if the pathogen load exceeded a certain quantity. Another commenter suggested that all animal manure that is used for ''organic farming'' must be composted for a minimum of 2 years, and tested for proper temperature range on a monthly basis, before its use on the farm.

b. FDA's Consideration of Comments. We proposed to use the 45-day minimum application interval as part of a multiple hurdle approach to the safe use of composted manures. Proposed § 112.56(a)(4)(i) refers to the use of composted manure under certain specified mitigation measures: (1) It is properly treated in accordance with our proposed requirements in § 112.54(c); (2) it is properly treated to meet the microbial standard we proposed in § 112.55(b); (3) it is applied in a manner that minimizes the potential for contact with covered produce during and after application; and (4) there is a minimum application interval of 45 days. Under the same treatment and microbial standard requirements, but where the composted manure is applied in a manner that does not contact covered produce during or after application, we proposed no minimum application interval, *i.e.,* 0 days (proposed § 112.56(a)(4)(ii)). Therefore, our proposal to use 45 days as a minimum application interval was intended as one among multiple mitigation measures that would be implemented in situations where covered produce is reasonably likely to contact the soil after application of the biological soil amendment of animal origin.

Further, we proposed to require certain records to document that composting processes conducted by farmers or independent composters are properly conducted and that the proposed minimum time between application and harvest was observed, when applicable (proposed § 112.60).

Overall, we believe that the use of proper composting methods in accordance with appropriate handling, storage, treatment, and microbial standard requirements that we proposed in §§ 112.51, 112.52, 112.54(c), and 112.55(b) are sufficient to minimize the likelihood of composted manure acting as a source of contamination and to provide reasonable assurance that produce is not contaminated. This approach also satisfies FDA's goal to reduce the risk to public health when using composted manures, and to encourage and facilitate the transition of farming practices that currently use raw manure to the safer option of using composted manure. Further, the AMS, NRCS, EPA, and other organizations support the use of composted manure given its benefits to soil, cropland, and the environment, and/or recommend the use of composted manure over raw manure (Refs. 35, 36, 37, 38, and 39). FDA has considered this widespread understanding of the benefits of use of compost, and the impact of proper composting treatments on the microbial populations in composted manure.

In recognition of the expected benefit to public health when composted manures are properly treated and handled, and to further facilitate the use of composted manure rather than raw manure, we are proposing to eliminate the 45-day minimum application interval for use of composted manure in proposed § 112.56(a)(4)(i). As amended, proposed § 112.56(a)(4)(i)) would establish that if the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements we proposed in § 112.54(c) to meet the microbial standard we proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (*i.e.,* time between application and harvest) is 0 days.

We seek comment on these amendments.

3. Corresponding Proposed Amendments

As a consequence of eliminating the 9-month minimum application interval in proposed § 112.56(a)(1)(i) and of revising the 45-day minimum application interval to 0 days in proposed § 112.56(a)(4)(i), by cross-reference, we are also proposing certain corresponding amendments. We are proposing to remove the proposed provisions §§ 112.12(a)(3), 112.12(a)(4), 112.56(b), which would have provided for the use of alternative application intervals in lieu of the previously proposed minimum application intervals, as these provisions would no longer be needed. We are also proposing to remove proposed provisions §§ 112.60(b)(1) and 112.60(b)(5) thus eliminating the documentation requirements relevant to the previously proposed 9-month and 45-day minimum application intervals. In addition, we are proposing to remove proposed §§ 112.182(d) and 112.182(e), which listed variances from the 9-month and 45-day minimum application intervals as examples of permissible types of variances.

Our current intent is that we will consider provisions for alternative application intervals, documentation requirements, and variances at the same time as provisions for an appropriate minimum application interval(s) for the use of an untreated biological soil amendment of animal origin (that is used in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application), after we first complete the actions discussed in section II.C.1.b.

4. Summary of FDA's Revisions and Request for Comment

We are proposing to: (1) Remove the minimum application interval in proposed § 112.56(a)(1)(i) and defer our decision on an appropriate minimum application interval while FDA pursues certain actions, including a robust research agenda, risk assessment, and efforts to support compost infrastructure development, in concert with USDA and other stakeholders. Following the completion of risk assessment and research work, FDA expects to share with stakeholders its tentative conclusions, taking into account new data and information, and consider public input to establish an appropriate minimum application interval(s) for the use of an untreated biological soil amendment of animal origin that is used in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application; (2) amend proposed § 112.56(a)(4)(i)) to establish that if the biological soil amendment of animal origin is treated by a composting process in accordance with the requirements we proposed in § 112.54(c) to meet the microbial standard we proposed in § 112.55(b), and is applied in a manner that minimizes the potential for contact with covered produce during and after application, then the minimum application interval (i.e., time between application and harvest) is 0 days; and (3) in light of the revisions explained in (1) and (2), eliminate the provisions to permit the use of alternative application intervals or variances, or require certain documentation related to the previously proposed 9-month and 45-day intervals (*i.e.,* delete proposed §§ 112.12(a)(3), 112.12(a)(4), 112.56(b), 112.60(b)(1), 112.60(b)(5), 112.182(d), and 112.182(e)).

We request comment on our current thinking on the issues described above. Specifically with respect to the use of untreated biological soil amendments of animal origin, we seek comment, including scientific data or information on the persistence of human pathogens in raw manure under various agro-ecological conditions, and the transfer of pathogens to various commodities grown in soils amended with raw manures; specific protocols for testing, and the reliability of specific methods for testing pathogens in manure; nitrogen availability and the costs associated with current options for fertilizers; information on the methods and prevalence of use of raw manure on small farms; and current barriers related to use of compost.

D. Proposed Subpart I—Standards for Domesticated and Wild Animals

In the previously published proposed rule, under subpart I of proposed part 112, we proposed certain standards related to domesticated and wild animals. Proposed subpart I includes standards that would be directed to the potential for biological hazards from animal excreta to be deposited by your own domesticated animals (such as livestock, working animals, and pets), by domesticated animals from a nearby area (such as livestock from a nearby farm), or by wild animals (such as deer and wild swine) on covered produce or in an area where you conduct a covered activity on covered produce. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3585 through 3587).

Specifically, in proposed § 112.82, we proposed that if animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, you must employ, at a minimum, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce. In addition, in proposed § 112.83, we proposed to establish requirements for measures related to animal intrusion in those areas that are used for covered activities for covered produce when, under the circumstances, there is a reasonable probability that animal intrusion will contaminate covered produce. We proposed to require that you monitor these areas as needed during the growing season, based on the covered produce being grown and your observations and experiences (proposed § 112.83(a)(1)(i) and (ii)), and immediately prior to harvest (proposed § 112.83(a)(2)). In addition, in proposed § 112.83(b), we proposed to require that, if animal intrusion occurs, as evidenced by observation of significant quantities of animals, animal excreta or crop destruction via grazing, you must evaluate whether the covered produce can be harvested in accordance with the requirements of proposed § 112.112.

As noted in the proposed rule, consistent with sections 419(a)(1)(A), 419(a)(3)(E), and 419(a)(3)(D) of the FD&C Act, we consulted with the NOP and USDA's NRCS, U.S. Fish and Wildlife Service, and the EPA to ensure that environmental and conservation standards and policies established by those agencies were appropriately considered in developing the requirements proposed in subpart I. We tentatively concluded that the provisions of proposed subpart I do not conflict with or duplicate the requirements of the NOP. In addition, we tentatively concluded that the provisions of proposed subpart I are consistent with existing conservation and environmental practice standards and policies while providing for enforceable public health protection measures. We also noted that the produce safety regulation would not require the destruction of habitat or the clearing of farm borders.

Specifically in relation to proposed § 112.83, we noted that this proposed provision should not be construed to require the ''taking'' of an endangered species, as the term is defined in the Endangered Species Act (ESA) (16 U.S.C. 1532(19)) (*i.e.,* to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), or to require farms to take measures to exclude animals from outdoor growing areas or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

We are reopening the comment period to solicit public comment on our current thinking on an issue related to the standards for domesticated and wild animals, i.e., the potential impact of this proposed rule on wildlife and animal habitat. We describe our current thinking on this issue in this section.

1. Relevant Comments

We received various comments that expressed the concern that the proposed rule, if finalized as proposed, would adversely affect wildlife, including threatened or endangered species, and animal habitat. Other comments noted that animal habitat, habitat connectivity, and wildlife populations would be at risk if our proposed provisions related to animal intrusion are perceived by produce growers to mean that less habitat and/or more fencing in the production environment is a necessary management strategy. Citing some of our statements in the preamble of the proposed rule, comments acknowledged FDA's interest in comanagement of both food safety and wildlife conservation, and urged us to provide similar language in the regulation.

2. FDA's Consideration of Comments

In publishing the Produce Safety proposed rule, we relied on a categorical exclusion from the need to prepare an Environmental Assessment (EA) or Environmental Impact Statement (EIS) under 21 CFR 25.30(j) (78 FR 3504 at 3616). However, as explained in the Notice of Intent To Prepare an Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (NOI), based on currently available information, including comments received, and upon further analysis, FDA has determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)), and therefore, an EIS is necessary for the final rule (78 FR 50358, August 19, 2013). In the EIS that will accompany the Produce Safety final rule, FDA will evaluate the potential environmental effects of the rule, including those resulting from the standards of domesticated and wild animals established in subpart I of part 112.

In response to concerns that the Produce Safety regulation may inadvertently promote practices that may adversely affect wildlife and animal habitat, including impacts on threatened or endangered species, we are proposing to include a new provision, i.e., proposed § 112.84, within subpart I of proposed part 112. We consulted with USDA's NRCS and the U.S. Fish and Wildlife Service to inform our current thinking on this issue.

Proposed § 112.84 would provide that the regulation in part 112 does not authorize or require covered farms to take actions that would constitute the ''taking'' of threatened or endangered species in violation of the ESA, as that term is defined by the ESA, *i.e.,* to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Proposed § 112.84 would also state that part 112 does not require covered farms to take measures to

exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

As discussed in the previously published proposed rule, we encourage the application of practices that can enhance food safety and that are also consistent with sustainable conservation. We believe that the provisions of proposed part 112, including subpart I, are consistent with existing conservation and environmental practice standards and policies. By adding proposed § 112.84, we are proposing to codify into the produce safety regulation that the requirements of proposed part 112 do not require or permit the use of practices in violation of the ESA, and that the regulation does not require the use of practices that may adversely affect wildlife, such as removal of habitat or wild animals from land adjacent to the produce field. Rather, we encourage the comanagement of food safety, conservation, and environmental protection. One set of examples of biodiversity and conservation practices that may enhance food safety is available from the Resource Conservation District of Monterey County, CA (Ref. 40). We provide this information as a resource and do not intend for it to suggest that we require or endorse a single approach.

Growers of produce should also be aware that clearing or manipulation of habitats, including activities affecting water resources, groundwater or natural vegetative cover, can affect species listed as threatened and endangered. Growers can determine whether any listed species may be present in their area by checking the U.S. Fish and Wildlife Service's Endangered Species Web site and the Information, Planning, and Conservation System Web site. You should coordinate with your local U.S. Fish and Wildlife Service office on any activity that could potentially affect listed species or critical habitat. We ask that you contact your local U.S. Fish and Wildlife Service office for any additional information.

3. Summary of FDA's Revisions and Request for Comment

We are proposing to add a new provision § 112.84 to state that part 112 does not authorize or require covered farms to take actions that would constitute the ''taking'' of threatened or endangered species in violation of the ESA, and that part 112 does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. We seek comment on our current thinking, including on proposed § 112.84.

E. Proposed Subpart R—Withdrawal of Qualified Exemption

In the previously published proposed rule, under subpart R of proposed part 112, we proposed to establish the procedures that would govern the circumstances and process whereby we may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of proposed § 112.5. Specifically, proposed § 112.201 listed the circumstances under which FDA may withdraw a qualified exemption applicable to a farm, while §§ 112.202 and 112.203 specified the procedure and information that FDA would include in an order to withdraw such qualified exemption. In addition, proposed §§ 112.204 through 112.207 provided for a process whereby you may submit a written appeal (which may include a request for a hearing) of an order to withdraw a qualified exemption applicable to your farm, and proposed §§ 112.208 through 112.211 provided a procedure for appeals, hearings, and decisions on appeals and hearings. We discussed each of the proposed provisions and explained our rationale (78 FR 3504 at 3611 through 3616).

We are reopening the comment period to solicit public comment on our current thinking on two specific issues related to the provisions for withdrawal of qualified exemptions: (1) The process under which FDA would withdraw a qualified exemption and (2) provisions for reinstatement of a qualified exemption that is withdrawn. We describe our current thinking on these two issues in this section.

1. Process for Withdrawal

As described in the previously published proposed rule, proposed § 112.201 would establish the circumstances under which FDA may withdraw an exemption applicable to a farm. Consistent with section 419(f)(3)(A) of the FD&C Act, we proposed that we may withdraw a qualified exemption: (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm (proposed § 112.201(a)) or (2) if we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm (proposed § 112.201(b)).

a. Relevant Comments. We received several comments expressing concern that the circumstances under which FDA would withdraw a qualified exemption, which are specified in proposed § 112.201, are unclear. In addition, some commenters urged us to provide for intermediary steps prior to resorting to withdrawal of an exemption, and recommended a three-tiered process that would include the issuance of a warning letter, followed by a temporary conditional withdrawal, and then a full withdrawal, as applicable. They noted that such a flexible approach would allow a farm to take corrective actions before having its exempt status fully withdrawn. Some other commenters suggested partially withdrawing a qualified exemption, thus requiring compliance with only those regulatory requirements that are related to the reason(s) for which the exemption is withdrawn. Several commenters also recommended that we establish a process that would require FDA to provide justification to a farm of FDA's decision to withdraw the farm's qualified exemption, and would provide an opportunity for the farm to respond to and/or submit arguments challenging FDA's decision to withdraw the exemption.

b. FDA's Consideration of Comments. We are proposing certain amendments, including taking into account comments that suggested that FDA consider other actions prior to invoking the provisions of subpart R to withdraw a qualified exemption. Depending on the circumstances, FDA may take a variety of actions, including education and warning letters, as well as enforcement actions such as administrative detention, seizure, and injunction to protect the public health and prevent or mitigate a foodborne illness outbreak. FDA may consider taking such actions prior to or in conjunction with a consideration to withdraw the qualified exemption.

To make our intent clear that we would consider other actions, as appropriate, before issuing an order to withdraw a qualified exemption, we are proposing to add a new provision under § 112.201. Proposed § 112.201(b) would establish that before FDA issues an order to withdraw your qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction (proposed § 112.201(b)(1)). If these other actions address the circumstances that could lead FDA to withdraw the

exemption, then FDA would likely determine that withdrawal of an exemption is not needed. We have provided two examples of potential scenarios and actions FDA might choose to take in such scenarios. Nothing in the discussion below should be construed to bind FDA in any future situation, however.

For example, consider the situation in which Farm A is growing, harvesting and packing heirloom tomatoes for sale to local restaurants. An outbreak of salmonellosis is epidemiologically linked to raw heirloom tomatoes served at those restaurants. The tomatoes are traced back to the farm. An inspection of Farm A reveals that conditions and practices at the farm appear to be generally consistent with good agricultural practices and that management appears to be committed to food safety, as evidenced by company policy documents, standard operating procedures (SOPs), and the conditions and practices of the operation. Inspectors note that the farm has two water sources, a holding pond used for drip irrigation of tomatoes and a deep well for any water use in the field where water directly contacts the tomatoes and for post-harvest practices such as washing. Inspectors sample pond water and find it is positive for *Salmonella* and that the isolate matches the outbreak strain. Upon further investigation, several workers admit that, when things are busy, especially close to harvest, they mix crop protection sprays with pond water because the pond is more conveniently located than the well, even though the farm's SOP specifies that only well water should be used for activities where water has direct contact with tomatoes.

We, in conjunction with State and local (or, if applicable, foreign) officials, may provide education to Farm A to reinforce awareness of the importance of ensuring that water that contacts produce is safe and sanitary for its intended use, especially close to harvest, and of managing water quality and use to minimize the potential for contamination of food. We may ask the farm to correct its water management procedures to minimize the potential for future illnesses from contaminated agricultural water. The farm's corrective actions might include taking steps, such as, remedial training, enhanced oversight, and/or other procedural changes. If a recall occurred, we may also work with the farm on its recall of any implicated tomatoes that may still be on the market. If we find, during a future inspection, that the farm has instituted procedures to minimize the likely reoccurrence of the problem, we might not proceed to withdrawal of the qualified exemption. However, if we find, during a future inspection, that the farm has not voluntarily taken appropriate steps to correct the conditions or conduct that led to the outbreak, we may consider other actions, which could include withdrawal of the qualified exemption.

As another example, consider the situation where routine surveillance sampling results in positive sample findings for *Shigella* in or on green onions. A traceback investigation identifies the source of the green onions as Farm B, which grows, harvests, packs, and holds its own green onions. An inspection of Farm B reveals a number of conditions and conduct that are material to the safety of the food, specifically: The farm does not have a training program for worker health and hygiene, it has an inadequate number and servicing of portable toilets for the number of people living at the farm, and it does not have procedures for what to do in the event of leakage or spilling of portable toilets in the field or housing area. In addition, water used for all growing activities and for washing green onions is from a well that is located in a depression and is not adequately designed or constructed to protect it from surface contamination; the farm does not test the microbiological quality of the well water that contacts produce during growing or washing; the farm adds chlorine to wash water but does not appear to have adequate procedures to accurately measure the amount of chlorine added to wash water or to monitor the levels of free chlorine available to maintain water quality over time.

We may inform Farm B of our concerns, noting conditions that may contaminate their food. We may ask the farm to correct their procedures to minimize the potential for future illnesses from ill workers or contaminated water. If the farm did not respond to FDA with the corrections it will take as a result of our observations, or if we did not believe the actions were adequate or timely, we may issue a warning letter to the farm. (In the case of foreign farms, we may refuse produce offered for import into the United States.) If a recall occurred, we may also work with the farm on its recall of any implicated food that may still be on the market. We, in conjunction with our State, local (or, if applicable, foreign) counterparts may provide education to the farm to ensure awareness of the importance of managing hazards such as waste and sewage disposal, worker health and hygiene practices and ensuring water that contacts produce is safe and sanitary for its intended use to minimize the potential for contamination.

If, during a subsequent inspection, we find continued conditions or conduct that could result in unsafe food, we may decide that withdrawal of the exemption is necessary to protect the public health and prevent or mitigate a foodborne illness based on these conditions and conduct. As an alternative to withdrawal of the exemption, or in addition to it, we may seek an injunction to prevent the farm from producing adulterated food.

We are also proposing amendments to proposed § 112.201 to ensure that, before FDA issues an order to withdraw a farm's qualified exemption, the farm has the opportunity to respond to the problems identified by FDA, and for FDA to consider the farm's response prior to proceeding with issuance of an order to withdraw the exemption. This intermediate step prior to FDA issuing an order to withdraw the exemption would provide an additional opportunity for a farm to submit information relevant to circumstances that may lead FDA to withdraw the exemption (including, as appropriate, any corrective actions taken by the farm), and for FDA to consider this information in making a determination regarding whether or not to proceed with issuing an order to withdraw the exemption.

Therefore, proposed § 112.201(b) would also state that before FDA issues an order to withdraw your qualified exemption, FDA must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 10 calendar days of the date of the notification, to FDA's notification (proposed § 112.201(b)(2)); and FDA must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption (proposed § 112.201(b)(3)).

Finally, we are also proposing corresponding amendments to proposed § 112.202 under paragraphs (a) and (b) of that section. As amended, proposed § 112.202(a) would make it clear that before an order to withdraw a qualified exemption is issued, such order must be approved by an FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)), or an FDA official senior to such Director, must approve an

order to withdraw the exemption before the order is issued. In addition, as amended, proposed § 112.202(b) would establish that any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with proposed § 112.202(a).

We seek comment on our current thinking on this issue, including new proposed provisions §§ 112.201(b), 112.202(a), and 112.202(b).

2. Reinstatement of a Qualified Exemption That Is Withdrawn

In the previously published proposed rule, under subpart R of proposed part 112, we proposed to establish the procedures that would govern the circumstances and process whereby we may issue an order withdrawing a qualified exemption applicable to a farm in accordance with the requirements of proposed § 112.5. Our proposed procedures did not include provisions for reinstatement of a qualified exemption once it is withdrawn.

a. Relevant Comments. We received several comments requesting that FDA provide for a process that would allow qualified farms to regain their exempt status after corrective actions are taken. Some commenters noted that FDA has a history of providing opportunities for facilities to fix a problem identified by FDA prior to suspending a facility's registration or starting an enforcement action, and that FDA should provide the same opportunities to farms that have a qualified exemption to fix the problems leading to the order to withdraw the exemption. Conversely, at least one commenter argued that FSMA provides no authority for restoring a qualified farm's exempt status after its withdrawal, and opposed any changes to the procedures in subpart R to provide for reinstatement of the exemption once it is withdrawn.

b. FDA's Consideration of Comments. We are proposing certain amendments, including taking into account comments that recommended providing a process for restoring the qualified exemption that was withdrawn. We also considered legal arguments presented by the commenter that opposed reinstatement of a qualified exemption. We have tentatively concluded that the absence of a specific provision in FSMA for the reinstatement of a qualified exemption that was withdrawn does not preclude FDA from providing for such a process if FDA determines that continued withdrawal is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

Therefore, proposed § 112.213 would list the process under which FDA would reinstate a qualified exemption that was withdrawn. Specifically, this new provision would establish that if the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) determines that the farm has adequately resolved problems with the conduct or conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) shall, on his own initiative or at the request of a farm, reinstate the qualified exemption (proposed § 112.213(a)). FDA would then notify the owner, operator, or agent in charge of the farm of such reinstatement of the qualified exemption.

In addition, proposed § 112.213(b) would provide that a farm may request FDA to reinstate a qualified exemption that has been withdrawn under the procedures of subpart R using the following procedure: (1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) and (2) present, in writing, data and information to demonstrate that you have adequately resolved the problems with the conduct or conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

Under proposed § 112.213(c), we are proposing that if your qualified exemption is withdrawn under § 112.201(a)(1) (*i.e.,* in the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm), and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

Finally, under proposed § 112.213(d), we are proposing that if your qualified exemption is withdrawn under both § 112.201(a)(1) (i.e., in the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm) and § 112.01(a)(2) (*i.e.,* if we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm), and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of proposed § 112.213(b). Unlike under the provisions of proposed § 112.213(c) where FDA would on its own initiative reinstate the qualified exemption, under this proposed provision § 112.213(d) we are proposing that the owner, operator, or agent in charge of the farm submit a request (in accordance with proposed § 112.213(b)) to demonstrate that the problems with the conduct or conditions associated with the farm that formed the basis, in part, for the withdrawal have been adequately resolved and that these corrections will be maintained if the exemption is reinstated.

We seek comment on our tentative decision to provide for reinstatement of a qualified exemption that is withdrawn, the proposed circumstances under which FDA would reinstate the qualified exemption, and the proposed procedures for such reinstatement.

3. Summary of FDA's Revisions and Request for Comment

We are proposing to: (1) Add a new proposed provision § 112.201(b)(1) to establish that, before FDA issues an order to withdraw a qualified exemption, FDA may consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction; (2) add new proposed provisions §§ 112.201(b)(2) and 112.201(b)(3) to establish that, before FDA issues an order to withdraw a qualified exemption, FDA must notify the farm of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the farm to respond to FDA's notification; and that FDA must consider actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption; (3) make corresponding amendments to proposed §§ 112.202(a) and 112.202(b) to clarify the procedure for issuing an order to withdraw a qualified exemption; and (4) add a new proposed

provision § 112.213 to list the circumstances under which FDA would reinstate a farm's qualified exemption that is withdrawn.

We seek comment on our new and amended proposed provisions, including our tentative decision that we may consider other actions, as appropriate, and we must provide certain specified intermediate steps before issuing an order to withdraw a qualified exemption. We also seek comment on our tentative decision to provide for reinstatement of a qualified exemption that is withdrawn, the proposed circumstances under which FDA would reinstate the qualified exemption, and the proposed procedures for such reinstatement.

Finally, in the amendments to the Preventive Controls for Human Food proposed rule, we are proposing to amend the timeframe for a facility to comply with an order to withdraw an exemption from the previous proposed ''within 60 days of the date of the order'' to ''within 120 days of the date of receipt of the order'' (see section XIII.D. of that document). We seek comment on whether, similar to these amendments to proposed part 117, we should amend the relevant provisions in proposed part 112 (*i.e.,* proposed §§ 112.203(d), 112.204(a), 112.205(b)), which would require compliance within 60 calendar days of the date of the order, to require that a farm comply with an order to withdraw its qualified exemption within 120 days of the date of receipt of the order.

III. Preliminary Regulatory Impact Analysis

A. Overview

As explained in the Produce Safety proposed rule, FDA performed the necessary analyses to examine the impacts of the previously published proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). FDA also provided the analyses for public input (78 FR 3504 at 3616).

We performed additional analyses to examine the impacts of the amended and new proposed provisions described in this document under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct 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). The Agency believes that this proposed rule is a significant regulatory action as defined by Executive Order 12866. We present our additional analyses, including the total estimated costs and benefits of the Produce Safety proposed rule as amended (Ref. 41). We seek comment on our additional analyses.

B. Regulatory Flexibility Analysis

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 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 rule on small entities consistent with statutory objectives. FDA tentatively concludes that the proposed rule will have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) defines farms involved in crop production as ''small'' if their total revenue is less than $750,000 (Ref. 42). Approximately 95 percent of all farms that grow covered produce are considered small by the SBA definition.

The proposed rule reduces the burden on small entities in part through the use of exemptions: Certain small entities are eligible for a qualified exemption based on average monetary value of food sold and direct sales to qualified end users (proposed § 112.5). The proposed rule additionally reduces the burden on small entities by not covering farms with $25,000 or less of average annual monetary value of produce sold (proposed § 112.4(a)).

The proposed rule additionally provides all farms flexibility for alternative practices to be used for certain listed requirements with adequate scientific support. The proposed rule also provides for States and foreign countries to submit a request for a variance for one or more requirements of the proposed rule. To be granted, the procedures, processes, and practices to be followed under the variance must be reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of the proposed rule.

Farms defined as small businesses have an additional 2 years to comply with most provisions of the rule after the effective date of FDA's final rule and farms defined as very small businesses have an additional 3 years. There is also an extended 2-year compliance period for certain proposed provisions for water quality in § 112.44 and related provisions in §§ 112.45 and 112.50 (specifically, §§ 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7)). The extended compliance dates for these specific water quality standards would then be 4 years from the effective date for small businesses and 5 years from the effective date for very small businesses.

For a more detailed description of the full regulatory flexibility options offered for this proposed rule, see the Preliminary Regulatory Impact Analysis (PRIA) (Ref. 43).

C. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement including an assessment of anticipated costs and benefits before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the 2012 Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this proposed rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on: Future costs; particular regions, communities, or industrial sectors; national productivity; economic growth; full employment; job creation; and exports.

The issues listed above are covered in detail in the cost benefit analysis of the preceding sections and in the PRIA (Ref. 43).

D. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 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 or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity,

or innovation; or significant adverse effects on the ability of U.S.-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 is a major rule for the purpose of congressional review.

IV. 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 and reporting burdens. 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: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.

Description: Section 105 of the FDA Food Safety and Modernization Act requires that ''not later than 1 year after the date of enactment, . . . shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death . . .''

Description of Respondents: The proposed rule applies to farms that grow produce, meaning fruits and vegetables such as berries, tree nuts, herbs, and sprouts. There are 40,211 farms in the United States, the District of Columbia, and the Commonwealth of Puerto Rico, excluding sprouting operations (Ref. 44), that would be covered by the proposed rule. We estimate that there are approximately 285 sprouting operations covered by this proposed rule.

The information collection estimate for the produce safety proposed rule will change due to the number of farms that are affected by the requirements and the revised testing requirements for agricultural water. Table 2 provides the revised estimates of the recordkeeping burden associated with supplemental requirements. The information collection estimate for the produce safety proposed rule was 1,289,959 annual hours, when the number of covered farms was 40,211. Under this supplemental codified, the number of covered farms is 35,503. After accounting for the decreased recordkeeping burden due to the lower number of farms, and the increased average hourly burden due to new records that may accompany the relaxed requirement for water usage and application intervals after, we estimate that it will take farms a total of 1,197,369 hours to collect information under this supplemental notice. This represents an annual hourly savings of 92,590 hours and approximately $5.16 million. For full information on the calculation of all recordkeeping hourly burdens please refer to the original PRA (Ref. 43). Estimates of two new information collections are presented in Table 2: §§ 112.50(b)(8) and 112.50(b)(9).

Section 112.50(b)(8) of this supplemental notice requires scientific data or information farms rely on to determine the time interval (in days) between harvest and end of storage and/or other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *E. coli,* in accordance with § 112.44(c)(2). Currently, no information is available to the Agency to estimate how many farms would choose to apply a post-harvest time interval that would require them to keep records to comply with § 112.50(b)(8). We do not expect this number to be zero annually, nor do we expect the number to be very large. We believe that farms are more likely to use the pre-harvest interval option offered in proposed § 112.44(c)(1), which would not require additional recordkeeping, where the farm applies the proposed microbial die-off rate to calculate an appropriate time interval. Based on our current understanding of operations in the produce industry, for the purposes of this analysis, it is estimated that, annually, 100 farms would choose to apply a post-harvest time interval as a result of this supplemental notice. We estimate that these farms will spend .33 hour (20 minutes) annually to obtain and maintain this documentation. Therefore, 100 records × .33 hour = 33 annual hours for farms to comply with this requirement. We acknowledge the uncertainty in these estimates. We request comment on the number of farms that would choose to apply a post-harvest time interval and the time needed to comply with this recordkeeping requirement.

Section 112.50(b)(9) of this supplemental notice requires scientific data or information you rely on to support your testing frequency for untreated surface water used for purposes that are subject to the requirements of § 112.44(a). No information is currently available that would allow us to estimate the number of farms that would be subject to this requirement. However, we expect that it would be extremely rare for a farm to use untreated surface water for activities, such as hand washing, that would be subject to the requirements of § 112.44(a). Therefore, for the purposes of this analysis, we estimate that one farm per year will engage in activity related to the requirement of § 112.50(b)(9) and that this farm will spend .33 hour (20 minutes) annually to obtain and maintain this documentation. Therefore, 1 record × .33 hour = .33 annual hours. We acknowledge the uncertainty in these estimates. We request comment on the number of farms that would use untreated surface water for purposes listed in § 112.44(a) (such as hand washing), and the time needed to comply with this recordkeeping requirement.

TABLE 2—NEW RECORDKEEPING HOURLY BURDENS

Documentation of Scientific Data to Support Time Interval Between Last Irrigation and End of Storage						
112.50(b)(8)	100	1	100	.33	33	$0
Documentation of Scientific Data to Support Testing Frequency for Untreated Surface Water Used for Purposes Subject to § 112.44(a)						
112.50(b)(9)	1	1	1	.33	.33	$0

V. Analysis of Environmental Impact

In publishing the Produce Safety proposed rule, we relied on a categorical exclusion from the need to prepare an EA or EIS under 21 CFR 25.30(j) (78 FR 3504 at 3616). However, as explained in the NOI, based on currently available information, including comments received, and upon further analysis, FDA has determined that the proposed action may significantly affect the quality of the human environment (21 CFR 25.22(b)), and therefore, an EIS is necessary for the final rule (78 FR 50358, August 19, 2013). Accordingly, FDA is in the process of preparing an EIS and, under that process, expects to provide a draft EIS for public comment prior to preparing a final EIS document and issuing the Record of Decision.

VI. Comments

Interested persons may submit either electronic comments regarding the specific issues identified for public comment in this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

VII. 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. These references are also available electronically at *http://www.regulations.gov.* (We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

1. Taylor, M., ''Your Input Is Bringing Change to Food Safety Rules,'' (*http://blogs.fda.gov/fdavoice/index.php/tag/produce-safety-rule/),* December 19, 2013. Accessed and printed on March 14, 2014.
2. Taylor, M., ''Getting Importers' Pulse About Food Safety Plans,'' (*http://blogs.fda.gov/fdavoice/index.php/tag/fda-food-safety-modernization-act-of-2011-fsma/),* November 4, 2013. Accessed and printed on March 14, 2014.
3. Taylor, M., ''We're Partnering With Mexico to Keep Foods Safe,'' (*http://blogs.fda.gov/fdavoice/index.php/2013/11/were-partnering-with-mexico-to-keep-foods-safe/),* November 14, 2013. Accessed and printed on March 14, 2014.
4. Taylor, M., ''Statement From FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers,'' (*http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm379397.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery),* December 19, 2013. Accessed and printed on March 14, 2014.
5. FDA, ''Title 21 of the Code of Federal Regulations, Proposed Part 112—Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Tracked Changes Compared to Proposed Part 112 issued on January 16, 2013,'' September 2014.
6. Cooley, M., D. Carychao, L. Crawford-Miksza, et al., ''Incidence and Tracking of *Escherichia Coli* O157:H7 in a Major Produce Production Region in California,'' *PLoS One,* 2:e1159, 2007.
7. Gemmell, M. E. and S. Schmidt, ''Is the Microbiological Quality of the Msunduzi River (KwaZulu-Natal, South Africa) Suitable for Domestic, Recreational, and Agricultural Purposes?,'' *Environmental Science and Pollution Research,* 20:6551–6562, 2013.
8. Holvoet, K., I. Sampers, M. Seynnaeve, and M. Uyttendaele, ''Relationships Among Hygiene Indicators and Enteric Pathogens in Irrigation Water, Soil and Lettuce and the Impact of Climatic Conditions on Contamination in the Lettuce Primary Production,'' *International Journal of Food Microbiology,* 171:21–31, 2014.
9. EPA, ''Ambient Water Quality Criteria for Bacteria—1986,'' 1986.
10. FDA and Interstate Shellfish Sanitation Conference, ''National Shellfish Sanitation Program: Guide for the Control of Molluscan Shellfish—2009 Revision,'' 2011.

11a. WHO, ''WHO Guidelines for the Safe Use of Wastewater, Excreta and Greywater,'' 2006.

11b. WHO, ''Guidelines for Drinking-Water Quality—Second Edition,'' 1997.

12. National Resource Management Ministerial Council, Environment Protection and Heritage Council, and Australian Health Ministers' Conference, ''National Water Quality Management Strategy: Australian Guidelines for Water Recycling: Managing Health and Environmental Risks (Phase 1),'' 2006.
13. Ravaliya, K., Marianne, F., and Snellman, E., ''Memorandum to the File—Review of Water Quality Standards in Development of Proposed Microbial Standard in § 112.44(c) of the Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,'' September 2014.
14. EPA, ''Recreational Water Quality Criteria,'' 2012.
15. Beuchat, L. R., ''Ecological Factors Influencing Survival and Growth of Human Pathogens on Raw Fruits and Vegetables,'' *Microbes and Infection,* 4:413–423, 2002.
16. Islam, M., M. P. Doyle, S. C. Phatak, et al., ''Persistence of Enterohemorrhagic *Escherichia Coli* O157:H7 in Soil and on Leaf Lettuce and Parsley Grown in Fields Treated With Contaminated Manure Composts or Irrigation Water,'' *Journal of Food Protection,* 67:1365–1370, 2004.
17. Snellman, E., Marianne, F., Ravaliya, K., and Assar, S., ''Memorandum to the File—Review of Microbial Decay Constants Reported in Field Trials of Contaminated Produce,'' September 2014.
18. WHO, *Monitoring Bathing Waters—A Practical Guide to the Design and Implementation of Assessments and Monitoring Programmes,* edited by J. Bartram and G. Rees, London, E & FN Spon, 2000.
19. Kay, D., J. Bartram, A. Pruss, et al., ''Derivation of Numerical Values for the World Health Organization Guidelines for Recreational Waters,'' *Water Research,* 38:1296–1304, 2004.
20. Wyer, M. D., D. Kay, J. M. Fleisher, et al., ''An Experimental Health-Related Classification for Marine Waters,'' *Water Research,* 33:715–722, 1999.
21. Bowers, J., ''Memorandum to the File—Minimum Sample Size for Surveys of Water Quality of Surface Water Sources to be Used for Agricultural Water,'' September 2014.
22. Ingham, S. C., M. A. Fanslau, R. A. Engel, et al., ''Evaluation of Fertilization-to-Planting and Fertilization-to-Harvest Intervals for Safe Use of Noncomposted Bovine Manure in Wisconsin Vegetable Production,'' *Journal of Food Protection,* 68:1134–1142, 2005.
23. Hutchison, M. L., L. D. Walters, T. Moore, et al., ''Fate of Pathogens Present in

Livestock Wastes Spread Onto Fescue Plots,'' *Applied and Environmental Microbiology,* 71:691–696, 2005.
24. Rosen, C. J. and P. M. Bierman, ''Nutrient Management for Fruit & Vegetable Crop Production: Using Manure and Compost As Nutrient Sources for Vegetable Crops,'' 2005.
25. Goss, M. J., A. Tubeileh, and D. Goorahoo, *A Review of the Use of Organic Amendments and the Risk to Human Health,* 2013.
26. Ketterings, Q. M., G. Albrecht, K. Czymmek, and S. Bossard, ''Agronomy Fact Sheet Series: Nitrogen Credits From Manure,'' 2005.
27. Hue, N. V. and J. A. Silva, ''Organic Soil Amendments for Sustainable Agriculture: Organic Sources of Nitrogen, Phosphorus and Potassium,'' in *Plant Nutrient Management in Hawaii's Soils, Approaches for Tropical and Subtropical Agriculture,* Manoa, Chapter 15, pp. 133–144, University of Hawaii, 2000.
28. Spargo, J. T., M. A. Cavigelli, S. B. Mirsky, et al., ''Mineralizable Soil Nitrogen and Labile Soil Organic Matter in Diverse Long-Term Cropping Systems,'' *Nutrient Cycling in Agroecosystems,* 90:253–266, 2011.
29. Russo, V. M. and M. Taylor, ''Frequency of Manure Application in Organic Versus Annual Application of Synthetic Fertilizer in Conventional Vegetable Production'' *Hortscience,* 45:1673–1680, 2010.
30. Miller, J. J., E. C. S. Olson, D. S. Chanasyk, et al., ''Phosphorus and Nitrogen in Rainfall Simulation Runoff After Fresh and Composted Beef Cattle Manure Application,'' *Journal of Environmental Quality,* 35:1279–1290, 2006.
31. Rynk, R., M. van de Kamp, G. B. Wilson, et al., *On-Farm Composting Handbook,* edited by R. Rynk, USDA Northeast Regional Agricultural Engineering Service Cooperative Extension, 1992.
32. Bonanomi, G., V. Antignani, C. Pane, and E. Scala, ''Suppression of Soilborne Fungal Diseases With Organic Amendments,'' *Journal of Plant Pathology,* 89:311–324, 2007.
33. Mohler, C. L. and S. E. Johnson, *Crop Rotation on Organic Farms: A Planning Manual, NRAES 177,* edited by C. L. Mohler and S. E. Johnson, Ithaca, Natural Resource, Agriculture and Engineering, 2009.
34. EPA, ''Composting: Environmental Benefits,'' (*http://www.epa.gov/composting/benefits.htm),* May 13, 2013. Accessed and printed on March 14, 2014.
35. Coleman, P., ''USDA Organic: Guide for Organic Crop Producers,'' (*http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101542),* November, 2012. Accessed and printed on March 14, 2014.
36. NRCS, *Part 637 Environmental Engineering National Engineering Handbook: Chapter 2 Composting,* USDA, 2000.
37. USDA and NRCS, ''Nutrient Management Technical Note No. 7: Reducing Risk of *E. Coli* O157:H7 Contamination,'' 2007.
38. EPA, ''Resource Conservation: Composting for Facilities Basics,'' (*http://www.epa.gov/epawaste/conserve/composting/basic.htm),* May 16, 2013. Accessed and printed on March 14, 2014.
39. Organic Trade Association, ''Manure Facts,'' (*http://www.ota.com/organic/foodsafety/manure.html),* June 7, 2011. Accessed and printed on March 14, 2014.
40. Resource Conservation District of Monterey County, *Handbook of Agricultural Conservation Practices, Photos and Descriptions with Food Safety Considerations,* edited by S. Ruffoni and N. Strong-Cvetich, 3rd ed., 2012.
41. FDA, ''Supplemental Notice of Proposed Rulemaking: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Economic Impact Analysis,'' September 2014.
42. ''Small Business Administration Gopher Server,'' (*http://www.sba.gov/content/small-business-size-standards),* 2014. Accessed and printed on September 4, 2014.
43. FDA, ''Analysis of Economic Impacts: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption,'' (*http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf),* 2013. Accessed and printed on September 4, 2014.
44. USDA, ''Census of Agriculture, 2007,'' (*http://www.agcensus.usda.gov/Publications/2007/Getting_Started/Guide_to_Census_Products/),* 2011. Accessed and printed on September 3, 2014.

List of Subjects in 21 CFR Part 112

Foods, Fruits and vegetables, Packaging and containers, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR Chapter I, as proposed to be added on January 16, 2013 (78 FR 3504), be further amended as follows:

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 112 continues to read as follows

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A—[Amended]

■ 2. In § 112.3, revise paragraphs (b)(1) and (b)(2) and in paragraph (c), revise the definitions for ''*Covered activity,*'' ''*Farm,*'' ''*Harvesting,*'' ''*Holding,*'' and ''*Packing*'' to read as follows:

§ 112.3 What definitions apply to this part?

* * * * *

(b) * * *

(1) *Very small business.* For the purpose of this part, your farm is a very small business if it is subject to this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $250,000.

(2) *Small business.* For the purpose of this part, your farm is a small business if it is subject to this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than $500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) * * *

* * * * *

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of ''farm'' as defined in this chapter. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

* * * * *

Farm means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes establishments that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a

distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

* * * * *

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.,* activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (*e.g.,* activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 3. In § 112.4, revise the first sentence of paragraph (a) to read as follows:

§ 112.4 Who is subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of produce (as ''produce'' is defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a ''covered farm'' subject to this part.* * *

* * * * *

Subpart B—[Amended]

■ 4. Section 112.12, is amended by adding the phrase ''as provided in § 112.44(d) and'' at the end of paragraph (a)(1); by removing '';'' and adding it its place ''.'' at the end of paragraph (a)(2); and by removing paragraphs (a)(3) and (a)(4).

Subpart E—[Amended]

■ 5. Section 112.44, is amended by revising paragraphs (c) and (d) to read as follows:

§ 112.44 What testing is required for agricultural water, and what must I do based on the test results?

* * * * *

(c) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N to develop and verify the water quality profile of the water source as described in § 112.45(b)(1). Using your water quality profile as described in § 112.45(b)(1), if you find that (when applicable) the estimate of the statistical threshold value (STV) of samples exceeds 410 colony forming units (CFU) of generic *E. coli* per 100 mL of water, or if you find that the geometric mean (GM) of samples exceeds 126 CFU of generic *E. coli* per 100 mL of water (or an alternative microbial standard consistent with paragraph (d)(1) of this section), you must either:

(1) Apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (or an alternative microbial die-off rate consistent with paragraph (d)(2) of this section) to achieve a (calculated) log reduction of your geometric mean of generic *E. coli* level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL, or an alternative microbial standard consistent with paragraph (d)(1) of this section;

(2) Apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of your geometric mean of generic *E. coli* level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL (or an alternative microbial standard consistent with paragraph (d)(1) of this section), provided you have adequate supporting scientific data and information. You may apply this time interval in addition to the time interval in accordance with paragraph (c)(1) of this section; or

(3) If options (c)(1) or (c)(2) are not selected, immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either reinspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

(d) You may establish and use alternatives to the following requirements provided you satisfy the requirements of § 112.12:

(1) Microbial quality standard established in paragraph (c) of this section; and

(2) Microbial die-off rate established in paragraph (c)(1) of this section that is used to determine the time interval between last irrigation and harvest.

■ 6. Section 112.45, is revised to read as follows:

§ 112.45 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:

(1) You receive water from a public water system, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water

supply program, and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

(b) If you use untreated surface water for purposes that are subject to the requirements of § 112.44(c), you must take the following steps for each source of the untreated surface water:

(1) Conduct a baseline survey to develop a water quality profile of the agricultural water source.

(i) You must conduct a baseline survey in order to initially develop the water quality profile of your water source. You must determine the appropriate way(s) in which the water may be used based on your water quality profile in accordance with § 112.44(c)(1) through (3).

(ii) The baseline survey must be conducted over a minimum period of 2 years by calculating the geometric mean (GM) and the statistical threshold value (STV) of generic *Escherichia coli* (*E. coli)* (colony forming units (CFU) per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. The water quality profile initially consists of the GM and STV of generic *E. coli* calculated using this data set.

(iii) You must develop a new water quality profile:

(A) At least once every 10 years by recalculating the GM and STV values using a minimum total of 20 samples collected during your most recent annual surveys (which are required under paragraph (b)(2) of this section); and

(B) When required under paragraphs (b)(2) and (b)(3) of this section.

(2) Conduct an annual survey to verify the water quality profile of your agricultural water.

(i) After the baseline survey described in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, you must test the water annually to verify your existing water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze a minimum number of five samples per year, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest.

(ii) If the GM and/or STV values of the annual survey samples do not support your water quality profile and therefore your existing water use as specified in § 112.44(c), you must develop a new water quality profile and, as appropriate, modify your water use based on the new water quality profile in accordance with § 112.44(c)(1) through (3) as soon as practical and no later than the following year. To develop a new water quality profile, you must calculate new GM and STV values using either:

(A) Your current annual survey data, combined with your most recent baseline or annual survey data from prior years, to make up a data set of at least 20 samples; or

(B) Your current annual survey data, combined with new data, to make up a dataset of at least 20 samples; and

(3) If you know or have reason to believe that your water quality profile no longer represents the quality of your water for reasons other than those in paragraph (b)(2) of this section (for example, if there are significant changes in adjacent land use, erosion, or other impacts to water outside your control that are reasonably likely to adversely affect the quality of your water source), you must develop a new water quality profile. To develop a new water quality profile, you must calculate new GM and STV values using your current annual survey data, combined with new data, to make up a data set of at least 20 samples. Then, as required by § 112.44(c)(1) through (3), you must modify your water use based on the new water quality profile as soon as practical and no later than the following year.

(c) If you use untreated ground water for purposes that are subject to the requirements of § 112.44, you must test the quality of each source of the water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected during a time period(s) as close as practical to harvest. If the samples tested meet the applicable microbial standard of § 112.44 (*i.e.,* no detectable generic *E. coli* per 100 mL under 112.44(a) or a geometric mean of generic *E. coli* of 126 CFU or less per 100 mL under 112.44(c), as applicable), you may test once annually thereafter, using a minimum of one sample collected during a time period as close as practical to harvest. You must resume testing at least four times per growing season or year if any annual test fails to meet the applicable microbial standard in § 112.44.

(d) If you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard. You must have adequate scientific data or information to support your testing frequency.

(e) You may meet the requirements related to agricultural water testing required under paragraphs (b), (c), and (d) of this section using:

(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or

(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.

■ 7. Section 112.50, is amended by adding new paragraphs (b)(8) and (b)(9) to read as follows:

§ 112.50 Under this subpart, what requirements apply regarding records?

* * * * *

(b) * * *

(8) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that is used to determine the time interval (in days) between harvest and end of storage and/or other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *E.coli* in accordance with the provision in § 112.44(c)(2); and

(9) Scientific data or information you rely on to support your testing frequency for untreated surface water used for purposes that are subject to the requirements of § 112.44(a).

Subpart F—[Amended]

■ 8. Section 112.56 is amended by removing from paragraph (a)(1)(i) the phrase ''9 months'' and adding in its place the phrase ''Reserved''; removing from paragraph (a)(4)(i) the phrase ''45 days'' and adding in its place the phrase ''0 days''; and removing and reserving paragraph (b).

■ 9. Section 112.60 is amended by removing paragraphs (b)(1) and (b)(5) and redesignating paragraphs (b)(2), (b)(3), and (b)(4) as paragraphs (b)(1), (b)(2), and (b)(3), respectively.

Subpart I—[Amended]

■ 10. Add § 112.84 to read as follows:

§ 112.84 Does this regulation require covered farms to take actions that would constitute a ''taking'' of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the ''taking'' of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (*i.e.,* to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Subpart P—[Amended]

■ 11. Section 112.182, is amended by removing '';'' and adding in its place ''.'' at the end of paragraph (c) and removing paragraphs (d) and (e).

Subpart R—[Amended]

■ 12. Section § 112.201, is revised to read as follows:

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

(a) We may withdraw your qualified exemption under § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

(b) Before FDA issues an order to withdraw your qualified exemption, FDA:

(1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 10 calendar days of the date of the notification, to FDA's notification; and

(3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

■ 13. Section 112.202 is revised to read as follows:

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

■ 14. Add § 112.213 to read as follows:

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) shall, on his own initiative or at the request of a farm, reinstate the qualified exemption.

(b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN); and

(2) Present, in writing, data and information to demonstrate that you have adequately resolved the problems with the conduct or conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (a)(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

Dated: September 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–22447 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL REGISTER

Vol. 79 Monday,

No. 188 September 29, 2014

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 117, and 507

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 117, and 507

[Docket No. FDA–2011–N–0922]

RIN 0910–AG10

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend our 2013 proposed rule for Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. In that 2013 proposed rule, we proposed to add CGMP requirements for animal food and to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. We are taking this action because the input we have received from public comments has led to significant changes in our current thinking on certain key provisions of this proposed rule. We are reopening the comment period only with respect to specific issues identified in this proposed rule.

DATES: Submit either electronic or written comments on the proposed rule by December 15, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 15, 2014 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No 2011–N–0922 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, 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.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kim Young, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9207, email: *kim.young@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
- Purpose and Coverage of the Supplemental Notice of Proposed Rulemaking
- Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking
- Costs and Benefits

I. Background
- A. Introduction
- B. 2013 Proposed Rule for Preventive Controls for Food for Animals

II. Public Comments
- A. Opportunities for Public Comment
- B. Overview of Public Comments on the 2013 Proposed Rule for Preventive Controls
- C. Our Decision To Issue a Supplemental Notice of Proposed Rulemaking for Public Comment

III. Scope of the Supplemental Notice of Proposed Rulemaking and Our Request for Public Comment

IV. Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act

V. The ''Farm'' Definition
- A. 2013 Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''
- B. Proposed Revisions to the Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''
- C. One General Physical Location
- D. Feed Mills Associated With Contract and Fully Vertically Integrated Farming

VI. Definitions of ''Holding'' and ''Packing''
- A. 2013 Proposed Definition of ''Holding''
- B. 2013 Proposed Exemptions Relevant to the Definition of ''Holding''
- C. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of RACs (Other Than Fruits and Vegetables) Intended for Further Distribution or Processing
- D. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment
- E. Proposed Revisions to the Definition of ''Holding''
- F. Proposed Revisions to the Definition of ''Packing''

VII. Impact of the Proposed Revisions to the Farm-Related Definitions on the Classification of On-Farm Activities
- A. Comments on the 2013 Organizing Principles for Classifying Activities Conducted on Farms and on Farm Mixed-Type Facilities
- B. Updated Organizing Principles That Would Apply to the ''Farm'' Definition
- C. Changes to Classification of On-Farm Activities

VIII. Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations
- A. The 2013 Proposed Exemptions
- B. Comments on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations
- C. Impact of the Proposed Revisions to the Definitions for ''Farm,'' ''Harvesting,'' Holding,'' and ''Packing'' on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations

IX. Proposed Applicability of Part 507 to the Holding and Distribution of Human Food By-Products for Use in Animal Food

X. Proposed Revisions to Subpart B—Current Good Manufacturing Practice

XI. Overall Framework for Hazard Analysis and Risk-Based Preventive Controls
- A. 2013 Proposed Overall Framework for Hazard Analysis and Risk-Based Preventive Controls
- B. Comments on the ''Reasonably Likely To Occur'' Construct Within the 2013 Overall Framework for Hazard Analysis and Risk-Based Preventive Controls
- C. Proposed Revisions to the Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

XII. Potential Requirements for Product Testing and Environmental Monitoring
- A. Our Request for Comment on Including Requirements for Product Testing and Environmental Monitoring in a Final Rule
- B. Product Testing
- C. Environmental Monitoring

XIII. Potential Requirements for a Supplier Program
- A. Our Request for Comment on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act
- B. Comments on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the

Statutory Framework of Section 418 of the FD&C Act
C. Potential Requirements for a Supplier Program
D. Request for Additional Comment on Requirements To Address Conflicts of Interest for Persons Conducting Verification Activities
XIV. Potential Requirements for the Hazard Analysis To Address Economically Motivated Adulteration
A. Our Request for Comment on Whether the Final Rule Should Address Economically Motivated Adulteration
B. Comments on Economically Motivated Adulteration
C. Potential Requirements To Address Economically Motivated Adulteration
XV. Provisions for Withdrawal of an Exemption for a Qualified Facility
A. 2013 Proposed Provisions for Withdrawal of an Exemption for a Qualified Facility
B. Proposed Clarification of What FDA Will Do Before Issuing an Order and Proposed Mechanism for Re-Instating an Exemption
C. Proposed Revisions to the Content of an Order To Withdraw an Exemption
D. Proposed Revisions to the Timeframes for a Facility To Comply With, or Appeal, an Order
XVI. Definition of Very Small Business
A. The 2013 Proposed Options for Definition of Very Small Business
B. Comments on the 2013 Proposed Options for Definition of Very Small Business
C. Proposed Revisions to the Definition of Very Small Business
XVII. Other New and Revised Proposed Provisions
A. Proposed New Definitions
B. Proposed Revisions to Definitions
C. Proposed Editorial Changes
D. Proposed Conforming Change to Proposed Part 117
XVIII. Preliminary Regulatory Impact Analysis
A. Overview
B. Regulatory Flexibility Act
C. Small Business Regulatory Enforcement Fairness Act of 1996
D. Unfunded Mandates Reform Act of 1995
XIX. Paperwork Reduction Act of 1995
XX. Analysis of Environmental Impact
XXI. Comments
XXII. References

Executive Summary

Purpose and Coverage of the Supplemental Notice of Proposed Rulemaking

We previously proposed to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals, as required by the FDA Food Safety Modernization Act (FSMA). The proposed requirements would apply to establishments that are required to register with us as an animal food ''facility.'' In this document we are proposing to revise several previously proposed requirements, taking into account the comments we have reviewed so far for the proposed rule for preventive controls for food for animals and the proposed rule for preventive controls for human food, because the extensive input we have received from public comments has led to significant changes in our current thinking on certain key provisions.

In the 2013 proposed rule, we asked for comment on when and how three provisions (i.e., product testing programs, environmental monitoring programs, and supplier programs) are an appropriate means of implementing the statutory directives of FSMA. We also requested comment on whether a facility should be required to address potential hazards that may be intentionally introduced for economic reasons. Some comments received to the 2013 proposed rule assert that additional public comment is warranted before consideration is given to whether a final rule includes or does not include provisions that were discussed in the 2013 proposal but for which we had not included regulatory text in the 2013 proposal. In this document we are providing an opportunity for such public comment on potential requirements for product testing programs, environmental monitoring programs, and supplier programs, and hazards that may be intentionally introduced for purposes of economic gain, which take into account the comments we have reviewed so far. We are seeking comment on whether such requirements should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate.

In the 2013 proposed rule, we requested comment on three options for classifying a facility as a ''very small business,'' with consequences for facilities in terms of eligibility for exemptions and the timeframe to comply with this rule. In this document we are proposing a definition for ''very small business'' (i.e., a business that has less than $2,500,000 in total annual sales of animal food adjusted for inflation).

We are proposing a revised version of the 2013 proposed current good manufacturing practice regulations. In addition, we added a section to the proposed current good manufacturing practice regulations for holding and distribution of human food by-products for food for animals. This would apply to human food facilities that hold and distribute by-products from the human food production that are used for food for animals.

Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking

The previously proposed (2013) current good manufacturing practice requirements (CGMPs) were based, in general, on FDA's existing human food CGMP regulations. The revised proposed CGMPs for food for animals would establish baseline standards for producing safe animal food that are more applicable to the animal food industry and that provide flexibility for the wide diversity in types of animal food facilities. Human food processors already complying with FDA human food safety requirements would not need to implement additional preventive controls or Current Good Manufacturing Practice regulations when supplying a by-product, except those proposed for the holding and distribution of certain human food by-products for food for animals (e.g., ensuring by-product is not co-mingled with garbage). Under the revised proposal, all other requirements of part 507, including the hazard analysis and preventive controls requirements, would not apply to these by-products of human food production.

The previously proposed requirements for hazard analysis and risk-based preventive controls applied a construct previously used in our Hazard Analysis and Critical Control Point (HACCP) regulations for seafood and juice—i.e., whether a known or reasonably foreseeable hazard was ''reasonably likely to occur.'' In general, our HACCP regulations for seafood and juice focus on critical control points to control hazards that are ''reasonably likely to occur.'' We are proposing to eliminate the term ''hazard reasonably likely to occur'' throughout the proposed requirements to reduce the potential for a misinterpretation that all necessary preventive controls must be established at critical control points (CCPs). The revised regulations would use a new term (''significant hazard'') in its place.

The defined term ''significant hazard'' would be linked to the facility's hazard analysis, which addresses risk (i.e., both the severity of a potential hazard and the probability that the hazard will occur). Thus, this term would reflect the risk-based nature of the requirements. In addition, the revised regulations would provide additional flexibility relative to the previous proposal by providing that a facility can take into account the nature of a preventive control in determining when and how to establish and implement appropriate preventive control management components,

including monitoring, corrections or corrective actions, verification, and records. Table 6 in the document provides examples of flexibility provided by the rule, including flexibility provided for a facility to take into account the nature of the preventive control when determining the appropriate preventive control management components.

The potential product testing provisions would, if included in a final rule, require that a facility conduct product testing as an activity for verification of implementation and effectiveness as appropriate to the facility, the animal food, and the nature of the preventive control. The facility would be required to have written procedures for product testing, corrective action procedures to address the presence of a pathogen or appropriate indicator organism in finished animal food detected as a result of product testing, and records of product testing.

The potential environmental monitoring provisions would, if included in a final rule, require that a facility conduct environmental monitoring as an activity for verification of implementation and effectiveness as appropriate to the facility, the animal food, and the nature of the preventive control if contamination of finished animal food with an environmental pathogen is a significant hazard. The facility would be required to have written procedures for environmental monitoring, corrective action procedures to address the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring, and records of environmental monitoring.

The potential supplier program would, if included in a final rule, require supplier controls when the facility's hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient (e.g., if a supplier tests a mineral mix for dioxin that a facility would use to manufacture finished cattle feed). A facility would not need to establish supplier controls if it controls that hazard, or if its customer controls that hazard. The supplier program would be written. With one exception, the receiving facility would have flexibility to determine the appropriate verification activity (e.g., onsite audit; sampling and testing of the raw material or ingredient; review of the supplier's food safety records; or other appropriate verification activity). The exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. In this circumstance, the receiving facility would be required to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter, unless the receiving facility determines and documents that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted.

The proposed requirements regarding potential hazards that may be intentionally introduced for economic reasons would, if included in a final rule, require that a facility consider in its hazard analysis hazards that may be intentionally introduced for purposes of economic gain.

We seek comment on whether these potential requirements discussed above should be included in a final rule.

The previously proposed requirements provided for an exemption for certain facilities defined by FSMA as ''qualified facilities.'' As required by FSMA, the previously proposed requirements also included an administrative procedure whereby we could withdraw that exemption under certain circumstances. In this document, we are proposing a series of modifications to the proposed withdrawal provisions. These modifications include describing the steps we would take before withdrawing an exemption, including advance notification to the facility; a procedure for re-instatement of a withdrawn exemption; and an additional 60 days for a facility whose exemption is withdrawn to comply with the full requirements for hazard analysis and risk-based preventive controls.

Costs and Benefits

We summarize the domestic annualized costs of the proposed regulation with the revised provisions, including the potential requirements for product testing, environmental monitoring, a supplier program, and potential requirements regarding hazards that may be intentionally introduced for economic reasons, using a discount rate of 7 percent and discounted over a 10 year period in the following table. The revised proposed regulation uses a very small business definition of less than $2,500,000 of total annual sales of animal food, adjusted for inflation, and includes potential additional requirements that facilities subject to subpart C institute risk-based environmental monitoring, product testing, and a supplier program as appropriate to the animal food, the facility and the nature of the preventive controls, and controls to help prevent hazards associated with economically motivated adulteration. As described in the updated Preliminary Regulatory Impact Analysis (PRIA), for the final rule we anticipate making several modifications to our estimate of the cost of our proposed rule (Ref. 1) (see section XVIII). As with the original proposal, we lack sufficient data to quantify the potential benefits of this supplemental notice of proposed rulemaking.

A summary of the domestic costs and potential benefits of the original and supplemental proposed rules is shown in the following table.

ORIGINAL AND REVISED ESTIMATED TOTAL DOMESTIC COSTS BASED ON ADDITIONAL PROVISIONS

[Very Small Business Defined as Annual Animal Food Sales < $2.5 million]

	Total (million)
Original Total Annualized Costs without additional provisions	$65
Additional costs because of potential new provisions	4
Revised Total Annualized Costs	69
Benefits	(1)

1 Unquantified.

If foreign facilities are included, the total annualized cost of this supplemental notice of proposed rulemaking is estimated at $93 million.

I. Background

A. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables us to better protect public (human and animal) health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides us with new enforcement authorities to help achieve higher rates of compliance with risk-

based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law gives us important new tools to better ensure the safety of imported foods and encourages us to form partnerships with State, local, tribal, and territorial authorities. Table 1 identifies three additional proposed rules, issued to implement FSMA, that we discuss in this document.

TABLE 1—PUBLISHED PROPOSED RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed rule for preventive controls for food for animals.	78 FR 64736, October 29, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed rule for preventive controls for human food.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed rule for produce safety	78 FR 3504, January 16, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed rule for FSVP	78 FR 45730, July 29, 2013.

B. 2013 Proposed Rule for Preventive Controls for Food for Animals

In the 2013 proposed rule for preventive controls, we:

- Proposed to add, in newly established part 507, regulations for Current Good Manufacturing Practice In Manufacturing, Processing, Packing, and Holding for Food for Animals (CGMPs);
- Proposed to add, in newly established part 507, requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to establish and implement hazard analysis and risk-based preventive controls for food for animals;
- Requested comment on when and how product testing programs, environmental monitoring programs, and supplier approval and verification are an appropriate means of implementing the statutory framework of FSMA; and
- Requested comment on whether a final rule should address potential hazards that may be intentionally introduced for economic reasons.

We proposed to establish the requirements for CGMPs, for hazard analysis and risk-based preventive controls, and related requirements in new part 507 as shown in Table 2:

TABLE 2—PROPOSED SUBPARTS IN NEW PART 507

Subpart	Title
A	General Provisions.
B	Current Good Manufacturing Practice.
C	Hazard Analysis and Risk-Based Preventive Controls.
D	Withdrawal of an Exemption Applicable to a Qualified Facility.
E	Reserved.
F	Requirements Applying to Records That Must be Established and Maintained.

In the 2013 proposed rule for preventive controls, we provided background discussing:

- The provisions of FSMA most directly applicable to the proposed requirements, particularly the statutory provisions of section 103 of FSMA (established in section 418 of the FD&C Act);
- Hazard Analysis and Critical Control Points (HACCP) Systems;
- Food Safety Problems Associated With Manufacturing, Processing, Packing, and Holding Food for Animal Consumption;
- The Role of Testing as a Verification Measure in a Food Safety System (including discussions about environmental monitoring as well as testing raw materials, ingredients, and finished product), largely in an Appendix to the 2013 proposed rule for preventive controls (the Appendix)); and
- The Role of Supplier Approval and Verification Programs in a Food Safety System (largely in the Appendix).

We also issued for public comment a ''Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the draft risk assessment) (78 FR 64428, October 29, 2013). The purpose of the draft risk assessment was to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk, when conducted in a facility co-located on a farm. We used the tentative conclusions of the draft risk assessment to propose to exempt animal food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities from the requirements for hazard analysis and risk-based preventive controls.

II. Public Comments

A. Opportunities for Public Comment

We requested comments on the 2013 proposed rule for preventive controls by February 26, 2014. We extended the comment periods for the 2013 proposed rule for preventive controls, its information collection provisions, and the draft risk assessment in response to several requests that we do so (see Table 3).

Since issuing the 2013 proposed rule for preventive controls, we conducted numerous outreach activities. Three public meetings were held to solicit oral stakeholder and public comments on the 2013 proposed rule for preventive controls, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the 2013 proposed rule for preventive controls (see Table 3) (Ref. 2, Ref. 3, Ref. 4).

TABLE 3—LIST OF FEDERAL REGISTER PUBLICATIONS REGARDING THE 2013 PROPOSED RULE FOR PREVENTIVE CONTROLS

Description	Publication
2013 proposed rule for preventive controls, requesting comments by February 26, 2014	78 FR 64736, October 29, 2013.
Notice of availability of the draft risk assessment, requesting comments by February 26, 2014	78 FR 64428 , October 29, 2013.
Notice of public meetings (to be held in College Park, MD on November 21, 2013; in Chicago, IL on November 25, 2013; and, in Sacramento, CA on December 6, 2013) on the 2013 proposed rule for preventive controls.	78 FR 64425, October 29, 2013.
Notice extending comment period, until March 31, 2014 , for the 2013 proposed rule for preventive controls and its information collections provisions.	79 FR 6111, February 3, 2014.
Notice extending comment period, until March 31, 2014 , for the draft risk assessment	79 FR 6116 , February 3, 2014.

B. Overview of Public Comments on the 2013 Proposed Rule for Preventive Controls

We received more than 2100 submissions by the close of the comment period, each containing one or more comments. Submissions were received from diverse members of the public, including in part, human and animal food facilities; trade organizations; consulting firms; law firms; pet owners; consumers; consumer groups; Congress, Federal, State, local and tribal Government Agencies. Some submissions included signatures and statements from multiple individuals.

Comments address many provisions of the 2013 proposed rule for preventive controls, including our requests for comment on including additional provisions that we did not include in the proposed regulatory text. Comments from some pet owners for the most part indicated they were pleased that new requirements were being established for the manufacture of pet food and that these requirements were comparable to the requirements for human food, which were covered by the 2013 proposed rule for preventive controls for human food. Some comments questioned whether the proposed requirements reflected the reality of production of food for animals with a particular concern that the proposed risk-based approach focuses too heavily on pathogens and not enough on other potential hazards in food for animals. Some comments assert that additional public comment would be warranted before any consideration on whether a final rule should or should not include provisions discussed in the proposed rule, but for which we had not included proposed regulatory text, such as potential requirements for product testing, environmental monitoring, a supplier approval and verification program, and potential hazards that may be intentionally introduced for economic reasons. The comment period did not close until March 31, 2014; we are still actively reviewing the comments.

C. Our Decision To Issue a Supplemental Notice of Proposed Rulemaking for Public Comment

In December 2013, we announced that we would propose revised rule language for key provisions of the 2013 proposed rule for preventive controls for human food. Because the 2013 proposed rule for preventive controls for food for animals is a companion rule to the proposed rule on human food, in March 2014, we announced our intent to publish revised language for the 2013 proposed rule for preventive controls for food for animals, as well (Ref. 5). Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to the 2013 proposed rule for preventive controls for human food. Many of the proposed provisions of the animal food preventive controls rule match those in the human food rule. Section IX and X discuss our reasons for changes to the proposed current good manufacturing practice regulations. Additional information regarding the basis of this supplemental notice of proposed rulemaking can be found in the supplemental notice of proposed rulemaking for preventive controls for human food.

III. Scope of the Supplemental Notice of Proposed Rulemaking and Our Request for Public Comment

In this document, we are proposing:

- Revisions to several definitions we proposed to apply to the requirements for hazard analysis and risk-based preventive controls, including definitions for ''environmental pathogen,'' ''reasonably foreseeable hazard,'' and ''very small business'';
- New definitions for ''significant hazard'' ''pathogen,'' and ''you'';
- Revisions to subpart B for current good manufacturing practice regulations to make the requirements more applicable for animal food facilities;
- To not subject human food by-products used for animal food by human food facilities that are subject to and in compliance with subpart B of proposed part 117 and other applicable human food safety requirements of the FD&C Act (and implementing regulations) for the human food if the by-products are not further processed at the facility to hazard analysis and preventive controls requirements and only require compliance for holding and distributing these by-products;
- Revisions to the proposed procedures that would govern withdrawal of an exemption from a ''qualified facility,'' including clarifications about the steps we would take before issuing an order to withdraw the exemption, an expanded timeframe for a facility to comply with an order withdrawing an exemption, and a mechanism for a withdrawn exemption to be re-instated;
- A series of revisions to the proposed requirements for hazard analysis and risk-based preventive controls (proposed subpart C) to:
- Emphasize the risk-based nature of the preventive controls and requirements for monitoring, corrective actions, and verification activities;
- Reduce the potential for misinterpretation that the rule requires that all necessary preventive controls be established at critical control points (CCPs) for all hazards that a facility addresses in its food safety plan;
- Change the wording in the ''Monitoring'' section to more closely match the language of the statute and the proposed rule for preventive controls for human food;
- Increase flexibility for a facility to determine, based on the nature of a preventive control, when requirements for ''preventive control management components'' (i.e., monitoring, corrective actions, and verification) are appropriate;
- Substitute the pronoun ''you'' for ''the owner, operator, or agent in charge of the facility'' throughout these proposed requirements;
- Substitute the term ''adequate'' (which is a term we proposed to define) in place of the term ''sufficient'' (which we did not propose to define);

• Improve readability, through rearrangement of some of the proposed regulatory text and editorial revisions (such as increased use of active voice).

In this document, we also are providing an opportunity for public comment on potential requirements for product testing, environmental monitoring, a supplier program, and hazards that may be intentionally introduced for purposes of economic gain, including definitions of terms (i.e., ''qualified auditor,'' ''receiving facility,'' and ''supplier'') that would be used in some of those potential requirements. We are seeking comment on whether such requirements should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate.

We discuss these proposed requirements in sections V through XVI. Because several of the proposed revisions relate to the overall framework in subpart C for hazard analysis and risk-based preventive controls, we are including the complete regulatory text for proposed subpart C. However, in this document, we are reopening the comment period only with respect to the issues specified in this section III.

Importantly, the proposed revisions to the provisions we have included in the regulatory text are based on preliminary review of comments. We will complete our review of comments previously submitted and consider the comments responsive to this Legal and Regulatory Framework Under of proposed rulemaking in developing the final rule.

IV. Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act

In the 2013 proposed rule for preventive controls for human food (78 FR 3646), we described the current legal and regulatory framework that governs the determination of when an establishment is required to register as a food facility in accordance with the section 415 registration regulations (21 CFR part 1, subpart H; the section 415 registration regulations). We focused on the framework that governs whether an establishment that grows and harvests crops satisfies the definition of ''farm'' because the facility registration requirements of section 415 of the FD&C Act do not apply to ''farms.'' When we implemented the statutory requirements for registration of food facilities, it established a definition for ''farm'' that first describes a farm as a facility devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both (§ 1.227; 68 FR 58894, October 10, 2003). Although that definition of ''farm'' then provides that farms also pack or hold food, it limits facilities that fall within the definition of ''farm'' to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Thus, under the current framework an establishment that is devoted to the growing and harvesting of crops, but also packs and holds food not grown or raised on that farm or on another farm under the same ownership, would fall outside the definition of ''farm'' and be required to register as a food facility. Because an establishment that is required to register as a food facility is subject to the requirements of section 418 of the FD&C Act, under the current framework a determination of whether an establishment devoted to the growing and harvesting of crops is subject to FSMA's requirements for hazard analysis and risk-based preventive controls depends, in part, on where the food that the establishment packs or holds is grown or raised.

Under the current framework, a key factor in whether an establishment falls within the definition of ''farm,'' even with respect to crops it grows and harvests itself, is whether the activities conducted by the farm fall within definitions of ''harvesting,'' ''packing'' or ''holding'' (which are within the ''farm'' definition). As discussed in the 2013 proposed rule for preventive controls for human food, section 103 of FSMA directs FDA to conduct rulemaking to clarify the on-farm manufacturing, processing, packing and holding activities that would trigger a requirement for a farm to register as a food facility and, thus, be subject to the requirements for hazard analysis and risk-based preventive controls (78 FR 3646 at 3674). In the 2013 proposed rule for preventive controls for human food, we explained how the status of a food as a raw agricultural commodity (RAC) or a processed food affects the requirements applicable to a farm under sections 415 and 418 of the FD&C Act. For further discussion see section IV of the preamble in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register.**

In sections V and VI, we discuss the proposed revised definitions for ''farm,'' ''harvesting,'' ''packing,'' and ''holding.''

V. The ''Farm'' Definition

We are reopening the comment period, in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register,** with respect to ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''.

A. 2013 Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''

Consistent with the organizing principles regarding classification of activities on-farm and off-farm, in the proposed rule for preventive controls for human food (78 FR 3646), we proposed to define ''harvesting,'' as a new definition in §§ 1.227 and 1.328, to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. We proposed that harvesting be limited to activities performed on the farm on which they were grown or raised, or another farm under the same ownership, and that harvesting does not include activities that transform a RAC into a processed food. The proposed definition included examples of activities that would be harvesting. As a conforming change to the proposed definition of ''harvesting,'' we proposed, to revise the definition of ''farm'' in current §§ 1.227(b)(3) and 1.328 to delete examples of harvesting that currently appear in the ''farm'' definition.

We also proposed, in the preventive controls proposed rule for human food, to revise the definition of ''holding'' in §§ 1.227 and 1.328 so that it would be a two-part definition that would include, for farms and farm mixed-type facilities, activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC into a processed food.

We proposed, in the preventive controls proposed rule for human food, to revise the definition of ''packing'' in §§ 1.227 and 1.328 so that it would be a two-part definition that would include, for farms and farm mixed-type facilities, activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on a farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC into a processed food.

See section V in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register** for additional discussion RACs.

B. Proposed Revisions to the Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''

In the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register**, we are proposing to revise the ''farm'' definition so that it would no longer limit establishments that fall within the ''farm'' definition to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Under the revised ''farm'' definition, an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the ''farm'' definition (and, thus, not be subject to the section 415 registration regulations and the proposed requirements for hazard analysis and risk-based preventive controls) even if it packs and holds raw agricultural commodities grown on another farm. To limit the potential for confusion related to the term ''facility,'' we are proposing to substitute the term ''establishment'' for the term ''facility'' in the revised definition of ''farm.'' We also are proposing that the packing activities (which may include packaging) that it had proposed to include in the expanded definition of ''packing'' for farms and farm mixed-type facilities be included in the ''farm'' definition rather than in an expanded definition of ''packing.'' Under the revised ''farm'' definition, it will be clear that an establishment devoted to the growing of crops, the raising of animals, or both, can remain within the ''farm'' definition if it packages RACs grown or raised on a farm to prepare them for storage and transport, without additional manufacturing/processing. The proposed revised definition of ''harvesting'' would also include ''field coring'' as an example of a harvesting activity to make clear that on farm ''field coring'' of a RAC (e.g., removing the core of lettuce in the field at the same time the stem is cut and wrapper leaves removed) is a harvesting activity, even though ''coring'' outside of ''field coring'' (e.g., during the production of fresh-cut lettuce) is a manufacturing/processing activity.

For further discussion, please see section V in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register**.

C. One General Physical Location

We received some comments on the 2013 proposed rule for preventive controls for human food stating that that farms throughout the country are now made up of multiple, often non-contiguous fields due to geographic and topographic conditions, local development patterns, and the fact that a single ''farm'' today often derives from multiple previous farms due to the need to achieve economic efficiencies. Some comments explain that as farm land increasingly is partitioned into smaller and smaller parcels through estate divisions or for other reasons, farmers purchasing land find that they are rarely able to purchase adjacent parcels. These comments ask us to modify or remove the phrase ''in one general location'' in the ''farm'' definition.

During the rulemaking to establish the ''farm'' definition in the section 415 registration regulations, we explained that a farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens (68 FR 5378 at 5381, February 3, 2003). However, we did not propose to include this explanatory sentence in the regulatory text. Comments addressing ''one general physical location'' focused on how specifying ''in one general physical location'' would affect whether the farm would be subject to the section 415 registration regulations. Our response to those comments focused on the nature of the activities being conducted rather than on the contiguous or non-contiguous nature of parcels of land or nets (68 FR 58894 at 58906, October 10, 2003).

The definition of ''facility'' in the section 415 registration regulations likewise specifies that a facility means ''any establishment, structure, or structures under one ownership at one general physical location . . .'' However, this definition specifically adds an explanatory statement that a facility may consist of one or more contiguous structures (§ 1.227). During the rulemaking to establish this definition of ''facility,'' we explained that we proposed to include this explanatory sentence in the regulatory text as a result of comments that we received during our early outreach efforts (68 FR 5378 at 5381, February 3, 2003).

We are requesting comment on whether we should retain, remove, or modify the phrase ''in one general physical location'' in the ''farm'' definition. Elsewhere in this issue of the **Federal Register**, in the supplemental notice of proposed rulemaking for preventive controls for human food, we are also requesting comment on the phrase ''in one general physical location'' in the ''farm'' definition. In responding to our request for comment on this issue, we ask commenters to carefully consider what, if any, impacts removing or modifying this phrase could have on other rules that already include (or have proposed to include) the same definition of ''farm'' as would be established in the section 415 registration regulations, as well as how such impacts would best be addressed. Please see section V.E in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register** for further discussion on this issue.

D. Feed Mills Associated With Contract and Fully Vertically Integrated Farming

We received some comments requesting clarification of whether all feed mills associated with contract farming or fully vertically integrated farming models would be required to comply with the proposed rule.

We are aware that there are a variety of farming models for raising animals. In one model, often referred to as contract farming, one entity owns the feed mill and the animals, but contracts with another entity that owns the establishment devoted to raising the animals. In this model, the feed mill would not be considered part of a farm under the current definition in 21 CFR 1.227 (see 68 FR 58894 at 58907 (Oct. 10, 2003) and 68 FR 5378 at 5382 (Feb. 3, 2003)). The feed mill also would not be considered part of a farm under the proposed revised definition of farm in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register**. Therefore, the feed mill would be required to register as a food facility under section 415 of the FD&C Act and would be subject to the proposed rule for preventive controls.

In a second model, often referred to as fully vertically integrated farming, one entity owns the feed mill, the animals, and the establishment devoted to raising the animals. In this model, the feed mill would be considered part of a farm under the current definition in 21 CFR 1.227 (68 FR 58894 at 58907), and the proposed revised definition. Therefore, the feed mill would be exempt from registering as a food facility under section 415 of the FD&C Act and would not be subject to the proposed rule for preventive controls rule.

Cooperative farming is another model and depending on how the cooperative is structured, it can resemble the contract model or the fully vertically integrated model. How the cooperative is structured determines whether the

feed mill is required to register as a food facility under section 415 of the FD&C Act.

We have no evidence that the safety of animal food varies depending on whether a feed mill is associated with vertically integrated or contract farming. Therefore, we are asking for comment on whether feed mills associated with fully vertically integrated farming operations, including cooperatives that fit this model, that meet the farm definition (current or proposed revision) should be required to register as a food facility under section 415 of the FD&C Act. If so, how should we revise the farm definition so the feed mills associated with these fully vertically integrated farming operations would not be considered farms, would be required to register under section 415, and thus would be subject to the proposed rule. Registration under section 415 of the FD&C Act would also subject these feed mills to additional statutory requirements under the FD&C Act, for example, recordkeeping requirements under section 414, requirements for the Reportable Food Registry under section 417, and requirements for mandatory recall under section 423.

If these fully vertical farming feed mills would be required to register under section 415 of the FD&C Act, we also request comment on whether there should be an exemption from registration under section 415 for some of these feed mills based on size, such as number of animals being fed or the amount of animal food being fed (based on tonnage, monetary value, or some other factor).

Under the fully integrated vertical farming operations and certain contract farming operations, there would be no total annual sales figure for the animal food that could be used to determine whether a facility is a qualified facility (and thus exempt from proposed subpart C). With regard to these feed mills, we request comment on how to value the animal food being fed to animals for purposes of determining whether the feed mill would be a qualified facility (proposed § 507.7) and in particular a very small business. Qualified facilities would be exempt from the requirements of subpart C (hazard analysis and risk-based preventive controls).

VI. Definitions of ''Holding'' and ''Packing''

A. 2013 Proposed Definition of ''Holding''

In the 2013 proposed rule for preventive controls for human food, we proposed to revise the definition of ''holding'' in §§ 1.227 and 1.328 (see section V.A).

B. 2013 Proposed Exemptions Relevant to the Definition of ''Holding''

We proposed two exemptions directed to facilities ''solely engaged'' in the storage (i.e., holding) of certain types of animal food, and explained our reasons for doing so.

First, we proposed to exempt facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing from the requirements for hazard analysis and risk-based preventive controls, and explained our reasons for proposing to do so (proposed § 507.5(g); see discussion at 78 FR 64736 at 64764). We intended this provision to exempt, for example, facilities that only store whole grains (such as corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, and soybeans) from the requirements for hazard analysis and risk-based preventive controls, provided that such facilities do not conduct other activities subject to FSMA's requirements for hazard analysis and risk-based preventive controls (78 FR 64736 at 64764).

Second, we proposed to exempt a ''facility solely engaged in the storage of packaged food for animals that is not exposed to the environment'' from the requirements for hazard analysis and risk-based preventive controls that would be established in subpart C (proposed § 507.10(a); see discussion at 78 FR 64736 at 64768). We intended this provision to exempt, for example, facilities that store packaged animal food in containers in a warehouse. However, a facility solely engaged in the storage of packaged animal food that is not exposed to the environment and that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens would be subject to modified requirements (see proposed §§ 507.10(b) and 507.51.

In this section of this document, we are proposing revisions to the definition of ''holding'' in addition to the revisions, discussed in section V.B, that would be conforming amendments in light of the revised ''farm'' definition. In this section of this document, we are reopening the comment period with respect to the revised definition of ''holding'' (proposed § 507.3).

C. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of RACs (Other Than Fruits and Vegetables) Intended for Further Distribution or Processing

Some comments support for the proposed exemption for a facility solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. However, some stakeholders expressed concern, during outreach activities such as the public meetings and in written comments, that the proposed definition of ''holding'' would preclude facilities such as grain elevators from being eligible for the exemption in proposed § 507.5(g) because most such facilities conduct a variety of activities in addition to ''storage.'' For example, grain elevators typically conduct the following activities that could be characterized as being practical necessities, either for the purposes of safe or effective storage or for meeting customer specifications:

- Fumigate grain to control pest infestation during storage;
- Clean grain using various mechanisms (sifting, sieving, and screening);
- Convey grain throughout the facility;
- Dry grain received with high moisture content; and
- Blend lots of grain.

Some comments recommended that we modify the proposed definition for ''holding'' to (1) encompass activities performed for the safe or effective storage of RACs (such as drying, screening, conditioning, and fumigating) off-farm and (2) encompass activities performed on RACs as a practical necessity for product distribution (such as blending different lots of the same commodity to meet a customer's quality specifications).

D. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

Some comments received during the public meetings for the 2013 proposed rule for preventive controls for animal food and received under the 2013 proposed rule for preventive controls for human food support the proposed exemption for a facility ''solely engaged in the storage of packaged food that is not exposed to the environment.'' These comments note that warehouses typically conduct the following activities that could be characterized as being practical necessities, either for the purposes of storage or for product distribution, including:

- Affix tracking labels;
- Transport to a storage location in the warehouse;
- Hold non-food products, including toys and grooming aids for pets;
- Break down pallets of packaged animal food for distribution to the retail level in less-than-pallet quantities;
- Assemble ''sales kits'' for use in fundraising drives;
- Assemble variety packs by packing; and
- Use packaged food to build store displays.

Some of these comments we received recommend that we modify the proposed definition for ''holding'' to encompass activities that are performed on packaged food that is not exposed to the environment (1) incidental to storage of the animal food (such as transport and storage of non-animal food products); and (2) as a practical necessity for product distribution (such as affixing tracking labels, breaking down pallets, assembling sales kits and variety packs, and building store displays).

E. Proposed Revisions to the Definition of ''Holding''

Taking into account the comments we have reviewed so far for the 2013 proposed rules for preventive controls, we tentatively conclude that we should revise the definition of ''holding'' to encompass activities performed incidental to storage of animal food (e.g., activities performed for the safe or effective storage of that animal food and activities performed as a practical necessity for the distribution of that animal food). In addition to the activities specifically identified in the comments, we are aware of other activities (Ref. 6) that can be considered incidental to storage of RACs, either for the purposes of safe or effective storage or for meeting customer specifications, including:

- Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation;
- Using modified atmosphere treatments to control pests;
- Using biological controls for pests;
- Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds;
- Weighing grain;
- Sampling and grading grain; and
- Aerating grain to control temperature.

In this document, we are proposing to revise the definition of holding to:

- Clarify that holding also includes activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that animal food and activities performed as a practical necessity for the distribution of that animal food (such as blending of the same commodity));
- Broaden ''activities . . . performed for the safe or effective storage of raw agricultural commodities'' to apply to all animal food, not just RACs;
- Broaden ''activities . . . performed for the safe or effective storage'' to apply to all establishments that hold animal food, not just farms and farm mixed-type activities;
- Add ''breaking down pallets'' to the examples in the revised definition of ''holding'' so that the examples reflect activities conducted on packaged animal food as well as activities conducted on RACs; and
- Specify that holding facilities ''could'' include the listed types of facilities to clarify that some of these facilities might not meet the definition of a holding facility if they perform other activities not included in the definition of holding (e.g., if a grain elevator mixes different commodities to prepare animal food).

As discussed in section V.B, the revised definition of ''holding'' also would remove limitations on where the food is grown or raised (as a conforming change to the revised definition of ''farm'' found in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this issue of the **Federal Register**. The revised definition of ''holding'' would now be a one-part definition that applies to all facilities that hold animal food, rather than a two-part definition that first specifies activities that are within the definition regardless of the type of establishment and then specifies additional activities that would apply only to establishments that are farms or farm mixed-type facilities.

With this revised definition of ''holding,'' facilities such as grain elevators and silos would, in most cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (proposed § 507.5(g)), because the definition would encompass activities performed as a practical necessity for the distribution of RACs. Other facilities that conduct operations similar to those conducted at grain elevators and silos, such as facilities that package and sell seed for crops, but sell the leftover seed for animal food, also may satisfy these criteria for exemption.

With this revised definition of ''holding,'' facilities such as warehouses would, in many cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of packaged animal food that is not exposed to the environment (proposed § 507.10(a)), because the definition would encompass activities that are a practical necessity for product distribution (such as breaking down pallets and affixing tracking labels). We are adding ''breaking down pallets'' to the examples in the revised definition of ''holding'' so that the examples reflect activities conducted on packaged animal food as well as activities conducted on RACs. Although we are not adding more examples to reflect activities conducted on packaged animal food, the revised definition of ''holding'' also would include activities such as assembling sales kits and variety packs, because such activities are similar to breaking down pallets except that the order of activities is reversed.

F. Proposed Revisions to the Definition of ''Packing''

Just as there are some activities that are performed incidental to storing food for animals, there are some activities that are performed incidental to packing an animal food. For example, sorting, culling, and grading RACs could be an activity incidental to packing on a farm or farm mixed-type facility, whereas off-farm some sorting or similar activities such as culling or grading may be required to ensure that like items are packed together, or to remove damaged items. As another example, animal food may need to be conveyed (moved) about an establishment for the purpose of packing it, and may need to be weighed to ensure that appropriate amounts are packed. We tentatively conclude that we should revise the definition of ''packing'' so that it includes activities performed incidental to packing food for animals. In this document, we are proposing to revise the definition of packing to:

- Clarify that packing also includes activities performed incidental to packing animal food (e.g., activities performed for the safe or effective packing of that animal food (such as sorting, culling and grading));
- Provide that activities performed incidental to packing an animal food would apply to all establishments that pack animal food, not just to farms and farm mixed-type facilities; and
- Delete the provision, in the 2013 proposed rule for preventive controls, that packing would include activities (which may include packaging) traditionally performed on a farm on

RACs grown on a farm for storage or transport, because this issue would be addressed in the revised ''farm'' definition in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register**.

VII. Impact of the Proposed Revisions to the Farm-Related Definitions on the Classification of On-Farm Activities

A. Comments on the 2013 Organizing Principles for Classifying Activities Conducted on Farms and on Farm Mixed-Type Facilities

See the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register**, for discussion of comments.

B. Updated Organizing Principles That Would Apply to the ''Farm'' Definition

We articulated the 2013 organizing principles for classifying on-farm activities to operate within the framework, already established in the section 415 registration regulations, in which an establishment that packs and holds others' RACs would be outside the ''farm'' definition and, thus, be required to register as a food facility. Our proposed revisions to the ''farm'' definition, found in the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this **Federal Register**, would change that framework and, as a consequence, require that we reconsider those organizing principles.

Organizing Principles Nos. 1, 3, and 5 remain consistent with the proposed revisions to the ''farm'' definition. However, there would be no need to specify, in Organizing Principle No. 2, that activities that farms traditionally do relate only to their own RACs. In addition, Organizing Principle No. 4 would no longer apply, because the revised ''farm'' definition would no longer classify an activity as within (or outside of) the ''farm'' definition based, in part, on whether an activity is conducted on a farm's own RACs or on others' RACs. Therefore, we tentatively conclude it is appropriate to delete Organizing Principle No. 4 in light of the proposed revisions to the ''farm'' definition.

Table 4 shows our current thinking regarding the organizing principles applicable to the revised ''farm'' definition.

TABLE 4—UPDATED ORGANIZING PRINCIPLES THAT WOULD APPLY TO THE REVISED ''FARM'' DEFINITION

No.	Organizing principle
1	The basic purpose of farms is to produce RACs, and RACs are the essential products of farms.
2	Activities that involve RACs and that farms traditionally do for the purposes of growing RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ''farm.''
3	Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food.
4	Manufacturing/processing, packing, or holding food— whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition.

C. Changes to Classification of On-Farm Activities

We reconsidered the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities. See the Appendix to this document for a comprehensive table comparing the classification of on-farm activities as harvesting, packing, holding, or manufacturing/processing in the 2013 proposed rule for preventive controls to our current thinking on the classification of these on-farm activities. As can be seen in the Appendix, several on-farm activities can be classified in more than one way, and most of the changes in activity classification merely reflect additional activities (relative to the 2013 proposed rule for preventive controls) that could be classified in more than one way. For example, in the 2013 proposed rule for preventive controls, we classified ''removing stems and husks'' as a harvesting activity (e.g., if RACs are husked while they are being removed from the field). In this supplemental notice of proposed rulemaking, we also consider ''removing stems and husks'' to be a packing activity (e.g., if RACs are husked after the RACs have been removed from the field).

See Table 5 in this document for a list of the activity classifications that would change in light of the proposed revisions to the ''farm'' definition and our reconsideration of activity classification. As shown in Table 5, changes in activity classification as a result of the proposed revisions to the ''farm'' definition would result in a single circumstance (drying/dehydrating RACs to create a distinct commodity without additional manufacturing/processing) where a farm conducting manufacturing/processing would no longer be required to register as an animal food facility. Importantly, the revised ''farm'' definition would not result in any new circumstance where a farm would now be required to register as a food facility.

Table 5 includes one activity (i.e., using pesticides on RACs as a packing activity) that we did not address in the 2013 proposed rule for preventive controls and excludes a number of activities (e.g., cooling RACs and coating RACs with wax/oil/resin) that were classified in the appendix of the draft risk assessment (Ref. 7) but are not performed on animal food.

Table 5 includes one activity (i.e., drying/dehydrating (incidental to holding)) that we now would classify in fewer ways than we did in the 2013 proposed rule for preventive controls. In the 2013 proposed rule for preventive controls, we classified drying/dehydrating (for purposes of storage or transport, rather than to create a distinct commodity) (e.g., drying alfalfa) as being either a packing activity or a holding activity, depending on when the drying/dehydrating took place. After reconsidering all of the activity classifications, we tentatively conclude that such drying/dehydrating should continue to be classified as ''holding,'' but does not constitute ''packing.'' We request comment on this narrowed classification of drying/dehydrating when the drying/dehydrating does not create a distinct commodity.

TABLE 5—CHANGES IN CLASSIFICATION OF ACTIVITIES CONDUCTED ON FARMS OR ON FARM MIXED-TYPE FACILITIES BASED ON THE PROPOSED REVISIONS TO THE ''FARM'' DEFINITION

Activity	Classified in 2013 proposed rule for preventive controls	Classified in supplemental notice of proposed rulemaking	Why would the re-classification represent a change from the 2013 proposed rule for preventive controls for animal food? [2]
Cooling	Harvesting; (§ 507.3); Mfg [1]/Processing (§ 507.3).	• Mfg/processing (e.g., cooling of processed animal food).	Acknowledge that field cooling of animal food RACs is not done.
Drying/dehydrating (incidental to holding).	Packing or Holding (Tables 1 and 15 of the draft risk assessment (RA)) (Ref. 7).	• Holding (e.g., drying hay or alfalfa)	Because we would no longer consider drying/dehydrating to be a packing activity.
Drying/dehydrating to create a distinct commodity (transforms a RAC into a processed animal food).	Mfg/Processing (Table 15 of the draft RA) (Ref. 7).	• Mfg/processing (e.g., drying grapes to create raisins, and drying herbs to create a distinct commodity) (because it transforms a RAC into a processed animal food) (but allowed within the farm definition).	Because we are including this specific mfg/processing activity within the ''farm'' definition, provided that there is no additional manufacturing/processing.
Filtering	Harvesting (§ 507.3)	• Harvesting (e.g., filtering honey)	Acknowledge that filtering is not done on animal food RACs.
Removing stems and husks	Harvesting (§ 507.3)	• Harvesting (e.g., in the field). • Packing (e.g., in a packing shed)	Acknowledge that removing stems/husks can occur during more than harvesting operations.
Sifting	Harvesting (§ 507.3)	• Harvesting (e.g., in the field). • Packing (e.g., in a packing shed)	Acknowledge that sifting can occur during more than harvesting operations.
Using pesticides on RACs.	Harvesting (Tables 1 and 15 of the draft RA discussed only fumigation) (Ref. 7).	• Harvesting (e.g., in the field). • Packing (e.g., in a packing shed)	Acknowledge that pesticides may be used at various points in preparation of RACs
Washing	Harvesting (§ 507.3), and Mfg/Processing (§ 507.3).	• Harvesting (e.g., washing in the field was deleted). • Mfg/processing (e.g., during production of an animal food).	Acknowledge that field washing of animal RACs does not occur but washing during processing may occur.

[1] Mfg = Manufacturing.
[2] This table focuses on any change in classification in this document compared to the classification, in the 2013 proposed rule for preventive controls for food for animals, for activities conducted on a farm's own RACs. The proposed revisions to the ''farm'' definition would make the distinction between whether a farm conducted an activity on its own RACs or on others' RACs irrelevant.

VIII. Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations

A. The 2013 Proposed Exemptions

In the 2013 proposed rule, we described provisions of FSMA that direct us to (1) conduct a science-based risk analysis to cover specific types of on-farm packing, holding, and manufacturing/processing activities that would be outside the ''farm'' definition and, thus, subject to the requirements for hazard analysis and risk-based preventive controls (78 FR 64736 at 64751 and 64752–64754); and (2) consider the results of that science-based risk analysis and exempt facilities that are small or very small businesses from these requirements (or modify these requirements, as we determine appropriate), if such facilities are engaged only in specific types of activities that we determine to be low risk involving specific animal foods that we determine to be low risk. Consistent with this statutory direction, we developed the draft risk assessment and made it available for public comment (Ref. 7 and 78 FR 64428); and proposed three exemptions for on-farm activity/animal food combinations conducted by farm-mixed-type facilities that are small or very small businesses (proposed § 507.5(e), (f)(1), and (f)(2)).

B. Comments on the Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations

Some comments received to the proposed rule for preventive controls for human food (78 FR 3646) request clarification on whether an establishment that conducts more than one activity/food combination listed in the proposed exemptions for on-farm low-risk activity/food combinations would be eligible for the exemption. Other comments recommend including additional on-farm packing and holding activity/food combinations, or on-farm manufacturing/processing activity/food combinations, as low-risk activity/food combinations eligible for inclusion in the proposed exemptions.

We are confirming that an establishment that conducts more than one activity/animal food combination listed in the proposed exemptions for on-farm low-risk activity/animal food combinations would be eligible for the exemption. The regulatory text is written in the plural (e.g., ''if the only packing and holding activities . . . that the business conducts are the following low-risk packing or holding activity/animal food combinations''; and ''if the only manufacturing/processing activities . . . that the business conducts are the following'').

We have not fully completed our review of comments on the 2013 proposed rule for preventive controls and the draft risk assessment. It is possible we may include additional activity/animal food combinations in these exemptions when we issue the final rule.

C. Impact of the Proposed Revisions to the Definitions for ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing'' on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Animal Food Combinations

The proposed revisions to the definitions of ''farm,'' ''harvesting,'' ''holding,'' and ''packing,'' if finalized, would have three principal effects on the proposed exemptions.

- First, the proposed exemption for on-farm packing or holding of animal food by a small or very small business would no longer identify any packing or holding activities for any RACs, because an on-farm establishment would no longer be subject to the requirements for hazard analysis and risk-based preventive controls when it packs or holds RACs, regardless of whether it is packing and holding its own RACs or others' RACs. The proposed exemption would continue to apply on-farm packing and holding of processed animal foods (e.g., packing and holding of silage when conducted by a farm mixed-type facility).
- Second, the proposed exemption for on-farm low-risk manufacturing/

processing activities conducted by a small or very small business would no longer distinguish between manufacturing/processing activities conducted on a farm mixed-type facility's own RACs and manufacturing/processing activities conducted on animal food other than the farm mixed-type facility's own RACs.

• Third, the proposed exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business would be revised to eliminate activities, conducted on others' RACs, which would no longer be classified as manufacturing/processing and instead would be classified as harvesting, packing, or holding. For example, blending different lots of the same RACs such as whole grains would remain within the ''farm'' definition, and not be considered manufacturing/processing, regardless of whether the RACs being blended are the farm's own RACs or others' RACs. However, mixing forage to make silage would be considered manufacturing/processing and, thus, would continue to be considered a low-risk manufacturing/processing activity listed within the exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business.

We will update these proposed exemptions when we issue the final rule, after considering comments, and reaching a decision in light of those comments, on the proposed revisions to the definitions that impact the proposed exemptions for low-risk activity/animal food combinations.

IX. Proposed Applicability of Part 507 to the Holding and Distribution of Human Food By-Products for Use in Animal Food

Historically, many facilities that manufacture/process or pack human food also provide by-products from that human food production for use as animal food (Ref. 8). These by-products are a significant source of animal food or animal food ingredients. While these by-products may not be nutritious, suitable, or desirable for human consumption, they can be a source of energy and nutrition for certain species of animals, many of which have different digestive systems, physiology, and nutritional requirements than humans (e.g., ruminants such as cattle and sheep). The differences enable these animals to digest and metabolize the by-products in a way humans cannot.

Some of the by-products do not undergo further processing (such as drying, grinding, pelleting, etc.) at the human food facility before being used for animal food. Examples of these by-products include culls, peels, trimmings, and pulp from fruit and vegetable manufacturing/processing; chaff, bran, and middlings from grain milling; wet brewers grains from beverage brewing operations; and liquid whey from dairy facilities. Some of the by-products from these facilities are human food products that did not meet quality specifications for human food use. These out-of-specification products may be, for example, the wrong size, shape, or texture for human food, but are safe for use as animal food. Examples of these types of by-products include potato chips, cookies, bread, pastry products and pasta. Facilities may distribute the human food by-products directly for use as livestock food, or may distribute them to another facility for further processing for food for animals.

Human food facilities are currently subject to the current good manufacturing practices (CGMPs) regulations found in 21 CFR part 110 and would be subject to the proposed preventive controls for human food, found in proposed 21 CFR part 117, subpart C, if finalized. In the 2013 proposed rule for preventive controls for food for animals, we addressed human food facilities that also provide food for animals (78 FR 64736 at 64754). Proposed § 507.1(d) would have applied to these facilities and allowed them, for the animal food, the choice of complying with proposed part 507 for food for animals, subparts B and C as applicable, or proposed part 117 for human food, subparts B and C as applicable, so long as the facility addressed any hazards specific to the animal food.

In the 2013 proposed rule for preventive controls, we also addressed breweries and distilleries that make alcoholic beverages (78 FR 64736 at 64765). Many of these facilities provide the spent grains from the brewing or distilling process for use as animal food. In the 2013 proposed rule for preventive controls for human food (78 FR 3646), we proposed that subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' would not apply to certain alcoholic beverages and a very narrow set of prepackaged other food at alcoholic beverage facilities, based on the our interpretation of section 116 of FSMA. Section 116(b) of FSMA (21 U.S.C. 2206(b)) provides that section 116(a) of FSMA ''shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food, except that [section 116(a) of FSMA] shall apply to a facility described in [section 116(a) of FSMA] that receives and distributes non-alcohol food, provided such food is received and distributed: (1) In a prepackaged form that prevents any direct human contact with such food; and (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.'' We stated in the proposed rule for preventive controls for food for animals that we were not aware of any animal food at any alcoholic beverage facility that would be exempt from proposed subpart C, ''Hazard Analysis and Risk-Based Preventive Controls,'' for food for animals as the spent grains for animal food is not an alcoholic beverage and is not in a prepackaged form as provided by section 116 of FSMA.

We have received comments from our stakeholders at public meetings and through comments to the proposed rule. Some comments stated that the requirements in proposed § 507.1(d) would potentially create a need for two separate food safety plans, one for human food and one for animal food. Some commented that requiring the facility to be subject to human food and animal food regulations would be a cost burden and as a result, some facilities would destroy their by-products, most likely by landfill, instead of complying with the rule for food for animals. Others commented that by-products used for animal food would not be a food safety concern because the human food is manufactured/processed or packed under CGMPs and many of these facilities also would be subject to the proposed rule for preventive controls for human food. Comments also said that the hazards that would be reasonably foreseeable for animal food (e.g., mycotoxins) would also be a hazard reasonably foreseeable for the human food and thus would be controlled by the facility by following CGMPs or implementing a food safety plan for the human food.

Based on comments reviewed to date and on comments made during public meetings, we considered other possible approaches to regulating packing and holding of by-products by a human food facility for distribution as animal food. We first conducted a review of the potential biological, chemical (including radiological), and physical hazards for these human food by-products used for animal food. We did not include hazards associated with human food by-products derived from animal products, including poultry and seafood (but did include dairy and egg products). We further limited our review to hazards associated with human food by-products that were not further processed

at the facility once separated from the human food because these processes could introduce hazards that would need to be addressed in a food safety plan. We reviewed the FDA Reportable Food Registry, published information about animal food recalls, as well as information from the CVM Feed Contaminants Program (Ref. 9). In addition, we conducted a scientific literature review on these by-products used as animal food (Ref.10).

Though there was not a large volume of data on human food by-products used as animal food, we tentatively conclude that while there are biological, chemical, and physical hazards that may be present in the human food by-products, the information reviewed indicates these hazards rarely occur.

For example, the reviewed information did not identify any instances of biological hazards in human food by-products (falling under the scope of the memorandum) used as animal food. Protein ingredients derived from meat, offal, poultry, and oil seed meal were found to be the most common source of biological hazards in animal food. Facilities providing by-products from these sources for use as animal food would be subject to proposed part 507, as explained in the discussion of proposed § 507.12 in this section. Chemical hazards such as mycotoxins or pesticides are known to be present in human food ingredients as well as animal food. We have tentatively concluded that these hazards would be controlled by the human food facilities for the human food, either under CGMPs or the proposed preventive controls for human food when finalized. The reviewed information did not identify any instances of chemical hazards from radionuclides in by-products used for animal food. The reviewed information did not identify any instances of physical hazards in human food by-products used as animal food except instances when the by-products were mistaken for trash and trash was added to them. We request comment, including additional data, on the findings of our research on biological, chemical, and physical hazards of human food by-product used as animal food.

Biological, chemical, or physical hazards in human food by-products used as animal food, as indicated by the reviewed information, were either hazards that are not known or reasonably foreseeable, are prevented or significantly minimized through the human food facility's compliance with current human food CGMP regulations, or would be prevented or significantly minimized through the human food facility's compliance with the proposed preventive controls regulations for human food, when finalized. The current CGMPs (and the proposed update to these requirements in the 2013 proposed rule for preventive controls for human food) as well as other applicable FDA human food safety regulations, are either the same as or more stringent than the proposed requirements for animal food. Therefore, we tentatively conclude that a facility's compliance with proposed subpart B of part 117 and all other applicable human food safety requirements of the FD&C Act and implementing regulations are sufficient to help provide animal food safety until the point of separation from the human food. We request comments on this tentative conclusion.

The review conducted did not include a search for hazards associated with seafood by-products. We request comment on how these by-products are used for animal food, including without further processing, and if these by-products should be subject to the requirements for animal food under proposed part 507.

Once the by-product is separated from the human food and is merely packed and/or held by the human food facility for distribution, the facility would need to take measures to ensure the animal food does not become contaminated. For example, during the time the animal food is held, the facility would need to ensure that the animal food is not treated like trash or garbage. The facility would need to protect the animal food from contamination with physical hazards such as floor sweepings containing glass or metal fragments and from chemical hazards such as equipment oil, cleaning chemicals, or pesticides used in the facility. Any of these could be inadvertently incorporated into the animal food if it was mistaken for trash.

As discussed in further detail in section X of this preamble, we are also proposing revisions to the proposed CGMPs for animal food. Particularly, we are proposing a section of CGMPs that would apply to the packing and holding of by-products in a human food facility for distribution as animal food. Once the by-product is separated from the human food, these proposed CGMPs for holding and distribution of the by-product intended for animal food would prevent or significantly minimize the known or reasonably foreseeable chemical and physical hazards that may occur after that separation. We tentatively conclude that biological and certain chemical hazards, such as mycotoxins and radionuclides, would not be known or reasonably foreseeable hazards in the by-products, given how unlikely those are to occur based on the review. We request comment on these conclusions. Based on the above conclusions, we have determined that, except for proposed § 507.28 regarding holding and distribution of human food by-products as animal food, proposed part 507 should not be applicable to these human food by-products used as animal food. Applying all the requirements set out in proposed part 507 for these by-products at human food facilities would not seem to provide any additional animal food safety benefit. Therefore, in this supplemental notice of proposed rulemaking, we are proposing revised requirements for human food facilities and the human food by-products they provide for animal food.

Proposed § 507.12 ''Applicability of this part to the holding and distribution of human food by-products for use in animal food,'' would address the applicability of part 507 to the holding and distribution of human food by-products for animal food. Except as provided in proposed § 507.12(b), the requirements of part 507 would not apply to by-products of human food production that are packed and held by that facility for distribution as animal food if the facility is subject to and in compliance with subpart B of part 117 and all other applicable human food safety requirements of the FD&C Act and implementing regulations and the facility does not further process the by-products intended for use as animal food. Proposed § 507.12(b) would require that once the animal food was separated from the human food, the facility would need to comply with proposed § 507.28 for the holding and distribution of that animal food.

A human food facility that further processes the human food by-product for animal food would be subject to proposed part 507 for those by-products. This would include by-products that undergo drying, pelleting, or heat-treatment such as dried brewers' grains, dried whey, or pelleted citrus pulp. These processes could introduce hazards that would need to be addressed in a food safety plan.

Proposed § 507.12 would not apply to human food products when contamination or adulteration has occurred that is materially related to food safety. We currently have two compliance policy guides that provide information to facilities that want to divert contaminated or adulterated human food for animal food use (Ref. 11, Ref.12). We handle the diversion requests on an individual basis and may not grant a request after review. Against the backdrop of proposed part 507, we

request comment on our compliance policy guides for diversion of adulterated human food products for animal food and whether we should include regulations for these types of requests.

Proposed § 507.12(b) would not apply to human food by-products derived from animal products (other than dairy and eggs), such as meat, offal, or poultry. We tentatively conclude that the hazards, particularly biological hazards, potentially associated with by-products from these animal products could be more substantial than those for the by-products addressed in the memorandum. We request comment on this conclusion.

Proposed § 117.145 of the supplemental notice of proposed rulemaking for preventive controls for human food, published elsewhere in this issue of the **Federal Register**, addresses proposed corrective actions and corrections for human food. If a preventive control was found to be ineffective or was not properly implemented, steps would need to be taken to evaluate the food for safety and prevent affected food from entering into commerce if the facility cannot ensure the food is not adulterated. We request comment on how the facility would address by-products linked to the affected human food, especially if the preventive control problem was not discovered until after the separation of the by-products from the human food and possibly after the by-products have entered into commerce for use as animal food.

We are also proposing a conforming change to the 2013 proposed rule for preventive controls for human food part 117 by adding proposed § 117.95. This proposed section would contain the same requirements as those contained in proposed § 507.28, but would allow the human food processor to reference one part of the Code of Federal Regulations (i.e., part 117, if finalized) to determine the requirements applicable to the human food by-products used for animal food. We request comment on this approach. We also request comment on whether proposed § 507.28 should be removed from part 507, if finalized, if proposed § 117.95 is added to part 117, if finalized.

We request comment on these proposed requirements for human food by-products going to animal food use and request comment on any additional information available on the known or reasonably foreseeable hazards in human food by-products packed or held by human facilities for distribution as animal food. We also request comment on whether by-products from human dietary supplement and infant formula production are used for animal food, and if so, how these by-products should be addressed to help ensure safety of the animal food.

X. Proposed Revisions to Subpart B—Current Good Manufacturing Practice

In this supplemental notice of proposed rulemaking, we are proposing revisions to the requirements for current good manufacturing practice regulations (CGMPs) as proposed in the 2013 preventive controls rule for food for animals. We are proposing these revisions to the CGMPs based on stakeholder input and initial review of some comments received in response to the 2013 proposed rule for preventive controls. In the 2013 proposed rule for preventive controls, we discussed several sets of CGMPs that had already been developed by regulatory and animal health organizations, both domestic and international, that we believed could serve as a starting point for our proposed CGMPs for manufacturing, processing, packing, and holding food for animals (78 FR 64736 at 64772). These existing CGMPs included FDA's CGMP regulations for human food and medicated animal feed (21 CFR part 110 and part 225 respectively), the Association of American Feed Control Officials (AAFCO) model GMPs for feed and feed ingredients, best practices recommended by Codex for the feed industry, and the GMPs recommended in Publicly Available Specification (PAS) 222 (Ref.13, Ref. 14, Ref. 15). We concluded this discussion by saying that because of our experience and expertise with the human food CGMPs, we tentatively concluded that our human food CGMPs were the appropriate starting point for the animal food CGMPs. We then requested comment on whether CGMPs similar to those for human food are appropriate for animal food, and whether CGMP requirements appropriate for some types of animal food might be inappropriate for other types.

Specifically, a major concern we wanted to address with the proposed revisions is the difficulty of applying one set of CGMPs to both pet food facilities and livestock feed facilities. Some pet food facilities, depending on the type of product being manufactured, resemble human food facilities in that they use wet cleaning procedures to clean and sanitize food contact surfaces. They also must maintain high sanitation standards so that their finished product, which will be handled by pet owners, is free of pathogenic microorganisms. Livestock feed manufacturers on the other hand avoid the use of water and liquid cleaning compounds because of the need to maintain dry surfaces in facilities that predominantly move dry grains, oilseeds, and other dry ingredients through mixing operations that produce dry finished products. Sanitizing surfaces is thought to be unnecessary in most livestock feed facilities because the environment is much less conducive to microbial growth. We have tentatively concluded that these proposed revised CGMPs are more applicable to the animal food industry, provide flexibility for a wide diversity in types of animal food facilities, and still meet our objectives of establishing enforceable baseline standards for producing safe animal food. We request comment on this conclusion.

Proposed § 507.27 ''Holding and distribution'' originated from § 507.28 ''Warehousing and distribution'' in the 2013 proposed rule for preventive controls for food for animals. We have retitled the section ''Holding and distribution'' to better indicate the requirements would apply to animal food plants in general, not simply warehouses or distributors/distribution centers. The very general requirement previously proposed that animal food be protected against deterioration and biological, chemical, physical, and radiological contamination during storage and transportation was revised to be more specific.

Proposed § 507.27(a) would require that animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration of the animal food. Deterioration of animal food refers to loss of taste, aroma, or nutritive value typically associated with the animal food. For animal foods, taste and aroma are linked to palatability and deterioration in these properties can result in food refusal and wastage. Deterioration of nutritive value refers to loss of nutrients below amounts that the food is typically expected to provide. Both food refusal and consumption of animal food containing fewer nutrients than expected could result in states of undernourishment that may cause poor performance and ill health. Animals are typically fed the same food containing the same ingredients for prolonged periods, making consistent delivery of expected nutrient content important to prevent nutritional deficiencies or imbalances.

Contamination of a food can result from biological, chemical, or physical agents with biological and chemical being the agents most likely to contribute to deterioration of

palatability, aroma, and nutritive value of animal food. Microorganism contamination can lead to production of a chemical hazard, such as when animal food is contaminated with a mold that subsequently produces a mycotoxin in the animal food. Holding under appropriate conditions that minimize the potential for growth of undesirable microorganisms is particularly important when the animal food is not itself shelf stable or could be subjected to conditions that adversely impact product stability. (e.g., raw or frozen pet food). Proposed paragraph (a)(1) would require that containers used to hold animal food before distribution be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food.

Proposed paragraph (a)(2) would require that animal food held for distribution be held in a way that would prevent contamination from sources such as trash and garbage. This is particularly important when the animal food is held in bulk containers that could be mistaken for trash bins.

Proposed paragraph (a)(3) would require that labeling that identifies the product by the common or usual name be affixed to or accompany the animal food. The common or usual name is one that is readily recognized, for example, oats, corn, corn gluten meal, poultry by-product meal, meat, or dried whey. For byproducts from processing human food, the names in the AAFCO Official Publication are commonly used and recognized by industry and state feed programs, and in Compliance Policy Guide 665.100 ''Common or Usual Names for Animal Feed Ingredients,'' FDA has generally regarded the AAFCO feed ingredient definitions as establishing common or usual name of ingredients (Ref. 16). We tentatively conclude that this labeling requirement would enable the animal producer to use the animal food appropriately or an establishment receiving the animal food for further manufacture to use it appropriately. We also tentatively conclude that this labeling requirement would help prevent accidental comingling or mix-ups of products at the facility.

Proposed § 507.27(b) would require that shipping containers such as totes, drums, and tubs, as well as bulk vehicles, used to distribute animal food be inspected prior to use to ensure the container or vehicle will not contaminate the animal food. The purpose of this proposed paragraph would be to help ensure that such articles for holding and conveying animal food are not a source of contamination of animal food products.

Proposed § 507.27(c) would require that animal food returned from distribution be assessed for safety to determine the appropriate disposition of the animal food and be identified and segregated until assessed. The animal food plant or facility would not know how that animal food had been handled prior to return so the animal food could have been exposed to potential hazards, e.g., the growth of mycotoxin producing microorganisms if held in a high humidity area. This returned animal food could contain hazards resulting in contamination that could result in a food safety concern. If redistributed prior to assessment, depending on the nature and severity of the contamination, it could result in injury (or death) to animals.

Proposed § 507.27(d) would require that unpackaged or bulk animal food be held in a manner that does not result in cross contamination with other animal food. The purpose of paragraph (d) is to prevent instances of cross contamination such as food for swine that contains mammalian protein (that is prohibited for use in food for ruminants) contaminating food intended for cattle.

Revised proposed § 507.28 is now titled ''Holding and distribution of human food by-products for use as animal food.'' The revised proposed requirements are a subset of those in proposed § 507.27 and would specifically apply to human food processers that have certain by-products (as identified in proposed § 507.12) as a result of manufacturing human food and pack or hold the by-products for distribution for use as animal food. Since the human food would be subject to proposed part 117 subpart B and any other applicable FDA human food safety requirements of the FD&C Act and implementing regulations, we have tentatively concluded that hazards would be adequately controlled by these requirements in conjunction with the requirements of proposed § 507.28. Proposed § 507.28 would contain the CGMPs we tentatively conclude would be necessary for animal food safety once the by-products are separated from human food and become animal food.

As discussed in section IX, we are proposing a new § 507.12 for the applicability of part 507 to human food by-products used for animal food. Under proposed § 507.12, part 507 would not apply to by-products of human food production meeting the requirements of proposed § 507.12(a), except as provided in § 507.12(b). Proposed § 507.12(b) would require that the animal food from by-products identified in proposed § 507.12(a), be held and distributed by that facility in accordance with § 507.28 of part 507 and proposed § 117.95 of part 117.

The following is a brief summary of the proposed revisions to the CGMPs in proposed subpart B. In making the revisions, we also found it necessary to rearrange and retitle some of the sections, and make wording changes that we felt simplified the requirements and improved clarity. The details of these proposed requirements are in the re-proposed regulatory text for proposed subpart B.

- § 507.14—Personnel
  - Removed paragraphs (a)(1) and (a)(2) pertaining to ill employees and the requirement for employees to report illnesses to their supervisors. This change was made because we are not aware of any evidence of disease being transmitted from ill employees involved in manufacturing animal food to animals through the animal food.
- § 507.17—Plant and grounds
  - Primarily wording changes to consolidate requirements.
- § 507.19—Sanitary operations
  - Changed section title to ''Sanitation'';
  - Divided paragraph (a) into two categories—(a) pertaining to buildings, fixtures, and other physical facilities, and (b) pertaining to utensils and equipment;
  - Changed the wording in new paragraph (b) to say that utensils and equipment must be cleaned, maintained, and stored as necessary and appropriate to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials;
  - Consolidated requirements, changed the order to group like requirements, and simplified the wording; and
  - Eliminated the requirement pertaining to single-service articles, which are not typically used in animal food facilities.
- § 507.20—Sanitary facilities and controls
  - The title was changed to ''Water supply and plumbing'';
  - This section contains only requirements related to the water supply and plumbing. The rubbish (reworded to trash and garbage) requirement was moved to § 507.19 Sanitation; and
  - Wording changes were made for simplification.

- § 507.22—Equipment and utensils
  - Requirements consolidated; and
  - Wording changes made for simplification.
- § 507.25—Processes and controls
  - Title changed to ''Plant operations'';
  - Changed paragraph (a)(1) to require that plant operations be conducted in accordance with the CGMPs in subpart B rather than in accordance with adequate sanitation principles;
  - Added requirements in paragraph (a)(9) that all animal food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of animal food;
  - Omitted the requirement in paragraph (b)(2) that raw materials and ingredients must not contain microorganisms injurious to human or animal health, or the raw materials and ingredients must be treated to eliminate them. This change was made because we do not intend that incoming raw materials and ingredients must be tested for pathogens, though the facility may choose to do so;
  - Requirements pertaining to processes and products used for human food but not animal food, such as heat blanching, batters, breading, sauces, and dressings were omitted; and
  - Requirements consolidated and wording simplified.
- § 507.28—Warehousing and distribution
  - Section renumbered to § 507.27;
  - Title changed to ''Holding and distribution'';
  - The very general requirement previously proposed that animal food be protected against deterioration and biological, chemical, physical, and radiological contamination during storage and transportation was revised to be more specific. We are now proposing that the following requirements apply to animal food held for distribution:
  - Animal food held for distribution must be held under conditions (for example, appropriate temperature, relative humidity, appropriate holding time) that minimize the potential for growth of undesirable microorganisms;
  - Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;
  - Animal food held for distribution must be held in a way that prevents contamination from sources such as trash and garbage;
  - Labeling identifying the product by the common or usual name must be affixed to or accompany the animal food;
  - Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food;
  - Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed; and
  - Unpackaged or bulk animal food must be held in a manner that does not result in cross contamination with other animal food.
- § 507.28—Holding and distribution of human food by-products for use as animal food
  - The following new requirements were added:
  - Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:
  - Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;
  - Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage;
  - Labeling identifying the by-product by the common or usual name must be affixed to or accompany animal food;
  - Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food; and

We request comments on these proposed revisions to subpart B.

XI. Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

A. 2013 Proposed Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

In general, in the 2013 proposed rule for preventive controls, we proposed that the owner, operator, or agent in charge of a facility:

- Prepare and implement a food safety plan, which would include documentation such as a written hazard analysis and various written procedures;
- Conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards to determine whether there are hazards that are ''reasonably likely to occur'';
- Identify and implement preventive controls, including at CCPs, if any, to provide assurances that hazards identified as ''reasonably likely to occur'' will be significantly minimized or prevented;
- Establish a written recall plan for animal food with a hazard identified as ''reasonably likely to occur'';
- Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed;
- Establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented;
- Take appropriate corrective action in the event of an unanticipated problem if a preventive control is not properly implemented and a specific corrective action procedure has not been established;
- Conduct certain verification activities; and
- Establish and maintain certain records.

These proposed provisions applied a construct we previously used in our Hazard Analysis and Critical Control Point (HACCP) regulations for seafood (21 CFR part 123) and juice (21 CFR part 120), i.e., whether a known or reasonably foreseeable hazard was ''reasonably likely to occur.'' In general, our HACCP regulations for seafood and juice focus on CCPs to control hazards that are ''reasonably likely to occur.''

B. Comments on the ''Reasonably Likely To Occur'' Construct Within the 2013 Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

Some stakeholders expressed concern, during outreach activities such as the public meetings and in written comments, about including the ''reasonably likely to occur'' approach in the 2013 proposed rules for preventive controls for human and animal food. The concern was that using the phrase ''reasonably likely to occur'' in two different contexts (i.e., within our HACCP regulations as well as in its proposed preventive controls regulations for human and animal food) would be confusing. Some comments received under the proposed rule for preventive controls for human food considered that the ''reasonably likely to

occur'' approach was already so closely linked to our HACCP regulations that the 2013 proposed rules for preventive controls for human and animal food would be interpreted as requiring that all necessary preventive controls be established at CCPs. These comments note that such an interpretation would be inconsistent with FSMA. For example, FSMA requires that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points, *if any* (emphasis added) (section 418(c) of the FD&C Act). In addition, the definition of ''preventive controls'' in FSMA is broader than CCPs (section 418(o)(3) of the FD&C Act). The comments ask that we more explicitly provide for implementation of a range of preventive controls (not just at CCPs). These comments also express concern that a facility that already had established controls to address hazards—but not at CCPs—would need to revise its food safety plan, re-create any applicable records (e.g., various written procedures) to satisfy the recordkeeping requirements of the rule, which would add costs but no food safety benefits. For further discussion of these comments, please see supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

C. Proposed Revisions to the Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

The 2013 proposed rule for preventive controls would not have required that all preventive controls be established at CCPs. However, we acknowledge that it could be confusing to use the same phrase ''reasonably likely to occur'' in both the our HACCP regulations and in the regulations we are proposing to establish to implement FSMA's requirements for hazard analysis and risk-based preventive controls, because the phrase ''reasonably likely to occur'' has been used as the basis for determining hazards that need to be addressed in a HACCP plan at CCPs.

Likewise, the 2013 proposed rule for preventive controls would not have limited a facility's flexibility to develop and implement a food safety system that was indeed risk-based. However, we acknowledge that some specific changes to the proposed regulatory text could help to clarify the risk-based nature of all provisions of subpart C.

We have not used the term ''prerequisite program'' in the proposed regulatory text because, like ''hazard reasonably likely to occur,'' it has a connotation with respect to our seafood and juice HACCP programs, that is, it connotes activities that a facility may do that have an impact on product safety but which are outside the scope of the regulatory program. However, comments are not suggesting that prerequisite programs that are essential to ensuring food safety should be outside the scope of this proposed regulatory scheme. In fact, comments asking that we recognize the role of prerequisite programs in the management of hazards point out that preventive controls include control measures that do not include CCPs and that companies would consider many of these to be prerequisite programs. We acknowledge that oftentimes preventive controls, other than those at critical control points, are important parts of a food safety system, and must therefore be included in the food safety plan that would be required by this proposed rule. We attempted to make that clear in the proposed requirement for preventive controls in § 507.36(a) by incorporating reference to ''controls, other than those at critical control points, that are necessary for food safety.''

We did not intend to require that a facility re-create or duplicate existing records associated with controls; we simply laid out in the 2013 proposed rule for preventive controls the activities for which we expect there to be records and the information we expect to find in those records.

Taking into account the comments we have reviewed so far, we are proposing a series of revisions to proposed subpart C and are reopening the comment period specifically with respect to these proposed revisions. These proposed revisions include:

- Eliminating the term ''hazard reasonably likely to occur'' throughout proposed subpart C (and, thus, deleting the definition we had proposed for this term).
- Adding a new defined term, ''significant hazard,'' and, in general, using this new term instead of ''hazard reasonably likely to occur'' throughout the proposed regulations. ''Significant hazard'' would mean a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food, and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the control.
- Defining ''known or reasonably foreseeable hazard'' in place of ''reasonably foreseeable hazard'' and clarifying that the new term means a hazard ''that has the potential to be associated with the facility or the food'' rather than ''a potential . . . hazard that may be associated with the facility or the animal food'';
- Providing additional flexibility to address concerns about re-writing existing plans or programs to conform with the requirement of the preventive controls rule by explicitly providing that:
- Preventive controls include controls, other than those at critical control points, that knowledgeable persons commonly recognize as appropriate for animal food safety;
- The preventive control management components (i.e., monitoring, corrective actions, and verification) depend on the nature of the control; and
- The recordkeeping requirements do not require duplication of existing records if those records contain all of the required information and satisfy the recordkeeping requirements of the regulation. Existing records may supplemented as necessary to include all of the required information. In addition, the required information does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by the preventive controls rule may be kept either separately or combined with the existing records.

The framework provided by ''significant hazard'' would reflect a two-part analysis on the part of a facility. First, the facility would narrow ''hazards'' to those hazards that are known or reasonably foreseeable—i.e., those biological, chemical (including radiological), or physical hazards that have the potential to be associated with the facility or the food. Second, the facility would narrow the known or reasonably foreseeable hazards to those that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food, as well as components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the control.

The framework established by ''significant hazard'' also would incorporate the concept of risk by specifying that ''significant hazards'' are based on the outcome of a hazard

analysis. The hazard analysis would require an evaluation of known or reasonably foreseeable hazards to assess two key aspects of risk—i.e., the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

See the revised regulatory text for the proposed new definition of ''significant hazard'' (proposed § 507.3). The term ''significant hazard'' has sometimes been used in the context of HACCP to refer to the hazards to be addressed in a HACCP plan through CCPs. However, this term is not used in the seafood, juice or meat and poultry HACCP regulations, which focus on ''hazards reasonably likely to occur.'' We request comment on both the proposed name of the term and the proposed meaning of the term. See also the proposed new provision for the use of existing records (proposed § 507.212, which would be established in subpart F). Table 6 provides some examples of the flexibility that a facility would have in complying with the revised requirements that would be established in subpart C.

TABLE 6—EXAMPLES OF FLEXIBILITY FOR COMPLYING WITH THE REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS IN THE REVISED REQUIREMENTS IN PROPOSED SUBPART C

Flexibility related to . . .	Example
Controls other than those at CCPs	Dividing a facility into zones based on the risk with respect to contamination of product can be a preventive control, but would not have a CCP.
Controls other than those at CCPs	Preventive maintenance that inspects and changes preconditioner blades for a single screw extruder system at regular intervals may be considered a PC in some instances but would not have a CCP.
Circumstances that do not require process controls	Supplier controls.
Monitoring activity that generally would not require records	Monitoring for pieces of ferrous metal with magnets.
Corrections that generally would not require records	Re-cleaning inadequately cleaned animal food contact surfaces before start up.
Preventive controls that would not require validation	Zoning controls.
Preventive controls that would not require validation	Segregation of animal food intended for different species during storage.
Preventive controls that would not require validation	Training.
Preventive controls that would not require validation	Preventive maintenance.
Preventive controls that would not require validation	Refrigerated storage.
Corrective action that generally would not require verification	Replacement of equipment.

XII. Potential Requirements for Product Testing and Environmental Monitoring

A. Our Request for Comment on Including Requirements for Product Testing and Environmental Monitoring in a Final Rule

In the 2013 proposed rule for preventive controls, we described the statutory framework of FSMA for product testing and environmental monitoring as verification measures. We also requested comment on when and how product testing programs and environmental monitoring are an appropriate means of implementing section 418 of the FD&C Act (78 FR 64736 at 64836 and 78 FR 3646 at 3762–3765). We specifically requested comment on including requirements for product testing programs and environmental monitoring in a final rule. Although we did not propose specific regulatory text, we asked a series of questions about what such requirements should include. Our discussions and questions about ''product testing'' focused on ''finished product testing.'' The Appendix contained extensive background on the role of testing as a verification measure in a modern food safety system (78 FR 64736 at 64834).

B. Product Testing

1. Comments on Product Testing

Some comments support product testing as a verification activity and make recommendations for what should be tested, how testing could be tied to risk, and how product testing could be used in a food safety plan. Some of these comments emphasize that product testing would not be appropriate as a control measure. Other comments do not support including requirements for ''finished product testing'' as a verification measure, but support including requirements for ''product testing'' in the final rule if the focus is broader than ''finished product testing,'' the use of product testing is tied to risk, and the regulations provide flexibility in how product testing is used in a food safety plan. Commenters with varying views on the issue nonetheless requested that FDA include proposed regulatory text for consideration.

For a full discussion of comments received to the 2013 proposed rule for preventive controls for human food, see section X.B.1 of the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

2. Potential Requirements for Product Testing

We acknowledge that there are limitations to product testing. Nonetheless, product testing programs, when implemented appropriately based on the facility, the animal food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for product testing. Such requirements would be tied to risk and addressed through flexible written procedures that would address both test procedures and corrective action plans.

In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how product testing programs are an appropriate means of implementing FSMA. We are seeking comment on whether requirements for product testing should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. The proposed regulatory

text would, if included in a final rule, establish requirements for:

- Product testing as an activity for verification of implementation and effectiveness as appropriate to the facility, the animal food, and the nature of the preventive control (proposed § 507.49(a)(2));
- Written procedures for product testing (proposed § 507.49(b)(2));
- Corrective action procedures for product testing (proposed § 507.42(a)(1)(ii)(A)); and
- Records of product testing (proposed § 507.45(b));

See the proposed regulatory text for proposed subpart C for the full text of such potential requirements. Consistent with the requests of the comments, proposed regulatory text would provide flexibility for a facility to make risk-based decisions on when product testing would be appropriate by providing that the facility can take into account the facility, the animal food, and the nature of the preventive control (e.g., whether the control is a kill step) rather than prescribe product testing in specific circumstance, or require that all types of facilities (including warehouses) conduct product testing. For supplementary information relevant to product testing, see the 2013 proposed rule for preventive controls (78 FR 64736 at 64805–64806), the Appendix in that proposed rule (78 FR 64736 at 64834–64836), and section X.B in the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

C. Environmental Monitoring

1. Comments on Environmental Monitoring

Some comments support environmental monitoring as a verification activity. In general, these comments recommend that the final rule specifically require environmental monitoring when ready to eat product (for human food) is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the animal food when it is exposed (note that under the 2013 preventive controls rule for animal food, the term ready to eat (RTE) is not used. All finished animal food is considered ready to eat, but it may not require packaging.) Comments emphasize the need for flexible requirements that would allow facilities to tailor their programs based on risk.

Some comments that generally support environmental monitoring as a verification activity nonetheless express concern about the potential for such requirements to be overly prescriptive. Comments particularly express concern about potentially prescriptive requirements for corrective actions if an environmental pathogen or appropriate indicator organism is detected.

Some comments do not support including requirements for environmental monitoring as a verification measure. Some of these comments assert that requirements for environmental monitoring would not be in accord with guidelines issued by the Codex Alimentarius Commission (Codex). Some comments note that environmental monitoring would not be relevant to all products, such as products that will be heat-treated or subject to a kill-step. Other comments note that environmental monitoring would not be relevant to facilities such as food distributors, due to the low likelihood of product contamination occurring in storage and distribution centers. Some of these comments express concern about broad requirements that would require environmental monitoring in a manner that was not risk-based, such as when an environmental pathogen is not reasonably likely to occur. Some commenters with varying views on the issue nonetheless asked FDA to issue proposed regulatory text for environmental monitoring for consideration.

2. Potential Requirements for Environmental Monitoring

Although the HACCP Annex of the Codex General Principles of Food Hygiene (Ref. 17) does not specifically recommend environmental monitoring as a verification activity in HACCP systems, the Codex General Principles of Food Hygiene (Ref. 18) does indicate that sanitation systems should be monitored for effectiveness and periodically verified, where appropriate, by microbiological sampling of environment and food contact surfaces, and regularly reviewed and adapted to reflect changed circumstances. Currently available data and information support the role of environmental monitoring in a food safety system that incorporates hazard analysis and risk-based preventive controls. (See, e.g., the 2013 proposed rules for preventive controls for animal food and human food (78 FR 64736 at 64806–64807 and 78 FR 3646 at 3764–3765 respectively) and the Appendices in the animal food and human food 2013 proposed rules (78 FR 64736 at 64834–64836 and 78 FR 3646 at 3812–3820 respectively.) See also and section X.C.2 of the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**). Environmental monitoring programs, when implemented appropriately based on the facility, the animal food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.

Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for environmental monitoring. The potential requirements would provide flexibility for animal food facilities to tailor their environmental monitoring programs based on risk. Environmental monitoring would be required in the specific circumstances where an animal food product is exposed to the environment prior to packaging, such as dog and cat food kibble, and the packaged animal food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the animal food when it is exposed. However, the potential requirements would not otherwise specify circumstances where environmental monitoring would be required and would instead require that the animal food facility conduct environmental monitoring as appropriate to the facility, the animal food, and the nature of the preventive control. The potential requirements would also not be prescriptive in the types of corrective actions needed in response to detecting an environmental pathogen or appropriate indicator organism in the environment; they would provide flexibility for facilities to establish and implement written corrective action procedures to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected animal food for safety, and, as necessary, prevent affected animal food from entering commerce.

In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how environmental monitoring is an appropriate means of implementing FSMA. We are seeking comment on whether requirements for environmental monitoring should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. The proposed regulatory text would, if

included in a final rule, establish requirements for:

- Performing, as part of the hazard evaluation, an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen (proposed § 507.33(c)(2));
- Environmental monitoring, for an environmental pathogen (e.g., *Salmonella* spp) or for an appropriate indicator organism (e.g., Listeria spp for L. monocytogenes), as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control, if contamination of an animal food with an environmental pathogen is a significant hazard (proposed § 507.49(a)(3));
- Records of environmental monitoring (proposed § 507.45(b));
- Written procedures for environmental monitoring (proposed § 507.49(b)(3)); and
- Corrective action procedures for environmental monitoring (proposed § 507.42(a)(1)(ii))(B).

See the proposed regulatory text for proposed subpart C for the full text of such potential requirements. For supplementary information relevant to environmental monitoring programs, see the 2013 proposed rules for preventive controls for animal food and human food (78 FR 64736 at 64806–64807 and 78 FR 3646 at 3764–3765), the Appendices for animal food and human food (78 FR 64736 at 64834–64836 and 78 FR 17142 at 17143–17151), and section X.C.2 of the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this issue of the **Federal Register.**

XIII. Potential Requirements for a Supplier Program

A. Our Request for Comment on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act

In the 2013 proposed rule for preventive controls, we described the statutory framework of FSMA for supplier controls, i.e., the supplier verification activities that section 418 of the FD&C Act includes as an example of preventive controls. We also requested comment on when and how supplier verification activities are an appropriate means of implementing section 418 (78 FR 64736 at 64804–64809). We specifically requested comment on including requirements for supplier approval and other verification activities in a final rule. Although we did not propose specific regulatory text, we asked a series of questions about what such requirements should include. The Appendix contained extensive background on the role of supplier programs in a modern food safety system (78 FR 64736 at 64836–64837).

B. Comments on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act

Some comments support including requirements for a supplier program in a final rule. These comments emphasize the need for flexible requirements that would allow facilities to tailor their programs based on risk, including risk inherent to raw materials and ingredients and risk that may be associated with a particular supplier (e.g., as reflected by the supplier's performance history). These comments provide many specific recommendations for what such requirements should—and should not—include. We summarize these recommendations in Table 7.

TABLE 7—SUMMARY OF SPECIFIC RECOMMENDATIONS IN COMMENTS THAT SUPPORT REQUIREMENTS FOR A SUPPLIER PROGRAM

Most comments support a requirement:	Most comments do not support a requirement:
For receiving raw material and ingredients from approved suppliers	For a written list of approved suppliers (because the list would be subject to frequent (perhaps daily) change).
For verification of a facility's immediate supplier	For verification of the supplier's supplier (because the facility has the greatest knowledge, leverage and ability to conduct meaningful oversight of its immediate supplier and because it is the supplier who is accountable to verify back one more step).
For records documenting that the basic requirements are being carried out.	For documents such as an underlying audit report (because of concerns about confidential information).
For audits as a verification activity, provided that the requirements are flexible and audits are not over-emphasized at the expense of other verification activities.	Prescribing the frequency of audits (particularly an annual frequency) (because an audit is only one tool and audits should be based on risk and on the performance of the supplier).
Limiting a supplier program to facilities that manufacture or process food.	Specifying that some hazards require more than one verification activity (because doing so would be too prescriptive and would not allow the facility the flexibility to determine the appropriate risk-based approach).
For oversight of a supplier program by a qualified individual	For a receiving facility to identify the regulations to which the supplier is subject (because the distinction would not be material to food safety).
That would be consistent with the Foreign Supplier Verification Program being established in a separate rulemaking.	
Specifying that a supplier program may be managed at a corporate level (rather than by specific facilities), because supplier programs are often managed at the corporate level. Some comments specifically recommend that inspection of a supplier program take place at the location where the program is managed, including at a corporate location rather than at an individual facility.	

Comments also address several other issues, such as whether the final rule should:

- Be limited to circumstances where a hazard is controlled by the supplier, or be required even if the hazard would be controlled by the receiving facility or by the receiving facility's customer.

• Include requirements for specific types of verification activities based only on the seriousness of hazards. Although some comments support such requirements, other comments do not because the basis should be risk (which includes probability as well as severity).

• Allow substitution of an inspection (e.g., by FDA) for an audit. Although some comments support such a substitution, others do not because they assert that an inspection and an audit are different in nature.

• Require a receiving facility to consider relevant regulatory information about the supplier. Although some comments support such requirements, others do not (e.g., because the information (which can be part of an overall supplier assessment) may not be available in a timely manner, is narrow in scope, and would diminish the importance of the supplier's food safety plan and the effectiveness of its implementation).

• Include requirements related to supplier non-conformance. Although some comments support such requirements, others maintain that supplier non-conformance would be better suited to guidance. Some comments specifically oppose a requirement for ''discontinuing use of the supplier'' and recommend flexibility for how a receiving facility would address supplier non-conformance.

• Provide for alternative verification requirements when a supplier is a qualified facility (which is subject to modified requirements; see proposed § 507.7 in the 2013 proposed rule for preventive controls). Although some comments support alternative requirements for suppliers that are qualified facilities, others express concern about whether alternative requirements can be practically implemented. Some comments state that the supplier verification requirements should not prevent facilities from sourcing ingredients from suppliers that are qualified facilities.

In general, comments that simply oppose including a supplier program in the final rule express concern about cost, ingredient diversity, and duplication of efforts. Some of these comments recommend that we issue guidance on supplier verification activities rather than establish requirements in the final rule. Some commenters, including those with varying views about the issue, nonetheless requested that FDA propose regulatory language for consideration.

C. Potential Requirements for a Supplier Program

Section 418 of the FD&C Act specifically identifies supplier verification activities as a preventive control (see section 418(o)(3) of the FD&C Act). Supplier controls, when implemented appropriately, are an important preventive control that can ensure that significant hazards will be significantly minimized or prevented for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient. Taking into account the comments reviewed so far, we are providing an opportunity for public comment on potential requirements for a supplier program as a preventive control. In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how supplier programs are an appropriate means of implementing FSMA. We are seeking comment on whether requirements for a supplier program should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to amend the 2013 proposed FSVP rule. In that supplemental notice we request comment, in light of the statutory provisions, on the manner and extent to which the FSVP and any preventive controls supplier verification provisions—as well as other aspects of the FSVP and preventive controls regulations—should be aligned in the final rules.

See the proposed regulatory text (proposed § 507.37 and the applicable definitions in proposed § 507.3) for the full text of such potential requirements. Briefly, the proposed regulatory text would, if included in a final rule:

• Establish definitions for terms used in the potential requirements for a supplier program (i.e., receiving facility; supplier; and qualified auditor) (proposed § 507.3)

• Establish a risk-based requirement for a written supplier program that:

• Would require, with some exceptions, a supplier program for raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of raw material or ingredient (proposed § 507.37(a)(1) and(a)(2)); and

• Would not apply to raw materials and ingredients for which there are no significant hazards, the preventive controls at the receiving facility are adequate, or the receiving facility relies on the customer and obtains written assurance (proposed § 507.37(a)(1)(ii));

• Require verification activities, as appropriate to the hazard, and documentation of such activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis, from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use) (proposed § 507.37(a)(3)(i));

• Require verification activities to verify that the hazard is significantly minimized or prevented, the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act, and the incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations (proposed § 507.37(a)(3)(ii));

• Provide flexibility for a receiving facility to determine and document the appropriate verification activities for raw materials and ingredients from particular suppliers, based on a series of factors, except when there is a reasonable probability that exposure to a significant hazard will result in serious adverse health consequences or death to humans or animals (proposed §§ 507.37(b) and 507.37(c)(1)) (see next bullet);

• Require an annual audit as a verification activity when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, unless the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (proposed § 507.37(c)(2));

• Provide for an alternative verification activity when the supplier is a qualified facility (proposed § 507.37(c)(3));

• Provide for alternative verification activities when the supplier is a farm that would not be subject to the requirements in the final produce safety rule under proposed § 112.4 (proposed § 507.37(c)(4));

• Require that an audit be conducted by a qualified individual who has technical expertise obtained by a combination of training and experience appropriate to perform the auditing

function (proposed § 507.37(d)(1)) and proposed § 507.53);

- Provide that inspection by FDA or an officially recognized or equivalent food safety authority may substitute for an audit (proposed § 507.37(e));
- Require action to address supplier non-conformance (proposed § 507.37(f)); and
- Require documentation of verification activities in records (listed in proposed § 507.37(g)), including minimum requirements for records documenting an audit, records of sampling and testing, and records documenting a review by the receiving facility of the supplier's relevant food safety records (proposed § 507.37(g)(5), (g)(6), and (g)(7), respectively).

In addition, the potential addition of requirements for a supplier program would require conforming amendments to other provisions of the rule, including the requirements for a food safety plan, preventive controls, validation, verification of implementation and effectiveness, and the list of implementation records for subpart C (see proposed §§ 507.31(c)(3), 507.36(c)(3), 507.39(b), 507.47(b)(3), 507.49(a)(4), and 507.55(a)(4) respectively). For supplementary information relevant to a supplier program, see the 2013 proposed rule for preventive controls (78 FR 64736 at 64807–64809), Appendix (78 FR 64736 at 64836–64837) and section XI.C of the supplemental notice of proposed rulemaking for the preventive controls for human food published elsewhere in this issue of the **Federal Register**. In the following paragraphs, we provide additional information about the potential requirements for a supplier program.

Reflecting the risk-based (including severity as well as probability) nature of a potential supplier program, a receiving facility's program would be limited to those raw materials and ingredients for which the receiving facility has identified a significant hazard. As discussed in section XI.C, ''significant hazard'' would be defined in the rule. Under the definition, hazards are determined to be significant based on the outcome of a hazard analysis and, thus the determination would incorporate the concept of risk. In addition, a receiving facility would establish and implement a supplier program only when a significant hazard is controlled before receipt; a receiving facility would not be required to establish and implement a supplier program if the receiving facility, or the receiving facility's customer, controls the hazard (and the customer provides assurances as to the control). Under this risk-based approach, a pet food manufacturer generally would be required to establish a supplier program for hazards associated with the minerals it processes (which would be controlled by the supplier during manufacture), but a manufacturer of dry pet food would not be required to establish a supplier program for microbial hazards in poultry by-products that it uses to produce the dry pet food if it will control that hazard for the poultry by-products during manufacture of the pet food (e.g., through a heat kill step such as the extrusion process).

The potential supplier program would include requirements applicable to a ''receiving facility'' and the proposed definition of ''receiving facility'' would describe a receiving facility as a facility that manufactures/processes a raw material or ingredient that it receives from a supplier. A supplier would be defined as the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consist solely of the addition of labeling or similar activity of a *de minimis* nature. The supplier could be an ''establishment'' rather than a ''facility'' because a supplier may be an entity that is not required to register under section 415 of the act and, thus, would not be a ''facility'' as that term would be defined for the purpose of this rule. Under this definition, a facility that packs or holds the animal food without any type of manufacturing/processing would not be a supplier. Under this approach, a facility would not be required to establish a supplier program for animal food products that it only packs or distributes. For example, a receiving facility might receive a raw material or ingredient from a distribution center that receives the raw material or ingredient from a manufacturing facility or a farm. The distribution center, which is the immediate previous source of the raw material or ingredient, would not be required to establish a supplier program and would not be considered the supplier; rather the supplier would be the manufacturer or the farm (which manufactured/processed the food or harvested the food that was provided to the distribution center and subsequently to the receiving facility). In such instance, if the receiving facility has identified a significant hazard for the raw material or ingredient, and that hazard is controlled by the supplier (the manufacturer or the farm), the receiving facility would establish verification activities related to the manufacturer or the farm that provided the raw material or ingredient to the distribution center.

If a facility receives an ingredient from a supplier, but the control of the hazard is by the supplier's supplier, under a potential supplier verification program, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that its supplier has controlled the hazard, i.e., the receiving facility would review the supplier's food safety records for its supplier's control of the hazard. For example, if a feed mill is receiving animal protein from a protein blender that receives meat and bone meal from a rendering facility, the feed mill could conduct verification activities related to the rendering plant controls at the rendering facility by reviewing the supplier program of, and verification activities conducted by, the protein blender for its supplier, the renderer (in addition to verifying the protein blender's control of pathogens).

We understand that, particularly for RACs, there may be multiple establishments, including cooperatives, packing houses, and distributers, between a receiving facility and the establishment that would be considered the supplier, which would make potential supplier verification very challenging under certain circumstances. We request comment on what verification activities would be appropriate for receiving facilities to conduct, should a supplier verification program be included in any final rule, when a raw material or ingredient passes through more than one facility that would not be required to verify control of hazards if supplier programs are limited to manufacturers/processors. For example if a receiving facility is a feed mill that receives oats from a distributor, who receives grains from a cooperative, and neither the distributor nor the cooperative is required to establish supplier controls for the farms, where the hazards are being controlled, what supplier controls should be applied for the grains coming from the farms? We request comment on whether and how any potential supplier verification should address such situations.

In addition, we seek comment regarding whether (and, if so, how) the final preventive controls rule should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain and Point B in the supply chain is a facility that only packs or holds

animal food, but does not manufacture/process animal food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain.

The potential supplier program would be included in the food safety plan and, thus, would be prepared (or overseen) by a qualified individual (see proposed § 507.31(b)). A supplier program could be established and maintained by a facility's corporate headquarters or parent entity. The recordkeeping requirements would specify that electronic records are considered to be onsite if they are accessible from an onsite location, and we expect that many records for the supplier program would be in electronic form (and thus easily retrievable by a facility during an inspection).

Rather than specifically require a written list of approved suppliers, the potential requirements would specify that the supplier program be written, and include verification activities, as appropriate to the hazard, and documentation of such activities, to ensure products are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use). Such a program could include, for example, written procedures for approving suppliers, for approving (or rejecting) specific raw materials and ingredients, and for documenting that raw materials or ingredients are only received from approved suppliers. The potential requirements would recognize that there can be circumstances that would require a facility to receive raw materials or ingredients on a temporary basis from an unapproved supplier (e.g., if there is a disruption in delivery of raw materials and ingredients from approved suppliers due to circumstances such as localized flooding or malfunctioning equipment). We request comment on examples of circumstances when it would be necessary and appropriate to receive raw materials and ingredients on a temporary basis from an unapproved supplier and on the types of verification activities that a facility should conduct on animal food from an unapproved supplier.

The potential requirements would provide flexibility for the verification activities that the receiving facility would conduct for raw materials and ingredients. With one exception, the receiving facility would have flexibility to select one or more of four possible activities: (1) Onsite audit; (2) sampling and testing of the raw material or ingredient, which could be conducted by either the supplier or the receiving facility; (3) review by the receiving facility of the supplier's relevant food safety records; and (4) other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier. To determine which option is appropriate, the receiving facility could consider (1) the severity of the hazards; (2) where the preventive controls for those hazards are applied (such as at the supplier or the supplier's supplier); (3) the supplier's procedures, processes, and practices related to the safety of the raw materials and ingredients; (4) applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the animal food; (5) the supplier's animal food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of supplier in correcting problems; and (6) any other factors as appropriate and necessary, such as storage and transportation. Thus, a receiving facility would have flexibility to select a verification activity based on the circumstances.

The exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. In this circumstance, under the potential supplier program, the receiving facility would be required to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter. The potential requirement for an annual audit is limited to when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. Further, the receiving facility could select less frequent audits or a different verification activity, if it documented its determination that the less frequent onsite auditing or other verification activity provides adequate assurance that the hazards are controlled. The potential recordkeeping requirements that would apply to audits would identify specific information that the records must provide about the audit, including the conclusions of the audit, but would not specify that the underlying audit report is part of the required documentation of an audit.

A person who conducts an audit would need to be qualified to do so. To be qualified, a person who conducts an audit (''qualified auditor'') would be required to satisfy the criteria for a ''qualified individual'' (a person who has successfully completed training in the development and application of risk-based preventive controls equivalent to that of an FDA-recognized standardized curriculum or is otherwise qualified through job experience to develop and apply a food safety system) and have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

The potential supplier program would require the receiving facility to know the FDA food safety regulations that apply to the supplier, and relevant information about the supplier's compliance with those regulations. The focus of section 418 of the FD&C Act is on preventing food safety problems rather than on reacting to them. Section 418 of the FD&C Act requires the owner, operator, or agent in charge of a facility to establish and implement preventive controls to significantly minimize or prevent known or reasonably foreseeable hazards. By specifying that supplier verification activities are a preventive control, section 418 requires the receiving facility to take necessary actions to ensure that raw materials and ingredients are not adulterated. To determine whether incoming raw materials and ingredients are adulterated, a receiving facility would need to know the regulatory framework that applies to the raw materials and ingredients, and to have confidence that its supplier is complying with that regulatory framework.

The potential supplier program would include provisions to address non-conformance by a supplier. This potential requirement would not prescribe when a particular corrective action (such as discontinuing a supplier) is necessary. A facility could substitute an inspection (whether by FDA or by the food safety authority of a country whose animal food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) for an audit. Even though inspection procedures and audit procedures are not identical, we tentatively conclude that a facility should have flexibility to determine whether an inspection could substitute for an audit based on characteristics such as the severity of

the hazard, how the supplier controls the hazard, and the supplier's performance history. For example, a facility that receives animal feed ingredients from a facility subject to the BSE feed regulations in 21 CFR 589.2000 may conclude that an FDA inspection for compliance with the BSE regulations (concluding that no action is indicated) provides adequate assurance that the facility is producing an animal food ingredient in compliance with the requirements of applicable FDA food safety regulations and is not adulterated under section 402 of the FD&C Act. For additional discussion of our reasons for tentatively concluding that it would be appropriate to substitute an inspection (whether by FDA or by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) for an audit, see the discussion in the proposed FSVP rule (78 FR 45730 at 45758). In addition, we are asking for comment on whether it would be appropriate to substitute an inspection in another country (Country A) for an audit when, for example, it is the food safety authority of Country B (whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) that conducted the inspection in Country A.

The potential requirements would provide for alternative verification requirements when a supplier subject to the requirements of section 418 of the FD&C Act is a qualified facility subject to the requirements of proposed § 507.7. Section 418 provides different requirements for qualified facilities, which are reflected in the different potential verification requirements for such facilities. Although the potential requirements would allow a receiving facility to conduct an alternative verification activity when the supplier is a qualified facility, they would not require this.

Likewise, the potential requirements would provide for alternative verification requirements when a supplier is a farm that would not be subject to the requirements of proposed § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm. Some of these farms would be not be subject to the requirements of proposed § 112.4 because they satisfy the criteria, in section 419(f) of the FD&C Act, for an exemption for direct farm marketing. Other farms would not be subject to the requirements of proposed § 112.4 because the crops they grow would not be covered by the proposed produce safety rule, either based on the findings of a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce (see the discussion of this qualitative assessment of risk in the 2013 proposed produce safety rule, 78 FR 3504 at 3508 and 3522–3529) or because they account for a very small percentage of covered produce (see proposed § 112.4 and the discussion at 78 FR 3504 at 3549). Although the potential requirements would allow a receiving facility to conduct an alternative verification activity for such farms, they would not require this. Although the potential requirements would provide for alternative verification requirements for farms that would not be subject to the produce safety rule, we would not issue a final rule on such alternative verification requirements until we issue the final produce safety rule.

D. Request for Additional Comment on Requirements To Address Conflicts of Interest for Persons Conducting Verification Activities

In the 2013 proposed FSVP rule, we tentatively concluded that it would be appropriate to address the independence of individuals conducting verification activities (78 FR 45730 at 45759). We proposed that an individual who conducts any verification activity must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity, and provided that this would not prohibit an importer, or the importer's employee, from conducting the verification activity (proposed § 1.506(g)). As discussed in the 2013 proposed FSVP rule, we considered such requirements necessary to prevent bias, or the appearance of bias, on the part of a person conducting a verification activity (78 FR 45730 at 45759).

We request comment on whether we should include in the final preventive controls rule requirements to address conflicts of interest for individuals conducting verification activities and, if so, the scope of such requirements. For example, should such requirements be directed to a subset of persons who conduct verification activities (such as auditors) or should they be directed more broadly? Would a requirement such as in the 2013 proposed FSVP rule be appropriate, or would some other requirement be more appropriate (such as a requirement that persons be free of conflicts of interest that are relevant to the outcome of the activity)? What would constitute a financial interest in a company sufficient to constitute a conflict of interest for a person conducting a supplier verification activity (e.g., conducting an audit of that company or conducting laboratory tests of that company's food)?

XIV. Potential Requirements for the Hazard Analysis To Address Economically Motivated Adulteration

A. Our Request for Comment on Whether the Final Rule Should Address Economically Motivated Adulteration

In the 2013 proposed rule for preventive controls, we announced our intent to implement the statutory requirements for hazards that may be intentionally introduced, including by acts of terrorism, in a separate rulemaking rather than include them in the requirements for hazard analysis and risk-based preventive controls (78 FR 64736 at 64745). We tentatively concluded that intentional hazards, which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, we also acknowledged that some kinds of intentional adulterants could be viewed as reasonably likely to occur, e.g., in foods concerning which there is a widely recognized risk of economically motivated adulteration in certain circumstances. We provided an example of this kind of hazard, i.e., the addition of the chemical melamine to certain food products, apparently to enhance the measured protein content and/or perceived quality of the product. We requested comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We also requested comment on when an economically motivated adulterant can be considered reasonably likely to occur.

When we developed the 2013 proposed intentional contamination rule, we tentatively concluded that economically motivated adulteration would be best addressed through the approach in the preventive controls rules for human food and for animal food (including hazard analysis, preventive controls, monitoring, corrective action, verification, and recordkeeping) rather than through the vulnerability assessment-type approach for intentional adulteration, where the intent is to cause wide-spread public health harm, such as acts of terrorism (see the 2013 proposed intentional adulteration rule, 78 FR 78014 at 78020). We also explained our view that the primary purpose of economically motivated adulteration is to obtain economic gain rather than to impact

public health, although public health harm may occur (78 FR 78014 at 78020).

B. Comments on Economically Motivated Adulteration

Some comments oppose including requirements directed to economically motivated adulteration in the preventive controls rule. These comments assert that the vast majority of economically motivated adulterants affect quality and value rather than safety. These comments also point out that the majority of food products could, in theory, be subject to economically motivated adulteration but that it would be difficult to determine if such adulteration is reasonably foreseeable. One comment recommends that we draw a clear distinction between hazards that are intentionally introduced and those that are not. Another comment expresses the view that food fraud is fundamentally different from both food safety and food defense. However, some comments do support including ''expected intentional adulterants'' in the preventive controls rule.

C. Potential Requirements To Address Economically Motivated Adulteration

Taking into account the comments we have reviewed so far for the proposed preventive controls rules for human food and for animal food, we are providing an opportunity for public comment on a potential requirement for the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain (see proposed § 507.33(b)(2)(iii) in proposed subpart C). In this section of this document, we are reopening the comment period with respect to our previous request for comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We are seeking comment on whether this preventive controls rule would be the most appropriate rule to address FSMA's requirements to address hazards that may be intentionally introduced (for purposes of economic gain) and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. We note that the preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 1) describes certain assumptions we are making about the preventive controls, and their implementation, that would be established and implemented by a facility that identifies a potential hazard that may be intentionally introduced for economic reasons as a significant hazard. We are seeking comment on alternative ways to control such hazards.

Under the definitions that would be established in the rule, a hazard would be an agent that is reasonably likely to cause illness or injury in the absence of its control. Thus, the focus of the potential requirement would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value with little or no potential for public (human or animal) health harm.

We believe that it is practicable to determine whether economically motivated adulteration is reasonably foreseeable. Importantly, we would not expect facilities to consider hypothetical economically motivated adulteration scenarios for their animal food products. As discussed in the 2013 proposed intentional adulteration rule, we would expect facilities to focus on circumstances where there has been a pattern of such adulteration in the past, suggesting a potential for intentional adulteration even though the past occurrences may not be associated with the specific supplier or the specific food product (78 FR 78014 at 78027). For example, in the 2013 proposed rule for preventive controls we discussed a widespread incident of economically motivated adulteration in which two ingredient suppliers added melamine, a nitrogen-rich industrial by-product (a non-protein nitrogen), to wheat gluten and rice protein concentrate to increase the apparent protein content (78 FR 64736 at 64746). The wheat gluten was imported by a U.S. broker and sold to U.S. pet food manufacturers and at least one distributor who then sold it to other pet food manufacturers. The melamine adulterated products later made their way into food for swine, poultry, and fish. This adulteration resulted in significant public health consequences for animals as well as concerns for human health from products produced from swine, poultry, and fish that had consumed melamine contaminated foods (72 FR 30014).

In light of this incident, a prudent person would include in its hazard analysis the potential for melamine to be an economically motivated adulterant in its animal food products when using certain protein ingredients for animal food and, based on the outcome of its hazard analysis, determine whether melamine is a hazard that must be addressed in the food safety plan.

There are other well-known substances that have been economically motivated adulterants and have potential to cause public (human and animal) health harm. The U.S. Pharmacopeial Convention (USP) has a free on-line food fraud database (Ref. 19) and a recent report from the Congressional Research Service provides additional information on economically motivated adulteration of food and food ingredients (Ref. 20).

XV. Provisions for Withdrawal of an Exemption for a Qualified Facility

A. 2013 Proposed Provisions for Withdrawal of an Exemption for a Qualified Facility

In the 2013 proposed rule for preventive controls, we explained the provisions of FSMA that establish criteria for a facility to be a qualified facility, establish an exemption for qualified facilities, establish requirements for qualified facilities, and provide that we may withdraw the exemption otherwise granted to qualified facilities in specified circumstances (section 418(l) of the FD&C Act; see 78 FR 64736 at 64743). We proposed to establish:

- Definitions relevant to these provisions (proposed § 507.3);
- An exemption from the requirements for hazard analysis and risk-based preventive controls for qualified facilities (proposed § 507.5(d));
- Requirements for qualified facilities (proposed § 507.7); and
- Procedural requirements that would govern our withdrawal of an exemption for a qualified facility (proposed subpart D; the 2013 proposed withdrawal provisions) (see 78 FR 64736 at 64762, 64765, and 64810).

The 2013 proposed withdrawal provisions would:

- Specify the circumstances under which we would withdraw an exemption for a qualified facility (proposed § 507.60);
- Establish procedures for us to issue an order to withdraw the exemption, including information that would be in the order (proposed §§ 507.62 and 507.65);
- Establish procedures whereby a qualified facility may submit a written appeal of our order to withdraw an exemption (proposed § 507.67 and 507.69);
- Establish procedures for appeals, hearings, and decisions on appeals and hearings (proposed §§ 507.71, 507.73, 507.75, and 507.77); and
- Specify the circumstances in which an order to withdraw an exemption is revoked (proposed § 507.80).

B. Proposed Clarification of What FDA Will Do Before Issuing an Order and Proposed Mechanism for Re-Instating an Exemption

For a full discussion on the comments received for provisions on withdrawal of an exemption for a qualified facility under the 2013 proposed rule for preventive controls for human food, see section XIII.B of the preamble for the supplemental notice of proposed rulemaking for preventive controls for human food published elsewhere in this **Federal Register.** See the revised regulatory text for proposed subpart D for the full text of the proposed requirements.

C. Proposed Revisions to the Content of an Order To Withdraw an Exemption

Based on comments reviewed to date for the proposed preventive controls rule for human food, which appear relevant to animal food, in this section of this document, we are reopening the comment period with respect to proposed § 507.65(d).

Some comments received under the 2013 proposed rule for preventive controls for human food recommend that the order explicitly state that the facility has the option to either comply with the order or appeal the order (with a request for an informal hearing) within 10 calendar days.

We tentatively conclude that it would be useful for the order to itself specify the two options that a facility has upon receipt of the order, even though the order would otherwise include this information (because the order will contain the full text of the withdrawal provisions). Therefore, we are proposing to revise the requirements for the contents of an order to explicitly mention these two options. See the revised regulatory text of proposed § 507.65(d).

D. Proposed Revisions to the Timeframes for a Facility To Comply With, or Appeal, an Order

In this section of this document, we are reopening the comment period with respect to the timeframes in proposed §§ 507.65(d) and 507.67(a) and (c).

1. Comments

Some comments received under the 2013 proposed rule for preventive controls for human food ask us to specify that a facility's timeframe for taking action begins when the facility receives the order, not when we issue the order. Other comments address the timeframes for a facility to compile information needed to appeal an order for withdrawal. These comments assert that the proposed timeframe of 10 days is insufficient, and recommend timeframes such as 30 days or 90 days.

Some comments contrast the proposed 60-day timeframe to comply with the requirements for hazard analysis and risk-based preventive controls when a facility loses its exemption as a qualified facility with the timeframe that a facility would have to comply with these requirements when the final rule first becomes effective. As discussed in the 2013 proposed rule for preventive controls, we proposed compliance dates that would be 2 years and 3 years after the date of the final rule for small and very small businesses, respectively (78 FR 64736 at 64751). The comments assert that these two situations are parallel, because a qualified facility that has had its exemption withdrawn would be coming into compliance with the full requirements for hazard analysis and risk-based preventive controls for the first time. These comments recommend that we change the timeframes in the 2013 proposed withdrawal provisions to better align with the compliance dates contemplated by the proposed rule and by FSMA for small and very small businesses. Some of the comments recommend that a small business have 6 months, and that a very small business have 18 months, to comply with the order. Other comments recommend that any business (whether small or very small) have two years to comply with the order. Some of these comments recommend that the timeframe be tied to the date of the final determination rather than to the date of the order.

2. Proposed Revisions to Timeframes

We tentatively conclude that the nature of what a facility would need to do to comply with an order, i.e., comply with the full requirements for hazard analysis and risk-based preventive controls—makes the timeframes in the 2013 proposed withdrawal provisions insufficient. However, it is relevant that in contrast to the general compliance dates, the proposed withdrawal provisions would only apply when a significant public health (human and animal) concern has been identified for a particular facility.

We also tentatively conclude that it is appropriate to link the timeframe for compliance to the date of receipt of the order, rather than to the date the order was issued. Doing so would be consistent with our other administrative procedures, such as appeal of an order for administrative detention (§ 1.402).

Taking into account the comments reviewed so far for the proposed rule for preventive controls for human food, which appear relevant to animal food, we are proposing to require that a facility comply with an order to withdraw an exemption within 120 days of the date of receipt of the order. See the revised regulatory text for proposed §§ 507.65(d) and 507.67(a) and (c).

XVI. Definition of Very Small Business

A. The 2013 Proposed Options for Definition of Very Small Business

We proposed three options for the definition of a very small business based on total annual sales of animal food, adjusted for inflation: Option 1, $500,000; Option 2, $1,000,000; and Option 3, $2,500,000. The 2013 proposed rule for preventive controls contained several provisions relevant to very small businesses, including exemptions from subpart C in §§ 507.5(e) and 507.5(f) for very small (and small) facilities engaged only in specific types of on-farm activities involving low-risk activity/animal food combinations, the exemption in § 507.5(d) and requirements in § 507.7 for a very small business as a qualified facility, and extended time to comply with the rule. In defining a very small business, we took into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act (''Food Processing Sector Study'' (Ref. 21); see 78 FR 64736 at 64758–64759). In the 2013 proposed rule for preventive controls, we requested comment regarding the three proposed options for the definition of ''very small business.'' We also requested comment on whether a dollar amount of sales that is more than, or less than, the $500,000; $1,000,000; or $2,500,000 amounts would be appropriate.

B. Comments on the 2013 Proposed Options for Definition of Very Small Business

Comments support a variety of dollar limits of total annual sales of animal food for defining a very small business, including each of the three proposed options ($500,000, $1,000,000, and $2,500,000) as well as other dollar limits that we did not include as proposed options (e.g., less than $10,000). Some comments assert that very small facilities will incur a large portion of the costs associated with implementing the 2013 proposed rule for preventive controls rule because very small facilities lack experience with HACCP-based models.

Some comments support defining a very small business as one with total annual animal food sales up to $2,500,000. Some of these comments express concern that using lower dollar

sales amounts to define a very small business would discourage growth of very small processing facilities (especially those co-located on a farm), would unfairly burden very small facilities, and could cause them to fail due to the estimated high cost of compliance; whereas setting a higher dollar sales amount would encourage growth, innovation and diversification. Some of these comments note that adopting the threshold of $2,500,000 would establish that the full preventive controls requirements would apply to the businesses that produce the vast majority of animal food products and that modified requirements would apply to smaller businesses that represent the majority of producers but the minority of the animal food supply.

Other comments support no amount of annual animal food sales for defining very small business stating that the requirements should apply uniformly to all facilities. Some comments state that even a $2,500,000 threshold would result in very few of certain types of animal food facilities qualifying as a very small business.

C. Proposed Revisions to the Definition of Very Small Business

In this supplemental notice of proposed rulemaking, we are proposing the definition of very small business as a business that has less than $2,500,000 in total annual sales of animal food adjusted for inflation. The statutory construct does not prevent us from establishing a definition for very small business that would include more facilities than those that would be included under the statutory provision that considers sales to qualified end-users (section 418(l)(1)(C) of the FD&C Act). Section 418(n)(1)(B) of the FD&C Act directs FDA to define the term ''very small business'' for the purposes of determining whether a facility is a ''qualified facility'' eligible for modified requirements. Further, section 418(n)(1)(B) requires us to consider the Food Processing Sector Study for the purpose of defining ''very small business.'' FDA notes that section 418 of the FD&C Act does not otherwise limit how FDA may define ''very small business.''

We tentatively conclude that it is not necessary for the dollar limit in the definition of ''very small business'' to be $500,000 or less to protect public health (human and animal). In the 2013 proposed rule for preventive controls, we estimated the number of facilities that would be affected by the size specified in the definition of ''very small business.'' The size specified in the definition of ''very small business'' would affect the compliance dates, the exemptions for qualified facilities, and the exemptions for on-farm low-risk packing and holding activity/animal food combinations and on-farm low-risk manufacturing/processing activity/animal food combinations (proposed §§ 507.5(d), (e), and (f), respectively) (see 78 FR 64736 at 64762–64763). As a group, businesses with less than $2,500,000 in total annual sales of animal foods produce less than two percent of all animal food produced in the United States when measured by dollar value. (In the 2013 proposed rule, this was stated as businesses with less than $2,500,000 in as total annual sales of animal food produce less than 20.8 percent of all pet food and animal feed produced in the United States when measured by dollar value (78 FR 64736 at 64760). This was an error and should have said less than 2 percent of all pet food and animal feed produced in the United States when measured by dollar value.) We acknowledge that this estimate of all animal food produced in the United States is higher than the estimates for lower dollar limits (less than one percent of all animal food produced in the United States, or less than one-half of one percent of all animal food produced in the United States, for limits of $1,000,000 or $500,000, respectively). Regardless, under the revised definition, the businesses that would be exempt from the requirements for hazard analysis and risk-based preventive controls would represent a small portion of the potential risk of foodborne illness.

We tentatively conclude that the definition of very small business should exempt from the rule only a small percent of animal food to minimize the risk of foodborne illness and, thus, are proposing a very small business definition of $2,500,000, which would exempt less than two percent of the dollar value of animal food produced in the United States. We request comment on this tentative conclusion and whether we should consider other dollar limits for very small business.

A dollar limit in the definition of ''very small business'' greater than $500,000 would not necessarily exempt those companies whose practices would be most improved by complying with the requirements for hazard analysis and risk-based preventive controls. The Food Processing Sector Study (Ref. 21) concluded that there was no consistent pattern across food categories, including the pet food and animal feed categories, in terms of which sizes of establishments contribute most to foodborne illness risk (78 FR 64736 at 64758). Moreover, the facilities that would be classified as qualified facilities would be subject to modified requirements (see proposed § 507.7). Furthermore, all facilities that would be exempt from the requirements for hazard analysis and risk-based preventive controls would continue to be subject to the prohibitions in the Federal Food, Drug, and Cosmetic Act against causing animal food to be adulterated or misbranded and against distributing such animal food, and to inspection by FDA.

We are not proposing that the definition of ''very small business'' consider number of employees as well as dollar limits, be based on number of employees for consistency with the definition of ''small business,'' or be based on volume of animal food sold rather than on dollar limits associated with sales of animal food. There are two alternative sets of criteria to be a qualified facility. The criteria in section 418(l)(1)(C) of the FD&C Act are set out with regard to sales. We believe it is appropriate for the other criteria (related to being a ''very small business'') similarly to be related to sales. As discussed in the 2013 proposed rule for preventive controls, we proposed number of employees for the definition of ''small business'' in part because it would be the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR 121 for most food manufacturers. We continue to believe that the proposed definition of ''small business,'' based on number of employees, is appropriate.

We are not proposing that the definition of ''very small business'' consider the risk associated with the animal food manufactured, processed, packed, or held by the facility. The description ''very small'' addresses size of a business, not risk associated with animal food that the facility manufactures, processes, packs, or holds.

XVII. Other New and Revised Proposed Provisions

A. Proposed New Definitions

1. Proposed Definition of ''Pathogen''

In the 2013 proposed rule for preventive controls for food for animals, we proposed to define ''environmental pathogen'' to mean a microorganism that is of animal or human health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. Variations of the phrase ''microorganism of animal or human health significance'' appear in several places in the 2013 proposed

rule. To both simplify the regulations and use the same term (i.e., ''pathogen'') when we mean a microorganism of animal or human significance, we are proposing to define the term ''pathogen'' to mean a microorganism that is of public (human or animal) health significance and to replace variations of the phrase ''microorganism of animal or human health significance'' with ''pathogen'' throughout the regulations.

2. Proposed Definition of ''You''

We acknowledge the potential for confusion if the phrase ''owner, operator, or agent in charge'' applies to both plant management and operators in proposed subpart B and to the ''owner, operator, or agent in charge of a facility'' in proposed subpart C. Most of the provisions of proposed subpart B do not specify the role of ''plant management'' or the ''operator'' of a plant or establishment. To prevent confusion, we tentatively conclude it is prudent to retain terms such as ''plant management'' and ''operator'' in proposed subpart B.

However, we tentatively conclude that we can simplify the regulations directed to the ''owner, operator, or agent in charge of a facility'' in provisions in subparts A, C and D by using pronouns, without creating confusion, if we (1) define the term ''you'' to mean, for purposes of part 507, the owner, operator, or agent in charge of a facility and (2) limit use of the term ''you'' to provisions in proposed subparts A, C and D. See the revised regulatory text for the definition of you (in proposed § 507.3) and its use throughout revised subpart C.

3. Proposed Definition of ''Significant Hazard''

As discussed in section XI.C, we are proposing to delete the proposed definition ''hazard reasonably likely to occur'' and instead establish a definition for ''significant hazard.'' See the revised regulatory text in proposed § 507.3.

4. Proposed Definition of ''Known or Reasonably Foreseeable Hazard''

As discussed in section XI.C, we are proposing to delete the proposed definition ''reasonably foreseeable hazard'' and instead establish a definition for ''known or reasonably foreseeable hazard.'' See the revised regulatory text in proposed § 507.3.

5. Potential Definitions of ''Qualified Auditor,'' ''Receiving Facility,'' and ''Supplier''

As discussed in section XIII.C, we are providing an opportunity for public comment on potential requirements for a supplier program. If such requirements are included in a final rule, we would establish definitions for three terms used in the potential requirements for a supplier program, i.e., ''qualified auditor,'' ''receiving facility,'' and ''supplier.'' See the proposed regulatory text in proposed § 507.3.

B. Proposed Revisions to Definitions

In the 2013 proposed rule for preventive controls, we proposed to establish several new definitions.

1. Revised Definition of ''Hazard'' and ''Reasonably Foreseeable Hazard''

Some comments received under the 2013 proposed rule for preventive controls for human food recommended that we include radiological hazards as a subset of chemical hazards in the definition ''hazard.'' Although radiological hazards would not be common, we believe that facilities in the past have considered them as chemical hazards when conducting a hazard analysis for the development of HACCP plans. The revised regulatory text uses the phrase ''chemical (including radiological)'' in the definition of ''hazard'' and as applicable throughout the regulations. As a conforming change, we are proposing to revise the definition of ''reasonably foreseeable hazard'' to mean a potential biological, chemical (including radiological), or physical hazard that may be associated with the facility or the food.

2. Revised Definition of Environmental Pathogen

We proposed to define the term ''environmental pathogen'' to mean a microorganism that is of public (human or animal) health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. We identified Salmonella spp. and Listeria monocytogenes as examples of environmental pathogens. There was some concern that our proposed definition of ''environmental pathogen'' would capture organisms such as pathogenic sporeformers whose presence in and of itself would not constitute a risk to public (human or animal) health.

We are proposing to revise the definition of an environmental pathogen to mean a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that animal food may be contaminated and may result in foodborne illness if that animal food is consumed (or in the case of pet food, handled by a human) without treatment at the facility to significantly minimize the environmental pathogen. The revised definition of ''environmental pathogen'' would specify that an environmental pathogen does not include the spores of pathogenic sporeformers and, thus, recognizes that consumption of animal food contaminated by the spores of a pathogenic sporeformer that is in the environment may not result in foodborne illness. For example, if animal food is contaminated with spores of C*lostridium botulinum,* the microorganism would not produce the botulinum toxin that causes illness unless these spores are subject to conditions that allow them to germinate into vegetative cells that produce the toxin. Pathogenic sporeformers are normally present in animal foods, and unless the foods are subjected to conditions that allow multiplication, they present minimal risk of causing illness.

C. Proposed Editorial Changes

The revised regulatory text includes several changes that we are making to make the requirements more clear and improve readability. We summarize the principal editorial changes in Table 8.

TABLE 8—PROPOSED EDITORIAL CHANGES

Designation in the revised regulatory text (Proposed §)	Proposed revision	Explanation
Throughout part 507	Substitute the term ''adequate'' for the term ''sufficient''	For the purposes of part 507, there is no meaningful difference between ''adequate'' and ''sufficient.'' We proposed a definition of ''adequate'' but did not propose to define ''sufficient.'' We tentatively conclude that the regulations will be clearer if we use the single term ''adequate'' throughout the regulations.

TABLE 8—PROPOSED EDITORIAL CHANGES—Continued

Designation in the revised regulatory text (Proposed §)	Proposed revision	Explanation
Throughout subparts A, C, and D.	Substitute the defined term ''you'' for ''owner, operator, or agent in charge of a facility''.	Improve clarity and readability.
507.31	Redesignate the section number from the original section number in the 2013 proposed preventive controls rule (proposed 507.30).	Accommodate insertions of new § 507.28 to subpart B.
507.31(d)	Specify that the food safety plan is a record that is subject to the requirements of subpart F within the requirements for the food safety plan (§ 507.31) rather than together with the requirements for other records required by the rule (§ 507.55).	Distinguish the requirements for the contents of the food safety plan from implementation records, which continue to be listed in § 507.55.
507.33(b)	Reordered the provisions in paragraph (b)	We tentatively conclude that it is more logical to specify what hazards must be considered (i.e., biological, chemical (including radiological), and physical) before specifying the reasons for how the hazards could get into the food products (i.e., naturally occurring, unintentionally introduced, or intentionally introduced for purposes of economic gain).
507.36	Shorten the title from ''Preventive controls for hazards that are reasonably likely to occur'' to ''Preventive Controls''.	Simplify the presentation of the requirements and conform with the proposed deletion of the term ''hazards that are reasonably likely to occur''.
507.36(c)(1)	Rearrange the requirements for (i) parameters associated with the control of the hazard and (ii) the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to be associated with process controls rather than be a standalone requirement.	It is more logical to place these requirements with process controls since their parameters and their values are associated with process controls.
507.36(c)(2) and 507.42(c)	Move requirements for corrections for sanitation controls from the requirements for preventive controls (proposed § 507.36) to the requirements for corrective actions (proposed § 507.42).	Improve clarity and readability.
507.38	Shorten the title from ''Recall plan for animal food with a hazard that is reasonably likely to occur'' to ''Recall plan''.	Simplify the presentation of the requirements and conform with the proposed deletion of the term ''animal food with a hazard that is reasonably likely to occur''.
507.40	Redesignate the section number from the original section number in the 2013 proposed preventive controls rule (proposed § 507.39) and modify the language.	Accommodate insertions of new § 507.37 (supplier program) and new § 507.39 (preventive control management components) and reword to more closely match the statutory language.
507.45, 507.47, 507.49, and 507.50.	Move the more extensive verification requirements for validation, implementation and effectiveness, and reanalysis from the single proposed section (proposed § 507.45) to separate sections (proposed §§ 507.47, 507.49, and 507.50, respectively).	Improve clarity and readability.
507.50(a)(4)	Revise the requirements for reanalysis of the food safety plan after an unanticipated event in which a preventive control is not properly implemented to refer to the requirements for corrective actions in light of such an event rather than repeat the full text of those requirements for corrective actions.	Simplify the presentation of requirements and reduce redundancy in regulatory text for inter-related requirements.
507.50(c)	Specify ''document the basis for the conclusion that no revisions are needed'' rather than ''document the basis for the conclusion that no additional or revised preventive controls are needed''.	Improve clarity and readability.
507.50(e)	Specify ''You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding'' rather than ''FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.''.	Improve clarity by specifying what the owner, operator, or agent in charge of the facility must do in certain circumstances rather than what FDA may require.
507.55	Change the title from ''Records required for subpart C'' to ''Implementation records''.	Accurately reflect the nature of the listed records after moving recordkeeping requirements for the food safety plan to § 507.31.
507.55(a)(3)(ii) and (iii)	Add ''verification of'' in front of ''monitoring'' and ''corrective actions''.	Distinguish these requirements for records applying to ''verification of monitoring'' and ''verification of corrective actions'' from other requirements for ''records of monitoring'' and ''records of corrective actions''.

D. Proposed Conforming Change to Proposed Part 117

As discussed in section IX, we are proposing a conforming change to proposed part 117, the preventive controls rule for human food. We are proposing to add § 117.95 to proposed subpart B that would add current good manufacturing practice requirements that would apply to human food manufacturers/processors when by-products from human food production are packed and held for animal food.

XVIII. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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). FDA has developed a PRIA that presents the benefits and costs of this proposed rule (Ref. 1). FDA believes that the proposed rule will be a significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 1) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–N–0922), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new preventive controls, FDA acknowledges that the final rules resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 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 or more; 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 finalized, would be a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

XIX. Paperwork Reduction Act of 1995

This supplemental notice of proposed rulemaking contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section with an estimate of the annual recordkeeping, reporting, and third-party disclosure 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: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.

Description: FDA is proposing to amend its 2013 proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals to add requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The amendments include potential provisions that would require facilities to establish and implement, as necessary, the following verification activities: product testing, environmental monitoring, and a supplier program. In addition, FDA is amending its proposed rule to require that the hazard analysis (HA) and risk-based preventive controls for animal food take into account the possibility of economically motivated adulteration (EMA) of animal food.

Description of Respondents: Section 418 of the FD&C Act is applicable to the owner, operator or agent in charge of a food facility required to register under section 415 of the FD&C Act. Generally, a facility is required to register if it manufactures, processes, packs, or holds food for consumption in the United States.

The information collection estimate for the supplemental proposal for preventive controls for food for animals may increase if the potential requirements (the addition of provisions for product testing, environmental monitoring, a supplier program, and identifying and evaluating any potential hazards caused because of economically motivated adulteration) are finalized. Additionally, proposed labeling requirements have been added for animal food, including labeling of human food by-products used for animal food.

Information Collection Burden Estimate

Supplemental Notice of Proposed Rulemaking Burden

Recordkeeping Burden

FDA estimates the burden for this information collection, should the potential provisions in this proposed rule be included in any final rule, as follows:

TABLE 9—ESTIMATED POTENTIAL ANNUAL RECORDKEEPING BURDEN

21 CFR part 507, subpart C	Number of record-keepers [1]	Number of records per record-keeper	Total annual records	Average burden per record-keeping (in hours)	Total hours	Capital costs [2]	Operating and maintenance costs
Potential product testing written procedures (small pet food manufacturers) (potential § 507.49(a)(2))	20	0.33	6.6	5.33	35	.....	[1] $131,400
Potential product testing written procedures (small ingredient manufacturers) (potential § 507.49(a)(2))	10	0.33	3.3	5.33	18	.....	([4])
Potential environmental monitoring written procedures (potential § 507.49(a)(3))	105	0.33	35	5.33	187	.....	[2] 368,200
Potential supplier program written procedures (potential § 507.37(a)(2))	4,325	0.33	1,428	5.33	7,611	$4,018,100	[2] 162,200
§ 507.37(c)(3) and (c)(4) qualified or exempt suppliers' assurances	134	0.5	67	2	134	.....	.....
§ 507.33(b)(2)(iii) written HA for EMA	4,325	0.33	1,428	3	4,284	$627,800	[2] 4,227,300
§ 507.33(b)(2)(iii) updating written HA for EMA	4,325	0.5	2,163	0.1	216	([5])	([5])
§ 507.49(a)(4)(ii) verification—review of records	952	12	11,424	0.5	5,712	.....	[1] 258,400
Total	.....	.....	.....	.....	18,197	$4,645,900	5,147,500

[1] From 2014 PRIA (Ref. 1).
[2] These numbers were obtained from FDA economics staff.
[3] Costs for product testing and EMA are broken out across 2 rows.
[4] Included in row 1 costs.[3]
[5] Included in row 6 costs.[3]

Table 9 indicates the potential hourly and cost burden for complying with the supplemental notice of proposed rulemaking: i.e., product testing, environmental monitoring, the supplier program, economically motivated adulteration, and verification review of records.

Should the potential provisions in this proposed rule be included in any final rule, we estimate 8,130 facilities would be subject to subpart C—Hazard Analysis and Risk-Based Preventive Controls. We also estimate the number of non-qualified facilities would be 4,325 and the number of qualified facilities would be 3,805.

Should the potential product testing provision be included in a final rule, product testing would be an activity for verification of implementation and effectiveness FDA estimates that 102 non-qualified small pet food manufacturers and 67 non-qualified small ingredient suppliers exist. The Eastern Research Group (ERG) cost model reports that only these categories contain facilities subject to Subpart C that do not currently test animal food products for *Salmonella* but that might do so under proposed § 507.49(a)(2). The ERG also estimates that 20% of facilities are out of perfect compliance and would need to develop and record written procedures. In Table 9, to obtain the amount for total records for product testing for small pet food manufacturers, 20 small pet food manufacturers (recordkeepers) (20% of 102) multiplied by 0.33 records per recordkeeper (1 written procedure during the 3-year PRA approval period) equals 6.6 total records annually. Then, to obtain total hours, 6.6 total records multiplied by 5.33 average burden per record in hours (time needed according to FDA subject matter experts (SMEs)) equals 35 hours annually. For small ingredient manufacturers (Table 9, row 2), to obtain the total number of records, 10 recordkeepers (20% of 67 rounded down to 10) multiplied by 0.33 records per recordkeeper (1 written procedure during the 3-year PRA approval period) equals 3.3 total records. Then, to obtain the total number of hours, 3.3 total records multiplied by 5.33 average burden per record in hours (time needed according to FDA SMEs) equals 18 hours annually.

Should the potential environmental monitoring provision be finalized, FDA estimates 105 recordkeepers would need to include environmental monitoring procedures as a verification activity, creating one written procedure per facility. In Table 9, to obtain the number of annual records, 105 recordkeepers multiplied by 0.33 environmental monitoring procedures per facility (over 3 years of the PRA approval period) equals 35 annual records. Then, to obtain the total number of hours, 35 total records multiplied by 5.33 average burden per record in hours (time needed according to FDA SMEs) equals 187 total hours annually.

Should the potential supplier program previously discussed be included in a final rule, a receiving facility establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient, a receiving facility would not be required to establish and implement a supplier program for raw materials and ingredients for which there are no significant hazards, for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards, or for which the receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. The potential procedures for the supplier program would need to be written should this provision be included in a final rule. FDA estimates that all facilities would need to develop a written supplier program. In Table 9, to obtain the total number of records, 4325 recordkeepers (keeping written records of written assurances) multiplied by 0.33 records per facility per year (during the three year PRA approval) equals 1,428 records annually. Then 1,428 multiplied by 5.33 hours to create each record (time needed according to FDA SMEs) equals 7,611 total hours annually.

Should the potential supplier program be finalized, suppliers that would be qualified facilities and suppliers that are farms not subject to the requirements in proposed 21 CFR part 112 regarding the raw material or ingredient that the receiving facility receives from the farm would need to create at least every 2 years a written assurance to be given to their receiving facility customers. This assurance would need to describe the processes and procedures that the supplier is following to ensure the safety of the animal food. FDA estimates that these few suppliers would require about two hours to create this documentation to be submitted to their receiving facility customers. To obtain the total number of records, 134 recordkeepers multiplied by 0.5 records per year (submitted every 2 years) equals 67 records annually. To obtain the total number of hours, 67 records multiplied by 2 hours per record equals 134 hours annually.

For proposed § 507.33(b)(2)(iii), FDA estimated an average of 3 hours additional time for the hazard analysis in order to account for the possibility of economically motivated adulteration. To obtain the total number of records, 4,325 recordkeepers multiplied by 1 record per facility (or 0.33 records annually for the 3-year PRA approval) for writing and developing the initial hazard analysis equals 1,428 total records annually. Then 1,428 multiplied by an additional 3 hours per hazard analysis equals 4,284 total hours annually. In the 2013 PRIA (Ref. 22), FDA estimated that on average, facilities will need to update their hazard analysis every two years. In addition, FDA estimates 0.1 hours additional time would be needed to update the hazard analysis. To obtain the total number of records, 4,325 recordkeepers multiplied by 0.5 records per year equals 2,163 total records. Then 2,163 total records multiplied by 0.1 hours per record equals 216 hours annually.

The potential supplier program would require verification of implementation and effectiveness, including review of records for product testing, environmental monitoring, and supplier verification activities. Based on the responses to the ERG survey of human food production facilities, FDA estimates that the percentage of animal food facilities without these verification records varies from about 39% of those with fewer than 20 employees, to less than one percent for those with 100 or more employees. This equates to about 952 facilities, all of which would be out of compliance with the record review verification requirements.

To obtain the total number of records, 952 multiplied by 12 records per year (or 1 record per month) equals 11,424 records. To obtain the total number of hours, 11,424 records multiplied by 0.5 hours per record (time needed according to FDA SMEs) equals 5,712 hours annually.

Reporting Burden

There is no reporting burden in this information collection.

Third Party Disclosure Burden

Under proposed § 507.27(a)(3), labeling identifying the product by the common or usual name would need to be affixed to or accompany the animal food. The number of disclosures per respondent and the average burden per disclosure in Table 10 below were obtained by consulting FDA SMEs.

FDA estimates the burden for this information collection as follows:

TABLE 10—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part 507, subpart B	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
§ 507.27 Holding and distribution	8130	20	162,600	0.25	40,650

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

There are 8,130 facilities which each would have 20 sets of labeling per facility to affix to or accompany the animal food for a total number of 162,600 disclosures (labeling) per year. To obtain total number of hours, 162,600 disclosures multiplied by 0.25 hour to print labeling, and affix to the containers if labels, equals 40,650 total hours annually.

Under proposed § 507.28(a)(3), labeling identifying the human food by-product by the common or usual name would need to be affixed to or accompany the animal food. The number of disclosures per respondent and the average burden per disclosure in Table 11 were obtained from FDA SMEs.

FDA estimates the burden for this information collection as follows:

TABLE 11—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part 507, subpart B	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
§ 507.28(a)(3) Holding and distribution of human food by-products for use as animal food	40,798	2	81,596	0.25	20,399

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

According to FDA SMEs, an estimated 60 percent of the 67,996 domestic human food manufacturing facilities (Ref. 23) or 40,798 facilities would be affected, with two sets of labeling per facility per year expected, equals 81,596 disclosures (labeling). To obtain the number of total hours, 81,596 disclosures multiplied by 0.25 hours to prepare labeling, and affix to the containers if labels, equals 20,399 total hours.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this supplemental notice of proposed rulemaking to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

XX. Analysis of Environmental Impact

As with the 2013 preventive controls proposed rule, we determined under 21 CFR 25.30(j) that this supplemental notice of proposed rulemaking is an action of a type that does not individually or cumulatively have a significant effect on the human environment (Ref. 24). Therefore, neither an environmental assessment nor an environmental impact statement is required.

XXI. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

XXII. 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, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, ''FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals. Preliminary Regulatory Impact Analysis,'' 2014.
2. FDA, ''Transcript: FSMA Proposed Rule on Preventive Controls for Animal Food (PCAF) Facilities Public Meeting, November 21, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm368989.htm* and in Docket No. FDA–2011–N–0922 (accessed on September 5, 2014).
3. FDA, ''Transcript: FSMA Proposed Rule on Preventive Controls for Animal Food (PCAF) Facilities Public Meeting, November 25, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm368988.htm* and in Docket No. FDA–2011–N–0922 (accessed on September 5, 2014).
4. FDA, ''Transcript: FSMA Proposed Rule on Preventive Controls for Animal Food (PCAF) Facilities Public Meeting, December 6, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm371844.htm* and in Docket No. FDA–2011–N–0922 (accessed on September 5, 2014).
5. FDA, ''Update on Proposed Rules under the FDA Food Safety Modernization Act (March 19, 2014).'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm389696.htm* and in Docket No. FDA–2011–N–0922 (accessed on September 5, 2014).
6. Cooperative Extension Service, Division of Agricultural Sciences and Natural Resources, Oklahoma State University; USDA, Federal Grain Inspection Service; USDA, Extension Service; USDA, Animal and Plant Health Inspection Service, ''Stored Product Management,'' Circular No. E–912, January 1995. Available at *http://entomology.k-state.edu/doc/extension-crop-pests/E912_All_Stored_Product_May3.pdf* (accessed on September 5, 2014).
7. FDA, ''Draft Qualitative Risk Assessment. Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2013.
8. Grasser, L.A., J.G. Fadel, I. Garnett, and E.J. DePeters, ''Quantity and Economic Importance of Nine Selected By-Products Used in California Dairy Rations,'' *Journal of Dairy Science,* 78:962–971, 1995.
9. FDA, ''Compliance Program 7371.003, Feed Contaminants'' December 13, 2005.
10. FDA Memorandum, ''Biological, Chemical, and Physical Hazards Associated With Human Food By-Products Used for Animal Food,'' 2014.
11. FDA, ''Compliance Policy Guide Sec. 675.100 Diversion of Contaminated Food for Animal Use'' Available at *http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074693.htm.* Revised: March 1995, Page Last Updated: December 15, 2009 (accessed on September 5, 2014).
12. FDA, ''Compliance Policy Guide Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use'' Available at *http://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074694.htm.* Revised: March 1995, Page Last Updated: December 15, 2009 (accessed on September 5, 2014).
13. Association of American Feed Control Officials (AAFCO), ''Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients'', In: AAFCO Official Publication, 210–215, 2010.
14. Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO), ''Good Practices for the Feed Industry—Implementing the Codex Alimentarius Code of Practice on Good Animal Feeding—Section 3 Good Production Practices,'' 2010.
15. British Standards Institute (BSI), ''Publicly Available Specification (PAS) 222:2011 Prerequisite Programmes for Food Safety in the Manufacture of Food and Feed for Animals,'' 2011
16. FDA, ''Compliance Policy Guide Sec. 665.100 Common or Usual Names for Animal Feed Ingredients'' Available at

http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074687.htm. Revised: March 1995, Page Last Updated: December 16, 2009 (accessed on September 5, 2014).
17. Codex Alimentarius Commission, ''Hazard Analysis And Critical Control Point (HACCP) System And Guidelines For Its Application. Annex to CAC/RCP 1–1969 (Rev. 4–2003),'' 2003.
18. Codex Alimentarius Commission, ''General Principles of Food Hygiene, CAC/RCP 1–1969 (Rev. 4–2003),'' 2003.
19. U.S.Pharmacopeial Convention, ''U.S. Pharmacopeial Convention (USP) Food Fraud Database,'' March 6, 2014. Available at *http://www.usp.org/food-ingredients/food-fraud-database* (accessed on September 5, 2014).
20. Congressional Research Service, ''Food Fraud and Economically Motivated Adulteration of Food and Food Ingredients,'' January 10, 2014. Available at *http://www.fas.org/sgp/crs/misc/R43358.pdf.* (accessed on September 5, 2014).
21. Muth, M. K., C. Zhen, M. Coglaiti, S. Karns, and C. Viator, ''Food Processing Sector Study, Contract HHSF 22320101745G, Task Order 13, Final Report,'' 2011.
22. FDA, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Food for Animals—Preliminary Regulatory Impact Analysis,'' 2013.
23. FDA, ''Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Human Food—Preliminary Regulatory Impact Analysis,'' 2013. Docket No. FDA–2011–N–0920.
24. FDA, ''Re-proposal of Select Provisions of the Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,'' 2014.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 117

Food packaging, Foods.

21 CFR Part 507

Animal foods, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under 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. In § 16.1 amend the entry in paragraph (b)(2), as proposed to be amended on October 29, 2013 (78 FR 64736), to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 507.60 through 507.85 (part 507, subpart D) relating to withdrawal of exemption applicable to a qualified facility.

* * * * *

PART 117—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

■ 3. The authority citation for 21 CFR part 117, as proposed to be added on January 16, 2013 (78 FR 3646), continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

■ 4. In part 117, as proposed to be added on January 16, 2013 (78 FR 3646), add § 117.95 to read as follows:

§ 117.95 Holding and distribution of human food by-products for use in animal food.

(a) Human food by-products held for distribution as animal food without additional manufacturing/processing by the human food processor, as identified in § 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage; and

(3) Labeling identifying the by-product by the common and usual name must be affixed to or accompany animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

PART 507—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

■ 5. The authority citation for part 507, as proposed to be added on October 29, 2013 (78 FR 64736), continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 350c, 350d note, 350g, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

■ 6. Amend § 507.1, as proposed to be added on October 29, 2013 (78 FR 64736), by removing paragraph (d).

■ 7. Amend § 507.3, as proposed to be added on October 29, 2013 (78 FR 64736), as follows:

■ a. By removing definitions for ''Hazard reasonably likely to occur'' and ''Reasonably foreseeable hazard'';

■ b. By alphabetically adding new definitions for ''Known or reasonably foreseeable hazard''; ''Pathogen''; ''Qualified auditor''; ''Receiving facility''; ''Significant hazard''; ''Supplier''; and ''You''; and

■ c. By revising the definitions for ''Environmental pathogen''; ''Harvesting''; ''Hazard;'' ''Holding''; ''Packing''; and ''Very small business''.

The additions and revisions read as follows:

§ 507.3 Definitions.

* * * * *

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and

Cosmetic Act. Gathering, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in humans or animals in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg).

Pathogen means a microorganism of public (human or animal) health significance.

* * * * *

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 507.53(c)(2).

* * * * *

Receiving facility means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

* * * * *

Significant hazard means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing/processing, packing, or holding of animal food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

* * * * *

Supplier means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

* * * * *

Very small business means, for purposes of this part, a business that has less than $2,500,000 in total annual sales of food for animals, adjusted for inflation.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

■ 8. Amend § 507.5, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraph (a) to read as follows:

§ 507.5 Exemptions.

(a)(1) Except as provided by paragraph (a)(2) of this section, this part does not apply to establishments (including ''farms'' as defined in § 1.227 of this chapter) that are not required to register under section 415 of the Federal Food, Drug, and Cosmetic Act.

(2) If a ''farm'' or ''farm mixed-type facility'' dries/dehydrates raw agricultural commodities to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

* * * * *

■ 9. Subpart A, as proposed to be added on October 29, 2013 (78 FR 64736), is amended by adding § 507.12 to read as follows:

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use in animal food.

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of human food production that are packed or held by that human food facility for distribution as animal food if:

(1) The human food processor is subject to and in compliance with subpart B of part 117 of this chapter, and in compliance with all applicable human food safety requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations; and

(2) The human food processor does not further manufacture/process the by-products intended for animal food.

(b) The animal food from by-products identified in paragraph (a) of this section must be held and distributed by that facility in accordance with § 507.28 and § 117.95 of this chapter.

■ 10. Revise subpart B, as proposed to be added on October 29, 2013 (78 FR 64736), to read as follows:

Subpart B—Current Good Manufacturing Practice

Sec.
507.14 Personnel.
507.17 Plant and grounds.
507.19 Sanitation.
507.20 Water supply and plumbing.
507.22 Equipment and utensils.
507.25 Plant operations.
507.27 Holding and distribution.
507.28 Holding and distribution of human food by-products for use in animal food.

Subpart B—Current Good Manufacturing Practice

§ 507.14 Personnel.

(a) Plant management must take all reasonable measures and precautions to ensure that all persons working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices to the extent necessary to protect against contamination of animal food. The methods for maintaining cleanliness include:

(1) Maintaining adequate personal cleanliness;

(2) Washing hands thoroughly in an adequate hand-washing facility as necessary and appropriate to prevent contamination;

(3) Removing or securing jewelry and other objects that might fall into animal food, equipment, or containers;

(4) Storing clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils are cleaned; and

(5) Taking any other necessary precautions to protect against contamination of animal food, animal

food-contact surfaces, or animal food-packaging materials.

(b) Personnel responsible for identifying sanitation failures or animal food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe animal food. Animal food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(c) Responsibility for ensuring compliance by all personnel with all requirements of this subpart must be clearly assigned to competent supervisory personnel.

§ 507.17 Plant and grounds.

(a) The grounds surrounding an animal food plant under the control of the operator must be kept in a condition that will protect against the contamination of animal food. Maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining driveways, yards, and parking areas so that they do not constitute a source of contamination in areas where animal food is exposed;

(3) Adequately draining areas that may contribute to contamination of animal food; and

(4) Treating and disposing of waste so that it does not constitute a source of contamination in areas where animal food is exposed.

(b) Buildings, structures, fixtures, and other physical facilities of the plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. This includes:

(1) Providing adequate space between equipment, walls, and stored materials to permit employees to perform their duties and to allow cleaning and maintenance of equipment;

(2) Being constructed in a manner such that drip or condensate from fixtures, ducts, and pipes does not serve as a source of contamination;

(3) Providing adequate ventilation or control equipment to minimize vapors (for example, steam) and fumes in areas where they may contaminate animal food; and locating and operating fans and other air-blowing equipment in a manner that minimizes the potential for contaminating animal food;

(4) Providing adequate lighting in hand-washing areas, toilet rooms, areas where animal food is received, manufactured/processed, packed, or stored, and areas where equipment or utensils are cleaned;

(5) Providing safety-type light bulbs, fixtures, and skylights, or other glass items suspended over exposed animal food in any step of preparation, to protect against animal food contamination in case of glass breakage; and

(6) Protecting animal food stored outdoors in bulk by any effective means, including:

(i) Using protective coverings;

(ii) Controlling areas over and around the bulk animal food to eliminate harborages for pests; and

(iii) Checking on a regular basis for pests and pest infestation.

§ 507.19 Sanitation.

(a) Buildings, structures, fixtures, and other physical facilities of the plant must be kept clean and in good repair to prevent animal food from becoming contaminated.

(b) Animal food-contact and non-contact surfaces of utensils and equipment must be cleaned and maintained and utensils and equipment stored as necessary and appropriate to protect against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. When necessary, equipment must be disassembled for thorough cleaning.

In addition:

(1) When it is necessary to wet-clean animal food-contact surfaces used for manufacturing/processing, or holding low-moisture animal food, the surfaces must be thoroughly dried before subsequent use.

(2) In wet processing, when cleaning and sanitizing is necessary to protect against the introduction of undesirable microorganisms into animal food, all animal food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the animal food-contact surfaces may have become contaminated.

(c) Cleaning compounds and sanitizing agents must be safe and adequate under the conditions of use.

(d) The following applies to toxic materials:

(1) Only the following toxic materials may be used or stored in a plant where animal food is manufactured/processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in the plant's operations;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in laboratory testing procedures.

(2) Toxic materials described in paragraph (d)(1) of this section (for example cleaning compounds, sanitizing agents, and pesticide chemicals) must be identified, used, and stored in a manner that protects against contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Effective measures must be taken to exclude pests from the manufacturing/processing, packing, and holding areas and to protect against the contamination of animal food by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of animal food, animal food-contact surfaces, and animal food-packaging materials.

(f) Trash and garbage must be conveyed, stored, and disposed of in a way that protects against contamination of animal food, animal food-contact surfaces, animal food-packaging materials, water supplies, and ground surfaces, and minimizes the potential for the trash and garbage to become an attractant and harborage or breeding place for pests.

§ 507.20 Water supply and plumbing.

(a) The water supply must be adequate for the operations and must be derived from a suitable source. Running water at a suitable temperature, and under suitable pressure as needed, must be provided in all areas where required for the manufacturing/processing of animal food, for the cleaning of equipment, utensils, and animal food-packaging materials, or for employee hand-washing facilities. Water that contacts animal food, animal food-contact surfaces, or animal food-packaging materials must be safe for its intended use. Water may be reused for washing, rinsing, or conveying animal food if it does not increase the level of contamination of the animal food.

(b) Plumbing must be designed, installed, and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant;

(2) Properly convey sewage and liquid disposable waste from the plant;

(3) Avoid being a source of contamination to animal food, animal food-contact surfaces, or animal food-packaging materials, water supplies,

equipment, or utensils, and avoid creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Ensure that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for animal food or animal food manufacturing/processing.

(c) Sewage must be disposed of through an adequate sewerage system or through other adequate means.

(d) Each plant must provide its employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

(e) Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of animal food, animal food-contact surfaces, or animal food-packaging materials.

§ 507.22 Equipment and utensils.

(a) The following apply to plant equipment and utensils:

(1) All plant equipment and utensils must be designed and of such material and workmanship to be adequately cleanable, and must be properly maintained;

(2) The design, construction, and use of equipment and utensils must preclude the contamination of animal food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants;

(3) Equipment should be installed and maintained in such a way as to facilitate the cleaning of the equipment and adjacent spaces;

(4) Animal food-contact surfaces must be:

(i) Made of materials that withstand the environment of their use and the action of animal food, and, if applicable, the action of cleaning compounds and sanitizing agents;

(ii) Made of nontoxic materials; and

(iii) Maintained to protect animal food from being contaminated.

(5) Equipment in the animal food manufacturing/processing area that does not come into contact with animal food must be designed and constructed in such a way that it can be kept in a clean condition.

(b) Holding, conveying, and manufacturing/processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in a way that does not contaminate animal food.

(c) Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature monitoring device.

(d) Instruments and controls used for measuring, regulating, or recording temperatures, pH, aw, or other conditions that control or prevent the growth of undesirable microorganisms in animal food must be accurate, precise, adequately maintained, and adequate in number for their designated uses.

(e) Compressed air or other gases mechanically introduced into animal food or used to clean animal food-contact surfaces or equipment must be used in such a way that animal food is not contaminated.

§ 507.25 Plant operations.

(a) Plant management must ensure that:

(1) All operations in the manufacturing/processing, packing, and holding of animal food (including operations directed to receiving, inspecting, transporting, and segregating) are conducted in accordance with the current good manufacturing practice requirements of this subpart;

(2) Containers holding animal food, including raw materials, ingredients, or rework, accurately identify the contents;

(3) The labeling for the finished animal food product contains information and instructions for safely using the product for the intended animal species;

(4) Animal food-packaging materials are safe and suitable;

(5) The overall cleanliness of the plant is under the supervision of one or more competent individuals assigned responsibility for this function;

(6) Reasonable precautions are taken so that plant operations do not contribute to contamination of animal food, animal food-contact surfaces, and animal food packaging materials;

(7) Chemical, microbial, or extraneous-material testing procedures are used where necessary to identify sanitation failures or possible animal food contamination; and

(8) Animal food that has become contaminated to the extent that it is adulterated is rejected, disposed of, or if permissible, treated or processed to eliminate the adulteration. If disposed of, it must be done in a manner that protects against the contamination of other animal food; and

(9) All animal food manufacturing/processing, packing, and holding is conducted under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms or for the contamination of animal food.

(b) Raw materials and ingredients:

(1) Must be inspected to ensure that they are suitable for manufacturing/processing into animal food and must be handled under conditions that will protect against contamination and minimize deterioration. In addition:

(i) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles holding raw materials and ingredients must be inspected upon receipt to determine whether contamination or deterioration of animal food has occurred;

(ii) Raw materials must be cleaned as necessary to minimize soil or other contamination; and

(iii) Raw materials and ingredients must be stored under conditions that will protect against contamination and deterioration.

(2) Susceptible to contamination with mycotoxins or other natural toxins must be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans;

(3) And all rework, must be held in containers designed and constructed in a way that protects against contamination, and must be held under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and in a manner that prevents the animal food from becoming adulterated; and

(4) If frozen, must be kept frozen. If thawing is required prior to use, it must be done in a manner that minimizes the potential for the growth of undesirable microorganisms.

(c) For the purposes of manufacturing/processing operations, the following apply:

(1) Animal food must be maintained under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms and prevent the animal food from becoming adulterated during manufacturing/processing, packing, and holding;

(2) Measures taken during manufacturing/processing, packing, and holding of animal food to significantly minimize or prevent the growth of undesirable microorganisms (for example, heat treating, freezing, refrigerating, irradiating, controlling pH, or controlling aw) must be adequate to prevent adulteration of animal food;

(3) Work-in-process and rework must be handled in such a way that it is

protected against contamination and the growth of undesirable microorganisms;

(4) Steps such as cutting, drying, defatting, grinding, mixing, extruding, pelleting, and cooling, must be performed in a way that protects animal food against contamination;

(5) Filling, assembling, packaging, and other operations must be performed in such a way that the animal food is protected against contamination and growth of undesirable microorganisms;

(6) Animal food that relies on the control of aw for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level;

(7) Animal food that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at the appropriate pH; and

(8) When ice is used in contact with animal food, it must be made from water that is safe and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subpart.

§ 507.27 Holding and distribution.

(a) Animal food held for distribution must be held under conditions that will protect against contamination and minimize deterioration, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way that prevents contamination from sources such as trash and garbage; and

(3) Labeling identifying the product by the common and usual name must be affixed to or accompany the animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

(c) Animal food returned from distribution must be assessed for animal food safety to determine the appropriate disposition. Returned animal food must be identified as such and segregated until assessed.

(d) Unpackaged or bulk animal food must be held in a manner that does not result in cross contamination with other animal food.

§ 507.28 Holding and distribution of human food by-products for use as animal food.

(a) Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following:

(1) Containers used to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution must be held in a way to prevent contamination from sources such as trash and garbage; and

(3) Labeling identifying the product by the common and usual name must be affixed to or accompany animal food.

(b) Shipping containers (for example, totes, drums, and tubs) and bulk vehicles used to distribute animal food must be inspected prior to use to ensure the container or vehicle will not contaminate the animal food.

■ 11. Revise subpart C, as proposed to be added on October 29, 2013 (78 FR 64736), to read as follows:

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

Sec.

507.31 Food safety plan.
507.33 Hazard analysis.
507.36 Preventive controls.
507.37 Supplier program.
507.38 Recall plan.
507.39 Preventive control management components.
507.40 Monitoring.
507.42 Corrective actions and corrections.
507.45 Verification.
507.47 Validation.
507.49 Verification of implementation and effectiveness.
507.50 Reanalysis.
507.51 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.
507.53 Requirements applicable to a qualified individual and a qualified auditor.
507.55 Implementation records.

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

§ 507.31 Food safety plan.

(a) You must prepare, or have prepared, and implement a written food safety plan.

(b) One or more qualified individuals must prepare, or oversee the preparation of, the food safety plan.

(c) The written food safety plan must include:

(1) The written hazard analysis as required by § 507.33(a)(2);

(2) The written preventive controls as required by § 507.36(b);

(3) The written supplier program as required by § 507.37(a)(2).

(4) The written recall plan as required by § 507.38(a)(1);

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);

(6) The written corrective action procedures as required by § 507.42(a)(1); and

(7) The written verification procedures as required by § 507.49(b).

(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 507.33 Hazard analysis.

(a) You must:

(1) Identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured/processed, packed, or held at your facility to determine whether there are significant hazards; and

(2) Develop a written hazard analysis.

(b) The hazard identification must consider:

(1) Hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and nutrient imbalances; and

(iii) Physical hazards; and

(2) Hazards that may be present in the animal food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever an animal food is exposed to the environment prior to packaging and the packaged animal food does not receive a treatment that would significantly minimize the pathogen.

(d) The hazard evaluation must consider the effect of the following on

the safety of the finished animal food for the intended animal:

(1) The formulation of the animal food;

(2) The condition, function, and design of the facility and equipment;

(3) Raw materials and ingredients;

(4) Transportation practices;

(5) Manufacturing/processing procedures;

(6) Packaging activities and labeling activities;

(7) Storage and distribution;

(8) Intended or reasonably foreseeable use;

(9) Sanitation, including employee hygiene; and

(10) Any other relevant factors.

§ 507.36 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that significant hazards will be significantly minimized or prevented and the animal food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(2) Preventive controls required by paragraph (a)(1) of this section include, as appropriate to the facility and animal food:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for animal food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and animal food:

(1) Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the applicable control:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.

(2) Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include as appropriate to the facility and the animal food, procedures, practices, and processes for the:

(i) Cleanliness of animal food-contact surfaces, including animal food-contact surfaces of utensils and equipment; and

(ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food packaging material, and other animal food-contact surfaces and from raw product to processed product.

(3) Supplier controls that include the supplier program as required by § 507.37;

(4) A recall plan as required by § 507.38; and

(5) Other preventive controls that include any procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 507.37 Supplier program.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.

(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:

(A) There are no significant hazards;

(B) The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or

(C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

(2) The supplier program must be written.

(3) The supplier program must include:

(i) Verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use); and

(ii) Verification activities, as appropriate to the hazard, and documentation of these activities, as required by paragraph (b) of this section, to verify that:

(A) The hazard is significantly minimized or prevented;

(B) The incoming raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act; and

(C) The incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations.

(4) When supplier verification activities are required under paragraph (c) of this section for more than one type of hazard in an animal food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards.

(5) For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

(b) In determining and documenting the appropriate verification activities, the receiving facility must consider the following:

(1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients;

(2) Where the preventive controls for those hazards are applied for the raw material and ingredients such as at the supplier or the supplier's supplier;

(3) The supplier's procedures, processes, and practices related to the safety of the raw material and ingredients;

(4) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the animal food;

(5) The supplier's food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the animal food, and responsiveness of the supplier in correcting problems; and

(6) Any other factors as appropriate and necessary. Examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation practices.

(c)(1) Except as provided in paragraph (c)(2) or (3) of this section, the receiving facility must conduct and document one or more of the following supplier verification activities determined by the

receiving facility under paragraph (b) of this section, for each supplier before using the raw material or ingredient and periodically thereafter:

(i) Onsite audits;

(ii) Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility;

(iii) Review by the receiving facility of the supplier's relevant food safety records; or

(iv) Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier.

(2)(i) Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter.

(ii) The requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(3) If a supplier is a qualified facility as defined by § 507.3, the receiving facility need not comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the supplier is a qualified facility as defined by § 507.3; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the animal food.

(4) If a supplier is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(d)(1) An onsite audit of a supplier must be performed by a qualified auditor;

(2) If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited.

(e)(1) Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted; and

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the animal food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(f) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 507.42 to ensure that raw materials or ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(g) The receiving facility must document the following in records and review such records in accordance with § 507.49(a)(4):

(1) The written supplier program;

(2) Documentation of the appropriate verification activities;

(3) The annual written assurance that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;

(4) Documentation demonstrating that products are received only from approved suppliers;

(5) Documentation of an onsite audit. This documentation must include:

(i) Documentation of audit procedures;

(ii) The dates the audit was conducted;

(iii) The conclusions of the audit;

(iv) Corrective actions taken in response to significant deficiencies identified during the audit; and

(v) Documentation that the audit was conducted by a qualified auditor.

(6) Records of sampling and testing. These records must include:

(i) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing.

(7) Records of the review by the receiving facility of the supplier's relevant food safety records. These records must include:

(i) The date(s) of review;

(ii) Corrective actions taken in response to significant deficiencies identified during the review; and

(iii) Documentation that the review was conducted by a qualified individual.

(8) Records of other appropriate supplier verification activities based on the risk associated with the ingredient.

(9) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled;

(10) Documentation of an alternative verification activity for a supplier that is a qualified facility, including:

(i) The documentation that the supplier is a qualified facility as defined by § 507.3; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with

applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:

(i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(12) Evidence of an inspection of the supplier by FDA or the food safety authority of another country.

(13) Documentation of actions taken with respect to supplier non-conformance.

§ 507.38 Recall plan.

(a) For animal food with a significant hazard you must:

(1) Establish a written recall plan for the animal food; and

(2) Assign responsibility for performing all procedures in the recall plan.

(b) The written recall plan must include procedures that describe the steps to perform the following actions as appropriate to the facility:

(1) Directly notify direct consignees about the animal food being recalled, including how to return or dispose of the affected animal food;

(2) Notify the public about any hazard presented by the animal food when appropriate to protect animal and human health;

(3) Conduct effectiveness checks (as described in part 7 of this chapter) to verify the recall has been carried out; and

(4) Appropriately dispose of recalled animal food (e.g., reprocessing, reworking, diverting to another use that would not present a safety concern, or destroying).

§ 507.39 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 507.36 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control:

(1) Monitoring in accordance with § 507.40;

(2) Corrective actions and corrections in accordance with § 507.42; and

(3) Verification in accordance with § 507.45.

(b) The supplier program established in § 507.37 is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supplier program, taking into account the nature of the hazard controlled before receipt of the raw material or ingredient:

(1) Corrective actions and corrections in accordance with § 507.42, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 507.49(a)(4)(ii); and

(3) Reanalysis in accordance with § 507.50.

(c) The recall plan established in § 507.38 is not subject to the requirements of paragraph (a) of this section.

§ 507.40 Monitoring.

(a) As appropriate to the preventive control you must:

(1) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(2) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(b) You must monitor the preventive controls with adequate frequency to provide assurance that the preventive controls are consistently performed.

(c) All monitoring of preventive controls in accordance with this section must be documented in records that are subject to verification in accordance with § 507.45(a)(2) and records review in accordance with § 507.49(a)(4)(i).

§ 507.42 Corrective actions and corrections.

(a) As appropriate to the preventive control, except as provided by paragraph (c) of this section:

(1)(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:

(A) The presence of a pathogen or appropriate indicator organism in animal food detected as a result of product testing conducted in accordance with § 507.49(a)(2); and

(B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 507.49(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected animal food is evaluated for safety; and

(iv) All affected animal food is prevented from entering into commerce if you cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(b)(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a specific corrective action procedure has not been established;

(ii) A preventive control is found to be ineffective; or

(iii) A review of records in accordance with § 507.49(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem;

(ii) Reduce the likelihood that the problem will recur;

(iii) Evaluate all affected animal food for safety;

(iv) As necessary, prevent affected animal food from entering commerce as would be done following the corrective action procedure under paragraph (a)(2) of this section; and

(v) When appropriate, reanalyze the food safety plan in accordance with § 507.50 to determine whether modification of the food safety plan is required.

(c) You do not need to comply with the requirements of paragraphs (a) and (b) of this section for conditions and practices that are not consistent with the sanitation controls in § 507.36(c)(2)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices.

(d) All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be

documented in records. These records are subject to verification in accordance with § 507.45(a)(3) and records review in accordance with § 507.49(a)(4)(i).

§ 507.45 Verification.

(a) Verification activities must include, as appropriate to the preventive control:

(1) Validation in accordance with § 507.47;

(2) Verification that monitoring is being conducted as required by § 507.39 (and in accordance with § 507.40);

(3) Verification that appropriate decisions about corrective actions are being made as required by § 507.39 (and in accordance with § 507.42);

(4) Verification of implementation and effectiveness in accordance with § 507.49; and

(5) Reanalysis in accordance with § 507.50.

(b) All verification activities conducted in accordance with this section must be documented in records.

§ 507.47 Validation.

(a) Except as provided by paragraph (b)(3) of this section, you must validate that the preventive controls identified and implemented in accordance with § 507.36 to control the significant hazards are adequate to do so as appropriate to the nature of the preventive control.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control significant hazards; and

(3) Need not address:

(i) The sanitation controls in § 507.36(c)(2);

(ii) The supplier program in § 507.37; and

(iii) The recall plan in § 507.38.

§ 507.49 Verification of implementation and effectiveness.

(a) You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so, you must conduct activities that include the following, as appropriate to the facility, the animal food, and the nature of the preventive control:

(1) Calibration of process monitoring and verification instruments;

(2) Product testing for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an animal food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Monitoring and corrective action records within a week after the records are created; and

(ii) Records of calibration, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are created.

(b) As appropriate to the facility, the food, and the nature of the preventive control, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments as required by paragraph (a)(1) of this section.

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 507.42(a)(1)(ii).

§ 507.50 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan:

(1) At least once every 3 years;

(2) Whenever a significant change is made in the activities conducted at your facility if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(3) Whenever you become aware of new information about potential hazards associated with the animal food;

(4) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and

(5) Whenever you find that a preventive control is ineffective.

(b) You must complete the reanalysis required by paragraph (a) of this section and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production.

(c) You must revise the written food safety plan if a significant change is made or document the basis for the conclusion that no revisions are needed.

(d) A qualified individual must perform (or oversee) the reanalysis.

(e) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 507.51 Modified requirements that apply to a facility solely engaged in the storage of packaged animal food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a facility solely engaged in the storage of packaged animal food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged animal food that requires time/temperature control to significantly minimize or prevent the

growth of, or toxin formation by, microorganisms of animal or human health significance:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin formation by, microorganisms of animal or human health significance;

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) Take appropriate corrective actions if there is a problem with the temperature controls for such refrigerated packaged animal food to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected animal food for safety; and

(iii) Prevent the animal food from entering commerce, if the owner, operator, or agent in charge of the facility cannot ensure the affected animal food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;

(ii) Reviewing records of calibration within a reasonable time after the records are made; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged animal food;

(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged animal food; and

(iii) Records documenting the verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

§ 507.53 Requirements applicable to a qualified individual and a qualified auditor.

(a) One or more qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 507.31(b));

(2) Validation of the preventive controls (§ 507.47(b)(1));

(3) Review of records (§ 507.49(a)(4)); and

(4) Reanalysis of the food safety plan (§ 507.50(d)).

(b) A qualified auditor must conduct an onsite audit (§ 507.37(d)).

(c)(1) To be a qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

(d) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 507.55 Implementation records.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Records that document the monitoring of preventive controls;

(2) Records that document corrective actions;

(3) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(4) Records that document the supplier program; and

(5) Records that document applicable training for the qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

■ 12. Section 507.60, as proposed to be added on October 29, 2013 (78 FR 64736), is revised to read as follows:

§ 507.60 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

(a) FDA may withdraw the exemption applicable to a qualified facility under § 507.5(d):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public (human or animal) health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the animal food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw an exemption applicable to a qualified facility, FDA:

(1) May consider one or more other actions to protect the public (human or animal) health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, import alert, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 10 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

■ 13. Section 507.62, as proposed to be added on October 29, 2013 (78 FR 64736), is revised to read as follows:

§ 507.62 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), or an FDA official senior to such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

■ 14. Amend § 507.65, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraph (d) to read as follows:

§ 507.65 Contents of an order to withdraw an exemption applicable to a qualified facility.

* * * * *

(d) A statement that the facility must either:

(1) Comply with subpart C of this part on the date that is 120 calendar days after the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

* * * * *

■ 15. Amend § 507.67, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraphs (a) and (c) to read as follows

§ 507.67 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) If you receive an order under § 507.65 to withdraw an exemption applicable to that facility under § 507.5(d), you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 507.69.

* * * * *

(c) If you appeal the order, and FDA confirms the order, you must comply with applicable requirements of this part within 120 calendar days of the date of receipt of confirmation of the order.

■ 16. Amend § 507.69, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraph (a) introductory text and paragraph (a)(1) to read as follows:

§ 507.69 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 507.5(d), you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of receipt of the order;

* * * * *

■ 17. Amend § 507.71, as proposed to be added on October 29, 2013 (78 FR 64736), by revising paragraph (a) to read as follows:

§ 507.71 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 507.69 within 10 calendar days of the date of receipt of the order.

* * * * *

■ 18. Subpart D, as proposed to be added on October 29, 2013 (78 FR 64736), is amended by adding § 507.85 to read as follows:

§ 507.85 Reinstatement of an exemption that was withdrawn.

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) determines that a facility has adequately resolved problems with the conditions and conduct that are material to the safety of the animal food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine); and

(2) Present data and information to demonstrate that you have adequately resolved the problems with the conditions or conduct that are material to the safety of the animal food manufactured/processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public (human and animal) health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 507.60(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 507.5(d), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both §§ 507.60(a)(1) and 507.60(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding and you may ask FDA to reinstate your exemption under § 507.5(d) in accordance with the requirements of paragraph (b) of this section.

§ 507.100 [Redesignated as § 507.200]

■ 19. Redesignate § 507.100, as proposed to be added on October 29, 2013 (78 FR 64736), as § 507.200.

■ 20. Revise § 507.102, as proposed to be added on October 29, 2013 (78 FR 64736), to read as follows:

§ 507.202 General requirements applying to records.

(a) Records must:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records, which must be kept in accordance with part 11 of this chapter;

(2) Contain the actual values and observations obtained during monitoring and as appropriate, during verification activities;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented; and

(5) Be as detailed as necessary to provide history of work performed.

(b) All records must include:

(1) The name and location of the plant or facility;

(2) The date and time of the activity documented;

(3) The signature or initials of the person performing the activity; and

(4) Where appropriate, the identity of the product and the production code, if any.

§§ 507.106 and 507.108 [Redesignated as §§ 507.206 and 507.208]

■ 21. Redesignate §§ 507.106 and 507.108, as proposed to be added on October 29, 2013 (78 FR 64736), as §§ 507.206 and 507.208, respectively.

■ 22. Subpart F, as proposed to be added on October 29, 2013 (78 FR 64736), is amended by adding § 507.212 to read as follows:

§ 507.212 Use of existing records.

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be

duplicated if they contain all of the required information and satisfy the requirements of this subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart F.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

Dated: September 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

The supplemental notice of proposed rulemaking that is the subject of this document includes a discussion of our reconsideration of the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities (see the discussion and Table 5 in section VII.C). Table 1 in this Appendix compares the classification of on-farm activities as harvesting, packing, holding, or manufacturing/processing in the 2013 proposed rule for preventive controls to our current thinking on the classification of these on-farm activities as a result of the proposed revisions to the ''farm'' definition.

TABLE 1—CLASSIFICATION OF ACTIVITIES CONDUCTED ON-FARMS AND FARM MIXED-TYPE FACILITIES

Classification	Examples using the 2013 proposed ''farm'' definition*	Examples using the proposed revisions to the ''farm'' definition
Harvesting Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as animal food. Harvesting does not include activities that change a RAC into processed animal food.	• Cooling RACs*** (activity deleted because is not done on RACs for animal food) • Filtering RACs*** (activity deleted because is not done on RACs for animal food) • Gathering RACs • Removing stems and husks from RACs • Shelling RACs • Sifting RACs • Threshing RACs • Trimming of outer leaves from RACs • Washing RACs*** (activity deleted because is not done on RACs for animal food)	• Gathering RACs • Removing stems and husks from RACs • Shelling RACs • Sifting RACs • Threshing RACs • Trimming outer leaves from RACs
Packing: Placing animal food in a container other than packaging the animal food and activities performed incidental to packing an animal food (e.g., activities performed for the safe or effective packing of that animal food (such as sorting, culling and grading)), but does not include activities that transform a RAC into a processed animal food.	• Coating RACs with wax/oil/resin for the purpose of storage or transport*** (deleted because is not done on RACs for animal food) • *Drying RACs for the purpose of storage or transport*** (would change to only be classified as ''holding'') • Labeling RACs • Mixing RACs • *Packaging a farm's or farm mixed-type facility's own RACs*** (would no longer be limited to ''own RACs'') • Putting RACs or individual unit cartons into non-consumer containers • Sorting/grading/culling RACs • Stickering RACs	• Labeling RACs • Blending RACs (e.g., blending different lots of the same RAC such as whole grains that does not result in a new commodity) • *Packaging RACs regardless of ownership*** (expanded to include others' RACs) • Putting RACs or individual unit cartons into non-consumer containers • *Removing stems and husks from RACs*** (add'l classification) • *Sifting RACS*** (add'l classification)**** • Sorting/culling/grading RACs • Stickering RACs • *Using pesticides on RACs*** (add'l classification)
Holding: Storage of animal food and activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that food, and activities performed as a practical necessity for the distribution of that animal food (such as blending of the same commodity and breaking down pallets)). Holding does not include activities that change a RAC into a processed animal food.	• Drying/dehydrating RACs during storage (incidental to *packing or* storing when the drying/dehydrating does not create a distinct commodity)** (would no longer be incidental to packing, would only be incidental to holding) • Fumigating RACs during storage • Sorting/culling/grading RACs • Storing food	• Drying/dehydrating RACs (incidental to storing when the drying/dehydrating does not create a distinct commodity) • Fumigating RACs during storage to control pests • Sorting/culling/grading RACs • Storing animal food

TABLE 1—CLASSIFICATION OF ACTIVITIES CONDUCTED ON-FARMS AND FARM MIXED-TYPE FACILITIES—Continued

Classification	Examples using the 2013 proposed "farm" definition*	Examples using the proposed revisions to the "farm" definition
Manufacturing/Processing: Making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, milling, grinding, extracting, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.	• Artificial ripening *** (this activity deleted because is not done on animal food) • Canning • Chopping • Coating RACs for purposes other than storage/transport *** (this activity deleted because is not done on animal food) • Cooking • Cooling • Coring • Cracking • Crushing • Cutting • Distilling • Drying/dehydrating RACS to create a distinct commodity • Extracting • Formulating • Freezing • Grinding • Homogenizing • Infusing • Irradiating • Labeling (other than RACs) • Milling • Mixing • Packaging (other than RACs) • Pasteurizing • Peeling • Rendering • Roasting • Salting • Slaughtering and post-slaughter operations • Slicing • Smoking • Sorting, culling, grading (not incidental to packing or holding) • Trimming • Washing	• Canning • Chopping • Cooking • Cooling • Coring (*except field coring*)** (because field coring would be newly classified as harvesting) • Cracking • Crushing • Cutting • Distilling • Drying/dehydrating RACs to create a distinct commodity • Extracting • Formulating • Freezing • Grinding • Homogenizing • Infusing • Irradiating • Labeling (other than RACs) • Milling • Mixing • Packaging (other than RACs) • Pasteurizing • Peeling • Rendering • Roasting • Salting • Slaughtering and post-slaughter operations • Slicing • Smoking • Sorting, culling, grading (not incidental to packing or holding) • Trimming • Washing

* Examples were included in Table 4, Table 5, and/or proposed §§ 507.3 and 507.5(e) and (f) in the 2013 proposed rule for preventive controls and/or in the Draft Risk Assessment (Ref. 1).

** Activities listed in italics represent a change between the 2013 "farm" definition and our current thinking in light of the proposed revisions to the "farm" definition.

*** Activities deleted because they are not typically performed in animal food.

**** add'l = additional.

The following reference has 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. This reference is also available electronically at *http://www.regulatons.gov*.

1. FDA, "Draft Qualitative Risk Assessment. Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2013.

[FR Doc. 2014–22445 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL REGISTER

Vol. 79 Monday,

No. 188 September 29, 2014

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16, 117, and 507

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, and 117

[Docket No. FDA–2011–N–0920]

RIN 0910–AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend our 2013 proposed rule for Current Good Manufacturing Practice (CGMP) and Hazard Analysis and Risk-Based Preventive Controls for Human Food. In that 2013 proposed rule, we proposed to amend the CGMP requirements to modernize them and to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food. We also proposed to revise certain definitions in our current regulation for Registration of Food Facilities to clarify the scope of an exemption from registration requirements for ''farms'' and, in so doing, to clarify which domestic and foreign facilities would be subject to the proposed requirements for hazard analysis and risk-based preventive controls for human food. We are taking this action because the extensive input we have received from public comments has led to significant changes in our current thinking on certain key provisions of these proposed rules. We are reopening the comment period only with respect to specific issues identified in this proposed rule.

DATES: Submit either electronic or written comments on the proposed rule by *December 15, 2014* Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by *December 15, 2014* (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2011–N–0920 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, 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.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2166.

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
- Purpose and Coverage of the Supplemental Notice of Proposed Rulemaking
- Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking
- Costs and Benefits

I. Background
- A. Introduction
- B. 2013 Proposed Preventive Controls Rule
- C. Definition of ''Retail Food Establishment''

II. Public Comments
- A. Opportunities for Public Comment
- B. Overview of Public Comments on the 2013 Proposed Preventive Controls Rule
- C. Our Decision To Issue a Supplemental Notice of Proposed Rulemaking for Public Comment

III. Scope of the Supplemental Notice of Proposed Rulemaking and Our Request for Public Comment

IV. Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act

V. The ''Farm'' Definition
- A. 2013 Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''
- B. Conducting Packing and Holding Activities on Others' RACs
- C. Field Coring as a Harvesting Activity
- D. Drying/Dehydrating Raw Agricultural Commodities To Create a Distinct Commodity
- E. One General Physical Location
- F. Proposed Revisions to the Exemption From CGMP Requirements for ''Farms'' and Activities of ''Farm Mixed-Type Facilities'' That Fall Within the ''Farm'' Definition
- G. Comparing Proposed Requirements for Packing Produce Under the 2013 Proposed Preventive Controls Rule to Proposed Requirements for Packing Produce Under the 2013 Proposed Produce Safety Rule

VI. Definitions of ''Holding'' and ''Packing''
- A. 2013 Proposed Definition of ''Holding''
- B. 2013 Proposed Exemptions Relevant to the Definition of ''Holding''
- C. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of RACs (Other Than Fruits and Vegetables) Intended for Further Distribution or Processing
- D. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment
- E. Proposed Revisions to the Definition of ''Holding''
- F. Proposed Revisions to the Definition of ''Packing''

VII. Impact of the Proposed Revisions to the Farm-Related Definitions on the Classification of On-Farm Activities
- A. Comments on the 2013 Organizing Principles for Classifying Activities Conducted on Farms and on Farm Mixed-Type Facilities
- B. Updated Organizing Principles That Would Apply to the ''Farm'' Definition
- C. Changes to Classification of On-Farm Activities

VIII. Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations
- A. The 2013 Proposed Exemptions
- B. Comments on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations
- C. Impact of the Proposed Revisions to the Definitions for ''Farm,'' ''Harvesting,'' Holding,'' and ''Packing'' on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations

IX. Overall Framework for Hazard Analysis and Risk-Based Preventive Controls
- A. 2013 Proposed Overall Framework for Hazard Analysis and Risk-Based Preventive Controls
- B. Comments on the ''Reasonably Likely to Occur'' Construct Within the 2013 Overall Framework for Hazard Analysis and Risk-Based Preventive Controls
- C. Proposed Revisions to the Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

X. Potential Requirements for Product Testing and Environmental Monitoring
- A. Our Request for Comment on Including Requirements for Product Testing and

Environmental Monitoring in a Final Rule
B. Product Testing
C. Environmental Monitoring
XI. Potential Requirements for a Supplier Program
A. Our Request for Comment on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act
B. Comments on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act
C. Potential Requirements for a Supplier Program
D. Request for Additional Comment on Requirements To Address Conflicts of Interest for Persons Conducting Verification Activities
XII. Potential Requirements for the Hazard Analysis To Address Economically Motivated Adulteration
A. Our Request for Comment on Whether the Final Rule Should Address Economically Motivated Adulteration
B. Comments on Economically Motivated Adulteration
C. Potential Requirements To Address Economically Motivated Adulteration
XIII. Provisions for Withdrawal of an Exemption for a Qualified Facility
A. 2013 Proposed Provisions for Withdrawal of an Exemption for a Qualified Facility
B. Proposed Clarification of What FDA Will Do Before Issuing an Order and Proposed Mechanism for Re-Instating an Exemption
C. Proposed Revisions to the Content of an Order To Withdraw an Exemption
D. Proposed Revisions to the Timeframes for a Facility To Comply With, or Appeal, an Order
XIV. Definition of Very Small Business
A. The 2013 Proposed Options for Definition of Very Small Business
B. Comments on the 2013 Proposed Options for Definition of Very Small Business
C. Proposed Revisions to the Definition of Very Small Business
XV. Other New and Revised Proposed Provisions
A. Proposed New Definitions
B. Proposed Revisions to Definitions
C. Proposed Editorial Changes
XVI. Holding Human Food By-Products Intended for Use in Animal Food
XVII. Preliminary Regulatory Impact Analysis
A. Overview
B. Regulatory Flexibility Act
C. Small Business Regulatory Enforcement Fairness Act of 1996
D. Unfunded Mandates Reform Act of 1995
XVIII. Paperwork Reduction Act of 1995
XIX. Analysis of Environmental Impact
XX. Comments
XXI. References

Executive Summary

Purpose and Coverage of the Supplemental Notice of Proposed Rulemaking

We previously proposed to add requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food, as required by the FDA Food Safety Modernization Act (FSMA). The proposed requirements would apply to establishments that are required to register with us as a food ''facility.'' In this document we are proposing to revise several previously proposed requirements, taking into account the comments we have reviewed so far, because the extensive input we have received from public comments has led to significant changes in our current thinking on certain key provisions.

''Farms'' are exempt from the registration requirements and, thus, would be exempt from the proposed requirements for hazard analysis and risk-based preventive controls for human food. We are proposing to revise the definition of ''farm,'' as well as definitions for three activities (''harvesting'', ''holding'', and ''packing'') that play a key role in determining whether an establishment is within the ''farm'' definition. The effect of the revised definitions would be that a farm would no longer be required to register as a food facility merely because it packs or holds raw agricultural commodities (RACs) grown on another farm not under the same ownership. The revised definitions would not create any new circumstances where a farm that would not have been required to register under the previous proposal would now be required to register.

In the previous proposal, we asked for comment on when and how three provisions (i.e., product testing programs, environmental monitoring programs, and supplier programs) are an appropriate means of implementing the statutory directives of FSMA. We also requested comment on whether a facility should be required to address potential hazards that may be intentionally introduced for economic reasons. Some comments to the previous proposal assert that additional public comment is warranted before consideration is given to whether a final rule includes or does not include provisions that were discussed in the previous proposal but for which we had not included regulatory text in the previous proposal. In this document we are providing an opportunity for such public comment on potential requirements for product testing programs, environmental monitoring programs, supplier programs, and hazards that may be intentionally introduced for purposes of economic gain, taking into account the comments we have reviewed so far. We are seeking comment on whether such requirements should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate.

In the previous proposal, we requested comment on three options for classifying a facility as a ''very small business,'' with consequences for facilities in terms of eligibility for exemptions and the timeframe to comply with this rule. In this document we are proposing a definition for ''very small business'' (i.e., a business that has less than $1,000,000 in total annual sales of human food adjusted for inflation).

Summary of the Major Provisions of the Supplemental Notice of Proposed Rulemaking

The revised ''farm'' definition would continue to describe a farm as an establishment devoted to the growing of crops, the raising of animals, or both. However, the revised ''farm'' definition would no longer limit packing and holding of RACs to the farm's own RACs; instead, a ''farm'' could now pack and hold RACs grown on another farm not under the same ownership. In addition, a farm could manufacture/process RACs by drying/dehydrating to create a distinct commodity (e.g., drying grapes to create raisins), and package and label the dried commodity, as long as there was no additional processing. An example of additional processing might include slicing fruit and then drying it, which would require additional manufacturing/processing prior to drying. Because drying/dehydrating RACs to create a distinct commodity creates a processed food, the packing and holding of raisins would be subject to the CGMP requirements for human food rather than to standards that we have separately proposed to apply to produce RACs. Given the nature of this processed food (i.e., dried RACs), we tentatively conclude that the requirements we separately proposed for packing and holding produce RACs would be sufficiently similar to the CGMP requirements to make it appropriate to specify in the regulatory text that compliance with the CGMP requirements may be achieved by complying with subpart B or with the applicable requirements for packing and holding produce RACs in the separate produce safety rule.

The previously proposed requirements for hazard analysis and risk-based preventive controls applied a construct we previously used in our Hazard Analysis and Critical Control Point (HACCP) regulations for seafood and juice—i.e., whether a known or reasonably foreseeable hazard was ''reasonably likely to occur.'' In general, our HACCP regulations for seafood and juice focus on critical control points to control hazards that are ''reasonably likely to occur.'' We are proposing to eliminate the term ''hazard reasonably likely to occur'' throughout the proposed requirements to reduce the potential for a misinterpretation that all necessary preventive controls must be established at critical control points (CCPs). The revised regulations would use a new term (''significant hazard'') in its place.

The defined term ''significant hazard'' would be linked to the facility's hazard analysis, which addresses risk (i.e., both the severity of a potential hazard and the probability that the hazard will occur). Thus, this term would reflect the risk-based nature of the requirements. In addition, the revised regulations would provide additional flexibility relative to the previous proposal by providing that a facility can take into account the nature of a preventive control in determining when and how to establish and implement appropriate preventive control management components, including monitoring, corrections or corrective actions, verification, and records. Table 6 in the document provides examples of flexibility provided by the rule, including flexibility provided for a facility to take into account the nature of the preventive control when determining the appropriate preventive control management components.

The proposed requirements for product testing would, if included in a final rule, require that a facility conduct product testing as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control. The facility would be required to have written procedures for product testing, corrective action procedures to address the presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing, and records of product testing.

The proposed requirements for environmental monitoring would, if included in a final rule, require that a facility conduct environmental monitoring as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard. The facility would be required to have written procedures for environmental monitoring, corrective action procedures to address the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring, and records of environmental monitoring.

The proposed requirements for a potential supplier program would, if included in a final rule, require supplier controls when the facility's hazard analysis identifies a significant hazard for a raw material or ingredient, and that hazard is controlled before the facility receives the raw material or ingredient (e.g., if a supplier roasts the nuts that a facility would use to manufacture an energy bar). A facility would not need to establish supplier controls if it controls that hazard, or if its customer controls that hazard. The supplier program would be written. With one exception, the receiving facility would have flexibility to determine the appropriate verification activity (e.g., onsite audit; sampling and testing of the raw material or ingredient; review of the supplier's food safety records; or other appropriate verification activity). The exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans. In this circumstance, the receiving facility would be required to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter, unless the receiving facility determines and documents that that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted.

The proposed requirements regarding potential hazards that may be intentionally introduced for economic reasons would, if included in a final rule, require that a facility consider in its hazard analysis hazards that may be intentionally introduced for purposes of economic gain.

We seek comment on whether these potential requirements discussed above should be included in a final rule.

The previously proposed requirements provided for an exemption for certain facilities defined by FSMA as ''qualified facilities.'' As required by FSMA, the previously proposed requirements also included an administrative procedure whereby we could withdraw that exemption under certain circumstances. In this document, we are proposing a series of modifications to the proposed withdrawal provisions. These modifications include describing the steps we would take before withdrawing an exemption, including advance notification to the facility; a procedure for re-instatement of a withdrawn exemption; and an additional 60 days for a facility whose exemption is withdrawn to comply with the full requirements for hazard analysis and risk-based preventive controls.

Costs and Benefits

We summarize the domestic annualized costs of the proposed regulation with the revised provisions, including the potential requirements for product testing, environmental monitoring, a supplier program, and potential requirements regarding hazards that may be intentionally introduced for economic reasons, using both a discount rate of 3 percent and 7 percent, discounted over a 7 year period in the following table. The revised proposed regulation uses a very small business definition of $1,000,000 and includes potential additional requirements for facilities subject to subpart C to institute risk-based environmental monitoring, product testing and a supplier program as appropriate to the food, the facility and the nature of the preventive controls, and controls to help prevent hazards associated with economically motivated adulteration. As described in the updated Preliminary Regulatory Impact Analysis, for the final rule we anticipate making several modifications to our estimate of the cost of our proposed rule (see section XVII).

As in our original proposal, we lack sufficient information to fully estimate the proposed rule's likely benefits. Instead we attempt to estimate the total economic burden of the domestic illnesses that could potentially be prevented by this rule. We do not expect that all of these illnesses will be prevented; rather, we expect that the rule would prevent some portion from occurring. We estimate that there are close to 1,000,000 illnesses each year that are attributable to FDA-regulated

food products that would fall under the scope of this proposed rule. The monetized cost of these illnesses is estimated to be nearly $2 billion. This ignores the costs to foreign firms and benefits to foreign consumers.

For the proposed rule to break even, by which we mean for the proposed rule to reduce the health burden to consumers by approximately the same amount as the compliance costs to industry, and if we include the costs to foreign firms but ignore the benefits to foreign consumers, the rule would have to reduce the annual social cost of the illnesses by approximately $471 million. We estimate that the average cost per illness is $2,063, so reducing the cost of illness by $471 million requires reducing the number of illnesses by at least 228,000 each year.

ORIGINAL AND REVISED ESTIMATED TOTAL COSTS BASED ON ADDITIONAL PROVISIONS AND REVISED FACILITY COUNT

	20 or fewer employees	20 to 99 employees	100 to 499 employees	500 or more employees	Total
Original Total Annualized Costs without additional provisions discounted at 7%	$208 million	$67 million	$43 million	$1 million	$319 million*
Original Total Annualized Costs without additional provisions discounted at 3%	$200 million	$65 million	$42 million	$1 million	$307 million*
Additional costs because of new provisions discounted at 7%	$19 million	$20 million	$10 million	$2 million	$52 million*
Additional costs because of new provisions discounted at 3%	$19 million	$20 million	$10 million	$2 million	$52 million*
Revised Total Annualized Costs discounted at 7%	$227 million	$87 million	$53 million	$3 million	$371 million*
Revised Total Annualized Costs discounted at 3%	$219 million	$85 million	$52 million	$3 million	$359 million*
Total Costs to Foreign Facilities (most likely cost) annualized at 7%					$100 million
Total Costs to Foreign Facilities (most likely cost) annualized at 3%					$100 million
Benefits					Unquantified

I. Background

A. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, enables us to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides us with new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law gives us important new tools to better ensure the safety of imported foods and encourages us to form partnerships with State, local, tribal, and territorial authorities. Table 1 identifies five proposed rules, issued to implement FSMA, that we discuss in this document.

TABLE 1—PUBLISHED PROPOSED RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed preventive controls rule	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety rule	78 FR 3504, January 16, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP rule	78 FR 45730, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration rule.	78 FR 78014, December 24, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal food rule	78 FR 64736, October 29, 2013.

B. 2013 Proposed Preventive Controls Rule

In the 2013 proposed preventive controls rule, we:

Proposed to amend our regulation for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (CGMPs; currently established in part 110 (21 CFR part 110)) to modernize it;

Proposed to adjust and clarify what activities fall within the current exemption from the CGMP requirements for establishments engaged solely in the harvesting, storage, or distribution of one or more RACs based on experience and changes in related areas of the law since issuance of the CGMP regulation;

Proposed to re-establish the provisions of current part 110 in new part 117 (21 CFR part 117);

Proposed to delete some non-binding provisions of current part 110 and requested comment on whether to revise other non-binding provisions to

establish new requirements in proposed part 117, or to simply retain them as useful provisions of a comprehensive CGMP;

Requested comment on additional proposed revisions or clarifications to our CGMP regulations, including whether to further implement opportunities for CGMP modernization, such as on how best to revise the current provisions for training;

Proposed to add, in newly established part 117, requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food;

Proposed to add a definition for the term ''mixed-type facilities,'' to add or modify definitions for certain activities (i.e., for ''harvesting,'' ''holding,'' ''manufacturing/processing,'' and ''packing'' activities), and to revise the definition of ''farm'' as a conforming revision in light of the proposed new definition of ''harvesting'' in our current regulation for Registration of Food Facilities (21 CFR part 1, subpart H; the section 415 registration regulations) to clarify the scope of the exemption from the section 415 registration requirements for ''farms;''

Proposed to revise the definitions, in our current regulation (implementing section 414 of the FD&C Act) for Establishment and Maintenance of Records for Foods (21 CFR part 1, subpart J; the section 414 recordkeeping requirements);

Requested comment on when and how product testing programs, environmental monitoring programs, and supplier approval and verification are an appropriate means of implementing the statutory framework of FSMA; and

Requested comment on whether a final rule should address potential hazards that may be intentionally introduced for economic reasons.

We proposed to establish the requirements for CGMPs, for hazard analysis and risk-based preventive controls, and related requirements in new part 117 as shown in Table 2:

TABLE 2—PROPOSED SUBPARTS IN NEW PART 117

Subpart	Title
A	General Provisions.
B	Current Good Manufacturing Practice.
C	Hazard Analysis and Risk-Based Preventive Controls.
D	Modified Requirements.
E	Withdrawal of an Exemption Applicable to a Qualified Facility.
F	Requirements Applying to Records That Must Be Established and Maintained.
G	Reserved.

In the 2013 proposed preventive controls rule, we provided an extensive background discussing:

The provisions of FSMA most directly applicable to the proposed requirements, particularly the statutory provisions of section 103 of FSMA (established in section 418 of the FD&C Act);

Hazard Analysis and Critical Control Points (HACCP) Systems;

Food Safety Problems Associated With Manufacturing, Processing, Packing, and Holding Food for Human Consumption;

The Role of Testing as a Verification Measure in a Food Safety System (including discussions about environmental monitoring as well as testing raw materials, ingredients, and finished product), largely in an Appendix to the 2013 proposed preventive controls rule (the Appendix)); and

The Role of Supplier Approval and Verification Programs in a Food Safety System (largely in the Appendix).

We also issued for public comment a ''Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the draft risk assessment) (78 FR 3824, January 16, 2013). The purpose of the draft risk assessment was to provide a science-based risk analysis of those activity/food combinations that would be considered low risk, when conducted in a facility co-located on a farm. We used the tentative conclusions of the draft risk assessment to propose to exempt food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities from the requirements for hazard analysis and risk-based preventive controls.

We also issued a document correcting several typographical and stylistic errors in the 2013 proposed preventive controls rule and a mistake in the date of a reference (78 FR 17142, March 20, 2013). In that correction document, we republished the Appendix in its entirety (78 FR 17142 at 17143 through 17155; the corrected Appendix) because all the references to the Appendix as published in the 2013 proposed preventive controls rule (78 FR 3646 at 3812 through 3824) had been numbered incorrectly.

C. Definition of ''Retail Food Establishment''

An establishment that meets the definition of ''retail food establishment'' is exempt from the requirements of the section 415 registration regulations and, thus, from FSMA's requirements for hazard analysis and risk-based preventive controls. Section 102(c) of FSMA requires that we revise the definition of ''retail food establishment'' in § 1.227 to clarify its intent. Some comments express concern that we did not address the requirements of section 102(c) of FSMA in the 2013 proposed preventive controls rule.

We are addressing the requirements of section 102(c) of FSMA in a separate rulemaking and plan to issue a proposed rule to amend the definition of ''retail food establishment'' in the section 415 registration regulations and the section 414 recordkeeping regulations in a future issue of the **Federal Register**.

II. Public Comments

A. Opportunities for Public Comment

We requested comments on the 2013 proposed preventive controls rule by May 16, 2013. We extended the comment periods for the 2013 proposed preventive controls rule, its information collection provisions, and the draft risk assessment in response to several requests that we do so (see Table 3).

Since issuing the 2013 proposed preventive controls rule, we conducted numerous outreach activities. For example, we held three public meetings to solicit oral stakeholder and public comments on the 2013 proposed preventive controls rule, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and respond to questions about the 2013 proposed preventive controls rule (see Table 3) (Ref. 1) (Ref. 2) (Ref. 3) (Ref. 4) (Ref. 5) (Ref. 6). We also traveled across the country and around the world to discuss the 2013 proposed preventive controls rule, as well as the other foundational FSMA proposed rules listed in section I.A, with persons who would be affected by them (Ref. 7) (Ref. 8) (Ref. 9).

TABLE 3—LIST OF **Federal Register** PUBLICATIONS REGARDING THE 2013 PROPOSED PREVENTIVE CONTROLS RULE

Description	Publication
2013 proposed preventive controls rule, requesting comments by May 16, 2013	78 FR 3646, January 16, 2013.
Notice of availability of the draft risk assessment, requesting comments by February 15, 2013.	78 FR 3824, January 16, 2013.
Notice of public meeting (held in Washington D.C. on February 28, 2013) on the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule.	78 FR 6762, January 31, 2013.
Notice of public meetings (held in Chicago, IL on March 11, 2013 and in Portland, OR on March 27, 2013) on the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule.	78 FR 10107, February 13, 2013.
Notice extending comment period, until May 16, 2013, for the information collection provisions of the 2013 proposed preventive controls rule.	78 FR 11611, February 19, 2013.
Reopening of the comment period, until May 16, 2013, for the draft risk assessment	78 FR 15894, March 13, 2013.
Notice of correction for the 2013 proposed preventive controls rule	78 FR 17142, March 20, 2013.
Notice extending the comment period, until September 16, 2013, for the 2013 proposed preventive controls rule and its information collection provisions.	78 FR 24691, April 26, 2013.
Notice extending the comment period, until September 16, 2013, for the draft risk assessment.	78 FR 24693, April 26, 2013.
Notice extending the comment period, until November 15, 2013, for the 2013 proposed preventive controls rule and its information collection provisions.	78 FR 48636, August 9, 2013.
Notice extending the comment period, until November 22, 2013, for the 2013 proposed preventive controls rule and its information collection provisions.	78 FR 69604, November 20, 2013.

B. Overview of Public Comments on the 2013 Proposed Preventive Controls Rule

We received more than 8000 submissions on the proposed rule by the close of the comment period, each containing one or more comments. We received submissions from diverse members of the public, including food facilities (including facilities co-located on a farm); farms; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress, Federal, State, local, and tribal Government Agencies; and other organizations. Some submissions included signatures and statements from multiple individuals.

Comments address virtually every provision of the 2013 proposed preventive controls rule, including our requests for comment on including additional provisions that we did not include in the proposed regulatory text. Although some comments focus on specific details of the proposed requirements (such as whether the rule should define the term ''allergen cross-contact'' rather than the term ''cross-contact''), other comments are broad in nature (such as comments addressing the overall framework of the proposed requirements for hazard analysis and risk-based preventive controls in proposed subpart C). Some comments question whether the proposed requirements reflected a risk-based approach (such as comments about how the requirements for hazard analysis and risk-based preventive controls would apply to facilities co-located on farms). Some comments assert that additional public comment would be warranted before any consideration of whether a final rule should or should not include provisions discussed in the proposed rule, but for which we had not included proposed regulatory text, such as potential requirements for product testing, environmental monitoring, a supplier approval and verification program, and potential hazards that may be intentionally introduced for economic reasons.

C. Our Decision To Issue a Supplemental Notice of Proposed Rulemaking for Public Comment

In December 2013, we issued a statement noting the extensive input we have received from produce farmers and others in the agricultural sector on the 2013 proposed produce safety rule and the 2013 proposed preventive controls rule (Ref. 8). We stated that we believe that significant changes will be needed in key provisions of the two proposed rules affecting small and large farmers, such as certain provisions affecting mixed-use facilities (i.e., facilities co-located on a farm). We also announced our intent to propose revised regulatory requirements and request comment on them, allowing the public the opportunity to provide input on our new thinking. We noted that there may be other revisions to the proposed rules that we would issue for public comment, and that we would determine the scope of the revised proposals after we complete our initial review of written comments.

III. Scope of the Supplemental Notice and Our Request for Public Comment

In this document, we are proposing:

Modifications to our proposed revisions to the definitions, in the section 415 registration regulations, for ''farm,'' ''harvesting,'' holding,'' and ''packing,'' with conforming changes in the section 414 recordkeeping regulations and the proposed preventive controls rule;

Modifications to our proposed revisions to the current exemption, in the CGMP regulations, for establishments engaged solely in the harvesting, storage, or distribution of one or more RACs;

Revisions to several definitions we proposed to apply to the requirements for hazard analysis and risk-based preventive controls, including definitions for ''environmental pathogen,'' ''hazard,'' ''reasonably foreseeable hazard,'' and ''very small business'';

New definitions for ''significant hazard,'' ''pathogen,'' and ''you'';

Revisions to the proposed procedures that would govern withdrawal of an exemption from a ''qualified facility,'' including clarifications about the steps we would take before issuing an order to withdraw the exemption, an expanded timeframe for a facility to comply with an order withdrawing an exemption, and a mechanism for a withdrawn exemption to be re-instated; and

A series of revisions to the proposed requirements for hazard analysis and risk-based preventive controls (proposed subpart C) to:

Emphasize the risk-based nature of the preventive controls and requirements for monitoring, corrective actions, and verification activities;

Reduce the potential for misinterpretation that the rule requires

that all necessary preventive controls be established at CCPs for all hazards that a facility addresses in its food safety plan;

Increase flexibility for a facility to determine, based on the nature of a preventive control, when requirements for ''preventive control management components'' (i.e., monitoring, corrective actions, and verification) are appropriate;

Substitute the pronoun ''you'' for ''the owner, operator, or agent in charge of the facility'' throughout these proposed requirements;

Substitute the term ''adequate'' (which is a term we proposed to define) in place of the term ''sufficient'' (which we did not propose to define);

Improve readability, through rearrangement of some of the proposed regulatory text and editorial revisions (such as increased use of active voice).

In this document, we also are providing an opportunity for public comment on potential requirements for product testing, environmental monitoring, a supplier program, and hazards that may be intentionally introduced for purposes of economic gain, including definitions of terms (i.e., ''qualified auditor,'' ''receiving facility,'' and ''supplier'') that would be used in some of those potential requirements. We are seeking comment on whether such requirements should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate.

In this document, we also are informing stakeholders of a supplemental notice of proposed rulemaking, published elsewhere in this issue of the **Federal Register,** to amend the 2013 proposed animal food rule. That supplemental notice includes proposed revisions that would address comments about the practice of human food manufacturers sending by-products to local farmers or animal food manufacturers for use as animal food.

We discuss these proposed requirements in sections V through XV. Because several of the proposed revisions relate to the overall framework in subpart C for hazard analysis and risk-based preventive controls, we are including the complete regulatory text for proposed subpart C. However, in this document, we are reopening the comment period only with respect to the issues specified in this section III.

Importantly, the proposed revisions to the provisions we have included in the regulatory text are based on a preliminary review of the comments. We will complete our review of comments previously submitted and consider the comments responsive to this supplemental notice of proposed rulemaking in developing the final rule.

IV. Legal and Regulatory Framework Under Sections 415 and 418 of the FD&C Act and Regulations Implementing Section 415 of the FD&C Act

In the 2013 proposed preventive controls rule, we described the current legal and regulatory framework that governs the determination of when an establishment is required to register as a food facility in accordance with the section 415 registration regulations. We focused on the framework that governs whether an establishment that grows and harvests crops or raises animals satisfies the definition of ''farm'' because the facility registration requirements of section 415 of the FD&C Act do not apply to ''farms.'' When we implemented the statutory requirements for registration of food facilities, we established a definition for ''farm'' that first describes a farm as a facility devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both (§ 1.227; 68 FR 58894, October 10, 2003). Although that definition of ''farm'' then provides that farms also pack or hold food, it limits facilities that fall within the definition of ''farm'' to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Thus, under the current framework, an establishment that is devoted to the growing and harvesting of crops, but also packs and holds food not grown or raised on that farm or on another farm under the same ownership, would fall outside the definition of ''farm'' and be required to register as a food facility. Because an establishment that is required to register as a food facility is subject to the requirements of section 418 of the FD&C Act, under the current framework a determination of whether an establishment devoted to the growing and harvesting of crops is subject to FSMA's requirements for hazard analysis and risk-based preventive controls depends, in part, on where the food that the establishment packs or holds is grown or raised.

Under the current framework, a key factor in whether an establishment falls within the definition of ''farm,'' even with respect to crops it grows and harvests itself, is whether the activities conducted by the farm fall within definitions of ''harvesting,'' ''packing'' or ''holding'' (which are within the ''farm'' definition). As discussed in the 2013 proposed preventive controls rule, section 103 of FSMA directs us to conduct rulemaking to clarify the on-farm manufacturing, processing, packing and holding activities that would trigger a requirement for an establishment that is also a farm to register as a food facility and, thus, be subject to the requirements for hazard analysis and risk-based preventive controls with regard to its non-farm activities (78 FR 3646 at 3674). In the 2013 proposed preventive controls rule, we explained how the status of a food as a raw agricultural commodity (RAC) or a processed food affects the requirements applicable to a farm under sections 415 and 418 of the FD&C Act.

In the 2013 proposed preventive controls rule, we also articulated a comprehensive set of organizing principles that formed the basis for proposed revisions to definitions that classify activities on-farm and off-farm in the section 415 registration regulations (the 2013 organizing principles; see Table 3 in the 2013 proposed preventive controls rule). Because these definitions also are established in the section 414 recordkeeping regulations, these organizing principles also would form the basis for proposed revisions to definitions that classify activities on-farm and off-farm in the section 414 recordkeeping regulations.

In the 2013 proposed preventive controls rule, we proposed to add a definition for the term ''mixed-type facilities,'' to add or modify definitions for certain activities (i.e., for ''harvesting,'' ''holding,'' ''manufacturing/processing,'' and ''packing'' activities), and to revise the definition of ''farm'' as a conforming revision in light of the proposed new definition of ''harvesting.''

In sections V and VI, we discuss comments on these and other provisions of the 2013 proposed preventive controls rule that are leading us to propose revised definitions for ''farm,'' ''harvesting,'' ''packing,'' and ''holding''; and re-classify some activities as harvesting, packing, or holding. Briefly, the proposed changes would:

Provide for on-farm packing and holding of RACs to remain within the farm definition regardless of ownership of the RACS;

Include, within the ''farm'' definition, a description of packing activities that include packaging RACs grown or raised on a farm without additional manufacturing/processing;

Provide for ''field coring'' as an example of a harvesting activity to make clear that on farm ''field coring'' of a RAC is an activity that is within the ''farm'' definition;

Provide that activities performed incidental to packing a food would be ''packing'' activities;

Provide that activities performed incidental to holding a food would be ''holding'' activities;

Provide for drying/dehydrating RACs to create a distinct commodity (such as the on-farm drying of grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing, to remain within the farm definition;

Seek comment on whether we should retain, remove, or modify the phrase ''in one general physical location'' in the ''farm'' definition;

Subject the packaging, packing, and holding of dried RACs by farms and farm mixed-type facilities to the CGMP requirements in subpart B of proposed part 117 as well as provide that compliance with these CGMP requirements may be achieved by complying with the applicable requirements for packing and holding produce RACs in the separate produce safety rule; and

Reconsidered the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities. These changes in activity classification would result in a single circumstance (drying/dehydrating RACs to create a distinct commodity without additional manufacturing/processing) where a farm conducting manufacturing/processing would no longer be required to register as a food facility, but would not result in any new circumstance where a farm would now be required to register as a food facility.

Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to amend the 2013 proposed animal food rule. That supplemental notice includes a discussion of farming models for raising animals, including contract farming, fully vertically integrated farming, and cooperative farming. That supplemental notice asks for comment on whether feed mills associated with fully vertically integrated farming operations, including cooperatives that fit this model, that meet the farm definition (current or proposed revision) should be required to register as a food facility under section 415 of the FD&C Act and, if so, what revisions to the farm definition would be necessary.

V. The ''Farm'' Definition

In this section of this document, we are:

Proposing modifications to our proposed revisions to the ''farm'' definition;

Proposing modifications to our proposed revisions to the definitions of ''harvesting,'' ''holding,'' and ''packing'' as conforming amendments to the revised ''farm'' definition''; and

Proposing modifications to our proposed revisions to the current exemption, in the CGMP regulations, for establishments engaged solely in the harvesting, storage, or distribution of one or more RACs.

We are reopening the comment period with respect to these revised definitions (proposed § 117.3) and this revised exemption (proposed § 117.3(k)). See section VI for additional revisions that we are proposing to the definitions of ''holding'' and ''packing.''

A. 2013 Proposed Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''

Consistent with the organizing principles regarding classification of activities on-farm and off-farm, we proposed to define ''harvesting,'' as a new definition in §§ 1.227 and 1.328, to apply to farms and farm mixed-type facilities and to mean activities that are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food. We proposed that harvesting be limited to activities performed on the farm on which they were grown or raised, or another farm under the same ownership, and that harvesting does not include activities that transform a RAC into a processed food. The proposed definition included examples of activities that would be harvesting. As a conforming change to the proposed definition of ''harvesting,'' we proposed to revise the definition of ''farm'' in current §§ 1.227(b)(3) and 1.328 to delete examples of harvesting that currently appear in the ''farm'' definition.

We proposed to revise the definition of ''holding'' in §§ 1.227 and 1.328 so that it would be a two-part definition that would include, for farms and farm mixed-type facilities, activities traditionally performed by farms for the safe or effective storage of RACs grown or raised on the same farm or another farm under the same ownership, but would not include activities that transform a RAC into a processed food.

We proposed to revise the definition of ''packing'' in §§ 1.227 and 1.328 so that it would be a two-part definition that would include, for farms and farm mixed-type facilities, activities (which may include packaging) traditionally performed by farms to prepare RACs grown or raised on a farm or another farm under the same ownership for storage and transport, but would not include activities that transform a RAC into a processed food.

B. Conducting Packing and Holding Activities on Others' RACs

1. Comments

Some stakeholders expressed concern, in public sessions and in written comments, about how the proposed requirements for packing and holding RACs would apply to a farm that would be subject to the requirements for hazard analysis and risk-based preventive controls because the farm packs or holds produce grown on others' farms. Comments assert that classifying establishments as being within the ''farm'' definition, or outside the ''farm'' definition, based on who owns the RACs being packed is not a risk-based classification. These comments also compare the requirements that would apply to a farm when packing produce in accordance with the 2013 proposed preventive controls rule to the requirements that would apply to a farm when packing produce in accordance with the 2013 proposed produce safety rule. In general, these comments express concern about the lack of clarity and consistency in the requirements for packing and holding RACs under the 2013 proposed preventive controls rule and the 2013 proposed produce safety rule. Some of these comments assert that treating on-farm packing and holding of RACs differently depending on whether the RACs are grown on that farm (or another farm under the same ownership) or grown on a different farm under different ownership, fails to reflect modern, cooperative farming practices and to be risk-based. Comments also assert that it unreasonable to force many farms to comply with two different sets of requirements depending on whether they are packing and holding their own produce or packing and holding produce from another farm. In essence, comments assert it would be more appropriate for farm activities such as packing and holding produce to be treated consistently under the two rules. Comments also generally assert that the requirements in the 2013 proposed produce safety rule for packing and holding activities (which would not require hazard analysis and risk-based preventive controls) are more appropriate for farms than the requirements in the 2013 proposed preventive controls rule for packing and holding activities (which would require

hazard analysis and risk-based preventive controls).

Some comments find it confusing for the definition of ''farm'' to start by describing a farm as a ''facility'' in light of the definition of ''facility'' in section 415(o)(2) of the FD&C Act as a facility required to register under section 415 of the FD&C Act.

2. Proposed Revisions to the Definitions of ''Farm,'' ''Harvesting,'' ''Holding,'' and ''Packing''

In the rulemakings to establish the section 415 registration regulations and the section 414 recordkeeping regulations, we defined ''farm'' with the goal of doing so in a manner recognizing the traditional activities of establishments commonly recognized to be farms (see the discussions at 78 FR 3646 at 3676–3677 and 3679). As already noted (see section V.A), we proposed to expand the definition of ''packing'' to include activities traditionally performed by a farm to prepare its own RACs for storage and transport and to expand the definition of ''holding'' to include activities traditionally performed by a farm for the safe or effective storage of its own RACs. Comments assert that the packing and holding of others' RACs is a traditional and common activity by farms and that the definition should not distinguish between activities performed by a farm on its own RACs and activities performed on RACs from other farms.

We tentatively conclude that it is appropriate for packing and holding of RACs, including produce, conducted on farms to remain within the farm definition. This would result in packing and holding of covered produce being subject to the proposed produce safety rule, regardless of whether the activity is conducted on the farm's own produce or whether the activity is conducted on others' produce. This also would have consequences beyond the preventive controls rule and the produce safety rule. For example, the revised ''farm'' definition would be established in both the section 415 registration regulations and in the section 414 recordkeeping regulations (see the revised regulatory text for proposed §§ 1.227 and 1.328, respectively). Under the revised ''farm'' definition in the section 414 recordkeeping regulations, an establishment that packs and holds others' RACs would no longer be required to establish and maintain records identifying the immediate previous sources of those RACs and immediate subsequent recipients of those RACs. In addition, the scope of covered establishments would change for other statutory requirements that depend, in relevant part, on whether an establishment is a facility subject to the section 415 registration regulations. For example, this would be the case for requirements for the Reportable Food Registry (under section 417 of the FD&C Act), mandatory recall (under section 423 of the FD&C Act), and regulations that we have proposed to establish regarding intentional contamination related to terrorism (under sections 418 and 420 of the FD&C Act; see the proposed intentional adulteration rule, 78 FR 78014). We tentatively conclude that impacts such as these, while not always optimal, are necessary to establish a sensible framework of risk-based regulations that both implement FSMA and reflect common farm activities. Elsewhere in this issue of the **Federal Register**, a supplemental notice of proposed rulemaking regarding the produce safety rule (the produce safety supplemental notice) discusses impacts such as these, including a request for comment on whether to include in the final produce safety rule a requirement that a farm supplying produce to another farm that will pack or hold that produce should provide to the farm that receives the produce its name, complete business address, and description of the produce in any individual shipment. The produce safety supplemental notice also requests comment on whether it would be appropriate to also require the farm that receives the shipment maintain such record of information and, if so, for what specified period of time.

Therefore, taking into account the comments we have reviewed so far we are proposing to revise the ''farm'' definition so that it would no longer limit establishments that fall within the ''farm'' definition to those that pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership. Under the revised ''farm'' definition, an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the ''farm'' definition (and, thus, not be subject to the section 415 registration regulations and the proposed requirements for hazard analysis and risk-based preventive controls) even if it packs and holds RACs grown on another farm. To limit the potential for confusion related to the term ''facility,'' we are proposing to substitute the term ''establishment'' for the term ''facility'' in the revised definition of ''farm.'' As a conforming change relevant to this substitution, we are adding to the ''farm'' definition the criterion, in the definition of ''facility,'' that the establishment is ''under one ownership,'' to retain that aspect of the current ''farm'' definition in the revised definition. For additional discussion about manufacturing/processing activities that would make an establishment subject to the section 415 registration regulations, see sections V.D and VII.

We also are proposing that the packing activities (which may include packaging) that we had proposed to include in the expanded definition of ''packing'' for farms and farm mixed-type facilities be included in the ''farm'' definition rather than in an expanded definition of ''packing.'' Under the revised ''farm'' definition, it will be clear that an establishment devoted to the growing of crops, the raising of animals, or both, can remain within the ''farm'' definition if it packages RACs grown or raised on a farm to prepare them for storage and transport, without additional manufacturing/processing. Packaging activities would continue to be considered manufacturing/processing (78 FR 3646 at 3681–3682); however, packaging a RAC would not transform the RAC into a processed food (see the discussion in the 2013 proposed preventive controls rule about whether an activity transforms a RAC into a processed food (78 FR 3646 at 3678–3679)). Importantly, we are proposing limitations on what would be included within this addition to the ''farm'' definition. This proposed provision would not provide that packaging RACs would remain within the ''farm'' definition if the packaging includes additional manufacturing/processing (e.g., the application of ''modified atmosphere packaging''). Such additional processing activities are not akin to packing (see the discussion in the 2013 proposed preventive controls rule (78 FR 3646 at 3686) that certain packaging activities conducted on a farm are akin to packing).

We are not proposing any changes to the ''farm'' definition that we would establish in part 117, because the proposed ''farm'' definition for the purpose of part 117 simply referred to the ''farm'' definition in the section 415 registration regulations.

The revised ''farm'' definition would require conforming changes to the proposed definitions of ''harvesting,'' ''holding,'' and ''packing'' (in the section 415 registration regulations, the section 414 recordkeeping regulations, and the proposed preventive controls rule) to remove limitations that the food be grown on the same farm or a farm under the same ownership. (See the revised regulatory text for proposed §§ 1.227, 1.328, and 117.3). In addition:

The revised regulatory text for the definition of ''harvesting'' includes ''field coring'' as an additional example of a harvesting activity. See section V.C for a discussion of this proposed additional example.

The revised regulatory text for the definition of ''holding'' includes revisions that we are proposing in response to comments about how the definition of ''holding'' would apply to facilities such as grain elevators and warehouses. See section VI.A through VI.E for a discussion of those proposed revisions.

The revised regulatory text for the definition of ''packing'' includes changes that we are proposing to provide for activities performed incidental to packing a food. See section VI.F for discussions of those proposed revisions.

The revised definitions of ''farm,'' ''harvesting,'' ''holding,'' and ''packing'' would, if finalized, require changes to guidance documents we issued regarding the section 415 registration regulations and the section 414 recordkeeping regulations, including specific examples of circumstances that would make an establishment subject to those requirements (e.g., Ref. 10, Ref. 11, Ref. 12, and Ref. 13). We intend to update affected guidance documents to reflect the final definitions.

C. Field Coring as a Harvesting Activity

1. Comments

Some comments ask us to specify that activities such as ''core in field'' and ''clean and core'' are considered harvesting, because these activities are no different from an example (i.e., ''trimming of outer leaves of'') included in the regulatory text of the definition of ''harvesting.''

2. Proposed Revision to the Definition of ''Harvesting''

We are proposing revisions to the definition of ''harvesting'' in addition to the revisions, discussed in section V.B.2, that would be conforming amendments in light of the revised ''farm'' definition. We are proposing to include ''field coring'' as an example of a harvesting activity to make clear that on farm ''field coring'' of a RAC (e.g., removing the core of lettuce in the field at the same time the stem is cut and wrapper leaves removed) is a harvesting activity, even though ''coring'' outside of ''field coring'' (e.g., during the production of fresh-cut lettuce) is a manufacturing/processing activity. Under the revised ''harvesting'' definition, it would be clear that an establishment devoted to the growing of crops, the raising of animals, or both, would remain within the ''farm'' definition (and, thus, not be subject to the section 415 registration regulations and the proposed requirements for hazard analysis and risk-based preventive controls) even if it conducts field coring of produce. The revised definition of ''harvesting'' would be included in the section 415 registration regulations, the section 414 recordkeeping regulations, and the preventive controls rule. In this section of this document, we are reopening the comment period with respect to including ''field coring'' as an example of a harvesting activity in this revised definition of ''harvesting'' (proposed § 117.3).

D. Drying/Dehydrating Raw Agricultural Commodities To Create a Distinct Commodity

1. Comments

Some comments refer to our discussion, in the 2013 proposed preventive controls rule, about guidance jointly developed by FDA and the U.S. Environmental Protection Agency (EPA) regarding whether or not various activities transform RACs into processed foods, including a joint conclusion that drying a RAC causes it to become a processed food, unless the drying is for the purpose of facilitating storage or transportation of the commodity (78 FR 3646 at 3678–3679). In our discussion, we described a series of policy statements and guidance documents, issued by FDA and EPA regarding whether or not various activities transform RACs into processed foods (78 FR 3646 at 3678–3679). We noted that FDA and EPA have jointly concluded that drying a RAC causes it to become a processed food, unless the drying is for the purpose of facilitating storage or transportation of the commodity (see, e.g., (Ref. 14). We referenced a policy statement issued by EPA on the status of dried commodities as RACs (the 1996 EPA policy statement; 61 FR 2386, January 25, 1996). We also gave two examples of when we would consider that drying a RAC created a processed food: (1) Drying grapes to create raisins; and (2) drying fresh herbs (such as peppermint) to create dried herbs, because in both these instances drying creates a distinct commodity and therefore a processed food.

The comments contrast the growing and harvesting (including drying) of ''natural condition raisins'' (produced with sun-drying or artificial dehydration) with raisins subject to additional processing and packing (e.g., sorting, cleaning or seeding) at an off-farm facility. The comments maintain that the traditional activities of raisin grape farmers associated with growing and harvesting ''natural condition raisins'' on farm are completely separate and distinct from the processing and packing of ''processed raisins'' at a raisin processing facility. They note that raisin grape farmers generally dry their grapes either by cutting the grape clusters and placing them on trays to be naturally sun dried, or by allowing the grapes to dry naturally on the vine. In both instances, there is no intervention by the farmer in the drying process; rather, the drying process occurs naturally through the action of the sun. These comments ask us to recognize this distinction and provide in the final rule that on-farm activities such as drying ''natural condition raisins'' in the field are exclusively subject to the produce safety rule and that processing facility operations are subject to the preventive controls rule. They also specifically mention the 1996 EPA policy statement and ask us to determine that it does not apply for the purposes of implementing FSMA.

2. Proposed Revisions to the ''Farm Definition'' Regarding Drying/Dehydrating RACs To Create a Distinct Commodity When the Drying/Dehydrating Is Akin to Harvesting and There Is No Additional Processing

The processes described in the comments for drying grapes to ''natural condition raisins'' are akin to other harvesting activities traditionally conducted by farms on RACs grown and harvested on farms, because they are traditionally performed by farms for the purpose of removing RACs from the place they were grown or raised and preparing them for use as food (see 78 FR 3646 at 3681 and the proposed definition of harvesting in proposed § 117.3).

We continue to consider that drying a RAC to create a distinct commodity causes it to become a processed food and, thus, is a manufacturing/processing activity for the purpose of the section 415 registration regulations. However, to the extent that the comments are asking us to determine that drying a RAC to create a distinct commodity can, under circumstances such as those described in the comments, remain within the ''farm'' definition, we tentatively conclude that it is appropriate to do so, provided that the drying/dehydrating process is akin to harvesting. However, we would continue to classify drying RACs to create a distinct commodity as manufacturing/processing rather than re-classify this activity as harvesting.

We do not consider it necessary or prudent to classify this activity in two different ways for the purposes of the ''farm'' definition and determining our responsibilities for antimicrobial substances.

To provide for drying/dehydrating that is akin to harvesting to remain within the farm definition, taking into account the comments we have reviewed so far we are proposing that farms include establishments that, in addition to growing and harvesting crops, raising animals, or both, manufacture/process RACs by drying/dehydrating the RACs to create a distinct commodity, and/or packaging and/or labeling such commodities, without additional manufacturing/processing (see the revised regulatory text for the ''farm'' definition in proposed §§ 1.227 and 1.328). This revised ''farm'' definition would specifically address this circumstance because otherwise it would not be within the ''farm'' definition. Drying/dehydrating that is akin to harvesting would not trigger the requirement to register as a facility and would not trigger the requirements for hazard analysis and risk-based preventive controls. Likewise, packaging and/or labeling the dried commodities (which are processed food), would not trigger the requirement to register as a facility and would not trigger the requirements for hazard analysis and risk-based preventive controls. As a companion change, we are proposing that the ''farm'' definition explicitly provide that packing and holding the dried commodities (which are processed food) is within the ''farm'' definition. Whether a farm would be subject to the produce safety rule would depend on factors included in the produce safety rule, such as whether the RACs satisfy criteria for ''covered produce.''

Importantly, we are proposing limitations on when this special circumstance would apply. This proposed provision would not provide that drying/dehydrating fruit would remain within the ''farm'' definition if the dried/dehydrated fruit is subject to additional manufacturing/processing, such as cutting the fruit or applying sulfites (e.g., when manufacturing/processing dried apples). Such additional processing activities are not akin to harvesting. They also are not necessary for safe storage of the crop (which would be holding; see sections VI.C., VI.E, and VII.C and Table 1 in the Appendix to this document). A farm that also manufactures/processes products such as dried, cut apples would be a farm mixed-type facility, subject to the section 415 registration regulations and FSMA's requirements for hazard analysis and risk-based preventive controls for such activities.

E. One General Physical Location

1. Comments on Whether the ''Farm'' Definition Should Specify That a Farm Is in ''One General Physical Location''

Some comments emphasize that farms throughout the country are now made up of multiple, often non-contiguous fields due to geographic and topographic conditions, local development patterns, and the fact that a single ''farm'' today often derives from multiple previous farms due to the need to achieve economic efficiencies. Some comments explain that as farm land increasingly is partitioned into smaller and smaller parcels through estate divisions or for other reasons, farmers purchasing land find that they are rarely able to purchase adjacent parcels. These comments ask us to modify or remove the phrase ''in one general physical location'' in the ''farm'' definition. One suggested modification is to replace the phrase ''in one general physical location'' with an explanatory sentence, such as one clarifying that a farm may consist of one or more parcels of land (or water) and may include one or more structures (e.g., outbuildings, barns, greenhouses, etc.).

2. Request for Additional Comment on Whether the ''Farm'' Definition Should Specify That a Farm Is in ''One General Physical Location''

During the rulemaking to establish the ''farm'' definition in the section 415 registration regulations, we explained that a farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens (68 FR 5378 at 5381, February 3, 2003). However, we did not propose to include this explanatory sentence in the regulatory text. Comments addressing ''one general physical location'' focused on how specifying ''in one general physical location'' would affect whether the farm would be subject to the section 415 registration regulations. Our response to those comments focused on the nature of the activities being conducted rather than on the contiguous or non-contiguous nature of parcels of land or nets (68 FR 58894 at 58906, October 10, 2003).

The definition of ''facility'' in the section 415 registration regulations likewise specifies that a facility means ''any establishment, structure, or structures under one ownership at one general physical location . . .'' However, this definition specifically adds an explanatory statement that a facility may consist of one or more contiguous structures (§ 1.227). During the rulemaking to establish this definition of ''facility,'' we explained that we proposed to include this explanatory sentence in the regulatory text as a result of comments that we received during our early outreach efforts (68 FR 5378 at 5381, February 3, 2003).

We are seeking comment on whether we should retain, remove, or modify the phrase ''in one general physical location'' in the ''farm'' definition. In responding to our request for comment on this issue, we ask commenters to carefully consider what, if any, impacts removing or modifying this phrase could have on other rules that already include (or have proposed to include) the same definition of ''farm'' as would be established in the section 415 registration regulations, as well as how such impacts would best be addressed. For example, elsewhere in this issue of the **Federal Register** the produce safety supplemental notice seeks comment on how we should interpret ''in one general physical location'' for the purposes of enforcing that rule. The produce safety supplemental notice explains that specifying that a farm is in ''one general physical location'' could impact classification of farms subject to the produce safety rule as a ''small business'' or ''very small business'' and, thus affect the compliance date for that farm.

F. Proposed Revisions to the Exemption From CGMP Requirements for ''Farms'' and Activities of ''Farm Mixed-Type Facilities'' That Fall Within the ''Farm'' Definition

1. 2013 Proposed Revisions to the Exemption From the CGMP Requirements for Establishments Engaged Solely in the Harvesting, Storage, or Distribution of One or More RACs

In the 2013 proposed preventive controls rule, we proposed to adjust and clarify what activities fall within the current exemption from the CGMP requirements for establishments engaged solely in the harvesting, storage, or distribution of one or more RACs (''RAC exemption'') based on experience and changes in related areas of the law since issuance of the CGMP regulation. We proposed to provide that the CGMP requirements of subpart B would not apply to ''farms,'' activities of ''farm mixed-type facilities'' that fall within the ''farm'' definition, or the

holding or transportation of one or more RACs (proposed § 117.5(k)).

In the 2013 proposed produce safety rule, we proposed to implement section 419 of the FD&C Act (standards for produce safety) by establishing, in part 112, standards for the growing, harvesting, packing, and holding of produce for human consumption. The proposed standards for produce safety would apply only to RACs (see proposed § 112.1(a) and section 419(a)(1)(A) of the FD&C Act).

2. Consequential Revision to the RAC Exemption in Light of Proposed Changes to the ''Farm'' Definition

As discussed in section V.D of this document, we are proposing that an establishment that is devoted to the growing and harvesting of crops, the raising of animals, or both can remain within the farm definition if it dries/dehydrates RACs to create a distinct commodity, and/or packages and/or labels such commodities, without additional manufacturing/processing. A farm that does so would transform a RAC into a processed food. The growing and harvesting of produce RACs that would be covered by the proposed produce safety rule would be subject to the standards for produce safety, but the dried commodities that are processed food would not. Like any other processed food, such dried commodities would be subject to the CGMP requirements (proposed subpart B) and would not be eligible for a ''RAC exemption,'' whether the current RAC exemption in § 110.19 or the proposed ''RAC exemption'' in proposed § 117.5(k).

Therefore, as a consequence of our proposal to provide for drying/dehydrating that is akin to harvesting to remain within the farm definition, we also are proposing to revise the exemption from CGMP requirements for ''farms'' and activities of ''farm mixed-type facilities'' that fall within the ''farm'' definition to provide that if a ''farm'' or ''farm mixed-type facility'' dries/dehydrates RACs to create a distinct commodity, the CGMP requirements apply to the packaging, packing, and holding of the dried commodities. As discussed in section V.G of this document, we tentatively conclude that the specific steps that are necessary to ensure the safety of produce that an establishment packs and holds would be the same regardless of the specific regulatory framework applicable to the establishment. Given the nature of the processed food that would be subject to the CGMP requirements (i.e., dried RACs), we tentatively conclude that the requirements we separately proposed for packing and holding produce RACs would be sufficiently similar to the CGMP requirements to make it appropriate to specify in the regulatory text that compliance with the CGMP requirements may be achieved by complying with subpart B or with the applicable requirements for packing and holding produce RACs in the separate produce safety rule. However, we do not intend to issue a final rule on this specific option for achieving compliance with the CGMP requirements that would apply to processed food produced through drying/dehydrating RACs until we issue the final produce safety rule.

3. Comments on the Proposed RAC Exemption

Some comments ask us to exempt the harvest and immediate transport of raw fishery commodities from the CGMP requirements. Other comments ask us to exempt facilities that conduct hulling and drying operations on shell nuts from the CGMP requirements.

4. Proposed Additional Revisions to the RAC Exemption To Clarify Applicability to Certain RACs

We are proposing to clarify how the RAC exemption applies to seafood RACs by specifying that subpart B does not apply to fishing vessels that are not subject to the registration requirements of part 1, subpart H of this part in accordance with § 1.226(f). Section 1.226(f) describes fishing vessels that are exempt from the registration requirements as those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel. Section 1.226(f) also specifies that fishing vessels otherwise engaged in processing fish are subject to the registration requirements, and describes ''processing'' for the purpose of determining the exemption to mean handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding, or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel. The practices identified in § 117.226(f) (heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel) that warrant an exemption from registration are activities conducted by establishments engaged solely in the harvesting, storage, or distribution of one or more RACs and, thus, fall within the current RAC exemption in § 110.19.

We also are proposing to clarify how this exemption applies to activities commonly conducted on nuts at a facility that is not a farm or farm-mixed type facility by specifying that subpart B does not apply to hulling, shelling, and drying nuts (without manufacturing/processing, such as roasting nuts). Hulling, shelling, and drying nuts (without additional manufacturing/processing), are activities conducted by establishments engaged solely in the harvesting, storage, or distribution of one or more RACs and, thus, fall within the current RAC exemption in § 110.19.

G. Comparing Proposed Requirements for Packing Produce Under the 2013 Proposed Preventive Controls Rule to Proposed Requirements for Packing Produce Under the 2013 Proposed Produce Safety Rule

1. Comments

Some stakeholders expressed concern, in public sessions and in written comments, about the proposed requirements that would apply to an off-farm facility that packs and holds produce. These comments focus on how the proposed requirements for an off-farm facility that packs and holds produce under the requirements of the 2013 proposed preventive controls rule would be different from the requirements, under the 2013 proposed produce safety rule, that would apply to on-farm packing and holding of produce. These comments assert that the status of an establishment as a facility subject to the section 415 registration requirements should not be used as justification to subject packing and holding activities to different standards if there is no risk-based reason to do so. Some comments assert that the standards described in the 2013 proposed produce safety rule are ''more than adequate'' for the safe handling and packing of raw, intact fresh produce, regardless of commodity, size of operation, or source of produce. These comments also assert that there is no evidence to suggest that different requirements for off-farm establishments that pack and hold produce are needed to prevent contamination.

2. Summary of the Similarities and Differences for Off-Farm Packing and Holding Compared to On-Farm Packing and Holding

The specific steps that are necessary to ensure the safety of produce that an establishment packs and holds generally would be the same regardless of whether the establishment is on-farm or off-farm. For example, several of the

CGMP requirements that would apply to an off-farm packing facility (e.g., provisions for employee health and hygiene, the plant and its grounds, sanitary operations and facilities, and equipment and utensils) have an analogous counterpart in the 2013 proposed produce safety rule. In addition, although an off-farm packing facility would be required to establish and implement a food safety plan, we expect that its food safety plan would focus on a few key preventive controls, including some that would have counterparts in the proposed produce safety rule. For example, we expect that the food safety plan for an off-farm packing facility would include preventive controls such as maintaining and monitoring the temperature of water used during packing. These preventive controls would have counterparts under the 2013 proposed produce safety rule (see, e.g., proposed § 112.46(c)). We also expect that an off-farm packing facility would establish sanitation controls to address the cleanliness of food-contact surfaces (including food-contact surfaces of utensils and equipment) and the prevention of cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces. See the discussion in the 2013 proposed preventive controls rule about an outbreak of listeriosis from cantaloupes, which was attributed to insanitary conditions at a facility that washed, packed, cooled, and stored intact cantaloupes (78 FR 3646 at 3814). On-farm packing facilities would be subject to similar, but not identical, requirements (see e.g., proposed § 112.111(b) for cleanliness of food contact surfaces and proposed § 112.113 for protection against contamination).

An off-farm packing facility also would be required to establish and implement appropriate preventive control management components, including monitoring, corrections or corrective actions, and verification as appropriate to the nature of the preventive control, and would establish and maintain records relative to these preventive controls. Some of these management components also would have counterparts under the 2013 proposed produce safety rule (see, e.g., proposed § 112.46(a) and (b)). Moreover, we consider it likely that industry associations and coalitions would develop a generic food safety plan applicable to off-farm packing and holding of produce covered by the produce rule, based in large part on the final provisions of the produce safety rule. An off-farm packing and holding facility would be able to start from such a generic food safety plan, or to start from the provisions of the final produce safety rule, in generating its own food safety plan, and to tailor its own food safety plan to its particular circumstances, such as the commodities it packs and holds.

The FD&C Act makes the status of an establishment as a facility subject to the section 415 registration requirements, rather than a farm, relevant to which requirements apply to packing and holding activities. Section 418(a) of the FD&C Act, which applies to facilities required to register, requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice. Section 418(h) of the FD&C Act requires the owner, operator, or agent in charge of a facility to prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of section 418 of the FD&C Act (see section 418(h) of the FD&C Act). In contrast, section 419 of the FD&C Act directs FDA (rather than the owner, operator, or agent in charge of a farm) to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are RACs for which FDA has determined that such standards minimize the risk of serious adverse health consequences or death.

VI. Definitions of ''Holding'' and ''Packing''

A. 2013 Proposed Definition of ''Holding''

We proposed to revise the definition of ''holding'' in §§ 1.227 and 1.328 (see section V.A).

B. 2013 Proposed Exemptions Relevant to the Definition of ''Holding''

We proposed two exemptions directed to facilities ''solely engaged'' in the storage (i.e., holding) of certain types of food, and explained our reasons for doing so.

First, we proposed to exempt facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing from the requirements for hazard analysis and risk-based preventive controls, and explained our reasons for proposing to do so (proposed § 117.5(j); see discussion at 78 FR 3646 at 3709). We intended this provision to exempt, for example, facilities that only store whole grains (such as corn, wheat, barley, rye, grain sorghum, oats, rice, wild rice, and soybeans), unpasteurized shell eggs, and unpasteurized milk from the requirements for hazard analysis and risk-based preventive controls, provided that such facilities do not conduct other activities subject to FSMA's requirements for hazard analysis and risk-based preventive controls (78 FR 3646 at 3709).

Second, we proposed to exempt a ''facility solely engaged in the storage of packaged food that is not exposed to the environment'' from the requirements for hazard analysis and risk-based preventive controls that would be established in subpart C (proposed § 117.7(a); see discussion at 78 FR 3646 at 3713). We intended this provision to exempt, for example, facilities that store packaged food in containers in a warehouse. However, a facility solely engaged in the storage of packaged food that is not exposed to the environment and that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens would be subject to modified requirements (see proposed §§ 117.7(b) and § 117.206).

In this section of this document, we are proposing revisions to the definition of ''holding'' in addition to the revisions, discussed in section V.B.2, that would be conforming amendments in light of the revised ''farm'' definition. In this section of this document, we are reopening the comment period with respect to the revised definition of ''holding'' (proposed § 117.3).

C. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of RACs (Other Than Fruits and Vegetables) Intended for Further Distribution or Processing

Some comments support the proposed exemption for a facility solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing. However, some stakeholders expressed concern, during outreach activities such as the public meetings and in written comments, that the proposed definition of ''holding'' would preclude facilities such as grain elevators from being eligible for the exemption in proposed § 117.5(j) because most such facilities conduct a variety of activities in addition to ''storage.'' For example, comments note that grain elevators typically conduct the following activities that could be characterized as being practical necessities, either for the

purposes of safe or effective storage or for meeting customer specifications:

Fumigate grain to control pest infestation during storage;
Clean grain using various mechanisms (sifting, sieving, and screening);
Convey grain throughout the facility;
Dry grain received with high moisture content; and
Blend lots of grain.

Some comments recommend that we modify the proposed definition for ''holding'' to (1) encompass activities performed for the safe or effective storage of RACs (such as drying, screening, conditioning, and fumigating) off-farm and (2) encompass activities performed on RACs as a practical necessity for product distribution (such as blending different lots of the same commodity to meet a customer's quality specifications).

D. Comments on the 2013 Proposed Exemption for a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

Some comments support the proposed exemption for a facility ''solely engaged in the storage of packaged food that is not exposed to the environment.'' These comments note that warehouses typically conduct the following activities that could be characterized as being practical necessities, either for the purposes of storage or for product distribution, including:

Affix tracking labels;
Transport to a storage location in the warehouse;
Hold non-food products, including toys and beauty aids;
Break down pallets of packaged food for distribution to the retail level in less-than-pallet quantities;
Assemble ''sales kits'' for use in fundraising drives;
Assemble variety packs by packing; and
Use packaged food to build store displays.

Some of these comments recommend that we modify the proposed definition for ''holding'' to encompass activities that are performed on packaged food that is not exposed to the environment (1) incidental to storage of the food (such as transport and storage of non-food products); and (2) as a practical necessity for product distribution (such as affixing tracking labels, breaking down pallets, assembling sales kits and variety packs, and building store displays).

E. Proposed Revisions to the Definition of ''Holding''

Taking into account the comments we have reviewed so far, we tentatively conclude that we should revise the definition of ''holding'' to encompass activities performed incidental to storage of food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food). In addition to the activities specifically identified in the comments, we are aware of other activities (Ref. 15) that can be considered incidental to storage of RACs, either for the purposes of safe or effective storage or for meeting customer specifications, including:

Treating stored grain with protectant chemicals and pesticide alternatives (other than by fumigation) to control infestation;

Using modified atmosphere treatments to control pests;

Using biological controls for pests;

Applying chemical preservatives to grain to prevent growth of mycotoxin-producing molds;

Weighing grain;

Sampling and grading grain; and

Aerating grain to control temperature.

The revised definition of ''holding'' would be included in the section 415 registration regulations, the section 414 recordkeeping regulations, and the preventive controls rule. Our previously proposed revisions already included activities traditionally performed by farms and farm mixed-type facilities for the safe or effective storage of RACs (78 FR 3646 at 3681). In this document, we are proposing to revise the definition of holding in all three regulations to:

Clarify that holding also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same commodity));

Broaden ''activities . . . performed for the safe or effective storage of raw agricultural commodities'' to apply to all food, not just RACs;

Broaden ''activities . . . performed for the safe or effective storage'' to apply to all establishments that hold food, not just farms and farm mixed-type activities;

Add ''breaking down pallets'' to the examples in the revised definition of ''holding'' so that the examples reflect activities conducted on packaged food as well as activities conducted on RACs; and

Specify that holding facilities ''could'' include the listed types of facilities to clarify that some of these facilities might not meet the definition of a holding facility if they perform other activities not included in the definition of holding (e.g., if a grain elevator mixes different commodities to prepare animal feed).

As discussed in section V.B.2, the revised definition of ''holding'' also would remove limitations on where the food is grown or raised (as a conforming change to the revised definition of ''farm''). The revised definition of ''holding'' would now be a one-part definition that applies to all facilities that hold food, rather than a two-part definition that first specifies activities that are within the definition regardless of the type of establishment and then specifies additional activities that would apply only to establishments that are farms or farm mixed-type facilities. See the proposed regulatory text for the definition of holding in proposed §§ 1.227, 1.328, and 117.3.

With this revised definition of ''holding,'' facilities such as grain elevators and silos would, in most cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (proposed § 117.5(j)), because the definition would encompass activities performed as a practical necessity for the distribution of RACs. Other facilities that conduct operations similar to those conducted at grain elevators and silos, such as some facilities that hold oilseeds, also may satisfy these criteria for exemption.

With this revised definition of ''holding,'' facilities such as warehouses would, in many cases, satisfy the criteria for the proposed exemption for facilities solely engaged in the storage of packaged food that is not exposed to the environment (proposed § 117.7(a)), because the definition would encompass activities that are a practical necessity for product distribution (such as breaking down pallets and affixing tracking labels). We are adding ''breaking down pallets'' to the examples in the revised definition of ''holding'' so that the examples reflect activities conducted on packaged food as well as activities conducted on RACs. Although we are not adding more examples to reflect activities conducted on packaged food, the revised definition of ''holding'' also would include activities such as assembling sales kits and variety packs, because such activities are similar to breaking down pallets except that the order of activities is reversed.

F. Proposed Revisions to the Definition of ''Packing''

Just as there are some activities that are performed incidental to storing a food, there are some activities that are performed incidental to packing a food. For example, sorting, culling, and grading RACs could be an activity

incidental to packing on a farm or farm mixed-type facility, whereas off-farm some sorting or similar activities such as culling or grading may be required to ensure that like items are packed together, or to remove damaged items. As another example, food may need to be conveyed (moved) about an establishment for the purpose of packing it, and may need to be weighed to ensure that appropriate amounts are packed. We tentatively conclude that we should revise the definition of ''packing'' so that it includes activities performed incidental to packing a food. The revised definition of ''packing'' would be included in the section 415 registration regulations, the section 414 recordkeeping regulations, and the preventive controls rule. Our previously proposed revisions already included activities traditionally performed by farms and farm mixed-type facilities for the safe or effective packing of RACs (78 FR 3646 at 3681–3682). In this document, we are proposing to revise the definition of packing in all three regulations to:

Clarify that packing also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading));

Provide that activities performed incidental to packing a food would apply to all establishments that pack food, not just to farms and farm mixed-type facilities; and

Delete the provision, in the 2013 proposed preventive controls rule, that packing would include activities (which may include packaging) traditionally performed on a farm on RACs grown on a farm for storage or transport, because this issue would be addressed in the revised ''farm'' definition.

See the revised regulatory text for the definition of packing in proposed §§ 1.227, 1.328, and 117.3.

VII. Impact of the Proposed Revisions to the Farm-Related Definitions on the Classification of On-Farm Activities

A. Comments on the 2013 Organizing Principles for Classifying Activities Conducted on Farms and on Farm Mixed-Type Facilities

Some comments object to one or more of the 2013 organizing principles. As previously discussed, some comments focused on the distinction (in the ''farm'' definition, and reflected in Organizing Principle No. 4) that conducting packing and holding activities on a farm's own RACs would be within the ''farm'' definition, but conducting packing and holding activities on others' RACs would be outside the ''farm'' definition (see section V.B.1). Other comments focused on Organizing Principle No. 3—i.e., that activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food (see section V.C.1). One comment asserts that the 2013 organizing principles rest on a flawed understanding of how farming works because they assume that farms exist simply to grow crops and that getting those crops to market is something that ''farms'' don't do. This comment also asserts that the reality is that a farm cannot stay in business without marketing its crops and preparing those crops for market, and that the imperative to maximize the value a farm receives for its crops creates the need for value-added marketing and cooperative distribution. This comment recommends that we revise the organizing principles to reflect the realities and range of activities that farms do to their crops to prepare those crops and get them to markets.

B. Updated Organizing Principles That Would Apply to the ''Farm'' Definition

We articulated the 2013 organizing principles for classifying on-farm activities to operate within the framework, already established in the section 415 registration regulations, in which an establishment that packs and holds others' RACs would be outside the ''farm'' definition and, thus, be required to register as a food facility. Our proposed revisions to the ''farm'' definition would change that framework and, as a consequence, require that we reconsider those organizing principles.

Organizing Principles Nos. 1, 3 and 5 remain fully consistent with the proposed revisions to the ''farm'' definition. However, there would be no need to specify, in Organizing Principle No. 2, that activities that farms traditionally do relate only to their own RACs. In addition, Organizing Principle No. 4 would no longer apply, because the revised ''farm'' definition would no longer classify an activity as within (or outside of) the ''farm'' definition based, in part, on whether an activity is conducted on a farm's own RACs or on others' RACs. Therefore, we tentatively conclude it is appropriate to delete Organizing Principle No. 4 in light of the proposed revisions to the ''farm'' definition.

Taking into account the comments we have reviewed so far, Table 4 shows our current thinking regarding the organizing principles applicable to the revised ''farm'' definition.

TABLE 4—UPDATED ORGANIZING PRINCIPLES THAT WOULD APPLY TO THE REVISED ''FARM'' DEFINITION

No.	Organizing principle
1	The basic purpose of farms is to produce RACs, and RACs are the essential products of farms.
2	Activities that involve RACs and that farms traditionally do for the purposes of growing RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of ''farm.''
3	Activities should be classified based in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms a RAC into a processed food.
4	Manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for consumption on the farm should remain within the farm definition.

C. Changes to Classification of On-Farm Activities

We reconsidered the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities. See the Appendix to this document for a comprehensive table comparing the classification of on-farm activities as harvesting, packing, holding, or manufacturing/processing in the 2013 proposed preventive controls rule to our current thinking on the classification of these on-farm activities. As can be seen in the Appendix, several on-farm activities can be classified in more than one way, and most of the changes in activity classification merely reflect additional activities (relative to the 2013 proposed preventive controls rule) that

could be classified in more than one way. For example, in the 2013 proposed preventive controls rule, we classified ''washing'' as a harvesting activity (e.g., if RACs are washed while they are being removed from the field) as well as a manufacturing/processing activity (e.g., during the production of fresh-cut produce). In this supplemental notice of proposed rulemaking, we also consider ''washing'' to be a packing activity (e.g., if RACs are washed in a flume or dump tank located at the farm's packing shed). (Because the definition of manufacturing/processing specifies that for farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding, including ''washing'' as an example of a manufacturing/processing activity would not mean that a farm is conducting a manufacturing/processing activity when it washes RACs in its packing shed on its farm, because washing RACs on a farm would be a packing activity.)

See Table 5 in this document for a list of the activity classifications that would change in light of the proposed revisions to the ''farm'' definition and our reconsideration of activity classification. As shown in Table 5, changes in activity classification as a result of the proposed revisions to the ''farm'' definition would result in a single circumstance (drying/dehydrating RACs to create a distinct commodity without additional manufacturing/processing) where a farm conducting manufacturing/processing would no longer be required to register as a food facility. Importantly, the revised ''farm'' definition would not result in any new circumstance where a farm would now be required to register as a food facility.

Table 5 includes one activity (i.e., field coring) that we did not address in the 2013 proposed preventive controls rule. As discussed in section V.C, we are including this activity to make clear that on farm ''field coring'' of produce (e.g., removing the core of lettuce in the field at the same time the stem is cut and wrapper leaves removed) is a harvesting activity, even though ''coring'' outside of ''field coring'' (e.g., during the production of fresh-cut lettuce) is a manufacturing/processing activity.

Table 5 includes one activity (i.e., drying/dehydrating (incidental to holding) that we now would classify in fewer ways than we did in the 2013 proposed preventive controls rule. In the 2013 proposed preventive controls rule, we classified drying/dehydrating (for purposes of storage or transport, rather than to create a distinct commodity) (e.g., drying alfalfa) as being either a packing activity or a holding activity, depending on when the drying/dehydrating took place. After reconsidering all of the activity classifications, we tentatively conclude that such drying/dehydrating should continue to be classified as ''holding,'' but does not constitute ''packing.'' We request comment on this narrowed classification of drying/dehydrating when the drying/dehydrating does not create a distinct commodity.

Table 5 includes one activity (i.e., fermenting cocoa beans and coffee beans) that we would now classify differently than we did in the draft risk assessment (issued in conjunction with the 2013 proposed preventive controls rule). In the draft risk assessment (Ref. 16), we classified fermenting cocoa beans and coffee beans as harvesting activities (see Footnote 2 in Table 23 of the draft risk assessment). After reconsidering all of the activity classifications, we tentatively conclude that fermenting cocoa beans and coffee beans should be classified as ''holding'' rather than as ''harvesting,'' because fermentation generally happens after cocoa beans and coffee beans are removed from the plants. We request comment on this reclassification of fermenting cocoa beans and coffee beans.

TABLE 5—CHANGES IN CLASSIFICATION OF ACTIVITIES CONDUCTED ON FARMS OR ON FARM MIXED-TYPE FACILITIES BASED ON THE PROPOSED REVISIONS TO THE ''FARM'' DEFINITION

Activity	Classified in 2013 proposed preventive controls rule	Classified in supplemental notice of proposed rulemaking	Why would the re-classification represent a change from the 2013 proposed preventive controls rule? [2]
Cooling	Harvesting; (§ 117.3); Mfg [1]/Processing (§ 117.3).	• Harvesting (e.g., hydro-cooling leafy vegetables in the field). • Packing (e.g., hydro-cooling in a packing shed) • Holding (e.g., cold storage) • Mfg/processing (e.g., refrigeration of processed food)	Acknowledge that cooling can occur during many farm operations.
Drying/dehydrating (incidental to holding).	Packing or Holding (Tables 4 and 5).	• Holding (e.g., drying hay or alfalfa)	Because we would no longer consider drying/dehydrating to be a packing activity.
Drying/dehydrating to create a distinct commodity (transforms a RAC into a processed food).	Mfg/Processing (Tables 4 and 5).	• Mfg/processing (e.g., drying grapes to create raisins, and drying herbs to create a distinct commodity) (because it transforms a RAC into a processed food) (but allowed within the farm definition).	Because we are including this specific mfg/processing activity within the ''farm'' definition, provided that there is no additional manufacturing/processing.
Fermenting cocoa beans and coffee beans.	Harvesting (Footnote 2 in Table 23 of the draft Risk Assessment (Ref. 16)).	• Holding	Because fermentation generally happens after cocoa beans and coffee beans are removed from the plants.
Field coring	N/A [3]	• Harvesting (e.g., coring lettuce in the field)	Because FDA is addressing the activity for the first time.
Filtering	Harvesting (§ 117.3)	• Harvesting (e.g., filtering honey) • Packing (e.g., before packing honey)	Acknowledge that filtering can occur during more than harvesting operations.
Removing stems and husks.	Harvesting (§ 117.3)	• Harvesting (e.g., in the field) • Packing (e.g., in a packing shed)	Acknowledge that removing stems/husks can occur during more than harvesting operations.
Sifting	Harvesting (§ 117.3)	• Harvesting (e.g., in the field) • Packing (e.g., in a packing shed)	Acknowledge that sifting can occur during more than harvesting operations.

TABLE 5—CHANGES IN CLASSIFICATION OF ACTIVITIES CONDUCTED ON FARMS OR ON FARM MIXED-TYPE FACILITIES BASED ON THE PROPOSED REVISIONS TO THE ''FARM'' DEFINITION—Continued

Activity	Classified in 2013 proposed preventive controls rule	Classified in supplemental notice of proposed rulemaking	Why would the re-classification represent a change from the 2013 proposed preventive controls rule? [2]
Using pesticides in wash water.	Harvesting (Table 5) ..	• Harvesting (e.g., in the field) ..... • Packing (e.g., in a packing shed)	Acknowledge that using pesticides in wash water can occur during more than harvesting operations.
Washing	Harvesting (§ 117.3), and Mfg/Processing (§ 117.3).	• Harvesting (e.g., in the field) ..... • Packing (e.g., in a dump tank or flume in the farm's packing shed) • Mfg/processing (e.g., during production of fresh-cut produce)	Acknowledge that washing can occur during packing operations.

[1] Mfg = Manufacturing
[2] This table focuses on any change in classification in this document compared to the classification, in the 2013 proposed preventive controls rule, for activities conducted on a farm's own RACs. The proposed revisions to the ''farm'' definition would make the distinction between whether a farm conducted an activity on its own RACs or on others' RACs irrelevant.
[3] N/A = Not applicable.

VIII. Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations

A. The 2013 Proposed Exemptions

In the 2013 proposed preventive controls rule, we described provisions of FSMA that direct us to (1) conduct a science-based risk analysis to cover specific types of on-farm packing, holding, and manufacturing/processing activities that would be outside the ''farm'' definition and, thus, subject to the requirements for hazard analysis and risk-based preventive controls (78 FR 3646 at 3674 and 3689–3691); and (2) consider the results of that science-based risk analysis and exempt facilities that are small or very small businesses from these requirements (or modify these requirements, as we determine appropriate), if such facilities are engaged only in specific types of on-activities that we determine to be low risk involving specific foods that we determine to be low risk. Consistent with this statutory direction, we developed the draft risk assessment and made it available for public comment (Ref. 16 and 78 FR 3824) and proposed three exemptions for on-farm activity/food combinations conducted by farm-mixed-type facilities that are small or very small businesses (proposed §§ 117.5(g), (h)(1), and (h)(2)).

B. Comments on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations

Some comments request clarification on whether an establishment that conducts more than one activity/food combination listed in the proposed exemptions for on-farm low-risk activity/food combinations would be eligible for the exemption. Other comments recommend including additional on-farm packing and holding activity/food combinations, or on-farm manufacturing/processing activity/food combinations, as low-risk activity/food combinations eligible for inclusion in the proposed exemptions.

We are confirming that an establishment that conducts more than one activity/food combination listed in the proposed exemptions for on-farm low-risk activity/food combinations would be eligible for the exemption. The regulatory text is written in the plural (e.g., ''if the only packing and holding activities . . . that the business conducts are the following low-risk packing or holding activity/food combinations''; and ''if the only manufacturing/processing activities . . . that the business conducts are the following'').

We have not yet completed either our review of comments asking us to include additional activity/food combinations in the proposed exemptions or our analysis of whether each of the recommended additions would satisfy the criteria, described in the draft risk assessment, for a low-risk activity/food combination. However, based on our experience with the draft risk assessment, and the similarity of some of the recommended activity/food combinations to activity/food combinations we evaluated in the draft risk assessment, we consider it likely that we will, after fully considering comments, include additional activity/food combinations in these exemptions when we issue the final rule.

C. Impact of the Proposed Revisions to the Definitions for ''Farm,'' ''Harvesting,'' Holding,'' and ''Packing'' on the 2013 Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations

The proposed revisions to the definitions of ''farm,'' ''harvesting,'' ''holding,'' and ''packing,'' if finalized, would have three principal effects on the proposed exemptions.

First, the proposed exemption for on-farm packing or holding of food by a small or very small business would no longer identify any packing or holding activities for any RACs, because an on-farm establishment would no longer be subject to the requirements for hazard analysis and risk-based preventive controls when it packs or holds RACs, regardless of whether it is packing and holding its own RACs or others' RACs. The proposed exemption would continue to apply to on-farm packing and holding of processed foods (e.g., packing and holding of hard candy, fudge, taffy and toffee when conducted by a farm mixed-type facility).

Second, the proposed exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business would no longer distinguish between manufacturing/processing activities conducted on a farm mixed-type facility's own RACs and manufacturing/processing activities conducted on food other than the farm mixed-type facility's own RACs.

Third, the proposed exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business would be revised to eliminate activities, conducted on others' RACs, which would no longer be classified as manufacturing/processing and instead would be classified as harvesting, packing, or holding. For example, mixing different lots of the same RACs (e.g., cocoa beans, coffee beans, intact fruits and vegetables, grain, honey, maple sap, and peanuts and tree nuts) would remain within the ''farm'' definition, and not be considered manufacturing/processing, regardless of whether the RACs being mixed are the farm's own RACs or others' RACs.

However, mixing grain products and maple syrup (which are processed foods rather than RACs) would be considered manufacturing/processing and, thus, would continue to be considered a low-risk manufacturing/processing activity listed within the exemption for on-farm low-risk manufacturing/processing activities conducted by a small or very small business.

We will update these proposed exemptions when we issue the final rule, after considering comments, and reaching a decision in light of those comments, on the proposed revisions to the definitions that impact the proposed exemptions for low-risk activity/food combinations.

IX. Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

A. 2013 Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

In general, in the 2013 proposed preventive controls rule we proposed that the owner, operator, or agent in charge of a facility:

Prepare and implement a food safety plan, which would include documentation such as a written hazard analysis and various written procedures;

Conduct a hazard analysis to identify and evaluate known or reasonably foreseeable hazards to determine whether there are hazards that are ''reasonably likely to occur'';

Identify and implement preventive controls, including at CCPs, if any, to provide assurances that hazards identified as ''reasonably likely to occur'' will be significantly minimized or prevented;

Establish a written recall plan for food with a hazard identified as ''reasonably likely to occur'';

Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed;

Establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented;

Take appropriate corrective action in the event of an unanticipated problem if a preventive control is not properly implemented and a specific corrective action procedure has not been established;

Conduct certain verification activities; and

Establish and maintain certain records.

These proposed provisions applied a construct we previously used in our Hazard Analysis and Critical Control Point (HACCP) regulations for seafood (21 CFR part 123) and juice (21 CFR part 120)—i.e., whether a known or reasonably foreseeable hazard was ''reasonably likely to occur.'' In general, our HACCP regulations for seafood and juice focus on CCPs to control hazards that are ''reasonably likely to occur.''

B. Comments on the ''Reasonably Likely To Occur'' Construct Within the 2013 Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

Some stakeholders expressed concern, during outreach activities such as the public meetings and in written comments, about including the ''reasonably likely to occur'' approach in the 2013 proposed preventive controls rule. Some comments express concern that using the phrase ''reasonably likely to occur'' in two different contexts (i.e., within our HACCP regulations as well as in our proposed preventive controls regulations) would be confusing. Some comments assert that the ''reasonably likely to occur'' approach was already so closely linked to our HACCP regulations that the 2013 proposed preventive controls rule would be interpreted as requiring that all necessary preventive controls be established at CCPs. These comments note that such an interpretation would be inconsistent with FSMA. For example, FSMA requires that the owner, operator, or agent in charge of a facility identify and implement preventive controls, including at critical control points, *if any* (emphasis added) (section 418(c) of the FD&C Act). In addition, the definition of ''preventive controls'' in FSMA is broader than CCPs (section 418(o)(3) of the FD&C Act). The comments ask that we more explicitly provide for implementation of a range of preventive controls (not just at CCPs.) These comments also express concern that a facility that already had established controls to address hazards—but not at CCPs—would need to revise its food safety plan and re-create any applicable records (e.g., various written procedures) to satisfy the recordkeeping requirements of the rule, which would add costs but no food safety benefits. Some comments suggest that the framework be clearer that the requirements for preventive controls apply to hazards that are of such a nature that control measures to significantly minimize or prevent them are necessary for the production of a safe food and therefore must be addressed in the food safety plan.

Other comments on the overall framework for hazard analysis and risk-based preventive controls express concern that the regulatory text, as proposed, would limit a facility's flexibility to develop and implement a food safety system that was indeed risk-based. For example, some comments assert that regulatory text such as ''[p]reventive controls must include, as appropriate to the facility and the food'' appears to provide flexibility, but the practical effect of the term ''must'' preceding the phrase ''include, as appropriate to the facility and the food'' is to remove any flexibility as to what preventive controls must be established and implemented. As another example, these comments emphasize that the proposed requirements did not sufficiently emphasize the risk-based nature of each component of the overall framework for hazard analysis and preventive controls, including monitoring, corrective action procedures, and verification activities, in addition to the hazard analysis and preventive controls. In general, these comments recommend that we provide greater flexibility to manage the control of hazards based on an assessment of both the severity of the hazard and the probability that the hazard will occur in the absence of preventive controls and that we recognize the role of prerequisite programs in the management of hazards. (One definition of ''prerequisite program'' is the ''procedures, including good manufacturing practices, that address operational conditions providing the foundation for the HACCP system'' (Ref. 17).)

C. Proposed Revisions to the Overall Framework for Hazard Analysis and Risk-Based Preventive Controls

The 2013 proposed preventive controls rule would not have required that all preventive controls be established at CCPs. However, we acknowledge that it could be confusing to use the same phrase ''reasonably likely to occur'' in both our HACCP regulations and in the regulations we are proposing to establish to implement FSMA's requirements for hazard analysis and risk-based preventive controls, because the phrase ''reasonably likely to occur'' has been used as the basis for determining hazards that need to be addressed in a HACCP plan at CCPs.

Likewise, the 2013 proposed preventive controls rule would not have limited a facility's flexibility to develop and implement a food safety system that was indeed risk-based. However, we acknowledge that some specific changes to the proposed regulatory text could help to clarify the risk-based nature of all provisions of subpart C.

We have not used the term ''prerequisite program'' in the proposed regulatory text because, like ''hazard reasonably likely to occur,'' it has a connotation with respect to our seafood and juice HACCP programs, that is, it connotes activities that a facility may do that have an impact on product safety but which are outside the scope of the regulatory program. However, comments are not suggesting that prerequisite programs that are essential to ensuring food safety should be outside the scope of this proposed regulatory scheme. In fact, comments asking that we recognize the role of prerequisite programs in the management of hazards point out that preventive controls include control measures that do not include CCPs and that companies would consider many of these to be prerequisite programs. We acknowledge that oftentimes preventive controls, other than those at critical control points, are important parts of a food safety system, and must therefore be included in the food safety plan that would be required by this proposed rule. We attempted to make that clear in the proposed requirement for preventive controls in § 117.135(a) by incorporating reference to ''controls, other than those at critical control points, that are necessary for food safety.''

We did not intend to require that a facility re-create or duplicate existing records associated with controls; we simply laid out in the 2013 proposed preventive controls rule the activities for which we expect there to be records and the information we expect to find in those records.

Taking into account the comments we have reviewed so far, we are proposing a series of revisions to proposed subpart C and are reopening the comment period specifically with respect to these proposed revisions. These proposed revisions include:

Eliminating the term ''hazard reasonably likely to occur'' throughout proposed subpart C (and, thus, deleting the definition we had proposed for this term).

Adding a new defined term, ''significant hazard,'' and, in general, using this new term instead of ''hazard reasonably likely to occur'' throughout the proposed regulations. ''Significant hazard'' would mean a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control.

Defining ''known or reasonably foreseeable hazard'' in place of ''reasonably foreseeable hazard'' and clarifying that the new term means a hazard ''that has the potential to be associated with the facility or the food'' rather than ''a potential . . . hazard that may be associated with the facility or the food'';

Providing additional flexibility to address concerns about re-writing existing plans or programs to conform with the requirement of the preventive controls rule by explicitly providing that:

Preventive controls include controls, other than those at critical control points, that knowledgeable persons commonly recognize as appropriate for food safety;

The preventive control management components (i.e., monitoring, corrective actions, and verification) depend on the nature of the control; and

The recordkeeping requirements do not require duplication of existing records if those records contain all of the required information and satisfy the recordkeeping requirements of the regulation. Existing records may be supplemented as necessary to include all of the required information. In addition, the required information does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by the preventive controls rule may be kept either separately or combined with the existing records.

The framework provided by ''significant hazard'' would reflect a two-part analysis on the part of a facility. First, the facility would narrow ''hazards'' to those hazards that are known or reasonably foreseeable—i.e., those biological, chemical (including radiological), or physical hazards that have the potential to be associated with the facility or the food. Second, the facility would narrow the known or reasonably foreseeable hazards to those that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food as well as components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the control.

The framework established by ''significant hazard'' also would incorporate the concept of risk by specifying that ''significant hazards'' are based on the outcome of a hazard analysis. The hazard analysis would require an evaluation of known or reasonably foreseeable hazards to assess two key aspects of risk—i.e., the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

See the revised regulatory text for the proposed new definition of ''significant hazard'' (proposed § 117.3). The term ''significant hazard'' has sometimes been used in the context of HACCP to refer to the hazards to be addressed in a HACCP plan through CCPs. However, this term is not used in the seafood, juice or meat and poultry HACCP regulations, which focus on ''hazards reasonably likely to occur.'' We request comment on both the proposed name of the term and the proposed meaning of the term. See also the proposed new provision for the use of existing records (proposed § 117.330, which would be established in subpart F). Table 6 provides some examples of the flexibility that a facility would have in complying with the revised requirements that would be established in subpart C.

TABLE 6—EXAMPLES OF FLEXIBILITY FOR COMPLYING WITH THE REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS IN THE REVISED REQUIREMENTS IN PROPOSED SUBPART C

Flexibility related to . . .	Example
Controls other than those at CCPs	Dividing a facility into zones based on the risk with respect to contamination of product can be a preventive control, but would not be required to have a CCP.
Controls other than those at CCPs	Preventive maintenance that inspects and changes chopper blades on a regular intervals may be considered a preventive control in some instances but would not be required to have a CCP.

TABLE 6—EXAMPLES OF FLEXIBILITY FOR COMPLYING WITH THE REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS IN THE REVISED REQUIREMENTS IN PROPOSED SUBPART C—Continued

Flexibility related to . . .	Example
Circumstances that do not require process controls	Preventive controls for allergen cross-contact.
Circumstances that do not require process controls	Supplier controls.
Monitoring activity that generally would not require monitoring records	Monitoring for foreign material with x-rays.
Corrections that generally would not require records	Re-cleaning and sanitizing inadequately cleaned food contact surfaces before start up.
Preventive controls that would not require validation	Zoning controls.
Preventive controls that would not require validation	Segregation of allergens during storage.
Preventive controls that would not require validation	Training.
Preventive controls that would not require validation	Preventive maintenance.
Preventive controls that would not require validation	Refrigerated storage.
Corrective action that generally would not require verification	Replacement of equipment.

X. Potential Requirements for Product Testing and Environmental Monitoring

A. Our Request for Comment on Including Requirements for Product Testing and Environmental Monitoring in a Final Rule

In the 2013 proposed preventive controls rule, we described the statutory framework of FSMA for product testing and environmental monitoring as verification measures. We also requested comment on when and how product testing programs and environmental monitoring are an appropriate means of implementing section 418 of the FD&C Act (78 FR 3646 at 3762–3765). We specifically requested comment on including requirements for product testing programs and environmental monitoring in a final rule. Although we did not propose specific regulatory text, we asked a series of questions about what such requirements should include. Our discussions and questions about ''product testing'' focused on ''finished product testing.'' The Appendix contained extensive background on the role of testing as a verification measure in a modern food safety system (78 FR 3646 at 3812–3820; see also the corrected Appendix, 78 FR 17142 at 17143 to 17151).

B. Product Testing

1. Comments on Product Testing

Some comments support product testing as a verification activity and make recommendations for what should be tested, how testing could be tied to risk, and how product testing could be used in a food safety plan. Some of these comments emphasize that product testing would not be appropriate as a control measure. Other comments do not support including requirements for ''finished product testing'' as a verification measure, but support including requirements for ''product testing'' in the final rule if the focus is broader than ''finished product testing,'' the use of product testing is tied to risk, and the regulations provide flexibility in how product testing is used in a food safety plan. Some comments assert that product testing is required by section 418 of the FD&C Act and that it is an appropriate means of verifying overall control, especially for products that support pathogen growth. In the following paragraphs, we describe some of the key recommendations in the comments regarding what should be tested, how testing could be tied to risk, and how product testing could be used in a food safety plan.

Some comments recommend that product testing include testing raw materials and ingredients, as well as in-line testing of product during production. Some comments recommend that requirements encompassing more than ''finished product testing'' would provide facilities with the flexibility to establish a risk-based testing program. For example, a facility that adds seasoning to chips after the chips have been cooked using a process that would significantly minimize pathogens may conclude that testing the seasoning used as an ingredient would be a more appropriate verification activity than testing finished product (i.e., the chips with the added seasoning). These comments also assert that requirements for ''product testing'' would be more consistent with the statutory direction in section 418 of the FD&C Act than requirements for ''finished product testing.''

Some comments that emphasize the risk-based nature of any requirements for product testing assert that product testing may be of limited value for a product that will undergo a ''kill step'' (a treatment to significantly minimize pathogens) later in processing or that does not support the survival or growth of environmental pathogens (because such organisms are unlikely to pose a risk in the finished food). Other comments note that product testing would not be appropriate for certain types of facilities, such as distributors. Some comments question whether product testing would be appropriate for products with a short shelf life (such as produce).

Some comments identify circumstances where product testing would—or would not—be appropriate to include as a verification activity in a food safety plan. For example, comments state that product testing would be an appropriate verification activity to include in a food safety plan in plants that produce high-risk products; when there is a risk of contamination of the product or product contact surfaces; when the outcome of a hazard analysis demonstrates that a hazard can remain or be placed on ready-to-eat (RTE) products; when an environmental pathogen is considered a hazard reasonably likely to occur; when a positive result is obtained as a result of environmental monitoring; after a corrective action has been implemented (such as after a product has been reworked because it tested positive for a pathogen); and in circumstances where testing is the only practical way to verify the absence of a contaminant (such as aflatoxin). Some comments state that product testing would not be an appropriate verification activity to include in a food safety plan if a positive result from environmental monitoring is found on a non-product-contact surface.

Some comments recommend written procedures for product testing. Some of these comments emphasize that any requirements for such written procedures should not be prescriptive.

Some comments question whether it would be appropriate to require product testing in light of known limitations such as those discussed in section I.F of the Appendix. For example, it is generally recognized that testing cannot

ensure the absence of a hazard, particularly when the hazard is present at very low levels and is not uniformly distributed. Moreover, these comments point out that the number of samples used for routine testing often is statistically inadequate to provide confidence in the safety of an individual lot in the absence of additional information about adherence to validated control measures (78 FR 3646 at 3819). Some commenters with varying views on the issue nonetheless asked FDA to issue proposed regulatory text for product testing for consideration.

2. Potential Requirements for Product Testing

We acknowledge that there are limitations to product testing. Nonetheless, product testing programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for product testing. Such requirements would be tied to risk and addressed through flexible written procedures that would address both test procedures and corrective action plans.

In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how product testing programs are an appropriate means of implementing FSMA. We are seeking comment on whether requirements for product testing should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. The proposed regulatory text would, if included in a final rule, establish requirements for:

Product testing as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control (proposed § 117.165(a)(2));

Written procedures for product testing (proposed § 117.165(b)(2));

Corrective action procedures for product testing (proposed § 117.150(a)(1)(ii)(A)); and

Records of product testing (proposed § 117.155(b));

See the proposed regulatory text for proposed subpart C for the full text of such potential requirements. Consistent with the requests of the comments, the proposed regulatory text would provide flexibility for a facility to make risk-based decisions on when product testing would be appropriate by providing that the facility can take into account the facility, the food, and the nature of the preventive control (e.g., whether the control is a kill step) rather than prescribe product testing in specific circumstance, or require that all types of facilities (including warehouses) conduct product testing. For supplementary information relevant to product testing, see the 2013 proposed preventive controls rule (78 FR 3646 at 3763–3764), the corrected Appendix (78 FR 17142 at 17143 to 17151), and Ref. 18.

C. Environmental Monitoring

1. Comments on Environmental Monitoring

Some comments support environmental monitoring as a verification activity. In general, these comments recommend that the final rule specifically require environmental monitoring when RTE product is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed. Comments emphasize the need for flexible requirements that would allow facilities to tailor their programs based on risk.

Some comments that generally support environmental monitoring as a verification activity nonetheless express concern about the potential for such requirements to be overly prescriptive. Comments particularly express concern about potentially prescriptive requirements for corrective actions if an environmental pathogen or appropriate indicator organism is detected. Some comments express concern about how potentially prescriptive requirements would impact products (such as produce) with a short shelf life.

Some comments do not support including requirements for environmental monitoring as a verification measure. Some of these comments assert that requirements for environmental monitoring would not be in accord with guidelines issued by the Codex Alimentarius Commission (Codex). Some comments note that environmental monitoring would not be relevant to all products, such as products that will be heat-treated or otherwise subject to a kill-step. Other comments note that environmental monitoring would not be relevant to facilities such as food distributors, due to the low likelihood of product contamination occurring in storage and distribution centers. Some of these comments express concern about broad requirements that would require environmental monitoring in a manner that was not risk-based, such as when an environmental pathogen is not reasonably likely to occur. Some commenters with varying views on the issue nonetheless asked FDA to issue proposed regulatory text for environmental monitoring for consideration.

2. Potential Requirements for Environmental Monitoring

Although the HACCP Annex of the Codex General Principles of Food Hygiene (Ref. 19) does not specifically recommend environmental monitoring as a verification activity in HACCP systems, the Codex General Principles of Food Hygiene (Ref. 20) does indicate that sanitation systems should be monitored for effectiveness and periodically verified, where appropriate, by microbiological sampling of environment and food contact surfaces, and regularly reviewed and adapted to reflect changed circumstances. Environmental monitoring is recommended in Codex Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods (see Annex I) (Ref. 21) and the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (see Annex III) (Ref. 22). Moreover, currently available data and information support the role of environmental monitoring in a food safety system that incorporates hazard analysis and risk-based preventive controls. (See, e.g., the 2013 proposed preventive controls rule (78 FR 3646 at 3764–3765), the corrected Appendix (78 FR 17142 at 17143 to 17151), and (Ref. 23). Environmental monitoring programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.

Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for environmental monitoring. The potential requirements would provide flexibility for facilities to tailor their environmental monitoring programs based on risk. Environmental monitoring would be required in the specific circumstances where RTE product is exposed to the environment prior to packaging and the packaged

food does not receive a treatment that would significantly minimize an environmental pathogen that could contaminate the food when it is exposed. However, the potential requirements would not otherwise specify circumstances where environmental monitoring would be required and would instead require that the facility conduct environmental monitoring as appropriate to the facility, the food, and the nature of the preventive control. The potential requirements would also not be prescriptive in the types of corrective actions needed in response to detecting an environmental pathogen or appropriate indicator organism in the environment; they would provide flexibility for facilities to establish and implement written corrective action procedures to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce.

In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how environmental monitoring is an appropriate means of implementing FSMA. We are seeking comment on whether requirements for environmental monitoring should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. The proposed regulatory text would, if included in a final rule, establish requirements for:

Performing, as part of the hazard evaluation, an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen (proposed § 117.130(c)(1)(ii));

Environmental monitoring, for an environmental pathogen (e.g., *L. monocytogenes*) or for an appropriate indicator organism (e.g., Listeria spp.), as an activity for verification of implementation and effectiveness as appropriate to the facility, the food, and the nature of the preventive control, if contamination of an RTE food with an environmental pathogen is a significant hazard (proposed § 117.165(a)(3));

Records of environmental monitoring (proposed § 117.155(b));

Written procedures for environmental monitoring (proposed § 117.165(b)(3)); and

Corrective action procedures for environmental monitoring (proposed § 117.150(a)(1)(ii)(B)).

See the proposed regulatory text for proposed subpart C for the full text of such potential requirements. For supplementary information relevant to environmental monitoring programs, see the 2013 proposed preventive controls rule (78 FR 3646 at 3764–3765), the corrected Appendix (78 FR 17142 at 17143 to 17151), and Ref. 23.

XI. Potential Requirements for a Supplier Program

A. Our Request for Comment on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act

In the 2013 proposed preventive controls rule, we described the statutory framework of FSMA for supplier controls—i.e., the supplier verification activities that section 418 of the FD&C Act includes as an example of preventive controls. We also requested comment on when and how supplier verification activities are an appropriate means of implementing section 418 (78 FR 3646 at 3763–3767). We specifically requested comment on including requirements for supplier approval and other verification activities in a final rule. Although we did not propose specific regulatory text, we asked a series of questions about what such requirements should include. The Appendix contained extensive background on the role of supplier programs in a modern food safety system (78 FR 3646 at 3820–3821; see also the corrected Appendix, 78 FR 17142 at 17151 to 17152).

B. Comments on When and How Supplier Verification Activities Are an Appropriate Means of Implementing the Statutory Framework of Section 418 of the FD&C Act

Some comments support including requirements for a supplier program in a final rule. These comments emphasize the need for flexible requirements that would allow facilities to tailor their programs based on risk, including risk inherent to raw materials and ingredients and risk that may be associated with a particular supplier (e.g., as reflected by the supplier's performance history). These comments provide many specific recommendations for what such requirements should—and should not—include. We summarize these recommendations in Table 7.

TABLE 7—SUMMARY OF SPECIFIC RECOMMENDATIONS IN COMMENTS THAT SUPPORT REQUIREMENTS FOR A SUPPLIER PROGRAM

Most comments support a requirement:	Most comments do not support a requirement:
For receiving raw material and ingredients from approved suppliers	For a written list of approved suppliers (because the list would be subject to frequent (perhaps daily) change).
For verification of a facility's immediate supplier	For verification of the supplier's supplier (because the facility has the greatest knowledge, leverage and ability to conduct meaningful oversight of its immediate supplier and because it is the supplier who is accountable to verify back one more step).
For records documenting that the basic requirements are being carried out.	For documents such as an underlying audit report (because of concerns about confidential information).
For audits as a verification activity, provided that the requirements are flexible and audits are not over-emphasized at the expense of other verification activities.	Prescribing the frequency of audits (particularly an annual frequency) (because an audit is only one tool and audits should be based on risk and on the performance of the supplier).
Limiting a supplier program to facilities that manufacture or process food.	Specifying that some hazards require more than one verification activity (because doing so would be too prescriptive and would not allow the facility the flexibility to determine the appropriate risk-based approach).
For oversight of a supplier program by a qualified individual	For a receiving facility to identify the regulations to which the supplier is subject (because the distinction would not be material to food safety).
That would be consistent with the Foreign Supplier Verification Program being established in a separate rulemaking	

TABLE 7—SUMMARY OF SPECIFIC RECOMMENDATIONS IN COMMENTS THAT SUPPORT REQUIREMENTS FOR A SUPPLIER PROGRAM—Continued

Most comments support a requirement:	Most comments do not support a requirement:
Specifying that a supplier program may be managed at a corporate level (rather than by specific facilities), because supplier programs are often managed at the corporate level. Some comments specifically recommend that inspection of a supplier program take place at the location where the program is managed, including at a corporate location rather than at an individual facility.	

Comments also address several other issues, such as whether the final rule should:

Be limited to circumstances where a hazard is controlled by the supplier, or be required even if the hazard would be controlled by the receiving facility or by the receiving facility's customer.

Include requirements for specific types of verification activities based only on the seriousness of hazards. Although some comments support such requirements, other comments do not because the basis should be risk (which includes probability as well as severity).

Allow substitution of an inspection (e.g., by FDA) for an audit. Although some comments support such a substitution, others do not because they assert that an inspection and an audit are different in nature.

Require a receiving facility to consider relevant regulatory information about the supplier. Although some comments support such requirements, others do not (e.g., because the information (which can be part of an overall supplier assessment) may not be available in a timely manner, is narrow in scope, and would diminish the importance of the supplier's food safety plan and the effectiveness of its implementation).

Include requirements related to supplier non-conformance. Although some comments support such requirements, others maintain that supplier non-conformance would be better suited to guidance. Some comments specifically oppose a requirement for ''discontinuing use of the supplier'' and recommend flexibility for how a receiving facility would address supplier non-conformance.

Provide for alternative verification requirements when a supplier is a qualified facility (which is subject to modified requirements; see proposed § 117.201 in the 2013 proposed preventive controls rule). Although some comments support alternative requirements for suppliers that are qualified facilities, others express concern about whether alternative requirements can be practically implemented. Some comments state that the supplier verification requirements should not prevent facilities from sourcing ingredients from suppliers that are qualified facilities.

In general, comments that simply oppose including a supplier program in the final rule express concern about cost, ingredient diversity, and duplication of efforts. Some of these comments recommend that we issue guidance on supplier verification activities rather than establish requirements in the final rule. Some commenters, including those with varying views about the issue, nonetheless requested that FDA propose regulatory language for consideration.

C. Potential Requirements for a Supplier Program

Section 418 of the FD&C Act specifically identifies supplier verification activities as a preventive control (see section 418(o)(3) of the FD&C Act), Supplier controls, when implemented appropriately, are an important preventive control that can ensure that significant hazards will be significantly minimized or prevented for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient. Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on potential requirements for a supplier program as a preventive control. In this section of this document, we are reopening the comment period with respect to our previous request for comment on when and how supplier programs are an appropriate means of implementing FSMA. We are seeking comment on whether requirements for a supplier program should be included in a final rule and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to amend the 2013 proposed FSVP rule. In that supplemental notice we request comment, in light of the statutory provisions, on the manner and extent to which the FSVP and preventive controls supplier verification provisions—as well as other aspects of the FSVP and preventive controls regulations—should be aligned in the final rules.

See the proposed regulatory text (proposed § 117.136 and the applicable definitions in proposed § 117.3) for the full text of such potential requirements. Briefly, the proposed regulatory text would, if included in a final rule:

Establish definitions for terms used in the potential requirements for a supplier program (i.e., receiving facility; supplier; and qualified auditor) (proposed § 117.3)

Establish a risk-based requirement for a written supplier program that:

Would require, with some exceptions, a supplier program for raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of raw material or ingredient (proposed § 117.136(a)(1) and (2); and

Would not apply to raw materials and ingredients for which there are no significant hazards, the preventive controls at the receiving facility are adequate, or the receiving facility relies on the customer and obtains written assurance (proposed § 117.136(a)(1)(ii));

Require verification activities, as appropriate to the hazard, and documentation of such activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use) (proposed § 117.136(a)(3)(i));

Require verification activities to verify that the hazard is significantly minimized or prevented, the incoming raw material or ingredient is not adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act, and the incoming raw material or ingredient is

produced in compliance with the requirements of applicable FDA food safety regulations (proposed § 117.136(a)(3)(ii));

Provide flexibility for a receiving facility to determine and document the appropriate verification activities for raw materials and ingredients from particular suppliers, based on a series of factors, except when there is a reasonable probability that exposure to a significant hazard will result in serious adverse health consequences or death to humans (proposed §§ 117.136(b) and 117.136(c)(1)) (see next bullet);

Require an annual audit as a verification activity when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, unless the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled (proposed § 117.136(c)(2));

Provide for an alternative verification activity when the supplier is a qualified facility (proposed § 117.136(c)(3));

Provide for alternative verification activities when the supplier is a farm that would not be subject to the requirements in the final produce safety rule under proposed § 112.4 (proposed § 117.136(c)(4));

Require that an audit be conducted by a qualified individual who has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function (proposed § 117.136(d)(1)) and proposed § 117.180);

Provide that inspection by FDA or an officially recognized or equivalent food safety authority may substitute for an audit (proposed § 117.136(e));

Require action to address supplier non-conformance (proposed § 117.136(f)); and

Require documentation of verification activities in records (listed in proposed § 117.136(g)), including minimum requirements for records documenting an audit, records of sampling and testing, and records documenting a review by the receiving facility of the supplier's relevant food safety records (proposed § 117.136(g)(5), (6), and (7), respectively).

In addition, the potential addition of requirements for a supplier program would require conforming amendments to other provisions of the rule, including the requirements for a food safety plan, preventive controls, validation, verification of implementation and effectiveness, and the list of implementation records for subpart C (see proposed §§ 117.126(b)(3), 117.135(c)(4), 117.140(b), 117.160(b)(3), 117.165(a)(4), and 117.190(a)(4), respectively). For supplementary information relevant to a supplier program, see the 2013 proposed preventive controls rule (78 FR 3646 at 3765–3767), the corrected Appendix (78 FR 17142 at 17151- 17152), and Ref. 24. In the following paragraphs, we provide additional information about the potential proposed requirements for a supplier program.

Reflecting the risk-based (including severity as well as probability) nature of a supplier program, a receiving facility's program would be limited to those raw materials and ingredients for which the receiving facility has identified a significant hazard. As discussed in section IX.C, ''significant hazard'' would be defined in the rule. Under the definition, hazards are determined to be significant based on the outcome of a hazard analysis and, thus the determination would incorporate the concept of risk. In addition, a receiving facility would establish and implement a supplier program only when a significant hazard is controlled before receipt; a receiving facility would not be required to establish and implement a supplier program if the receiving facility, or the receiving facility's customer, controls the hazard (and the customer provides assurances as to the control). Under this risk-based approach, a processor of fresh-cut produce generally would be required to establish a supplier program for hazards associated with the fresh produce it processes (which would be controlled by the supplier during growing and harvesting), but a manufacturer of an acidified food would not be required to establish a supplier program for peppers that it uses to produce salsa if it will control any significant hazard for the peppers during manufacture of the salsa.

The potential supplier program would include requirements applicable to a ''receiving facility'' and the proposed definition of ''receiving facility'' would describe a receiving facility as a facility that manufactures/processes a raw material or ingredient that it receives from a supplier. A supplier would be defined as the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consist solely of the addition of labeling or similar activity of a *de minimis* nature. The supplier could be an ''establishment'' rather than a ''facility'' because a supplier may be an entity that is not required to register under section 415 of the act and, thus, would not be a ''facility'' as that term would be defined for the purpose of this rule. Under this definition, a facility that packs or holds the food without any type of manufacturing/processing would not be a supplier. Under this approach, a facility would not be required to establish a supplier program for food products that it only packs or distributes. For example, a receiving facility might receive a raw material or ingredient from a distribution center that receives the raw material or ingredient from a manufacturing facility or a farm. The distribution center, which is the immediate previous source of the raw material or ingredient, would not be required to establish a supplier program and would not be considered the supplier; rather the supplier would be the manufacturer or the farm (which manufactured/processed the food or harvested the food that was provided to the distribution center and subsequently to the receiving facility). In such instance, if the receiving facility has identified a significant hazard for the raw material or ingredient, and that hazard is controlled by the supplier (the manufacturer or the farm), the receiving facility would establish verification activities related to the manufacturer or the farm that provided the raw material or ingredient to the distribution center.

If a facility receives an ingredient from a supplier, but the control of the hazard is by the supplier's supplier, the receiving facility would conduct supplier verification activities that would include verifying that the supplier has conducted appropriate verification that its supplier has controlled the hazard, i.e., the receiving facility would review the supplier's food safety records for its supplier's control of the hazard. For example, if a salad manufacturer is receiving cut produce such as celery from a fresh-cut produce supplier that receives celery from a farm, the salad manufacturer could conduct verification activities related to the on-farm controls by reviewing the supplier program of, and verification activities conducted by, the fresh-cut produce supplier for its supplier, the farm (in addition to verifying the fresh-cut produce supplier's control of pathogens).

We understand that, particularly for RACs, there may be multiple establishments, including cooperatives, packing houses, and distributers, between a receiving facility and the establishment that would be considered the supplier, which would make

supplier verification very challenging under certain circumstances. However, we believe that supplier verification is very important for RACs, in particular produce that will be further processed or consumed without a treatment that will significantly minimize or prevent pathogens. We request comment on what verification activities would be appropriate for receiving facilities to conduct when a raw material or ingredient passes through more than one facility that would not be required to verify control of hazards if supplier programs are limited to manufacturers/processors. For example if a receiving facility is a fresh-cut processing facility that receives produce from a distributor, who receives produce from a cooperative, and neither the distributor nor the cooperative is required to establish supplier controls for the farms where the hazards are being controlled, what supplier controls should be applied for the produce coming from the farms? We request comment on whether and how the requirements for supplier verification should address such situations.

In addition, we seek comment regarding whether (and, if so, how) the final preventive controls rule should address the potential for gaps in supplier controls when a hazard is controlled at Point A in the supply chain (e.g., by Supplier A, a farm), and Point B in the supply chain is a facility (such as Warehouse B, Distributor B, or Packing Shed B) that only packs or holds food, but does not manufacture/process food (and therefore would not be required to have a supplier program) before passing it on to Point C in the supply chain, which also would not be required to have a supplier program (e.g., Retail Food Establishment C or Consumer C). For example, if Packing Shed B distributes produce it packs after receiving the produce from Farm A directly to retail facilities (which would not be subject to the requirements of this preventive controls rule), no supplier controls would be applied to Farm A. Should verification activities be required in circumstances in which a RAC such as fresh produce will not be sent to any facilities that would be required to have preventive controls before reaching consumers?

The potential supplier program would be included in the food safety plan and, thus, would be prepared (or overseen) by a qualified individual (see proposed § 117.126(b)(7)). A supplier program could be established and maintained by a facility's corporate headquarters or parent entity. The recordkeeping requirements would specify that electronic records are considered to be onsite if they are accessible from an onsite location, and we expect that many records for the supplier program would be in electronic form (and thus easily retrievable by a facility during an inspection).

Rather than specifically require a written list of approved suppliers, the potential requirements would specify that the supplier program be written and include verification activities, as appropriate to the hazard, and documentation of such activities, to ensure products are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use). Such a program could include, for example, written procedures for approving suppliers, for approving (or rejecting) specific raw materials and ingredients, and for documenting that raw materials or ingredients are only received from approved suppliers. The potential requirements would recognize that there can be circumstances that would require a facility to receive raw materials or ingredients on a temporary basis from an unapproved supplier (e.g., if there is a disruption in delivery of raw materials and ingredients from approved suppliers due to circumstances such as localized flooding or malfunctioning equipment). We request comment on examples of circumstances when it would be necessary and appropriate to receive raw materials and ingredients on a temporary basis from an unapproved supplier and on the types of verification activities that a facility should conduct on food from an unapproved supplier.

The potential requirements would provide flexibility for the verification activities that the receiving facility would conduct for raw materials and ingredients. With one exception, the receiving facility would have flexibility to select one or more of four possible activities: (1) onsite audit; (2) sampling and testing of the raw material or ingredient, which could be conducted by either the supplier or the receiving facility; (3) review by the receiving facility of the supplier's relevant food safety records; and (4) other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier. To determine which option is appropriate, the receiving facility could consider (1) the severity of the hazards; (2) where the preventive controls for those hazards are applied (such as at the supplier or the supplier's supplier); (3) the supplier's procedures, processes, and practices related to the safety of the raw materials and ingredients; (4) applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the food; (5) the supplier's food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and (6) any other factors as appropriate and necessary, such as storage and transportation. Thus, a receiving facility would have flexibility to select a verification activity based on the circumstances.

The exception would be when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans. In this circumstance, under the potential supplier program, the receiving facility would be required to have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter. The potential requirement for an annual audit is limited to when there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans. Further, the receiving facility could select less frequent audits or a different verification activity, if it documented its determination that the less frequent onsite auditing or other verification activity provides adequate assurance that the hazards are controlled. The potential recordkeeping requirements that would apply to audits would identify specific information that the records must provide about the audit, including the conclusions of the audit, but would not specify that the underlying audit report is part of the required documentation of an audit.

A person who conducts an audit would need to be qualified to do so. To be qualified, a person who conducts an audit (''qualified auditor'') would be required to satisfy the criteria for a ''qualified individual'' (a person who has successfully completed training in the development and application of risk-based preventive controls equivalent to that of an FDA-recognized standardized curriculum or is otherwise qualified through job experience to develop and apply a food safety system) and have technical expertise obtained

by a combination of training and experience appropriate to perform the auditing function.

The potential supplier program would require the receiving facility to know the FDA food safety regulations that apply to the supplier, and relevant information about the supplier's compliance with those regulations. The focus of section 418 of the FD&C Act is on preventing food safety problems rather than on reacting to them. Section 418 of the FD&C Act requires the owner, operator, or agent in charge of a facility to establish and implement preventive controls to significantly minimize or prevent known or reasonably foreseeable hazards. By specifying that supplier verification activities are a preventive control, section 418 requires the receiving facility to take necessary actions to ensure that raw materials and ingredients are not adulterated. To determine whether incoming raw materials and ingredients are adulterated, a receiving facility would need to know the regulatory framework that applies to the raw materials and ingredients, and to have confidence that its supplier is complying with that regulatory framework.

The potential supplier program would include provisions to address non-conformance by a supplier. This potential requirement would not prescribe when a particular corrective action (such as discontinuing a supplier) is necessary. A facility could substitute an inspection (whether by FDA or by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) for an audit. Even though inspection procedures and audit procedures are not identical, we tentatively conclude that a facility should have flexibility to determine whether an inspection could substitute for an audit based on characteristics such as the severity of the hazard, how the supplier controls the hazard, and the supplier's performance history. For example, a facility that receives pickles from a facility subject to the acidified foods regulations in 21 CFR 114 may conclude that an FDA inspection for compliance with acidified foods regulations (concluding that no action is indicated) provides adequate assurance that the facility is producing pickles in compliance with the requirements of applicable FDA food safety regulations and that the pickles are not adulterated under section 402 of the FD&C Act. For additional discussion of our reasons for tentatively concluding that it would be appropriate to substitute an inspection (whether by FDA or by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) for an audit, see the discussion in the proposed FSVP rule (78 FR 45730 at 45758). In addition, we are asking for comment on whether it would be appropriate to substitute an inspection in another country (Country A) for an audit when, for example, it is the food safety authority of Country B (whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States) that conducted the inspection in Country A.

The potential requirements would provide for alternative verification requirements when a supplier subject to the requirements of section 418 of the FD&C Act is a qualified facility subject to modified requirements. Section 418 provides different requirements for qualified facilities, which are reflected in the different potential verification requirements for such facilities. Although the potential requirements would allow a receiving facility to conduct an alternative verification activity when the supplier is a qualified facility, they would not require this.

Likewise, the potential requirements would provide for alternative verification requirements when a supplier is a farm that would not be subject to the requirements of proposed § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm. Some of these farms would be not be subject to the requirements of proposed § 112.4 because they satisfy the criteria, in section 419(f) of the FD&C Act, for an exemption for direct farm marketing. Other farms would not be subject to the requirements of proposed § 112.4 because the crops they grow would not be covered by the proposed produce safety rule, either based on the findings of a qualitative assessment of risk associated with growing, harvesting, packing, and holding of produce (see the discussion of this qualitative assessment of risk in the 2013 proposed produce safety rule, 78 FR 3504 at 3508 and 3522–3529) or because they account for a very small percentage of covered produce (see proposed § 112.4 and the discussion at 78 FR 3504 at 3549). Although the potential requirements would allow a receiving facility to conduct an alternative verification activity for such farms, they would not require this. Although the potential requirements would provide for alternative verification requirements for farms that would not be subject to the produce safety rule, we would not issue a final rule on such alternative verification requirements until we issue the final produce safety rule.

D. Request for Additional Comment on Requirements To Address Conflicts of Interest for Persons Conducting Verification Activities

In the 2013 proposed FSVP rule, we tentatively concluded that it would be appropriate to address the independence of individuals conducting verification activities (78 FR 45730 at 45759). We proposed that an individual who conducts any verification activity must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity, and provided that this would not prohibit an importer, or the importer's employee, from conducting the verification activity (proposed § 1.506(g)). As discussed in the 2013 proposed FSVP rule, we considered such requirements necessary to prevent bias, or the appearance of bias, on the part of a person conducting a verification activity (78 FR 45730 at 45759).

We request comment on whether we should include in the final preventive controls rule requirements to address conflicts of interest for individuals conducting verification activities and, if so, the scope of such requirements. For example, should such requirements be directed to a subset of persons who conduct verification activities (such as auditors) or should they be directed more broadly? Would a requirement such as in the 2013 proposed FSVP rule be appropriate, or would some other requirement be more appropriate (such as a requirement that persons be free of conflicts of interest that are relevant to the outcome of the activity)? What would constitute a financial interest in a company sufficient to constitute a conflict of interest for a person conducting a supplier verification activity (e.g., conducting an audit of that company or conducting laboratory tests of that company's food)?

XII. Potential Requirements for the Hazard Analysis To Address Economically Motivated Adulteration

A. Our Request for Comment on Whether the Final Rule Should Address Economically Motivated Adulteration

In the 2013 proposed preventive controls rule, we announced our intent to implement the statutory requirements for hazards that may be intentionally introduced, including by acts of terrorism, in a separate rulemaking rather than include them in the requirements for hazard analysis and

risk-based preventive controls (78 FR 3646 at 3659). We tentatively concluded that intentional hazards, which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking. However, we also acknowledged that some kinds of intentional adulterants could be viewed as reasonably likely to occur, e.g., in foods concerning which there is a widely recognized risk of economically motivated adulteration in certain circumstances. We provided an example of this kind of hazard—i.e., the addition of the chemical melamine to certain food products, apparently to enhance the measured protein content and/or perceived quality. We requested comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We also requested comment on when an economically motivated adulterant can be considered reasonably likely to occur.

When we developed the 2013 proposed intentional contamination rule, we tentatively concluded that economically motivated adulteration would be best addressed through the approach in the preventive controls rules for human food and for animal food (including hazard analysis, preventive controls, monitoring, corrective action, verification, and recordkeeping) rather than through the vulnerability assessment-type approach for intentional adulteration, where the intent is to cause wide-spread public health harm, such as acts of terrorism (see the 2013 proposed intentional adulteration rule, 78 FR 78014 at 7802). We also explained our view that the primary purpose of economically motivated adulteration is to obtain economic gain rather than to impact public health, although public health harm may occur (78 FR 78014 at 78020).

B. Comments on Economically Motivated Adulteration

Some comments oppose including requirements directed to economically motivated adulteration in the preventive controls rule. These comments assert that the vast majority of economically motivated adulterants affect quality and value rather than safety. These comments also point out that the majority of food products could, in theory, be subject to economically motivated adulteration but that it would be difficult to determine if such adulteration is reasonably foreseeable. One comment recommends that we draw a clear distinction between hazards that are intentionally introduced and those that are not. Another comment expresses the view that food fraud is fundamentally different from both food safety and food defense. However, some comments do support including ''expected intentional adulterants'' in the preventive controls rule and note that the U.S. Pharmacopeial Convention (USP) has a free on-line food fraud database (Ref. 25). (USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide.)

C. Potential Requirements To Address Economically Motivated Adulteration

Taking into account the comments we have reviewed so far, we are providing an opportunity for public comment on a potential requirement for the hazard identification to consider hazards that may be intentionally introduced for purposes of economic gain (see proposed § 117.130(b)(2)(iii) in proposed subpart C). In this section of this document, we are reopening the comment period with respect to our previous request for comment on whether to include potential hazards that may be intentionally introduced for economic reasons. We are seeking comment on whether this preventive controls rule would be the most appropriate rule to address FSMA's requirements to address hazards that may be intentionally introduced (for purposes of economic gain) and, if so, what (if any) modifications to the proposed regulatory text would be appropriate. We note that the preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 26) describes certain assumptions we are making about the preventive controls, and their implementation, that would be established and implemented by a facility that identifies a potential hazard that may be intentionally introduced for economic reasons as a significant hazard. We are seeking comment on alternative ways to control such hazards.

Under the definitions that would be established in the rule, a hazard would be an agent that is reasonably likely to cause illness or injury in the absence of its control. Thus, the focus of the potential requirement would be on those economically motivated adulterants that are reasonably likely to cause illness or injury in the absence of their control, not on economically motivated adulterants that solely affect quality and value with little or no potential for public health harm.

We believe that it is practicable to determine whether economically motivated adulteration is reasonably foreseeable. Importantly, we would not expect facilities to consider hypothetical economically motivated adulteration scenarios for their food products. As discussed in the 2013 proposed intentional adulteration rule, we would expect facilities to focus on circumstances where there has been a pattern of such adulteration in the past, suggesting a potential for intentional adulteration even though the past occurrences may not be associated with the specific supplier or the specific food product (78 FR 78014 at 78027). For example, in both the 2013 proposed preventive controls rule and the 2013 proposed intentional contamination rule we discussed a widespread incident of economically motivated adulteration in which some milk firms in one country added melamine, a nitrogen-rich industrial by-product, to diluted dairy products to increase the apparent protein content (78 FR 3646 at 3659 and 78 FR 78014 at 78021, respectively). This adulteration resulted in significant public health consequences, with more than 290,000 ill infants and 6 deaths in that country. In light of this incident, a prudent person would include in its hazard analysis the potential for melamine to be an economically motivated adulterant in a facility's food products when using milk products from a country where melamine adulteration had occurred and, based on the outcome of that hazard analysis, determine whether melamine is a hazard that must be addressed in the food safety plan. As none of this adulterated milk was exported to the United States and no US suppliers have been a source of food safety problems due to milk products adulterated for economic gain, FDA does not expect a facility to consider the potential for melamine to be a significant hazard when using domestic milk products, or milk products from other countries when there is no history of melamine adulteration associated with those countries.

There are other well-known substances that have been used in economically motivated adulteration schemes, have potential to cause public health harm, and would be prudent to consider in the types of food products that have been the subject of these schemes. For example, dyes containing the heavy metal lead have been added to ingredients such as spices to enhance color. Lead can accumulate in the body over time and can cause health problems, including such as impaired

cognitive development in children (Ref. 27). Lead chromate is a chemical with a vibrant yellow color that has been used as an adulterant in turmeric to change the color of the spice to suggest that it is of a higher quality (Ref. 28). Lead oxide is a red chemical that has been used as an adulterant in paprika to change the color of the spice to suggest that it is of a higher quality; in 1995, an incident was reported in Hungary in which dozens of people were made ill and several people died as a result of consuming contaminated paprika (Ref. 29). Sudan I is an orange-red powder that had been added to chili powder as a coloring agent, but is now banned in many countries because the International Agency for Research on Cancer has classified it as a category 3 carcinogen (not classifiable as to its carcinogenicity to humans) (Ref. 30); in 2005, contamination of an ingredient prepared using chili powder containing Sudan I led to a massive recall of food products in the United Kingdom (Ref. 31).

In addition to the food-fraud database mentioned in the comments, a recent report from the Congressional Research Service provides additional information on economically motivated adulteration of food and food ingredients (Ref. 32). A recent report identified 137 unique incidents in 11 food categories (Ref. 33).

XIII. Provisions for Withdrawal of an Exemption for a Qualified Facility

A. 2013 Proposed Provisions for Withdrawal of an Exemption for a Qualified Facility

In the 2013 proposed preventive controls rule, we explained the provisions of FSMA that establish criteria for a facility to be a qualified facility, establish an exemption for qualified facilities, establish modified requirements for qualified facilities, and provide that we may withdraw the exemption otherwise granted to qualified facilities in specified circumstances (section 418(l) of the FD&C Act; see 78 FR 3646 at 3657). We proposed to establish:

Definitions relevant to these provisions (proposed § 117.3);

An exemption from the requirements for hazard analysis and risk-based preventive controls for qualified facilities (proposed § 117.5(a));

Modified requirements for qualified facilities (proposed § 117.201); and

Procedural requirements that would govern our withdrawal of an exemption for a qualified facility (proposed subpart E; the 2013 proposed withdrawal provisions) (see 78 FR 3702–3703, 3768–3771, and 3775–3780).

The 2013 proposed withdrawal provisions would:

Specify the circumstances under which we would withdraw an exemption for a qualified facility (proposed § 117.251);

Establish procedures for us to issue an order to withdraw the exemption, including information that would be in the order (proposed §§ 117.254 and 117.257);

Establish procedures whereby a qualified facility may submit a written appeal of our order to withdraw an exemption (proposed § 117.260 and 117.264);

Establish procedures for appeals, hearings, and decisions on appeals and hearings (proposed §§ 117.267, 117.270, 117.274, and 117.277); and

Specify the circumstances in which an order to withdraw an exemption is revoked (proposed § 117.280).

B. Proposed Clarification of What FDA Will Do Before Issuing an Order and Proposed Mechanism for Re-Instating an Exemption

1. Comments

Some comments generally support the overall framework of the 2013 proposed withdrawal provisions and express the view that withdrawal of exemption should be both prompt and permanent to protect public health. Some comments ask us to explain the difference between withdrawal of an exemption and suspension of registration. One comment asks us to clarify the effect a suspension has on a qualified facility and recommends that suspension automatically result in loss of the exemption. One comment recommends that we withdraw an exemption at the earliest signs of problems, because doing so would be most protective of public health and would be consistent with the principle that a broad interpretation of statutory exemptions is disfavored when they affect public health and safety. This comment also asserts that section 418 of the FD&C Act provides a very low threshold for initiating a withdrawal action, makes that withdrawal permanent, and was designed to operate on a ''one strike, you're out'' principle. This comment asserts that the exemption section 418 provides to qualified facilities has no basis in food safety science or sound policy and endangers consumers and that withdrawal of an exemption would not result in overly harsh consequences because it would not close the facility. One comment discusses our authority to suspend the registration of a facility (section 102 of FSMA). This comment contrasts FSMA's provisions for withdrawal with those for suspension, noting that FSMA's provisions for suspension specify a method to lift that suspension (i.e., submission of a corrective action plan) but FSMA's provisions for withdrawal of an exemption provide no remedy for an exemption that is withdrawn.

In contrast, other comments express concern that the 2013 proposed withdrawal provisions fail to establish a fair and clear process for withdrawing a qualified facility's exempt status and recommend that we revise the 2013 proposed withdrawal provisions to provide a more flexible framework that would be both fair and clear. Some of these comments express concern that withdrawal of an exemption would subject very small and small facilities to unexpectedly high compliance costs that could put them out of business. Some comments recommend that we add a provision allowing a facility to voluntarily withdraw its exemption. Some comments recommend more safeguards to ensure that the process to withdraw an exemption is not abused. In general, these comments recommend the following three principal revisions to the 2013 proposed withdrawal provisions:

Establish a high threshold for withdrawing an exemption, including an evidentiary standard that would apply to the criteria for withdrawing an exemption;

Provide for ''due process'' before we take steps to withdraw an exemption, including an opportunity for a qualified facility to maintain its exempt status (e.g., by addressing the specified issues of concern); and

Provide an opportunity for reinstatement of a withdrawn exemption.

In the following paragraphs, we provide more detail about comments recommending these three principal revisions.

Threshold for withdrawing an exemption. Some comments assert that the 2013 proposed withdrawal provisions are extremely vague and appear to give us broad authority to withdraw an exemption from a qualified facility without adequate evidence of an actual harm or likely severe problem related to the facility's practices. Some comments assert that we should narrowly interpret the statutory criteria for withdrawing an exemption to avoid action that is arbitrary and capricious, and that to do so we must show necessity and direct linkage between an active investigation of a foodborne illness outbreak and the qualified facility. Some of these comments

recommend that we define and clarify key terms (including ''directly linked,'' ''necessary,'' ''associated,'' and ''material to the safety of food''). Some of these comments also recommend that we introduce a standard (such as ''credible evidence'' or ''credible and substantial evidence'' that shows direct linkage to a problem at a specific facility) that would require us to meet an explicit evidentiary threshold when we find that conduct or conditions exist in a qualified facility sufficient to warrant withdrawal of an exemption. Some comments recommend that the final withdrawal provisions explicitly provide that the credible and substantial evidence would only apply to an individual facility, and would not apply to a group or class of facilities.

Due process before withdrawing an exemption. Some comments note that we have many enforcement tools that we can use in lieu of withdrawing an exemption, particularly if there is an immediate risk to public health. These include seeking an injunction (21 U.S.C. 332; section 302 of the FD&C Act); seizing the food at issue (21 U.S.C. 334(a)–(f); section 304(a)–(f) of the FD&C Act); and administrative detention of the food (21 U.S.C. 334(h); section 304(h) of the FD&C Act). Other comments note that we have a history of providing a facility with opportunities to fix a problem before starting such an enforcement action (e.g., by issuing a warning letter). These comments recommend that we provide such opportunities to qualified facilities before we take steps to withdraw an exemption.

Some comments recommend that the final withdrawal provisions allow for partial withdrawal of an exemption in which FDA would indicate specific sections of the rule that the facility must comply with. These comments assert that small businesses should be able to seek targeted solutions as needed without falling under all the substantive, costly provisions of the rule. Some comments recommend that the final withdrawal provisions establish a three-tiered process—Tier 1: Warning letter; Tier 2: Temporary conditional withdrawal of an exemption; and Tier 3: Full withdrawal of an exemption. For example, a warning letter would identify the material conduct or conditions in question or how the facility is directly linked to an active investigation of a foodborne illness outbreak; include information about how the facility could remedy the situation; and notify the facility that it has 15 calendar days from receipt of the warning letter to respond with a plan for remedying the problem within a suitable timeframe. These comments state that if the facility does not adequately address the problem in its response to the warning letter and subsequent actions to correct the problem, we would issue a temporary (e.g., six months) conditional withdrawal, targeted to a particular issue, outlining how the facility can remedy the problem. These comments further state that if the facility still fails to correct the problem after receiving the temporary conditional withdrawal, we would proceed with steps for full withdrawal of an exemption.

Reinstatement of an exemption that was withdrawn. Some comments recommend that we provide a process for each of three situations in which a qualified facility might regain its exemption status:

Before reaching the deadline for compliance specified in the withdrawal order, if the facility demonstrates that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved;

After the compliance deadline passes if, during an informal hearing, the facility can show that the conduct or conditions that triggered the withdrawal have been sufficiently resolved; or

Automatically if we determine, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the facility.

2. Specific Proposed Additions and Modifications to the 2013 Proposed Withdrawal Provisions

As discussed more fully in the following paragraphs, taking into account the comments we have reviewed so far we are proposing to modify the 2013 proposed withdrawal provisions to:

Include specific regulatory actions that we must take, and other regulatory actions that we may consider, before we issue an order to withdraw an exemption (proposed § 117.251(b));

Clarify that an order to withdraw an exemption must be approved by an FDA District Director before it can be issued (proposed § 117.254(a) and (b)); and

Provide a process for reinstating an exemption that has been withdrawn (proposed § 117.287).

See the revised regulatory text for proposed §§ 117.251(b), 117.254(a) and (b), and 117.287. In this section of this document, we are reopening the comment period with respect to these specific proposed provisions.

Both of the proposed circumstances for withdrawal of an exemption specify significant public health reasons for doing so, related to an outbreak of foodborne illness, or being necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility (proposed §§ 117.251(a) and (b), respectively). We do not consider it necessary to define terms such as ''directly linked,'' ''necessary,'' ''associated,'' or ''material to the safety of food,'' or to introduce a standard (such as ''credible evidence'' or ''credible and substantial evidence'' that shows direct linkage to a problem on a specific farm or facility) to provide for a fair process that is neither arbitrary nor capricious.

We may suspend the registration of a facility if we determine that food manufactured, processed, packed, received, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals. If we suspend a facility's registration, no person can import or export food into the U.S. from such facility, offer to import or export food into the U.S. from such facility, or otherwise introduce food from such facility into intrastate or interstate commerce in the U.S. (See section 415(b) of the FD&C Act (21 U.S.C. 350d(b)). In contrast, we may withdraw an exemption from a qualified facility in two circumstances: (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or (2) if we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility. (See section 418(l)(3) of the FD&C Act). A facility that loses its exemption may distribute food if it is in compliance with applicable requirements.

The statutory criteria for suspension of registration are separate and distinct from the statutory criteria for withdrawal of an exemption and must be considered separately. Suspension of a facility's registration does not change a facility's status as a qualified facility. If we take steps to suspend a qualified facility's registration, we may also separately consider whether the circumstances that may lead us to withdraw the facility's exemption exist and, if so, may follow the process that would be established in the final withdrawal provisions for doing so.

As the comments point out, in many circumstances we have provided facilities with opportunities to fix a

problem before starting an enforcement action. Indeed, we consider that issuing an order to withdraw an exemption would be a rare event, in part because alternative actions may provide a more expeditious approach to correcting a problem than withdrawing an exemption. However, taking into account the concerns expressed in the comments we have reviewed so far, we are proposing to include specific actions that we must take, and other actions that we may consider, before we issue an order to withdraw an exemption. (See the revised regulatory text for proposed § 117.251(b)). Briefly, the proposed regulatory text would provide that we:

Notify a qualified facility in writing of circumstances that may lead us to withdraw its exemption, and provide an opportunity for the facility to respond, before we issue an order to withdraw the exemption;

May consider alternative regulatory actions before issuing an order to withdraw an exemption; and

Consider actions taken by the facility to address the circumstances that may lead us to withdraw its exemption before issuing an order to withdraw the exemption.

We are not proposing that we always must take steps to withdraw an exemption at the earliest signs of problems. Not all problems would satisfy the statutory threshold for withdrawal of the exemption. Further, we believe it is appropriate to consider each situation on its individual merits, such as whether there are illnesses, whether there are significant violations that could have contributed to the problem, whether the facility has taken corrective actions to address the problem, and whether the actions taken are likely to prevent a reoccurrence of the situation. Moreover, FDA has other tools that may be available to more quickly protect public health, including recall and administrative detention.

Regarding reinstatement, we tentatively conclude that the absence of a specific provision in section 418 of the FD&C Act for the re-instatement of an exemption that is withdrawn does not preclude us from providing for such a process, by which a facility may regain its status as a qualified farm. The proposed regulatory text (see proposed § 117.287) would:

Provide that we could reinstate an exemption on our own initiative or in response to a written request from the facility;

Require that a written request from a facility include such data and information as are necessary to demonstrate that the facility has adequately resolved the problems with the conditions or conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak;

Provide that if we had withdrawn the exemption due, in whole or in part, to an active investigation of a foodborne illness outbreak that had been directly linked to the qualified facility and later determine, after finishing the active investigation, that the outbreak was not directly linked to the facility, we would either;

Reinstate the exemption (if the only reason for the withdrawal had been the outbreak investigation); or

Inform the facility of our finding that the outbreak investigation was not directly linked to the facility, and provide an opportunity for the facility to request reinstatement (if the exemption was withdrawn, in part, due to conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility).

We are not proposing to provide for partial withdrawal of an exemption or establish the three-tiered process recommended in the comments (i.e., Warning letter; Temporary conditional withdrawal of an exemption; and Full withdrawal of an exemption). Such a process is not required by section 418 and would deprive FDA of needed flexibility to address the varying circumstances that might give rise to a possible withdrawal of the exemption. Further, the revised regulatory text provides for a qualified facility to receive written notification that circumstances may lead us to withdraw an exemption, and provides an opportunity for the facility to respond. FDA will consider this response and actions taken by the facility in determining whether to withdraw the exemption. In addition the newly proposed provision for reinstatement of an exemption provides an opportunity for a facility to return to its status as a qualified facility.

C. Proposed Revisions to the Content of an Order To Withdraw an Exemption

In this section of this document, we are reopening the comment period with respect to proposed § 117.257(d).

Some comments recommend that the order explicitly state that the facility has the option to either comply with the order or appeal the order (with a request for an informal hearing) within 10 calendar days.

We tentatively conclude that it would be useful for the order to itself specify the two options that a facility has upon receipt of the order, even though the order would otherwise include this information (because the order will contain the full text of the withdrawal provisions). Therefore, we are proposing to revise the requirements for the contents of an order to explicitly mention these two options. See the revised regulatory text of proposed § 117.257(d).

D. Proposed Revisions to the Timeframes for a Facility To Comply With, or Appeal, an Order

In this section of this document, we are reopening the comment period with respect to the timeframes in proposed §§ 117.257(d) and 117.260(a) and (c).

1. Comments

Some comments ask us to specify that a facility's timeframe for taking action begins when the facility receives the order, not when we issue the order. Other comments address the timeframes for a facility to compile information needed to appeal an order for withdrawal. These comments assert that the proposed timeframe of 10 days is insufficient, and recommend timeframes such as 30 days or 90 days.

Some comments contrast the proposed 60-day timeframe to comply with the requirements for hazard analysis and risk-based preventive controls when a facility loses its exemption as a qualified facility with the timeframe that a facility would have to comply with these requirements when the final rule first becomes effective. As discussed in the 2013 proposed preventive controls rule, we proposed compliance dates that would be 2 years and 3 years after the date of the final rule for small and very small businesses, respectively. These comments assert that these two situations are parallel, because a qualified facility that has had its exemption withdrawn would be coming into compliance with the full requirements for hazard analysis and risk-based preventive controls for the first time. These comments recommend that we change the timeframes in the 2013 proposed withdrawal provisions to better align with the compliance dates contemplated by the proposed rule and by FSMA for small and very small businesses. Some of these comments recommend that a small business have 6 months, and that a very small business have 18 months, to comply with the order. Other comments recommend that any business (whether small or very small) have two years to comply with

the order. Some of these comments recommend that the timeframe be tied to the date of the final determination rather than to the date of the order.

2. Proposed Revisions to Timeframes

We tentatively conclude that the nature of what a facility would need to do to comply with an order—i.e., comply with the full requirements for hazard analysis and risk-based preventive controls—makes the timeframes in the 2013 proposed withdrawal provisions insufficient. However, it is relevant that in contrast to the general compliance dates, the proposed withdrawal provisions would only apply when a significant public health concern has been identified for a particular facility.

We also tentatively conclude that it is appropriate to link the timeframe for compliance to the date of receipt of the order, rather than to the date the order was issued. Doing so would be consistent with our other administrative procedures, such as appeal of an order for administrative detention (§ 1.402).

Taking into account the comments we have reviewed so far, we are proposing to require that a facility comply with an order to withdraw an exemption within 120 days of the date of receipt of the order. See the revised regulatory text for proposed §§ 117.257(d) and 117.260(a) and (c).

XIV. Definition of Very Small Business

A. The 2013 Proposed Options for Definition of Very Small Business

We proposed three options for the definition of a very small business based on total annual sales of food, adjusted for inflation: Option 1, $250,000; Option 2, $500,000; and Option 3, $1,000,000. The 2013 proposed preventive controls rule contained several provisions relevant to very small businesses, including exemptions from subpart C in § 117.5(g) and § 117.5(h) for very small (and small) facilities engaged only in specific types of on-farm activities involving low-risk activity/food combinations, the exemption in§ 117.5(a) and modified requirements in § 117.201 for a very small business as a qualified facility, and extended time to comply with the rule. In defining a very small business, we took into consideration the study of the food processing sector required by section 418(l)(5) of the FD&C Act (''Food Processing Sector Study'' (Ref. 34); see 78 FR 3646 at 3700–3701). In the 2013 proposed preventive controls rule we requested comment regarding the three proposed options for the definition of ''very small business.'' We also requested comment on whether a dollar amount of sales that is more than, or less than, the $250,000, $500,000, or $1,000,000 amounts would be appropriate.

B. Comments on the 2013 Proposed Options for Definition of Very Small Business

Comments support a variety of dollar limits of total annual sales of food for defining a very small business, including each of the three proposed options ($250,000, $500,000, and $1,000,000) as well as other dollar limits that we did not include as proposed options (i.e., $2,000,000, $5,000,000 and $10,000,000). Comments assert that very small facilities will incur a large portion of the costs associated with implementing the 2013 proposed preventive controls rule because very small facilities lack experience with HACCP-based models.

Some comments support defining a very small business as one with total annual food sales up to $1,000,000. Some of these comments express concern that using lower dollar sales amounts to define a very small business would discourage growth of very small processing facilities (especially those co-located on a farm), would unfairly burden very small facilities, and could cause them to fail due to the estimated high cost of compliance; whereas setting a higher dollar sales amount would encourage growth, innovation and diversification. Some of these comments note that adopting the threshold of $1,000,000 would establish that the full preventive controls requirements would apply to the businesses that produce the vast majority of food products and that modified requirements would apply to smaller businesses that represent the majority of producers but the minority of the food supply.

Other comments support defining a very small business as one with total annual food sales up to $500,000. These comments maintain that the $500,000 limit would simplify the definition of a qualified facility, and make it easier for us to enforce than a lower dollar amount, because facilities would not need to calculate how much of their sales were to qualified end-users (as they would under section 418(l)(1)(C) of the FD&C Act).

Other comments support defining a very small business as one with total annual food sales up to $250,000. These comments maintain that the $250,000 limit would exempt the fewest facilities among the three proposed options and that this would be in the interest of public health. Comments assert that higher dollar limits would remove from the coverage of the 2013 proposed preventive controls rule precisely those companies whose practices would be most improved by it. Some of these comments evaluate the $250,000 limit in the context of section 418(l) of the FD&C Act, which defines a qualified facility as either a very small business or a business with annual sales of less than $500,000, provided a majority of its sales are made directly to qualified end-users. These comments note that the options with a limit higher than $250,000 would equal or exceed the amount allowed for sales by qualified facilities to nonqualified end users under section 418(l)(1)(C) of the FD&C Act and assert that statutory structure and intent of section 418(l) of the FD&C Act make the proposed $250,000 limit the only available option from among the three options we proposed. The comments also assert that the close producer-customer relationship was a control for safety when a business is smaller than $500,000 in sales and primarily sells directly to consumers or locally to food retailers and restaurants.

Some comments support defining a very small business as one with total annual food sales up to $2,000,000, $5,000,000 or $10,000,000. In general, these comments express concern about the costs associated with implementing the requirements for hazard analysis and risk-based preventive controls. For example, the comments assert that these costs would deter small farms with gross annual sales between $250,000 and $5 million from expanding their businesses (e.g., to develop value-added products), particularly when annual food sales include foods that would not be not covered by the requirements for hazard analysis and risk-based preventive controls (such as for animal food, whole produce, and low-risk activity/food combinations conducted by a small or very small business co-located on a farm), and the sales would largely be to qualified end-users. A comment recommending a $10,000,000 limit expresses concern that the costs associated with implementing the requirements for hazard analysis and risk-based preventive controls would be passed on to consumers.

Some comments do not support defining a very small business based on total annual food sales and recommend an alternative definition based on the number of employees (e.g., fewer than 20 employees). These comments assert that defining very small business based on number of employees would be consistent with the proposed definition of small business (which is based on number of employees) and with the smallest establishment size in the Food

Processing Sector Study. Other comments support using a combination of criteria for defining a very small business, including gross sales, number of employees and risk level of the food being prepared.

Some comments support using the volume of food rather than total annual food sales. Some comments express concern that the dollar sales would be applied to all food sold, including food for animals, and recommend that we base the value on food subject to the preventive controls for human food rule, on produce and processed food, on human food (excluding animal feed) or on ''high-risk processed foods.''

C. Proposed Revisions to the Definition of Very Small Business

In this supplemental notice of proposed rulemaking, we are proposing the definition of very small business as a business that has less than $1,000,000 in total annual sales of human food adjusted for inflation. This definition would, as recommended by some comments, simplify a facility's determination of whether it is a qualified facility because the facility would only need to calculate its total sales of human food rather than determine how much food was sold to qualified end-users. The statutory construct does not prevent us from establishing a definition for very small business that would include more facilities than those that would be included under the statutory provision that considers sales to qualified end-users (section 418(l)(1)(C) of the FD&C Act). Section 418(n)(1)(B) of the FD&C Act directs FDA to define the term ''very small business'' for the purposes of determining whether a facility is a ''qualified facility'' eligible for modified requirements. Further, section 418(n)(1)(B) requires us to consider the Food Processing Sector Study for the purpose of defining ''very small business.'' FDA notes that section 418 of the FD&C Act does not otherwise limit how FDA may define ''very small business.''

We tentatively conclude that it is reasonable for the sales limit in the definition of ''very small business'' to be directed to human food rather than all food, including animal food. The proposed definition of ''very small business'' in this document is consistent with the proposed definition of ''very small business'' in the 2013 proposed rule ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals'' (78 FR 64736, October 29, 2013), which would define such a business with respect to sales of animal food rather than all food. We do not expect that this proposed change would have a significant effect on the number of facilities that satisfy the definition of ''very small business,'' because most facilities subject to the statutory requirements for hazard analysis and risk-based preventive controls do not make both human and animal food. However, some facilities co-located on a farm that would not satisfy the definition of ''very small business'' if the limit on the sales of food includes animal food as well as human food may fall within the revised definition that would include a limit only on the sales of human food.

We tentatively conclude that it is not necessary for the dollar limit in the definition of ''very small business'' to be $250,000 or less to protect public health. In the 2013 proposed preventive controls rule, we estimated the number of facilities that would be affected by the size specified in the definition of ''very small business.'' The size specified in the definition of ''very small business'' would affect the compliance dates, the exemptions for qualified facilities, and the exemptions for on-farm low-risk packing and holding activity food/combinations and on-farm low-risk manufacturing/processing activity food/combinations (proposed §§ 117.5(a), (g), and (h), respectively) (see 78 FR 3646 at 3702). We noted that as a group, businesses with less than $1,000,000 in total annual sales of foods produce less than two percent of all food produced in the United States when measured by dollar value. We acknowledge that this estimate of all food produced in the United States is higher than the estimates for lower dollar limits (one-half of one percent of all food produced in the United States, or less than one-half of one percent of all food produced in the United States, for limits of $500,000 or $250,000, respectively). Regardless, under the revised definition the businesses that would be exempt from the requirements for hazard analysis and risk-based preventive controls would represent a small portion of the potential risk of foodborne illness.

In the proposed rule, we calculated the costs of the rule, and estimated the percent of food produced in the United States that would be subject to modified requirements (i.e., produced by qualified facilities), by determining which facilities would be qualified based on ''per facility'' sales. We believe our current calculation based on firm sales rather than facility sales is more consistent with section 418(l)(1)(B). In the updated PRIA (Ref. 26), we compare the numbers and their market share of qualified and non-qualified facilities under different definitions for a very small business using (1) the method in our original PRIA (the number of *facilities* with less than $1 million in annual sales) and (2) the number of *firms* with less than $1 million in annual sales (in which multiple facilities may be under the ownership of one firm). As noted in the updated PRIA (Ref. 26), in the final rule we will calculate the number of qualified facilities based on sales on a ''per firm'' basis. Calculating sales at the ''per firm'' level, we estimate that, as a group, those businesses that have less than $1,000,000 in total annual sales of foods produce less than one percent of the dollar value of food produced in the United States that would be covered by the rule without any special provisions for such businesses (Ref. 26), roughly equivalent to the percentage of food produced by very small businesses when the level for such entities is set at $250,000 if the ''per facility'' method of calculation is used. In contrast, higher dollar limits for very small business (such as the $2,000,000 or $5,000,000 limits recommended in some of the comments) using the ''per firm'' method would affect more of the food produced in the United States (approximately one percent and two percent, respectively, roughly equivalent to the levels of food affected when the level is set at $500,000 and $1,000,000, respectively, using the ''per facility'' method) (Ref. 26). We tentatively conclude that the definition of very small business should exempt from the rule only a small percent of food to minimize the risk of foodborne illness and, thus, are proposing a very small business definition of $1,000,000, which would exempt less than one percent of the dollar value of food produced in the United States. We request comment on this tentative conclusion and whether we should consider other dollar limits for very small business.

A dollar limit in the definition of ''very small business'' greater than $250,000 would not necessarily exempt those companies whose practices would be most improved by complying with the requirements for hazard analysis and risk-based preventive controls. The Food Processing Sector Study (Ref. 34) concluded that there was no consistent pattern across food categories in terms of which sizes of establishments contribute most to foodborne illness risk (78 FR 3646 at 3701). Moreover, the facilities that would be classified as qualified facilities would be subject to modified requirements (see proposed

§ 117.201). Furthermore, all facilities that would be exempt from the requirements for hazard analysis and risk-based preventive controls would continue to be subject to the prohibitions in the Federal Food, Drug, and Cosmetic Act against causing food to be adulterated or misbranded and against distributing such food and to inspection by FDA.

We are not proposing that the definition of ''very small business'' consider number of employees as well as dollar limits, be based on number of employees for consistency with the definition of ''small business,'' or be based on volume of food sold rather than on dollar limits associated with sales of food. There are two alternative sets of criteria to be a qualified facility. The criteria in section 418(l)(1)(C) of the FD&C Act are set out with regard to sales. We believe it is appropriate for the other criteria (related to being a ''very small business'') similarly to be related to sales. As discussed in the 2013 proposed preventive controls rule, we proposed number of employees for the definition of ''small business'' in part because it would be the same definition for small business as that which has been established by the U.S. Small Business Administration under 13 CFR 121 for most food manufacturers. We continue to believe that the proposed definition of ''small business,'' based on number of employees, is appropriate.

We are not proposing that the definition of ''very small business'' consider the risk associated with the food manufactured, processed, packed or held by the facility. The description ''very small'' addresses size of a business, not risk associated with food the facility manufactures, processes, packs, or holds.

XV. Other New and Revised Proposed Provisions

A. Proposed New Definitions

1. Proposed Definition of ''Pathogen''

In the 2013 proposed rule, we proposed to define ''environmental pathogen'' to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. Variations of the phrase ''microorganism of public health significance'' appear in several places in the existing CGMP regulations and in the 2013 proposed preventive controls rule. To both simplify the regulations and use the same term (i.e., ''pathogen'') when we mean a microorganism of public significance, we are proposing to define the term ''pathogen'' to mean a microorganism that is of public health significance and to replace variations of the phrase ''microorganism of public health significance'' with ''pathogen'' throughout the regulations.

2. Proposed Definition of ''You''

In the 2013 proposed preventive controls rule, we requested comment on whether there is any meaningful difference between the persons identified in current part 110 (i.e., ''plant management'' and ''operator'') and the ''owner, operator, or agent in charge'' identified in section 418 of the FD&C Act. We also requested comment on whether it would be appropriate to refer to the ''owner, operator, or agent in charge'' of a plant, establishment, or facility throughout proposed part 117 and, if so, whether the requirements would be clear if we revised the proposed rule to use pronouns (such as ''you'' and ''your'') within proposed part 117.

Comments that responded to this request for comment focused on an approach that would make the regulations clear. However, the comments were divided in terms of how to best provide clarity, particularly with respect to use of pronouns such as ''you'' and ''your.'' Some of these comments express concern that it would be confusing if the phrase ''owner, operator, or agent in charge'' applied both to plant management and operators in the CGMP requirements (proposed subpart B, derived from current part 110) and to the ''owner, operator, or agent in charge of a facility'' in the requirements for hazard analysis and risk-based preventive controls (proposed subpart C). Other comments do not express this concern and note that the use of pronouns would, as we suggested, make the regulations more clear.

We acknowledge the potential for confusion if the phrase ''owner, operator, or agent in charge'' applies to both plant management and operators in proposed subpart B and to the ''owner, operator, or agent in charge of a facility'' in proposed subpart C. Most of the provisions of proposed subpart B do not specify the role of ''plant management'' or the ''operator'' of a plant or establishment. To prevent confusion, we tentatively conclude it is prudent to retain terms such as ''plant management'' and ''operator'' in proposed subpart B.

However, we tentatively conclude that we can simplify the regulations directed to the ''owner, operator, or agent in charge of a facility'' in provisions in subparts C, D, and E by using pronouns, without creating confusion, if we (1) define the term ''you'' to mean, for purposes of part 117, the owner, operator, or agent in charge of a facility and (2) limit use of the term ''you'' to provisions in proposed subparts C, D, and E. See the revised regulatory text for the definition of you (in proposed § 117.3) and its use throughout revised subpart C.

3. Proposed Definition of ''Significant Hazard''

As discussed in section IX.C, we are proposing to delete the proposed definition ''hazard reasonably likely to occur'' and instead establish a definition for ''significant hazard.'' See the revised regulatory text in proposed § 117.3.

4. Proposed Definition of ''Known or Reasonably Foreseeable Hazard''

As discussed in section IX.C, we are proposing to delete the proposed definition ''reasonably foreseeable hazard'' and instead establish a definition for ''known or reasonably foreseeable hazard.'' See the revised regulatory text in proposed § 117.3.

5. Potential Definitions of ''Qualified Auditor,'' ''Receiving Facility,'' and ''Supplier''

As discussed in section XI.C, we are providing an opportunity for public comment on potential requirements for a supplier program. If such requirements are included in a final rule, we would establish definitions for three terms used in the potential requirements for a supplier program—i.e., ''qualified auditor,'' ''receiving facility,'' and ''supplier.'' See the proposed regulatory text in proposed § 117.3.

B. Proposed Revisions to Definitions

In the 2013 proposed preventive controls rule, we proposed to:

Delete the definition of the term ''shall'' from the existing CGMP regulations;

Revise the definitions of several other terms in the existing CGMP regulations;

Retain the definitions of several other terms in the existing CGMP regulations, with no changes; and

Establish several new definitions.

We received comment on many of these proposed definitions. Taking into account the comments we have reviewed so far, we are proposing to revise the definitions for three of these terms.

1. Revised Definition of ''Cross-contact''

We proposed to define the term ''cross-contact'' to mean the unintentional incorporation of a food

allergen into a food. Some comments recommend that we define the term to be ''allergen cross-contact'' rather than ''cross-contact'' to reduce the potential for confusion with the term ''cross-contamination.'' We tentatively conclude that the term ''allergen cross-contact'' may reduce the potential for confusion with the term ''cross-contamination'' and are proposing to establish a definition for the term ''allergen cross-contact'' rather than the term ''cross-contact.''

2. Revised Definition of ''Hazard'' and ''Reasonably Foreseeable Hazard''

Some comments recommend that we include radiological hazards as a subset of chemical hazards in the definition ''hazard.'' Although radiological hazards would not be common, we believe that facilities in the past have considered them as chemical hazards when conducting a hazard analysis for the development of HACCP plans. The revised regulatory text uses the phrase ''chemical (including radiological) '' in the definition of ''hazard'' and as applicable throughout the regulations. As a conforming change, we are proposing to revise the definition of ''reasonably foreseeable hazard'' to mean a potential biological, chemical (including radiological), or physical hazard that may be associated with the facility or the food.

3. Revised Definition of Environmental Pathogen

We proposed to define the term ''environmental pathogen'' to mean a microorganism that is of public health significance and is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment. We identified *Salmonella* spp. and *Listeria monocytogenes* as examples of environmental pathogens. Some comments express concern that our proposed definition of ''environmental pathogen'' would capture organisms such as pathogenic sporeformers whose presence in and of itself would not constitute a risk to public health.

We are proposing to revise the definition of an environmental pathogen to mean a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. The revised definition of ''environmental pathogen'' would specify that an environmental pathogen does not include the spores of pathogenic sporeformers and, thus, recognizes that consumption of food contaminated by the spores of a pathogenic sporeformer that is in the environment may not result in foodborne illness. For example, if food is contaminated with spores of *Clostridium botulinum,* the microorganism would not produce the botulinum toxin that causes illness unless these spores are subject to conditions that allow them to germinate into vegetative cells that produce the toxin. Pathogenic sporeformers are normally present in foods, and unless the foods are subjected to conditions that allow multiplication, they present minimal risk of causing illness.

C. Proposed Editorial Changes

The revised regulatory text includes several changes that we are making to make the requirements more clear and improve readability. We summarize the principal editorial changes in Table 8.

TABLE 8—PROPOSED EDITORIAL CHANGES

Designation in the revised regulatory text (Proposed §)	Proposed revision	Explanation
Throughout part 117	Substitute the term ''adequate'' for the term ''sufficient''.	For the purposes of part 117, there is no meaningful difference between ''adequate'' and ''sufficient.'' We proposed to retain the definition of ''adequate'' that is in the existing CGMP requirements in current part 110, but did not propose to define ''sufficient.'' We tentatively conclude that the regulations will be clearer if we use the single term ''adequate'' throughout the regulations.
Throughout subparts C, D, and E	Substitute the defined term ''you'' for ''owner, operator, or agent in charge of a facility''.	Improve clarity and readability.
117.126(c), 117.170(a)(4), 117.170(a)(5), 117.170(d).	Re-phrase the proposed requirements in active voice.	Improve clarity and readability.
117.126(d)	Specify that the food safety plan is a record that is subject to the requirements of subpart F within the requirements for the food safety plan (§ 117.126) rather than together with the requirements for other records required by the rule (§ 117.190).	Distinguish the requirements for the contents of the food safety plan from implementation records, which continue to be listed in § 117.190.
117.130(b)(1) and (b)(2)	Switch the order of paragraphs (b)(1) and (b)(2) compared to the order in the 2013 proposed preventive controls rule.	We tentatively conclude that it is more logical to specify what hazards must be considered (i.e., biological, chemical (including radiological), and physical) before specifying the reasons for how the hazards could get into the food products (i.e., naturally occurring, unintentionally introduced, or intentionally introduced for purposes of economic gain).
117.135	Shorten the title from ''Preventive controls for hazards that are reasonably likely to occur'' to ''Preventive Controls''.	Simplify the presentation of the requirements and conform with the proposed deletion of the term ''hazards that are reasonably likely to occur''.

TABLE 8—PROPOSED EDITORIAL CHANGES—Continued

Designation in the revised regulatory text (Proposed §)	Proposed revision	Explanation
117.135(c)(1)	Rearrange the requirements for (1) parameters associated with the control of the hazard and (2) the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to be associated with process controls rather than be a standalone requirement.	It is more logical to place these requirements with process controls since their parameters and their values are associated with process controls.
117.135(c)(3) and 117.150(c)	Move requirements for corrections for sanitation controls from the requirements for preventive controls (proposed § 117.135) to the requirements for corrective actions (proposed § 117.150).	Improve clarity and readability.
117.137	Shorten the title from ''Recall plan for hazards that are reasonably likely to occur'' to ''Recall plan''.	Simplify the presentation of the requirements and conform with the proposed deletion of the term ''hazards that are reasonably likely to occur''.
117.145, 117.150, 117.155	Redesignate the section numbers from the original section numbers in the 2013 proposed preventive controls rule (proposed §§ 117.140, 117.145, and 117.150, respectively).	Accommodate insertions of new § 117.136 (supplier program) and new § 117.140 (preventive control management components).
117.155, 117.160, 117.165, and 117.170.	Move the more extensive verification requirements for validation, implementation and effectiveness, and reanalysis from the single proposed section (proposed § 117.150) to separate sections (proposed §§ 117.160, 117,165, and 117.170, respectively).	Improve clarity and readability.
117.170(a)(4)	Revise the requirements for reanalysis of the food safety plan after an unanticipated event in which a preventive control is not properly implemented to refer to the requirements for corrective actions in light of such an event rather than repeat the full text of those requirements for corrective actions.	Simplify the presentation of requirements and reduce redundancy in regulatory text for inter-related requirements.
117.170(c)	Specify the ''written food safety plan'' rather than the ''written plan.''.	Use the term ''food safety plan'' for consistency throughout subpart C.
117.170(c)	Specify ''document the basis for the conclusion that no revisions are needed'' rather than ''document the basis for the conclusion that no additional or revised preventive controls are needed''.	Improve clarity and readability.
117.170(e)	Specify ''You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding'' rather than ''FDA may require a reanalysis of the food safety plan to respond to new hazards and developments in scientific understanding.''	Improve clarity by specifying what the owner, operator, or agent in charge of the facility must do in certain circumstances rather than what FDA may require.
117.190	Change the title from ''Records required for subpart C'' to ''Implementation records''.	Accurately reflect the nature of the listed records after moving recordkeeping requirements for the food safety plan to § 117.126.
117.190(a)(3)(ii) and (iii)	Add ''verification of'' in front of ''monitoring'' and ''corrective actions''.	Distinguish these requirements for records applying to ''verification of monitoring'' and ''verification of corrective actions'' from other requirements for ''records of monitoring'' and ''records of corrective actions''.

XVI. Holding Human Food By-Products Intended for Use in Animal Food

Section 116 of FSMA (21 U.S.C. 2206) (Alcohol-Related Facilities) provides a rule of construction for certain facilities engaged in the manufacturing, processing, packing, or holding of alcoholic beverages and other food. Based on our interpretation of section 116, we proposed that subpart C would not apply with respect to alcoholic beverages at facilities meeting two specified conditions (proposed § 117.5(i); 78 FR 3646 at 3707 to 3709). We also proposed that subpart C would not apply with respect to food other than alcoholic beverages at facilities described in the exemption, provided such food is in prepackaged form that prevents direct human contact with the food and constitutes not more than 5 percent of the overall sales of the facility. However, we did note that in the case of a brewery manufacturing animal feed, section 418 of the FD&C Act would apply to the spent grain sold as animal feed once the spent grain is physically separated from the beer.

Some comments ask us to include the production of by-products of the alcoholic beverage manufacturing process (such as spent grains, distillers' grains, and grape pomace) within the exemption applicable to alcoholic beverages. These comments argue that the mere act of separating and disposing of those by-products by sale or otherwise should not trigger an

obligation to meet onerous and expensive food safety regulations.

The byproducts described in these comments appear to be products that would be used in food for animals rather than in human food. In response to the 2013 proposed animal food rule, we received many comments expressing concerns from brewers and distillers about whether that rule would allow them to continue providing spent grains for animal food. These spent grains are very commonly used as animal food, and are a subset of the much broader practice of human food manufacturers sending their peels, trimmings, and other by-products to local farmers or animal food manufacturers rather than to landfills.

Elsewhere in this issue of the **Federal Register**, we are issuing a supplemental notice of proposed rulemaking to amend the 2013 proposed animal food rule. Human food processors already complying with human food safety requirements would not need to implement additional preventive controls or Current Good Manufacturing Practice regulations when supplying a by-product (e.g., wet spent grains, fruit or vegetable peels, liquid whey) for animal food, except for proposed CGMPs to prevent physical and chemical contamination when holding and distributing the by-product (e.g., ensuring the by-product it is not comingled with garbage when being held or distributed). However, further processing a by-product for use as animal food (e.g., drying, pelleting, heat-treatment) would require compliance with the Preventive Controls for Animal Food rule. If any requirement regarding preventing physical and chemical contamination in human food by-products for use as animal food is finalized, it will be finalized as part of a final preventive controls rule for human food.

XVII. Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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). FDA has developed a PRIA that presents the benefits and costs of this proposed rule (Ref. 26). FDA believes that the proposed rule will be a significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 26) which is available at *http://www.regulations.gov* (enter Docket No. FDA–2011–N–0920), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses will need to implement a number of new preventive controls, FDA acknowledges that the final rules resulting from this proposed rule will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

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 or more; 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 is a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule will result in a 1-year expenditure that would exceed this amount.

XVIII. 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). The collections of information in the proposed rule have been submitted to OMB for review under Section 3507(d) of the Paperwork Reduction Act of 1995. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed Rule and Amendments to Proposed Rule

Description: FDA is proposing to amend its proposed regulation for Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food (CGMPs) to add requirements for domestic and foreign facilities that are required to register under section 415 of the FD&C Act. The amendments include potential provisions that would require facilities to establish and implement, as necessary, the following verification activities: product testing, environmental monitoring, and a supplier program. In addition, FDA is amending its proposed rule to require that the hazard analysis and risk-based preventive controls for human food take into account the possibility of economically motivated adulteration of food.

Description of Respondents: Section 418 of the FD&C Act is applicable to the owner, operator or agent in charge of a food facility required to register under section 415 of the FD&C Act. Generally, a facility is required to register if it

manufactures, processes, packs, or holds food for consumption in the United States. There are 97,646 such facilities; 74,900 of which are considered ''qualified'' facilities under a very small business definition with a $1 million threshold and thus have reduced requirements in regards to this rule-making.

The information collection estimate for the preventive controls for human food proposed rule may increase if the potential requirements (the addition of provisions for product testing, environmental monitoring, a supplier program, and identifying any potential hazards caused because of economically motivated adulteration) are finalized. The information collection burden was previously estimated to be 3,686,897 hours; the revised estimate includes an additional 74,692 hours should the newly proposed provisions be finalized. To see the calculations for these additional burden hours, see Table 9. For more information on the original calculation of the information burden estimate please refer to the proposed rule PRA (See Ref. 194 in Docket FDA–2011–N–0920).

Information Collection Burden Estimate

Supplemental Notice of Proposed Rulemaking Burden

FDA estimates the burden for this information collection as follows:

Recordkeeping Burden

Should the potential provisions in this proposed rule be included in any final rule, we estimate 1,867 facilities subject to subpart C—Hazard Analysis and Risk-Based Preventive Controls will choose to include environmental monitoring procedures as a verification activity under § 117.165(a)(3). These facilities would need to write-up such procedures; a one-time burden of 16 hours (5.33 hours annualized). We also estimate that 319 food manufacturers would choose to make use of product testing as a verification activity under § 117.165(a)(2). These facilities would create written procedures for such testing. This is a one-time potential burden of 16 hours (5.33 hours annualized). These potential burdens are shown in Table 9 rows 1 and 2.

Should the potential supplier program discussed above be finalized a receiving facility would establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a hazard that needs to be addressed in the food safety plan; this includes whenever the receiving facility determines that a hazard that needs to be addressed in the food safety plan is controlled before receipt of the raw material or ingredient. We estimate that should this potential provision be included, about 2,417 receiving facilities would incur a one-time burden of 16 hours (5.33 hours annualized) to write up such a program. This potential burden is shown in Table 9 row 3.

Should product testing, environmental monitoring, and supplier programs be finalized, records would need to be reviewed and maintained. We estimate that there are 689 facilities that would review and keep such records as a result. These records would require on average about 30 minutes a month to review and file. There are operating and maintenance costs associated with the creation of these records in the form of product testing costs ($6,400,000 annually) and environmental monitoring sampling costs ($7,200,000 annually) and audits and ingredient testing costs of/for suppliers ($7,000,000 audits annually + $1,000,000 testing annually). This potential burden is shown in Table 9 row 4.

Under § 117.130(b)(2)(iii) the supplemental notice of proposed rulemaking adds a new element to the required hazard analysis to be performed by each facility. Facilities must now also consider hazards that may be intentionally introduced for purposes of economic gain. We estimate that this added requirement will increase the one-time needed to write up the hazard analysis by 1 to 5 hours (average 3 hours; 1 hour annualized burden over 3 years) depending on facility size and number of processes for 16,000 facilities. The operating and maintenance costs associated with conducting the initial hazard analysis to assess the possibility of EMA are $5,100,000. These estimates are shown in Table 9 row 5.

We estimate on an annual basis that all 16,000 facilities will spend 0.1 hours per year updating the EMA section of their hazard analyses and that this recurring burden has an associated operating and maintenance cost of $1,300,000. This burden is shown in Table 9 row 6.

Some receiving facilities will have supplying facilities that meet the definition of ''qualified'' facilities; these facilities are not required to comply with subpart C of the proposed rule. In addition, in some cases the supplier may be a farm not subject to the requirements in part 112 regarding the raw material or ingredient that the receiving facility receives from the farm. Under proposed § 117.136(c)(3) and § 117.136(c)(4) these qualified facilities and exempt farms will need to create written assurances (to be given to their receiving facility customers) to describe the processes and procedures that the supplier is following to ensure the safety of the food. We estimate that there are 14,212 facility suppliers and farms that would need to create these documents. We estimate that it will take 2 hours annually to prepare such documentation. This burden is shown in Table 9, row 7.

TABLE 9—ESTIMATED POTENTIAL ANNUAL RECORDKEEPING BURDEN

21 CFR Part 117, subpart C	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping (in hours)	Total hours	Total operating and maintenance costs
Potential product testing written procedures (potential § 117.165(a)(2))	319	1	319	5.33	1,700	.....
Potential environmental monitoring written procedures (potential § 117.165(a)(3))	1,867	1	1,867	5.33	9,951	.....
Potential supplier program written (potential § 117.136(a)(2))	2,417	1	2,417	5.33	12,883	.....

TABLE 9—ESTIMATED POTENTIAL ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Part 117, subpart C	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours	Total operating and maintenance costs
§ 117.136(a)(3); § 117.165(a)(4) verification records	689	12	8,268	0.5	4,134	$21,600,000
§ 117.130(b)(2)(iii) written HA for EMA	16,000	1	16,000	1	16,000	$5,100,000
§ 117.130(b)(2)(iii) updating written HA for EMA	16,000	1	16,000	0.1	1,600	$1,300,000
§ 117.136(c)(3); § 117.136(c)(4) qualified or exempt suppliers assurances	14,212	1	14,212	2	28,424	
Total annual burden hours and costs					74,692	$28,000,000

Reporting Burden

There is no additional reporting burden under this supplemental notice of proposed rulemaking.

Third Party Disclosure Burden

There is no additional third party disclosure burden under this supplemental notice of proposed rulemaking.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Human Food.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

XIX. Analysis of Environmental Impact

FDA 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 (Ref. 35) (Ref. 36). Therefore, neither an environmental assessment nor an environmental impact statement is required.

XX. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

XXI. 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. These references are also available electronically at *http://www.regulatons.gov.* We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.

1. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day One. February 28, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm336329.htm* and in Docket No. FDA–2011–N–0920.
2. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day Two. March 1, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm336329.htm* and in Docket No. FDA–2011–N–0920.
3. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day One. March 11, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm339097.htm* and in Docket No. FDA–2011–N–0920.
4. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day Two. March 12, 2013.'' Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm339097.htm* and in Docket No. FDA–2011–N–0920.
5. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day One. March 27, 2013. Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm339096.htm* and in Docket No. FDA–2011–N–0920.
6. FDA, ''Transcript: FSMA Proposed Rules On Produce Safety And Preventive Controls For Human Food Facilities. Public Meeting, Day Two. March 28, 2013. Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm339096.htm* and in Docket No. FDA–2011–N–0920.
7. FDA, ''Record of Outreach Sessions on FDA Proposed Rules,'' 2013. Available in Docket No. FDA–2011–N–0920.
8. Taylor, M., ''Statement From FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers,'' December 19, 2013. Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm379397.htm.* Accessed and printed on January 29, 2014.
9. Taylor, M., ''Your Input Is Bringing Change to Food Safety Rules,'' December 19, 2013. Available at *http://blogs.fda.gov/fdavoice/index.php/2013/12/your-input-is-bringing-change-to-food-safety-rules.* Accessed and printed on January 29, 2014.
10. FDA, ''Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition),'' 2012.
11. FDA, ''Guidance for Industry: What You Need to Know About Registration of Food Facilities; Small Entity Compliance Guide,'' 2012.
12. FDA, ''Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport,

Distribute, Receive, Hold, or Import Food (Edition 5),'' 2012.
13. FDA, ''What You Need to Know About Establishment and Maintenance of Records,'' 2014.
14. FDA, ''Guidance for Industry: Antimicrobial Food Additives,'' 1999.
15. Cooperative Extension Service, Division of Agricultural Sciences and Natural Resources, Oklahoma State University; USDA, Federal Grain Inspection Service; USDA, Extension Service; USDA, Animal and Plant Health Inspection Service, ''Stored Product Management,'' Circular No. E–912, January 1995. Available at *http://entomology.k-state.edu/doc/extension—crop-pests/E912_All_Stored_Product_May3.pdf.* Accessed and printed on August 14, 2014.
16. FDA, ''Draft Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2012.
17. National Advisory Committee on Microbiological Criteria for Foods, ''Hazard Analysis and Critical Control Point Principles and Application Guidelines,'' Journal of Food Protection, 61:1246–1259, 1998.
18. FDA Memorandum, ''Product Testing,'' 2014.
19. Codex Alimentarius Commission, ''Hazard Analysis And Critical Control Point (HACCP) System And Guidelines For Its Application. Annex to CAC/RCP 1–1969 (Rev. 4–2003),'' 2003.
20. Codex Alimentarius Commission, ''General Principles of Food Hygiene, CAC/RCP 1–1969 (Rev. 4–2003),'' 2003.
21. Codex Alimentarius Commission, ''Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods, CAC/GL 61—2007,'' 2007.
22. Codex Alimentarius Commission, ''Code of Hygienic Practice for Powdered Formulae for Infants and Young Children, CAC/RCP 66–2008,'' 2008.
23. FDA Memorandum, ''Environmental Monitoring,'' 2014.
24. FDA Memorandum, ''Supplier Program,'' 2014.
25. U.S. Pharmacopeial Convention, ''U.S. Pharmacopeial Convention (USP) Food Fraud Database,'' March 6, 2014. Available at *http://www.usp.org/food-ingredients/food-fraud-database.* Accessed and printed on February 20, 2014.
26. FDA, ''FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. Preliminary Regulatory Impact Analysis,'' 2014.
27. FDA, ''Supporting Document for Recommended Maximum Level for Lead in Candy Likely to Be Consumed Frequently by Small Children,'' November, 2006.
28. FDA, ''Best Value, Inc., Recalls PRAN Bran[d] Turmeric Powder Due to Elevated Levels of Lead,'' October 16, 2013. Available at *http://www.fda.gov/safety/recalls/ucm371042.htm.* Accessed and printed on February 25, 2014.
29. LEAD Action News, ''Adulteration of Paprika in Hungary,'' 1995. Available at *http://www.lead.org.au/lanv3n3/lanv3n3-6.html.* Accessed and printed on February 20, 2014.
30. International Agency for Research on Cancer, ''Agents Classified by the IARC Monographs, Volumes 1–109,'' January 14, 2014. Available at *http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf.* Accessed and printed on August 13, 2014.
31. U.K. Food Standards Agency, ''Sudan I Timeline,'' February 24, 2005. *http://webarchive.nationalarchives.gov.uk/20111206002505/http://www.food.gov.uk/safereating/chemsafe/sudani/sudanitimeline.* Accessed and printed on February 25, 2014.
32. Congressional Research Service, ''Food Fraud and ''Economically Motivated Adulteration'' of Food and Food Ingredients,'' January 10, 2014. Available at *http://www.fas.org/sgp/crs/misc/R43358.pdf.* Accessed and printed on March 6, 2014.
33. Everstine, K., J. Spink, and S. Kennedy, ''Economically Motivated Adulteration (EMA) of Food: Common Characteristics of EMA Incidents,'' Journal of Food Protection, 76:723–735, 2013.
34. Muth, M.K., C. Zhen, M. Coglaiti, S. Karns, and C. Viator, ''Food Processing Sector Study, Contract HHSF 22320101745G, Task Order 13, Final Report,'' 2011.
35. FDA Memorandum, ''Re-proposal of select provisions of the Proposed Rule: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,'' 2014.
36. FDA Memorandum, ''Modernization of food current Good Manufacturing Practices (cGMP) as required by the Food Safety Modernization Act of 2011,'' 2011.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 117

Food packaging, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I, as proposed to be amended on January 16, 2013 (78 FR 3646), be further amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.227 is amended by revising the definitions for ''Farm'', ''Harvesting'', ''Holding'', and ''Packing'' to read as follows:

§ 1.227 What definitions apply to this subpart?

* * * * *

Farm means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes establishments that, in addition to these activities:

(1) Pack or hold raw agricultural commodities;

(2) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (3)(ii)(A) of this definition; and

(3) Manufacture/process food, provided that:

(i) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(ii) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(A) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(B) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and

cooling raw agricultural commodities grown on a farm are examples of harvesting.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 3. Section 1.328 is amended by revising the definitions for ''Farm'', ''Harvesting'', ''Holding'', and ''Packing'' to read as follows:

§ 1.328 What definitions apply to this subpart?

* * * * *

Farm means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term ''farm'' includes establishments that, in addition to these activities:

(1) Pack or hold raw agricultural commodities;

(2) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (3)(ii)(A) of this definition; and

(3) Manufacture/process food, provided that:

(i) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(ii) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(A) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(B) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 4. 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.

■ 5. Section 16.1 is amended by revising the entry for ''§§ 117.251 through 117.284'' in paragraph (b)(2) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§§ 117.251 through 117.287 (part 117, subpart E), relating to withdrawal of an exemption applicable to a qualified facility.

* * * * *

PART 117—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

■ 6. The authority citation for part 117, as proposed to be added on January 16, 2013 (78 FR 3646), continues to read as follows:

Authority: 21 U.S.C. 331, 342, 343, 350d note, 350g note, 371, 374; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions

§ 117.3 [Amended]

■ 7. Section 117.3 is amended as follows:

■ a. By removing the definitions for ''cross-contact'', ''hazard reasonably likely to occur'', and ''reasonably foreseeable hazard'';

■ b. By adding definitions for ''allergen-cross contact'', ''known or reasonably foreseeable hazard'', ''pathogen'', ''qualified auditor'', ''receiving facility'', ''significant hazard'', ''supplier'', and ''you ''; and

■ c. By revising the definitions for ''environmental pathogen'', ''harvesting'', ''hazard,'' ''holding'', ''packing'', and ''very small business''.

The additions and revisions read as follows:

§ 117.3 Definitions.

* * * * *

Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

* * * * *

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

* * * * *

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, field coring, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that has the potential to be associated with the facility or the food.

* * * * *

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

* * * * *

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function as required by § 117.180(c)(2).

* * * * *

Receiving facility means a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

* * * * *

Significant hazard means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

* * * * *

Supplier means the establishment that manufactures/processes the food, raises the animal, or harvests the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

* * * * *

Very small business means, for purposes of this part, a business that has less than $1,000,000 in total annual sales of human food, adjusted for inflation.

* * * * *

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

■ 8. Amend § 117.5 by revising paragraph (k) to read as follows:

§ 117.5 Exemptions.

* * * * *

(k)(1) Except as provided by paragraph (k)(2) of this section, subpart B of this part does not apply to any of the following:

(i) ''Farms'' (as defined in § 1.227 of this chapter);

(ii) Fishing vessels that are not subject to the registration requirements of part 1, subpart H of this part in accordance with § 1.226(f);

(iii) The holding or transportation of one or more ''raw agricultural commodities,'' as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act;

(iv) Activities of ''farm mixed-type facilities'' (as defined in § 1.227) that fall within the definition of ''farm''; or

(v) Hulling, shelling, and drying nuts (without manufacturing/processing, such as roasting nuts).

(2) If a ''farm'' or ''farm mixed-type facility'' dries/dehydrates raw agricultural commodities to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B or with the applicable requirements for packing and holding in part 112 of this chapter.

■ 9. Revise subpart C to read as follows:

Subpart C—Hazard Analysis and Risk-Based Preventive Controls

Sec.

117.126 Food safety plan.
117.130 Hazard analysis.
117.135 Preventive controls.
117.136 Supplier program.
117.137 Recall plan.
117.140 Preventive control management components.
117.145 Monitoring.
117.150 Corrective actions *and corrections.*
117.155 Verification.
117.160 Validation.
117.165 Verification of implementation and effectiveness.
117.170 Reanalysis.
117.180 Requirements applicable to a qualified individual and a qualified auditor.
117.190 Implementation records.

§ 117.126 Food safety plan.

(a) Requirement for a food safety plan. (1) You must prepare, or have prepared, and implement a written food safety plan.

(2) The food safety plan must be prepared, or its preparation overseen, by one or more qualified individuals.

(b) Contents of a food safety plan. The written food safety plan must include:

(1) The written hazard analysis as required by § 117.130(a)(2);

(2) The written preventive controls as required by § 117.135(b);

(3) The written supplier program as required by § 117.136(a)(2);

(4) The written recall plan as required by § 117.137(a); and

(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);

(6) The written corrective action procedures as required by § 117.150(a)(1); and

(7) The written verification procedures as required by § 117.165(b).

(c) Records. The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 117.130 Hazard analysis.

(a) Requirement for a hazard analysis. (1) You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are significant hazards.

(2) The hazard analysis must be written.

(b) Hazard identification. The hazard identification must consider:

(1) Hazards that include:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

(iii) Physical hazards; and

(2) Hazards that may be present in the food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced; or

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) Hazard evaluation. (1)(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the facility and equipment;

(iii) Raw materials and ingredients;

(iv) Transportation practices;

(v) Manufacturing/processing procedures;

(vi) Packaging activities and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors.

§ 117.135 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that significant hazards will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(2) Preventive controls required by paragraph (a)(1) of this section include, as appropriate to the facility and the food:

(i) Controls at critical control points (CCPs), if there are any CCPs; and

(ii) Controls, other than those at CCPs, that are also appropriate for food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and the food:

(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the applicable control:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a significant hazard.

(2) Food allergen controls. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:

(i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

(ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(4) Supplier controls. Supplier controls include the supplier program as required by § 117.136.

(5) Recall plan. Recall plan as required by § 117.137.

(6) Other controls. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 117.136 Supplier program.

(a) Supplier program. (1)(i) Except as provided in paragraph (a)(1)(ii) of this section, the receiving facility must establish and implement a risk-based supplier program for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient.

(ii) The receiving facility is not required to establish and implement a supplier program for raw materials and ingredients for which:

(A) There are no significant hazards;

(B) The preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards; or

(C) The receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that

will significantly minimize or prevent the hazard.

(2) The supplier program must be written.

(3) The supplier program must include:

(i) Verification activities, as appropriate to the hazard, and documentation of these activities, to ensure raw materials and ingredients are received only from suppliers approved for control of the hazard(s) in that raw material or ingredient (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or ingredients the receiving facility subjects to adequate verification activities before acceptance for use); and

(ii) Verification activities and documentation of these activities, as required by paragraph (b) of this section, to verify that:

(A) The hazard is significantly minimized or prevented;

(B) The incoming raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act: and

(C) The incoming raw material or ingredient is produced in compliance with the requirements of applicable FDA food safety regulations.

(4) When supplier verification activities are required under paragraph (c) of this section for more than one type of hazard in a food, the receiving facility must conduct the verification activity or activities appropriate for each of those hazards.

(5) For some hazards, in some situations under paragraph (b) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

(b) Determination and documentation of the appropriate verification activities. In determining and documenting the appropriate verification activities, the receiving facility must consider the following:

(1) The hazard analysis, including the nature of the hazard, applicable to the raw material and ingredients;

(2) Where the preventive controls for those hazards are applied for the raw material and ingredients—such as at the supplier or the supplier's supplier;

(3) The supplier's procedures, processes, and practices related to the safety of the raw material and ingredients;

(4) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of the food;

(5) The supplier's food safety performance history relevant to the raw materials or ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and

(6) Any other factors as appropriate and necessary. Examples of factors that a receiving facility may determine are appropriate and necessary are storage and transportation practices.

(c) Supplier verification activities for raw materials and ingredients. (1) Except as provided in paragraph (c)(2) or (3) of this section, the receiving facility must conduct and document one or more of the following supplier verification activities as determined by the receiving facility under paragraph (b) of this section, for each supplier before using the raw material or ingredient and periodically thereafter:

(i) Onsite audits;

(ii) Sampling and testing of the raw material or ingredient, which may be conducted by either the supplier or receiving facility.

(iii) Review by the receiving facility of the supplier's relevant food safety records; or

(iv) Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier.

(2)(i) Except as provided by paragraph (c)(2)(ii) of this section, when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the receiving facility must have documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier and at least annually thereafter.

(ii) The requirements of paragraph (c)(2)(i) of this section do not apply if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(3) If a supplier is a qualified facility as defined by § 117.3, the receiving facility need not comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the supplier is a qualified facility as defined by § 117.3; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. The written assurance must include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

(4) If a supplier is a farm that is not subject to the requirements established in part 112 of this chapter in accordance with § 112.4 regarding the raw material or ingredient that the receiving facility receives from the farm, the receiving facility does not need to comply with paragraphs (c)(1) and (2) of this section if the receiving facility:

(i) Documents, at the end of each calendar year, that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(d) Onsite audit. (1) An onsite audit of a supplier must be performed by a qualified auditor.

(2) If the raw material or ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any, including its implementation, for the hazard being audited.

(e) Substitution of inspection by FDA or an officially recognized or equivalent food safety authority. (1) Instead of an onsite audit, a receiving facility may rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted.

(2) For inspections conducted by the food safety authority of a country whose

food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(f) Supplier non-conformance. If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as significant, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(g) Records. The receiving facility must document the following in records and review such records in accordance with § 117.165(a)(4).

(1) The written supplier program;

(2) Documentation of the appropriate verification activities;

(3) The annual written assurance that a receiving facility's customer who is controlling a significant hazard has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard;

(4) Documentation demonstrating that products are received only from approved suppliers;

(5) Documentation of an onsite audit. This documentation must include:

(i) Documentation of audit procedures;

(ii) The dates the audit was conducted;

(iii) The conclusions of the audit;

(iv) Corrective actions taken in response to significant deficiencies identified during the audit; and

(v) Documentation that the audit was conducted by a qualified auditor.

(6) Records of sampling and testing. These records must include:

(i) Identification of the raw material or ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing.

(7) Records of the review by the receiving facility of the supplier's relevant food safety records. These records must include:

(i) The date(s) of review;

(ii) Corrective actions taken in response to significant deficiencies identified during the review; and

(iii) Documentation that the review was conducted by a qualified individual.

(8) Records of other appropriate supplier verification activities based on the risk associated with the ingredient.

(9) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled;

(10) Documentation of an alternative verification activity for a supplier that is a qualified facility, including:

(i) The documentation that the supplier is a qualified facility as defined by § 117.3; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(11) Documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or ingredient that is not subject to part 112 of this chapter, including:

(i) The documentation that the raw material or ingredient provided by the supplier is not subject to part 112 of this chapter; and

(ii) The written assurance that the supplier is producing the raw material or ingredient in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

(12) Evidence of an inspection of the supplier by FDA or the food safety authority of another country.

(13) Documentation of actions taken with respect to supplier non-conformance.

§ 117.137 Recall plan.

For food with a significant hazard:

(a) You must establish a written recall plan for the food.

(b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food).

§ 117.140 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control:

(1) Monitoring in accordance with § 117.145;

(2) Corrective actions and corrections in accordance with § 117.150; and

(3) Verification in accordance with § 117.155.

(b) The supplier program established in § 117.136 is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supplier program taking into account the nature of the hazard controlled before receipt of the raw material or ingredient:

(1) Corrective actions and corrections in accordance with § 117.150, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 117.165(a)(4); and

(3) Reanalysis in accordance with § 117.170.

(c) The recall plan established in § 117.137 is not subject to the requirements of paragraph (a) of this section.

§ 117.145 Monitoring.

(a) As appropriate to the preventive control, you must:

(1) Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls; and

(2) Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(b) All monitoring of preventive controls in accordance with this section

must be documented in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 117.165(a)(4)(i).

§ 117.150 Corrective actions and corrections.

(a) Corrective action procedures. As appropriate to the preventive control, except as provided by paragraph (c) of this section:

(1)(i) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented.

(ii) The corrective action procedures required by paragraph (a)(1)(i) of this section must include procedures to address, as appropriate:

(A) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and

(B) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected food is evaluated for safety; and

(iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) Corrective action in the event of an unanticipated food safety problem. (1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraph (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a specific corrective action procedure has not been established;

(ii) A preventive control is found to be ineffective; or

(iii) A review of records in accordance with § 117.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and

(ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required.

(c) Corrections applicable to food allergen controls and sanitation controls. You do not need to comply with the requirements of paragraphs (a) and (b) of this section for conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii) if you take action, in a timely manner, to correct such conditions and practices.

(d) Documentation. All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with § 117.155(a)(3) and records review in accordance with § 117.165(a)(4)(i).

§ 117.155 Verification.

(a) Verification activities. Verification activities must include, as appropriate to the preventive control:

(1) Validation in accordance with § 117.160.

(2) Verification that monitoring is being conducted as required by § 117.140 (and in accordance with § 117.145).

(3) Verification that appropriate decisions about corrective actions are being made as required by § 117.140 (and in accordance with § 117.150).

(4) Verification of implementation and effectiveness in accordance with § 117.165; and

(5) Reanalysis in accordance with § 117.170.

(b) Documentation. All verification activities conducted in accordance with this section must be documented in records.

§ 117.160 Validation.

(a) Except as provided by paragraph (b)(3) of this section, you must validate that the preventive controls identified and implemented in accordance with § 117.135 to control the significant hazards are adequate to do so as appropriate to the nature of the preventive control.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a qualified individual:

(i) Prior to implementation of the food safety plan or, when necessary, during the first 6 weeks of production; and

(ii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include collecting and evaluating scientific and technical information (or, when such information is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the significant hazards; and

(3) Need not address:

(i) The food allergen controls in § 117.135(c)(2);

(ii) The sanitation controls in § 117.135(c)(3);

(iii) The supplier program in § 117.136; and

(iv) The recall plan in § 117.137.

§ 117.165 Verification of implementation and effectiveness.

(a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the significant hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control:

(1) Calibration of process monitoring instruments and verification instruments;

(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within a week after the records are created.

(ii) Records of calibration, product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are created.

(b) Written procedures. As appropriate to the facility, the food, and

the nature of the preventive control, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments as required by paragraph (a)(1) of this section.

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

§ 117.170 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan:

(1) At least once every 3 years;

(2) Whenever a significant change is made in the activities conducted at your facility if the change creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(3) Whenever you become aware of new information about potential hazards associated with the food;

(4) Whenever appropriate after an unanticipated food safety problem in accordance with § 117.150(b); and

(5) Whenever you find that a preventive control is ineffective.

(b) You must complete the reanalysis required by paragraph (a) of this section and implement any additional preventive controls needed to address the hazard identified, if any, before the change in activities at the facility is operative or, when necessary, during the first 6 weeks of production.

(c) You must revise the written food safety plan if a significant change is made or document the basis for the conclusion that no revisions are needed.

(d) A qualified individual must perform (or oversee) the reanalysis.

(e) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

§ 117.180 Requirements applicable to a qualified individual and a qualified auditor.

(a) One or more qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(a)(2));

(2) Validation of the preventive controls (§ 117.160(b)(1));

(3) Review of records (§ 117.165(a)(4)); and

(4) Reanalysis of the food safety plan (§ 117.170(d)).

(b) A qualified auditor must conduct an onsite audit (§ 117.136(d)).

(c)(1) To be a qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained by a combination of training and experience appropriate to perform the auditing function.

(d) All applicable training must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 117.190 Implementation records.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Records that document the monitoring of preventive controls;

(2) Records that document corrective actions;

(3) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(4) Records that document the supplier program; and

(5) Records that document applicable training for the qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

■ 10. Revise § 117.251 to read as follows:

§ 117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

(a) FDA may withdraw the exemption applicable to a qualified facility under § 117.5(a):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw an exemption applicable to a qualified facility, FDA:

(1) May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak, including, a warning letter, recall, administrative detention, suspension of registration, import alert, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 10 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

■ 11. Revise § 117.254 to read as follows:

§ 117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

■ 12. Amend § 117.257 by revising paragraph (d) to read as follows:

§ 117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.

* * * * *

(d) A statement that the facility must either:

(1) Comply with subpart C of this part on the date that is 120 calendar days after the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

* * * * *

■ 13. Amend § 117.260 by revising paragraphs (a) and (c) to read as follows:

§ 117.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

(a) If you receive an order under § 117.254 to withdraw an exemption applicable to that facility under § 117.5(a), you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order; or

(2) Appeal the order within 10 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

* * * * *

(c) If you appeal the order, and FDA confirms the order, you must comply with applicable requirements of this part within 120 calendar days of the date of receipt of confirmation of the order.

■ 14. Amend § 117.264 by revising paragraphs (a) introductory text and (a)(1) to read as follows:

§ 117.264 Procedure for submitting an appeal.

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 117.5(a), you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date of receipt of the order;

* * * * *

■ 15. Amend § 117.267 by revising paragraph (a) to read as follows:

§ 117.267 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 117.264 within 10 calendar days of the date of receipt of the order.

* * * * *

■ 16. Add § 117.287 to subpart E to read as follows:

§ 117.287 Reinstatement of an exemption that was withdrawn.

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that a facility has adequately resolved problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or on the request of a facility, reinstate the exemption.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(2) Present data and information to demonstrate that you have adequately resolved the problems with the conditions or conduct that are material to the safety of the food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.

(c) If your exemption was withdrawn under § 117.251(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 117.5(a), and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your exemption was withdrawn under both § 117.251(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding, and you may ask FDA to reinstate your exemption under § 117.5(a) in accordance with the requirements of paragraph (b) of this section.

■ 17. Amend § 117.305 by revising paragraph (b) to read as follows:

§ 117.305 General requirements applying to records.

* * * * *

(b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

* * * * *

■ 18. Add § 117.330 to subpart F to read as follows:

§ 117.330 Use of existing records.

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart F. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart F.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

Dated: September 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix

The proposed rule that is the subject of this document includes a discussion of our reconsideration of the classification of specific activities as harvesting, packing, holding, or manufacturing/processing, when conducted on farms or on farm mixed-type facilities (see the discussion of the proposed additional example of a harvesting activity in the definition of ''harvesting'' in section V.C and the discussion and Table 5 in section VII.C). Table 1 in this Appendix compares the classification of on-farm activities as harvesting, packing, holding, or manufacturing/processing in the 2013 proposed preventive controls rule to our current thinking on the classification of these on-farm activities as a result of the proposed revisions to the ''farm'' definition. As can be seen in Table 1, several on-farm activities can be classified in more than one way, and most of the changes in activity classification merely reflect additional activities (relative to the 2013 proposed preventive controls rule) that could be classified in more than one way.

TABLE 1—CLASSIFICATION OF ACTIVITIES CONDUCTED ON-FARMS AND FARM MIXED-TYPE FACILITIES

Classification	Examples using the 2013 proposed ''farm'' definition *	Examples using the proposed revisions to the ''farm'' definition
Harvesting: Activities traditionally performed by farms for the purpose of removing RACs from growing areas and preparing them for use as food. Harvesting does not include activities that change a RAC into processed food.	• Cooling RACs. • *Fermenting cocoa beans and coffee beans** (would change to ''holding''). • Filtering RACs. • Gathering RACs. • Removing stems and husks from RACs. • Shelling RACs. • Sifting RACs. • Threshing RACs. • Trimming of outer leaves from RACs. • Using pesticides in wash water on RACs. • Washing RACs.	• Cooling RACs. • *Field coring RACs ** (new example, not previously classified). • Filtering RACs. • Gathering RACs. • Removing stems and husks from RACs. • Shelling RACs. • Sifting RACs. • Threshing RACs. • Trimming outer leaves from RACs. • Using pesticides in wash water on RACs. • Washing RACs.
Packing: Placing food in a container other than packaging the food and activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a RAC into a processed food.	• Coating RACs with wax/oil/resin for the purpose of storage or transport. • *Drying RACs for the purpose of storage or transport** (would change to only be classified as ''holding''). • Labeling RACs. • Mixing RACs. • *Packaging a farm's or farm mixed-type facility's own RACs** (would no longer be limited to ''own RACs''). • Putting RACs or individual unit cartons into non-consumer containers. • Sorting/grading/culling RACs. • Stickering RACs.	• Coating RACs with wax/oil/resin for the purpose of storage or transport. • *Cooling RACs** (add'l classification) ***. • *Filtering RACs** (add'l classification). • Labeling RACs. • Mixing RACs. • *Packaging RACs regardless of ownership** (expanded to include others' RACs). • Putting RACs or individual unit cartons into non-consumer containers. • *Removing stems and husks from RACs** (add'l classification). • *Sifting RACS** (add'l classification). • Sorting/culling/grading RACs. • Stickering RACs. • *Using pesticides in wash water on RACs** (add'l classification). • *Washing RACs** (add'l classification).
Holding: Storage of food and activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, and activities performed as a practical necessity for the distribution of that food (such as blending of the same commodity and breaking down pallets)). Holding does not include activities that change a RAC into a processed food.	• Drying/dehydrating RACs during storage (incidental to *packing or* storing when the drying/dehydrating does not create a distinct commodity) ** (would no longer be incidental to packing, would only be incidental to holding). • Fumigating RACs during storage. • Sorting/culling/grading RACs. • Storing food.	• *Cooling RACs ** (add'l classification). • Drying/dehydrating RACs (incidental to storing when the drying/dehydrating does not create a distinct commodity). • *Fermenting cocoa beans and coffee beans* (change from previous classification as harvesting). • Fumigating RACs during storage to control pests. • Sorting/culling/grading RACs. • Storing food.

TABLE 1—CLASSIFICATION OF ACTIVITIES CONDUCTED ON-FARMS AND FARM MIXED-TYPE FACILITIES—Continued

Classification	Examples using the 2013 proposed "farm" definition *	Examples using the proposed revisions to the "farm" definition
Manufacturing/Processing: Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.	• Artificial ripening. • Baking. • Boiling/Evaporating. • Bottling. • Canning. • Chopping. • Coating RACs for purposes other than storage/transport. • Cooking. • Cooling. • Coring. • Cracking. • Crushing. • Cutting. • Distilling. • Drying/dehydrating RACS to create a distinct commodity. • Eviscerating. • Extracting. • Formulating. • Freezing. • Grinding. • Homogenizing. • Infusing. • Irradiating. • Labeling (other than RACs). • Milling. • Mixing. • Packaging (other than RACs). • Pasteurizing. • Peeling. • Rendering. • Roasting. • Salting. • Slaughtering and post-slaughter operations. • Slicing. • Smoking. • Sorting, culling, grading (not incidental to packing or holding). • Trimming. • Washing. • Waxing.	• Artificial ripening. • Baking. • Boiling/Evaporating. • Bottling. • Canning. • Chopping. • Coating RACs for purposes other than storage/transport. • Cooking. • Cooling. • Coring (*except field coring*) ** (because field coring would be newly classified as harvesting). • Cracking. • Crushing. • Cutting. • Distilling. • Drying/dehydrating RACs to create a distinct commodity. • Eviscerating. • Extracting. • Formulating. • Freezing. • Grinding. • Homogenizing. • Infusing. • Irradiating. • Labeling (other than RACs). • Milling. • Mixing. • Packaging (other than RACs). • Pasteurizing. • Peeling. • Rendering. • Roasting. • Salting. • Slaughtering and post-slaughter operations. • Slicing. • Smoking. • Sorting, culling, grading (not incidental to packing or holding). • Trimming. • Washing. • Waxing.

* Examples were included in Table 4, Table 5, and/or Proposed §§ 117.3 and 117.5(g) and (h) in the 2013 Proposed Preventive Controls Rule and/or in the Draft Risk Assessment (Ref. 1).

** Activities listed in italics represent a change between the 2013 "farm" definition and our current thinking in light of the proposed revisions to the "farm" definition.

*** Add'l = additional.

The following reference has 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. This reference is also available electronically at *http://www.regulatons.gov.*

1. FDA, "Draft Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm," 2012.

[FR Doc. 2014–22446 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL REGISTER

Vol. 79 Monday,

No. 188 September 29, 2014

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2011–N–0143]

RIN 0910–AG64

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; supplemental notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is revising certain provisions of the proposed rule, issued in July 2013, on foreign supplier verification programs (FSVPs) for importers of food for humans and animals. We are primarily revising the proposed requirements concerning compliance status review of food and foreign suppliers, hazard analysis, and supplier verification activities. We are taking this action in response to the extensive public input we have received regarding these provisions and in coordination with revisions we are concurrently making to the proposed rule on current good manufacturing practice (CGMP) and hazard analysis and risk-based preventive controls for human food. We are seeking public comment on the revised proposed FSVP regulations. We are reopening the comment period on the proposed rule only with respect to the specific provisions identified in this **Federal Register** document.

DATES: Submit either electronic or written comments on the supplemental notice of proposed rulemaking by December 15, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 15, 2014 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA–2011–N–0143) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, 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.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4614; or Domenic Veneziano, Office of Enforcement and Import Operations (ELEM–3108), Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, 301–796–6673.

SUPPLEMENTARY INFORMATION:

Table of Contents

Executive Summary
- Purpose of the Supplemental Notice of Proposed Rulemaking
- Summary of the Revisions to the Proposed Rule
- Costs and Benefits

I. Background
- A. Proposed Rule on FSVPs
- B. Public Comments
- C. Alignment of FSVP Regulations With Potential Supplier Verification Provisions in the Proposed Preventive Controls Regulations
- D. Decision To Issue Supplemental Notice of Proposed Rulemaking Regarding Certain Preventive Controls Requirements
- E. Scope of FSVP Supplemental Notice of Proposed Rulemaking

II. Revisions to the Proposed Rule
- A. Compliance Status Review
- B. Hazard Analysis
- C. Supplier Verification
- D. Definitions of Very Small Importers and Very Small Foreign Suppliers
- E. Other Related Revisions

III. Preliminary Regulatory Impact Analysis
IV. Paperwork Reduction Act of 1995
V. Analysis of Environmental Impact
VI. Comments
VII. References

Executive Summary

Purpose of the Supplemental Notice of Proposed Rulemaking

We are revising certain provisions of the proposed rule, issued in July 2013, on FSVPs for importers of food for humans and animals. The revisions primarily concern the proposed rule's requirements on compliance status review of food and foreign suppliers, hazard analysis, and supplier verification activities. We are issuing these revisions in response to extensive public input we have received regarding these provisions and in alignment with certain revisions we are concurrently making to the proposed rule on preventive controls for human food.

Summary of the Revisions to the Proposed Rule

One revision to the proposed rule would, consistent with many comments we received, delete the previously proposed section on compliance status review but incorporate some of the provisions into the requirements concerning hazard analysis and evaluation of certain risk factors in determining appropriate foreign supplier verification and related activities.

Another revision would modify some of the previously proposed hazard analysis requirements. In accordance with several comments we received, as well as the revised hazard analysis provisions and new supplier program provisions in the revised preventive controls proposal that we are concurrently issuing, the revised FSVP proposal changes the requirement to analyze hazards that are reasonably likely to occur to a requirement to analyze known or reasonably foreseeable hazards to determine if they are significant. Under the revised proposal, a significant hazard would be defined as a known or reasonably foreseeable hazard in a food for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records), as appropriate to the food, the facility, and the control.

Other changes related to the proposed hazard analysis requirements that are consistent with the proposed hazard analysis requirements in the preventive controls proposal include requiring analysis of hazards that may be intentionally introduced for purposes of economic gain, requiring evaluation of environmental pathogens in certain ready-to-eat food, and minor changes to other hazard evaluation factors.

Another revision to the previous proposed rule would specify that, along with the hazard analysis, the importer must consider other factors primarily related to supplier risks in determining appropriate supplier verification and related activities before importing a food from a particular foreign supplier and thereafter when the importer becomes aware of new information about these risks. These proposed changes respond to numerous comments stating that industry best practice is to base supplier verification activities on an assessment of information about the risks presented by a food as well as by the supplier of the food, rather than focusing primarily on hazards inherent in food. Under the revised proposal, in addition to the hazard analysis, the importer would be required to consider the following in approving suppliers and determining appropriate verification activities:

- The entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier's raw material or ingredient supplier.
- The foreign supplier's procedures, processes, and practices related to the safety of the food.
- Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert.
- The foreign supplier's food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food, and the supplier's record of correcting problems.
- Any other factors as appropriate and necessary, such as storage and transportation practices.

We also are revising certain proposed requirements regarding supplier verification measures themselves and related activities. Instead of maintaining a list of their foreign suppliers, importers would be required to establish and follow procedures to ensure that they import foods only from foreign suppliers that they have approved (except, when necessary and appropriate, from unapproved suppliers on a temporary basis). Consistent with the revised proposal's focus on a broader evaluation of risks, we are proposing that, rather than being designed to ensure that identified hazards are adequately controlled, the purpose of importers' supplier verification activities should be to provide adequate assurances that the foreign supplier produces the food in a manner consistent with FDA's regulations on preventive controls or produce safety, if either is applicable to the foreign supplier, and to assure that the food is not adulterated and not misbranded regarding allergen labeling. This approach is consistent with the purpose for foreign supplier verification specified in section 805(a)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 384a).

After considering comments on the alternative proposals we presented in the 2013 proposed rule regarding supplier verification activities, we are proposing an approach that gives importers the flexibility to determine appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods. Under the revised proposal, based on the risk evaluation the importer conducts, the importer would be required to determine and document what supplier verification activities are appropriate for a particular food and foreign supplier, as well as the frequency with which those activities should be conducted. Appropriate supplier verification activities could include onsite auditing of the foreign supplier, sampling and testing of food, review of the supplier's food safety records, or some other procedure determined to be appropriate based on the identified risks.

However, the revised proposal also specifies that, when there is a hazard in a food that could result in serious adverse health consequences or death to humans or animals (a ''SAHCODHA'' hazard), an importer would need to conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer specifically determined that some other supplier verification activity and/or less frequent auditing would adequately address the identified risks. This requirement would establish a clear verification standard for these most serious food hazards yet permit importers to employ a different approach if they can confirm that the alternative approach will provide adequate assurance that the identified risks are addressed.

We tentatively conclude that this revised proposal regarding supplier verification activities strikes an appropriate balance between granting importers the flexibility to adopt risk-based verification measures while increasing the likelihood that importers will apply the most rigorous verification measures to the most serious risks.

The revised proposal also would specify that if a foreign supplier is a farm that is not subject to the produce safety regulations, the importer of food from the supplier would not be subject to the ''standard'' verification requirements previously noted but would instead be required to obtain written assurance biennially that the supplier is producing the food in compliance with the FD&C Act. This proposed change reflects the different treatment of food from such farms under the produce safety regulations and would be consistent with the potential requirement for a supplier program in the preventive controls regulations.

In addition, we are proposing to add provisions stating that when importers or their customers are in compliance with the requirements on supplier programs in the proposed preventive controls regulations, the importers would be deemed in compliance with most of the FSVP requirements (in cases involving customer compliance with the supplier program requirements, the importer would need to obtain written assurance of compliance annually from the customer). This proposed change is consistent with our intent, stated in the FSVP and preventive controls proposed rules, to avoid imposing redundant regulatory requirements on food importers who also are food facilities subject to the preventive controls regulations.

Finally, we are increasing, from $500,000 to $1 million, the annual sales ceiling used in the proposed definition of ''very small importer'' and ''very small foreign supplier'' to be consistent with our revised approach to the proposed definition of ''very small business'' under the proposed preventive controls regulations.

Costs and Benefits

We summarize the annualized costs (over a 10-year time period discounted at both 3 percent and 7 percent) of the revised proposed rule in the following table.

	3 percent	7 percent
Annualized Cost	$396,780,114	$397,478,400
Reduction in Cost Relative to Original Option 1	76,191,228	75,901,638
Reduction in Cost Relative to Original Option 2	64,627,341	64,343,306

The reduction in FSVP requirements for importers who also would be subject to the preventive controls regulations, and other proposed changes in the requirements, results in a cost savings of $76 million per year (compared to Option 1 of the 2013 proposed rule). The overall potential net benefit from the revised proposed rule is estimated at $714 million per year. These figures are based on a 3 percent discount rate, a scenario for inflation, over 10 years. (The figures are the same for a 7 percent discount rate.)

Although the FSVP proposed rule would not itself establish safety requirements for food manufacturing and processing, it would benefit the public health by helping to ensure that imported food is produced in a manner consistent with other applicable food safety regulations. The Preliminary Regulatory Impact Analyses for the proposed rules on preventive controls for human food and standards for produce safety consider and analyze the number of illnesses and deaths that the proposed regulations are aimed at reducing. The greater the compliance with those regulations, the greater the expected reduction in illnesses and deaths as well as the costs associated with them. The FSVP regulations would be an important mechanism for improving and ensuring compliance with the previously noted food safety regulations as they apply to imported food. For this reason, we account for the public health benefits of the FSVP proposed rule in the preventive controls, produce safety, and other applicable food safety regulations instead of in this rule.

I. Background

A. Proposed Rule on FSVPs

On July 29, 2013, FDA published in the **Federal Register** a proposed rule entitled ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals'' (''the 2013 FSVP proposed rule'' or ''the previous proposed rule'') (78 FR 45730) to require importers to perform certain activities to help ensure that the food they bring into the United States is produced in a manner consistent with U.S. standards.

FDA proposed the FSVP regulations as part of our implementation of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). Section 301 of FSMA adds section 805 to the FD&C Act to require persons who import food into the United States to perform risk-based foreign supplier verification activities for the purpose of verifying the following: (1) The food is produced in compliance with section 418 (concerning hazard analysis and risk-based preventive controls) or 419 (concerning standards for the safe production and harvesting of certain fruits and vegetables that are raw agricultural commodities (RACs)) of the FD&C Act (21 U.S.C. 350g and 350h), as appropriate; (2) the food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and (3) the food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning food allergen labeling). Section 805(c) of the FD&C Act directs FDA to issues regulations on the content of importers' FSVPs.

The FSVP proposed rule would require food importers to adopt programs to ensure that the food they import meets the previously noted statutory standards. The previous proposed rule would have required importers to take the following actions as part of their FSVPs:

- Use a qualified individual to perform most FSVP activities.
- Review the compliance status of foods and foreign suppliers.
- Analyze the hazards reasonably likely to occur with foods.
- Determine and perform appropriate foreign supplier verification activities for foods. As discussed in more detail in section II.C.5, the proposal set forth two optional approaches to verification requirements that differ primarily with respect to the verification activities that importers must conduct when a SAHCODHA hazard is present in a food.
- Review complaints, conduct investigations of adulterated or misbranded food, take corrective actions when appropriate, and modify the FSVP when it is determined to be inadequate.
- Reassess the effectiveness of the FSVP.
- Ensure that information identifying the importer is submitted upon entry of a food into the United States.
- Maintain records of FSVP procedures and activities.

In addition to these ''standard'' FSVP requirements that would apply to most food importers, the previous proposed rule included modified requirements for the following:

- Importers of dietary supplements and dietary supplement components.
- Very small importers and importers of food from very small foreign suppliers.
- Importers of food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to the U.S. food safety system.

B. Public Comments

We requested comments on the FSVP proposed rule by November 26, 2013. We extended the comment period for the proposed rule and its information collection provisions (which are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520)) (78 FR 69602, November 20, 2013). The comment period for the proposed rule closed on January 27, 2014.

After we published the FSVP proposed rule in July 2013, we held two public meetings to solicit stakeholder and public comments on the proposed rule, inform the public about the rulemaking process, and respond to questions about the proposed rule (see 78 FR 57320, September 18, 2013). We also made other presentations, participated in Webinars, and met with stakeholders in the United States and abroad to discuss the FSVP proposed rule along with proposed rules implementing other FSMA provisions.

Over 350 comments were submitted to the docket on the FSVP proposed rule. We continue to review these comments as part of our development of the final rule on FSVPs. However, for the reasons discussed in sections I.C through I.E, we are issuing revisions to certain provisions in the previous proposed rule and requesting comment on the revisions.

C. Alignment of FSVP Regulations With Potential Supplier Verification Provisions in the Proposed Preventive Controls Regulations

In the FSVP proposed rule, we stated that we recognized the importance of coordinating the FSVP regulations with any supplier verification provisions that might be included in the regulations on preventive controls for human and animal food (78 FR 45730 at 45740 to

45741, 45747 to 45748). We had first expressed that intent in the proposed rule on ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food'' (the ''Preventive Controls proposed rule'') (78 FR 3646, January 16, 2013). Although the Preventive Controls proposed rule did not include specific regulations on supplier verification, the Agency requested comment on when and how approval and verification of suppliers of raw materials and ingredients are an appropriate part of preventive controls, and sought comment on different aspects of supplier approval and verification programs (78 FR 3646 at 3665 to 3667). We also stated that we intended to align any supplier verification provisions in the preventive controls regulations with the FSVP regulations to avoid imposing duplicative requirements on entities that are subject to each of those sets of regulations because they are both registered food facilities and food importers. We expressed a similar intent regarding alignment with any supplier verification provisions that might be included in the proposed regulations on preventive controls for animal food (see ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,'' 78 FR 64736 at 64808, October 29, 2013).

In the FSVP proposed rule, we requested comment on how to address foreign supplier verification by importers who could be subject to both the FSVP and preventive controls regulations to avoid imposing duplicative requirements on such firms. In particular, we requested comment on whether the FSVP regulations should state that if an importer was required to establish a supplier approval and verification program under the preventive controls regulations for a food, and was in compliance with those regulations, the importer would be deemed to be in compliance with the FSVP regulations that address those matters (78 FR 45730 at 45748).

D. Decision To Issue Supplemental Notice of Proposed Rulemaking Regarding Certain Preventive Controls Requirements

In December 2013, we issued a statement (Ref. 1) noting the extensive input we had received from produce farmers and others in the agricultural sector on the Preventive Controls proposed rule and FDA's 2013 proposed rule on ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (''the Produce Safety proposed rule'') (78 FR 3504, January 16, 2013). We expressed our belief that significant changes would be needed in key provisions of the two proposed rules affecting small and large farmers, such as certain provisions affecting mixed-use facilities (i.e., facilities co-located on a farm). We also announced our intent to propose revised regulatory requirements and request comment on them, allowing the public the opportunity to provide input on our new thinking. We noted that there might be other revisions to these proposed rules that we would issue for public comment, and that we would determine the scope of the revised proposals as we completed our initial review of the submitted comments on the proposed rules.

E. Scope of FSVP Supplemental Notice of Proposed Rulemaking

In accordance with our December 2013 statement, elsewhere in this issue of the **Federal Register** we are issuing a supplemental notice of proposed rulemaking regarding the preventive controls for human food proposed rule (''Preventive Controls supplemental document'') and a supplemental notice of proposed rulemaking regarding the rule on preventive controls for animal food. In addition to revisions to previously proposed requirements, the Preventive Controls supplemental document includes proposed provisions on supplier programs for food facilities that receive raw materials and ingredients. To align the FSVP proposed regulations with the provisions on supplier programs in the revised Preventive Controls proposed rule, and in response to comments that we have received concerning certain related issues in the FSVP proposal, we are revising the FSVP proposed rule. As discussed in detail in section II, the principal changes to the FSVP proposal include the following:

- Deleting the previously proposed section requiring importers to conduct a compliance status review of the food and foreign supplier but incorporating some parts of this section into the previously proposed requirement to conduct a hazard analysis of the food and a newly proposed requirement to evaluate other risks associated with the food and foreign supplier.
- Replacing the previously proposed requirement to analyze hazards that are ''reasonably likely to occur'' with a proposed requirement to analyze ''known or reasonably foreseeable'' hazards to determine if they are significant (i.e., necessitate control measures).
- Giving importers the flexibility to conduct the supplier verification activities that they have determined, based on their evaluation of food and foreign supplier risks, can provide adequate assurance that the supplier is producing the food in a manner consistent with U.S. food safety requirements. For foods that are associated with a SAHCODHA hazard, the revised proposal specifically requires initial and subsequent annual onsite auditing of the foreign supplier unless the importer determines, based on its risk evaluation of the food and foreign supplier, that other verification activities are appropriate and adequate.

We discuss these revised proposed requirements in section II. We are reopening the comment period on the proposed rule only with respect to these matters. In the FSVP final rule, we will take into account public comments already received and any comments received in response to this document in finalizing the FSVP requirements.

The previous proposed rule and the revisions and new provisions in this supplemental notice of proposed rulemaking, taken together, constitute the entirety of the proposed rule on FSVPs. Throughout this document, we discuss revisions to the previously proposed subpart L of 21 CFR part 1 and, in the codified section of this supplemental notice of proposed rulemaking, we list each of the revised and new provisions of proposed subpart L. For the convenience of readers and ease of reference, we prepared a separate document (to be included in the public docket for this rulemaking) that identifies the changes to the previous codified provisions and provides the complete proposed subpart L of 21 CFR part 1, as revised through this document (Ref. 2).

II. Revisions to the Proposed Rule

As stated in section I.E, in response to comments we have received and as part of our effort to align the FSVP requirements with the supplier program provisions in the revised Preventive Controls proposed rule, we are making several revisions to the FSVP proposed rule. These changes focus primarily on importers' evaluation of the risks associated with the foods they import and the foreign suppliers of this food, along with the supplier verification activities that importers must conduct.

Although we have tried to align the supplier verification provisions in the FSVP and preventive controls regulations as much as possible, there are some differences between the two. These differences are largely due to statutory language and the fact that

while supplier verification is the principal focus of the FSVP regulations, it would only be a component of the preventive controls regulations if it is included in the final preventive controls regulations. These factors result in the two sets of proposed regulations being structured somewhat differently. We request comment, in light of the statutory provisions, on the manner and extent to which the FSVP and preventive controls supplier verification provisions—as well as other aspects of the FSVP and preventive controls regulations—should be aligned in the final rules.

A. Compliance Status Review

The previous FSVP proposed rule included two requirements concerning importers' review of information related to the risk associated with foods and/or foreign suppliers. These are:

- A requirement to review the compliance status of each food to be imported and each foreign supplier being considered (previously proposed § 1.504); and
- A requirement to analyze the hazards in each food (previously proposed § 1.505).

Regarding compliance status review, proposed § 1.504 would have required an importer, before importing a food from a foreign supplier, to assess the compliance status of the food and the foreign supplier, including whether either is the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the FD&C Act (21 U.S.C. 381(q)) relating to the safety of the food, to determine whether it would be appropriate to import the food from the foreign supplier. Proposed § 1.504 also would have required an importer to document this review and to continue to monitor and document the compliance status as long as the importer obtains the food from the foreign supplier.

1. Comments

We received many comments about the proposed compliance status review provisions. A frequent comment by food importers on the compliance status review requirements is that the proposal places too much emphasis on compliance status review, in particular on warning letters and import alerts, as a basis for determining appropriate supplier verification activities. Several comments maintain that compliance status review should be regarded as just one part of an analysis of the risks associated with a food and the foreign supplier of the food. However, several comments state that supplier verification activities should be based not solely on an analysis of the hazards in a food but also on the potential risks associated with a foreign supplier of the food.

Some comments state that an importer should consider both positive and negative compliance information about a foreign supplier. One comment states that each importer should determine on its own what information is relevant to review about a supplier's risk, which might include assessing a supplier's compliance status.

Some comments express concern that certain information about a firm's compliance status, such as FDA Form 483 inspection reports and consent decrees, could be too difficult to obtain because they might be available only through a request under the Freedom of Information Act. In addition, some comments maintain that the FDA Web site is insufficiently organized and would have to be updated to track food and foreign supplier compliance status. Some comments state that an importer should be free to determine on its own what information about the risk of a foreign supplier is relevant to consider.

Many comments express concern that the proposal did not specify how frequently an importer must conduct a compliance status review. Several comments recommend that importers be required to conduct these reviews annually. Some comments object to a continuous monitoring requirement as unnecessary and suggest instead that an importer be required to reassess its supplier's compliance status as part of the importer's reassessment of its FSVP when the importer becomes aware of new information about potential hazards associated with the food or supplier.

2. Revisions Regarding Food and Foreign Supplier Risk Evaluation

Contrary to how some of the commenters read the proposed requirements, the previous proposal would not have required importers to consider only whether there was a relevant warning letter, import alert, or certification requirement under section 801(q) of the FD&C Act; rather, the importer would have needed to consider information relevant to the compliance status of the food and the foreign supplier, e.g., warning letters and import alerts. The preamble to the 2013 proposed rule discussed other types of information about a food or foreign supplier's compliance status, such as Form FDA 483s, Establishment Inspection Reports, and recall notices.

We agree, however, that importers should consider both food and supplier risks in developing their supplier verification plans. Therefore, we tentatively conclude that it is appropriate to more clearly specify that importers must consider certain information relevant to the risks associated with a food and the foreign supplier. Rather than have a separate section requiring importers to conduct a compliance status review of foods and potential foreign suppliers, we are incorporating these compliance concerns into the proposed risk evaluation requirements.

We now are proposing to establish provisions requiring importers to evaluate the risks associated with the food and the potential foreign supplier to determine whether it is appropriate to approve the importation of the food from the foreign supplier. In addition to requiring importers to consider the hazards they determine to be significant under proposed § 1.504 in the revised regulatory text (discussed in section II.B), proposed § 1.505(a)(1) in the revised regulatory text would require importers to consider the following:

- *The entity that will be applying controls for the identified hazards, such as the foreign supplier or the foreign supplier's raw material or ingredient supplier.* As stated in the preamble to the 2013 proposed rule, we believe that the person who will be controlling a hazard in a food is an important, though not necessarily the only, factor in determining an appropriate supplier verification activity for the food.
- *The foreign supplier's procedures, processes, and practices related to the safety of the food.* Many comments state that various aspects associated with the manner in which a foreign supplier produces a food can affect the risk associated with the supplier.
- *Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter or import alert.* There is widespread acknowledgement among the comments that a foreign supplier's history of compliance with applicable FDA regulations is an important component (though not the only component) of supplier risk evaluation. Documents such as warning letters and import alerts are available on FDA's Web site; we tentatively conclude that we would not require importers to consider non-public information regarding compliance with FDA regulations unless such information was available to the importer (e.g., provided to the importer by the foreign supplier).
- *The foreign supplier's food safety performance history, including results from testing foods for hazards, audit*

results relating to the safety of the food, and the supplier's record of correcting problems. Several comments state that an importer typically considers a foreign supplier's performance in providing products that meet the importer's specifications, as verified through onsite auditing, testing, or other measures, in determining the form and frequency of verification activities to conduct.

• *Any other factors as appropriate and necessary, such as storage and transportation practices.* We believe that there might be factors not previously specified that in certain circumstances an importer should consider in evaluating food and supplier risks, such as storage and transportation practices or recent changes to the management of a foreign supplier.

Proposed § 1.505(a)(2) in the revised proposed regulatory text would require the importer to document each risk evaluation it conducts.

We tentatively conclude that this approach to risk evaluation requirements provides a more complete and specific listing (compared to the combined requirements in the previous proposal regarding compliance status review and hazard analysis) of the factors noted by many comments as being the issues that importers typically consider in evaluating food and foreign supplier risks. Under the revised proposal, importers would need to consider each of the previously listed factors in performing their food and foreign supplier risk evaluations. We intend to issue guidance on the specific information that we believe should be considered under each of these factors and how these factors might be weighed in evaluating overall risk.

These proposed risk evaluation factors closely align with the factors that receiving facilities must consider in determining appropriate raw material and ingredient supplier verification activities under the supplier program provisions of the revised Preventive Controls proposed rule.

We believe that it is not necessary to mandate a specific frequency (e.g., on an annual basis) for a complete reanalysis of the risks associated with a food or foreign supplier. Instead, we believe that an importer should reevaluate food and supplier risks when it obtains new information about these risks, either through the importer's own investigation or from the foreign supplier, FDA, or some other source. Therefore, proposed § 1.504(b) in the revised regulatory text would require an importer to promptly evaluate the risks associated with a food or foreign supplier when the importer becomes aware of new information about the risks. We intend to provide guidance on the circumstances under which importers should reevaluate food and supplier risks.

B. Hazard Analysis

The other requirement in the previous proposed rule that concerned evaluation of food and supplier risk was the requirement to conduct a hazard analysis. Previously proposed § 1.505(a) would require each importer (with certain exceptions) to determine, for each food imported, the hazards, if any, that are reasonably likely to occur with the food and, for each, the severity of the illness or injury if such a hazard were to occur. The importer would need to document this determination and use it to determine appropriate supplier verification activities.

Previously proposed § 1.505(b) states that an importer's evaluation of the hazards that are reasonably likely to occur with each food that is imported must consider the following potential hazards that may occur naturally or may be unintentionally introduced: Biological hazards, including microbiological hazards such as parasites and environmental pathogens, and other microorganisms of public health significance; chemical hazards, including substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; physical hazards; and radiological hazards.

Previously proposed § 1.505(c) states that, in evaluating the hazards in § 1.505(b), the importer must consider the effect of several factors on the safety of the finished food for the intended consumer. These factors are as follows: The ingredients of the food; the condition, function, and design of the foreign supplier's establishment and equipment; transportation practices; harvesting, raising, manufacturing, processing, and packing procedures; packaging and labeling activities; storage and distribution; intended or reasonably foreseeable use; sanitation, including employee hygiene; and any other relevant factors.

Previously proposed § 1.505(d) would permit an importer to identify the hazards that are reasonably likely to occur for a particular food by reviewing and evaluating the hazard analysis conducted by the foreign supplier (rather than conducting an entirely separate evaluation of hazards using information that the importer itself has obtained).

Finally, under previously proposed § 1.505(e), for a RAC that is a fruit or vegetable, an importer would not be required to conduct a hazard analysis regarding the microbiological hazards that might be reasonably likely to occur with this food. Instead, the importer would need to verify that this kind of food is produced in compliance with FDA's produce safety standards, once finalized, or equivalent standards.

As stated in section II.A.2, our revised proposal would continue to require an importer to analyze the hazards in a food that it imports, with the hazard analysis being one part of the food and foreign supplier risk evaluation that the importer must conduct under § 1.505 in the revised regulatory text. In this section, we discuss certain revisions we are making to the hazard analysis requirements in the proposed rule.

1. Nature of the Hazards That Importers Must Analyze

a. Comments

Several comments object to the proposed requirement that importers' hazard analyses focus on hazards that are ''reasonably likely to occur'' with a food. We proposed to define a hazard reasonably likely to occur as one for which a prudent importer would establish controls or verify that the supplier controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being imported in the absence of those controls. One comment states that the ''reasonably likely to occur'' standard should not be used because it goes beyond and is inconsistent with the ''known or reasonably foreseeable'' statutory standard in FSMA's preventive controls provisions (section 418(b)(1) of the FD&C Act). Several comments maintain that the term reasonably likely to occur typically has been used to determine critical control points for hazard analysis and critical control points (HACCP) systems and is inappropriate for use in a program like supplier verification that is a ''prerequisite,'' foundational food safety program. The comments recommend instead that importers be required to consider ''known or reasonably foreseeable'' hazards because determining such hazards requires knowledge of the facility in which the food is produced.

b. Revisions Regarding Nature of Hazards To Be Evaluated

The hazard analysis provisions in both the FSVP and preventive controls previously proposed rules would have required evaluation of hazards that are reasonably likely to occur. As we state

in the Preventive Controls supplemental document, we acknowledge that it might be confusing to use the phrase ''reasonably likely to occur'' in both our HACCP regulations and in the preventive controls and FSVP regulations, because the phrase ''reasonably likely to occur'' has been used as the basis for determining hazards that need to be addressed in a HACCP plan at critical control points. In light of this concern, and consistent with our revision of the hazard analysis provisions in the preventive controls proposed rule, we tentatively conclude that the potential hazards that importers should be required to consider in their risk analyses are hazards that are known or reasonably foreseeable rather than hazards that are reasonably likely to occur. We believe that it is appropriate to align the hazard analysis provisions in the FSVP regulations with those in the proposed preventive controls regulations because hazard analysis is an import component of supplier verification.

We now propose to define a ''known or reasonably foreseeable hazard'' as a potential biological, chemical (including radiological), or physical hazard that is known to, or has the potential to be, associated with a food or the facility in which it is manufactured/processed (§ 1.500 in the revised regulatory text). (We accordingly propose to add a definition of ''facility,'' which would be defined as a domestic facility or a foreign facility that is required to register under section 415 of the FD&C Act (21 U.S.C. 350d), in accordance with the requirements of 21 CFR part 1, subpart H.) We also are revising the hazard analysis provisions to make clear that they apply to analysis of known or reasonably foreseeable hazards.

Section 1.504(a) in the revised regulatory text would require an importer to analyze the known or reasonably foreseeable hazards in a food, based on experience, illness data, scientific reports, and other information, to determine whether they are ''significant'' hazards. We propose to define a ''significant hazard'' as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records), as appropriate to the food, the facility, and the control (§ 1.500 in the revised regulatory text). This means that importers must conduct hazard analyses to determine whether any known or reasonably foreseeable hazard in a food poses such a risk to health that it is necessary to establish controls to significantly minimize or prevent the hazard. This definition of significant hazard and the proposed requirement to determine whether known or reasonably foreseeable hazards are significant are consistent with the approach that we are proposing in the supplier program provisions of the preventive controls regulations.

2. Biological Hazards

As previously stated, previously proposed § 1.505(b)(1) would require importers to consider whether there are biological hazards in the food they import, including microbiological hazards such as parasites and environmental pathogens, and other microorganisms of public health significance. In the Preventive Controls supplemental document, we are replacing the phrase ''microorganism of public health significance'' in the proposed preventive controls hazard analysis provisions with the phrase ''pathogen'' and proposing to define ''pathogen'' as a microorganism of public health significance. To better align the FSVP requirements with those proposed for preventive controls, we are proposing to describe biological hazards in the same way in § 1.504(b)(1)(i) in the revised regulatory text and adding a definition of ''pathogen'' to proposed § 1.500. In addition, we are including the same revised definition of ''environmental pathogen'' as is set forth in the Preventive Controls supplemental document, which proposes to define ''environmental pathogen'' as a pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen (the definition also specifies that spores of pathogenic sporeformers are not environmental pathogens).

3. Radiological Hazards

As previously stated, the proposed rule included radiological hazards among the types of hazards (along with biological, chemical, and physical hazards) that importers must consider in their hazard analyses.

a. Comments

Some comments maintain that radiological hazards should be included among the chemical hazards rather than in a separate category. One comment states that treating radiological hazards as a separate category would mean that FSMA regulations would differ from Codex and world-wide HACCP standards, which require evaluation only of biological, chemical, and physical hazards, and would create a potential for misunderstanding and lack of acceptance by foreign suppliers. The comment states that making radiological hazards a subset of chemical hazards would help mitigate concerns about a requirement to consider radiological hazards.

b. Revisions Regarding Radiological Hazards

We tentatively conclude that it is appropriate to consider radiological hazards as a type of chemical hazard. Therefore, we have revised the definition of ''hazard'' and the reference to radiological hazards in the revised hazard analysis provisions (§§ 1.500 and 1.504(b)(1)(ii), respectively, in the revised regulatory text). However, this does not mean that consideration of radiological hazards would be optional; rather, importers would be required to review such hazards when considering possible chemical hazards in a food.

4. Intentional Hazards

In the previous FSVP proposed rule, we stated our tentative conclusion that importers need only consider those hazards that occur naturally or might be unintentionally introduced (78 FR 45730 at 45749). We noted that we planned to address the issue of certain intentionally introduced hazards as part of our rulemaking to implement section 106 of FSMA, which directs FDA to issue regulations to protect against the intentional adulteration of food. But we acknowledged that some kinds of intentional adulterants could be viewed as reasonably likely to occur, such as in foods for which there is a known risk of economically motivated adulteration. Therefore, we requested comment on whether to include in the FSVP requirements potential hazards that may be intentionally introduced for economic reasons.

a. Comments

Comments were submitted both for and against requiring importers to consider hazards intentionally introduced for economic reasons. One comment states that although importers should consider economically motivated adulterants, most such adulterants should not be regarded as reasonably likely to occur and do not pose a food safety hazard. Some

comments question the feasibility of determining which economically motivated adulterants should be viewed as reasonably likely to occur. Some comments state that economically motivated adulteration is best addressed through food defense plans. One comment states that importers should not be required to consider intentional hazards, including economically-motivated hazards, because such hazards require different kinds of preventive measures than those traditionally used in supplier verification programs.

b. Revisions Regarding Intentional Hazards

We are proposing to add hazards that may be intentionally introduced for purposes of economic gain to the types of known or reasonably foreseeable hazards that an importer would be required to consider in its hazard analysis (see § 1.504(b)(2)(iii) in the revised regulatory text). As discussed in the Preventive Controls supplemental document, several substances, such as melamine and dyes containing lead, have been used in economically motivated adulteration schemes and have potential to harm public health. Because some economically motivated adulterants should be regarded as known or reasonably foreseeable hazards, we believe it is appropriate that importers consider them when conducting hazard analyses. We are no longer proposing that importers analyze hazards that are reasonably likely to occur, so the concerns related to applying that standard to economically motivated adulterants are no longer relevant. In addition, because the proposed regulations define a ''hazard'' as an agent that is reasonably likely to cause illness or injury in the absence of its control, importers need only consider those economically motivated adulterants that are reasonably likely to harm consumers' health, not economically motivated adulterants that solely affect quality or value.

We disagree with the comment that economically motivated adulteration requires different kinds of preventive measures than those traditionally used in supplier verification programs. Industry currently uses audits, sampling, and testing to verify that hazards are being controlled, including hazards from economic adulteration. Nevertheless, as discussed in section II.C.5, the revised proposed supplier verification requirements provide considerable flexibility to importers in conducting supplier verification, including the ability to determine and implement any appropriate supplier verification activity based on the risks associated with the food and foreign supplier.

5. Environmental Pathogens in Certain Ready-To-Eat Food

To better align the hazard analysis requirements in the FSVP regulations with those in the proposed preventive controls regulations, we are adding a proposed requirement, in § 1.504(c)(2) in the revised regulatory text, for importers to include in their hazard analysis of a food an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.

6. Factors Affecting the Safety of Finished Food

Also to better align the FSVP hazard analysis requirements with those in the proposed preventive controls regulations, we are making two minor revisions to the list of proposed items that importers must consider regarding their potential effect on the safety of finished food for the intended consumer. In § 1.504(c)(3)(i) in the revised regulatory text, we are replacing ''ingredients of the food'' with ''formulation of the food,'' and in § 1.504(c)(3)(iii) in the revised regulatory text we are adding a requirement to consider ''raw materials and ingredients.''

C. Supplier Verification

We are revising several aspects of the proposed requirements concerning foreign supplier verification procedures and related activities. The revisions include a revised proposal regarding the alternative options presented in the proposed rule concerning appropriate supplier verification activities when foreign suppliers control (or verify control of) hazards in food.

1. List of Foreign Suppliers

To help ensure that importers are obtaining food only from appropriate foreign suppliers, previously proposed § 1.506(a) would require each importer to maintain a written list of the foreign suppliers from which they are importing food. The list would also help importers to quickly and accurately identify their foreign suppliers for purposes of conducting FSVP activities such as supplier verification, investigations, and corrective actions, and help ensure consistent performance of these activities by importers' employees or other qualified individuals.

a. Comments

Several comments express support for the proposed requirement that importers maintain a list of their foreign suppliers. However, some comments oppose this requirement on the basis that it would present logistical or administrative challenges. Some comments state that it would be burdensome to constantly update the list of foreign suppliers. Some comments suggest that importers instead be required to provide a list of suppliers upon the Agency's request. One comment states that the identity of suppliers is confidential business information that importers should not be required to disclose to FDA on a routine basis.

Some comments state that some importers might not maintain a single list of approved suppliers but use a corporate-wide or centralized system to confirm receipt of food from approved suppliers. These comments instead recommend that importers be required to establish a system that will allow them to confirm that imported food is from a foreign supplier that the importer has approved for use.

One comment states that in emergency situations to avoid production disruptions, an importer might need to obtain food from foreign suppliers that they have not audited. The comment maintains that use of food from such suppliers would be acceptable provided that the food is inspected or analyzed before use.

b. Revisions Regarding Process for Confirming Receipt of Food From Approved Suppliers.

We are uncertain how an importer could verify that a food it receives is from an approved foreign supplier yet be unable to generate a list of such approved suppliers, especially when the importer uses a centralized, corporate-wide system. We understand that use of multiple supplier databases could necessitate some compilation procedure, but it does not appear to us that this would be significantly burdensome. Nevertheless, we tentatively conclude that requiring importers to establish a system or procedure to confirm that imported foods are from approved suppliers, rather than maintain a list of foreign suppliers, would enhance the safety of imported food at least as much as merely maintaining a list of suppliers while reducing the apparent administrative burden on importers. Therefore, we have replaced the proposed requirement to maintain a list of foreign suppliers with a proposed requirement, in § 1.506(a) in the revised

regulatory text, to establish and follow written procedures to ensure that foods are imported from foreign suppliers the importer has approved based on the risk evaluation it conducts under § 1.505 and to document use of these procedures. These procedures might address approval of suppliers, approval or rejection of particular shipments of foods, and documentation of receipt from approved suppliers. It is essential that such procedures be capable of accurately identifying foreign suppliers for purposes of meeting FSVP requirements.

However, we believe that, in limited circumstances, it might be appropriate for an importer to use a supplier for which the importer has not completed a full risk evaluation provided that the importer takes other steps to ensure that food from such a supplier is safe. For example, because of a problem with a long-time supplier due to an equipment breakdown, an environmental or weather-related crisis (e.g., severe drought or flooding), or some other unexpected circumstance, it might be necessary for an importer to obtain a food on a temporary basis from a new supplier. Because the importer would be unable to immediately fully evaluate the potential supplier, the importer would need to take other steps to verify that the food obtained from that supplier was safe. Such verification measures might include sampling and testing individual shipments from the supplier. Therefore, revised § 1.506(a) would permit the use of unapproved foreign suppliers on a temporary basis when necessary and appropriate, provided that the importer subjects the food from such suppliers to adequate verification activities before using or distributing the food. The importer's written procedures regarding the use of approved suppliers also would need to address the circumstances under which unapproved suppliers might be used, and the importer would need to document the verification activities it conducts when using unapproved suppliers. We request comment on circumstances under which it might be necessary and appropriate to receive food from unapproved foreign suppliers and on the types of verification activities that an importer should conduct on food from an unapproved supplier.

2. Purpose of Supplier Verification

Section 1.506(c) of the 2013 proposed rule would have required the importer to conduct foreign supplier verification activities to provide adequate assurances that the hazards the importer had identified as reasonably likely to occur were adequately controlled. However, we tentatively concluded that this provision should not apply to microbiological hazards in RACs that are fruits or vegetables and that would be subject to the produce safety regulations in proposed part 112 (21 CFR part 112) because importers of these fruits or vegetables would not be required to conduct a hazard analysis regarding the microbiological hazards in this food. Instead, proposed § 1.506(h) stated that verification for these hazards should address whether foreign suppliers are producing these fruits and vegetables in accordance with the produce safety regulations.

a. Comments

One comment maintains that directing that supplier verification activities be designed to provide assurances that hazards are adequately controlled is inconsistent with the statute and does not focus on the key issues affecting the safety of imported food. The comment states that supplier verification activities should consider not just the hazards in food but supplier-related risks. Some comments maintain that linking supplier verification activities solely to food hazards incorrectly implies that verification controls the hazard and suggests that the supplier can pose no significant safety risks.

b. Revisions Regarding Purpose of Supplier Verification

We do not believe, nor does the preamble to the 2013 proposed rule state, that supplier verification activities actually control hazards. Rather, a key purpose of verification is to provide assurance that hazards are being effectively controlled by the foreign supplier or some other entity. However, as stated in section II.A.2, we tentatively conclude that importers should consider both food and supplier risks in determining what supplier verification activities to conduct. In accordance with this approach, we believe that the purpose of supplier verification activities should not be limited to verifying control of hazards. Therefore, we now propose to require (in § 1.506(c) in the revised regulatory text) that supplier verification activities provide adequate assurances that the foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the FD&C Act (the preventive controls and produce safety provisions, respectively), if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. This more directly links supplier verification activities to the statutory purpose for FSVPs in section 805(a)(1) of the FD&C Act.

With this change to the proposed purpose of supplier verification activities, we tentatively conclude that there is no need for a separate requirement concerning supplier verification activities related to microbiological hazards in RACs that are fruits or vegetables subject to the produce safety regulations. With respect to microbiological hazards in such food, under revised § 1.506(c), the importer of the food would need to conduct activities to verify that: (1) The foreign supplier is using processes and procedures that provide at least the same level of protection as those required under the produce safety regulations, when finalized and (2) the food is not adulterated or misbranded regarding allergen labeling.

3. No Hazards Identified

Under § 1.506(d) of the previous proposed rule, if an importer determines that no hazards are reasonably likely to occur with a food, the importer would not be required to conduct supplier verification activities. However, under the supplier program provisions in the revised preventive controls proposal, when there are no significant hazards in a raw material or ingredient, the receiving facility would not be required to have a supplier program for the food, including the requirement to determine appropriate verification activities by considering food and supplier risks. To better align the proposed FSVP regulations with the proposed preventive controls regulations, we propose to specify, in § 1.504(f) in the revised regulatory text, that if an importer evaluates the known and reasonably foreseeable hazards in a food and determines that there are no significant hazards, the importer would not be required to determine what foreign supplier verification and related activities it should conduct and would not be required to conduct any such activities. (As under the proposed rule, revised § 1.504(f) states that this exemption would not apply if the food is a RAC that is a fruit or vegetable and that is subject to the produce safety regulations.)

4. Hazards Controlled by the Importer or Its Customer

The preamble to the 2013 proposed rule noted that some hazards associated with an imported food are controlled through actions that the importer or its customer takes after the food is brought into the United States. We tentatively

concluded that if an importer or its customer has established validated preventive controls to ensure that a hazard is adequately controlled through processing in the United States, there would be no need for the importer to conduct a foreign supplier verification activity with respect to that hazard (78 FR 45730 at 45752). Therefore, when an importer is adequately controlling a hazard that it has identified, proposed § 1.506(e) would have required the importer to document, at least annually, that it had established and was following procedures that adequately controlled the hazard. Similarly, when an importer's customer was controlling a hazard, proposed § 1.506(f) would have required the importer to document that its customer controlled the hazard by obtaining written assurance, at least annually, from the customer that it had established and was following procedures (identified in the written assurance) that adequately controlled the hazard.

However, we also requested comment on whether it would be appropriate to deem importers who are in compliance with any applicable supplier verification provisions that are included in the preventive controls regulations to be in compliance with the FSVP requirements, to avoid duplicative regulation of importers who are also registered with FDA as food facilities. We tentatively concluded that, if a provision to this effect were included in the FSVP regulations, proposed § 1.506(e) would be unnecessary, as importers that control hazards in foods they import would be subject to the supplier verification provisions in the preventive controls regulations (78 FR 45730 at 45752). Similarly, we tentatively concluded that proposed § 1.506(f) would be unnecessary if the FSVP regulations were to include a provision stating that an importer whose customer was in compliance with any adopted preventive controls supplier verification provisions was deemed to be in compliance with the FSVP requirements. We requested comment on this proposed approach to supplier verification when the importer or its customer controls a hazard.

a. Comments

Several comments agree with proposed § 1.506(e) requiring importers who control hazards in food they import to document their control of these hazards. In addition, several comments express support for avoiding imposing redundant verification requirements on importers that would be required to conduct supplier verification under the preventive controls regulations. One comment agrees that proposed § 1.506(e) would be unnecessary if importers who were in compliance with supplier verification provisions in the preventive controls regulations were deemed in compliance with the FSVP requirements.

One comment states that supplier verification activities should not turn on the entity that is controlling a hazard in a food. The comment states that verification activities may be needed even when the foreign supplier does not control the hazard, adding that importers should not be required to engage in a paperwork exercise to obtain assurances of their customers' food safety controls. Similarly, another comment opposes not requiring standard verification activities when a hazard is to be controlled by the importer or its customer, maintaining that nearly all suppliers should be subject to verification activities. The comment states that not requiring any supplier verification would overlook important issues such as the supplier's compliance with CGMP requirements and the need for programs to avoid introducing any unforeseen hazards. The comment also states that the proposal is problematic because the intended use of the food may not be known at the time of entry or different parts of a product batch might be destined for different customers with different processes. However, elsewhere in its submitted comments, the commenter maintains that FDA must harmonize the supplier verification provisions in the preventive controls regulations with the FSVP regulations so that imported ingredients need only be verified once.

b. Revisions Regarding Importers Subject to the Supplier Program Provisions in the Preventive Controls Regulations

As stated previously in this document, elsewhere in this issue of the **Federal Register** we are proposing a potential requirement for a supplier program in the proposed preventive controls regulations. Therefore, consistent with the discussion in the 2013 FSVP proposed rule, we propose to specify, in § 1.502(c) in the revised regulatory text, that if an importer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer is in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the United States). Similarly, under § 1.502(d) in the revised regulatory text, if an importer's customer is required to establish and implement a risk-based supplier program under the preventive controls regulations (for either human or animal food), and the importer annually obtains written assurance that its customer is in compliance with those requirements, the importer would be deemed in compliance with the FSVP regulations (except for the requirement to identify the importer at entry of the food into the United States and the requirement to maintain records of the written assurances). Because the importer or its customer would be performing supplier verification activities under the preventive controls regulations, we tentatively conclude that this approach addresses concerns about a lack of supplier verification when the importer or its customer controls a hazard, while also avoiding imposing redundant verification requirements.

However, even though we are proposing to add these provisions regarding importers who are facilities that are subject to the supplier program requirements in the preventive controls regulations, we tentatively conclude that it would not be appropriate to delete the previously proposed provisions concerning foods with hazards to be controlled by the importer or its customer. The reason for this is that we tentatively conclude that it is appropriate to align the FSVP requirements with the potential supplier program provisions discussed in the preventive controls proposed rule, should they be adopted. The potential supplier program requirements would not apply under the following circumstances:

- When the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards in a raw material or ingredient; or
- When the receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

In such circumstances, requiring an importer that also is a facility subject to the preventive controls regulations to conduct foreign supplier verification activities would not impose a redundant regulatory burden because such importer-facilities would not also be subject to the preventive controls supplier program requirements. Nevertheless, we tentatively conclude that it still would impose an

unnecessary burden because the importer's (and/or its customer's) control of all significant hazards in the food would effectively resolve the food safety concerns that supplier verification is intended to address. Therefore, we propose to specify, in § 1.504(g) of the revised regulatory text (in the hazard analysis section of the proposed FSVP regulations), that if the preventive controls that an importer and/or its customer implements under the preventive controls regulations are adequate to significantly minimize or prevent all significant hazards in a food, the importer is not required to determine appropriate foreign supplier verification and related activities under § 1.505 and is not required to conduct such activities under § 1.506. Proposed § 1.504(g) further states that if the importer's customer controls one or more significant hazards in a food, the importer must annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

5. Hazards Controlled by the Foreign Supplier

The previous proposed rule set forth two options for the requirements regarding supplier verification activities for hazards that are controlled, or for which control is verified, by the importer's foreign supplier (see previously proposed § 1.506(g), Options 1 and 2). Option 1 would have established certain requirements for SAHCODHA hazards to be controlled by the foreign supplier, and different requirements for non-SAHCODHA hazards and SAHCODHA hazards that the foreign supplier verified had been controlled by its raw material or ingredient supplier. (The preamble to the 2013 proposed rule described a SAHCODHA hazard as one for which a recall of a violative product posing such hazard is designated as ''Class I'' under 21 CFR 7.3(m)(1).) Option 2 would have required the importer to determine the supplier verification activity it would use for all hazards that the foreign supplier controlled or for which it verified control.

Under Option 1, for a SAHCODHA hazard that was to be controlled at the foreign supplier's establishment, the importer would have been required to conduct and document certain initial and subsequent periodic (at least annual) onsite audits of the foreign supplier. Onsite auditing also would be required under Option 1 for microbiological hazards in certain RACs that are fruits or vegetables. When onsite auditing alone could not provide adequate assurances that such a hazard was adequately controlled, the importer would have had to conduct one or more additional verification activities to provide such assurances. For non-SAHCODHA hazards to be controlled by the foreign supplier and all hazards for which the supplier verified control by its raw material or ingredient supplier, Option 1 would have required that the importer conduct, upon consideration of the risk presented by the hazard and the food and foreign supplier's compliance status, one or more of the following verification activities before using or distributing the food and periodically thereafter:

- Onsite auditing of the foreign supplier.
- Periodic or lot-by-lot sampling and testing of the food.
- Review of the foreign supplier's food safety records.
- Any other procedure established as being appropriate based on the risk associated with the hazard.

On the other hand, Option 2 would have allowed the importer to determine, for all hazards either controlled by the foreign supplier or for which the foreign supplier verified control by its supplier, which of the previously listed verification activities would be appropriate to verify that the hazard was adequately controlled. In determining the appropriate verification activities and how frequently they should be conducted, Option 2 would have required the importer to consider the risk presented by the hazard, the probability that exposure to the hazard would result in serious adverse health consequences or death to humans or animals, and the food and foreign supplier's compliance status.

a. Comment

We received many comments in support of Option 1 and many that favor Option 2. Comments in favor of Option 1 include the following:

- Option 1 would provide greater protection to consumers than Option 2.
- Option 1 is risk-based in that it would require the most rigorous form of supplier verification—onsite auditing—when the most serious hazards are present in food.
- Option 2 would provide too much discretion to importers, who would have an incentive to choose lower-cost and less effective verification methods, which could result in an increase in contaminated imported food.
- A single, streamlined requirement would be more easily enforced without confusion, and regulated entities often prefer such clarity.
- Option 1 would reduce industry costs by avoiding the need for importers to make verification decisions on a product-by-product basis.

Comments in favor of Option 2 include the following:

- Option 2 would provide importers with the flexibility needed to tailor the supplier verification to the particular food and supplier risk.
- Option 2 is more closely aligned with current industry practice, which often uses onsite audits but also relies on other verification methods depending on food and supplier risk.
- Option 2 is more risk-based and would result in a better allocation of resources by not requiring onsite auditing when it would not be justified by risk.
- Requiring different supplier verification activities for different types of hazards in a food is inconsistent with current industry practice.
- Option 1 could lead importers to simply ''check the box'' that a foreign supplier has been audited rather than analyze the audit results and consider whether additional verification activities are needed.
- The SAHCODHA standard is not well understood and might not be workable as a factor for determining supplier verification activities.

One comment recommends what it describes as a hybrid of the two options. The comment suggests that annual onsite auditing should be the default requirement for SAHCODHA hazards and for microbiological hazards for RACs that are fruits or vegetables, but an importer would be permitted to use alternative verification measures if it could justify, based on a comprehensive risk assessment, that risks are reduced and that the alternative measures would adequately verify that the foreign supplier adequately controlled the hazards.

b. Revisions Regarding Supplier Verification Activities

Although we acknowledge the concerns regarding Option 2 expressed by supporters of Option 1, we tentatively conclude that allowing importers the flexibility to determine the appropriate supplier verification activity (or activities) based on the importer's evaluation of food and supplier risks would be a more risk-based approach. We believe that this would more closely align the verification requirements with Congress's directive that importers perform risk-based verification activities. In turn, this should result in safer imported food by allowing importers to optimize their verification

efforts in accordance with the relative risks to public health posed by different foods and suppliers.

Therefore, we are proposing, in § 1.506(d)(1) in the revised regulatory text, that importers be required to conduct and document one or more of four supplier verification activities—onsite auditing, sampling and testing of food, review of the foreign supplier's food safety records, or some other appropriate risk-based verification activity—before initially importing a food and periodically thereafter. The importer would be required to determine and document which verification activity or activities are appropriate, as well as the frequency with which the activities must be conducted, based on the risk evaluation that the importer conducts for the food and supplier under proposed § 1.505. As in both Option 1 and Option 2 under the previous proposed rule, the revised proposal recognizes that for some foods or foreign suppliers it might be necessary to conduct more than one verification activity to provide the required assurances (see § 1.506(d)(3) in the revised regulatory text).

The revised proposal states that an onsite audit of a foreign supplier must be conducted by a qualified auditor (§ 1.506(d)(1)(i)(A) in the revised regulatory text), who is defined as a person who is a qualified individual and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function (§ 1.500 in the revised regulatory text). (The proposed definition also specifies that a foreign government employee could be a qualified auditor.) The revised proposal also states that sampling and testing of a food may be conducted by either the importer or the foreign supplier (§ 1.506(d)(1)(ii)(A) in the revised regulatory text).

We are proposing a slight modification to this general rule regarding verification activities in the case of foods with SAHCODHA hazards, similar to the ''hybrid'' approach suggested by one comment. As expressed by some Option 1 supporters, we believe that requiring onsite auditing when there is a SAHCODHA hazard in a food is risk-based because it would require what is arguably the most robust supplier verification activity—annual onsite auditing—for the most serious hazards in foods. However, we acknowledge the possibility that: (1) Use of some other verification activity, (2) less frequent onsite auditing, or (3) some combination of those two approaches could provide adequate assurances regarding the safety of the food. We also recognize that although some importers might prefer the ease of not having to make a determination of appropriate supplier verification activities when a SAHCODHA hazard is present in a food, others would prefer being able to tailor verification activities (and the frequency with which they are conducted) to a particular food and supplier risk profile.

For these reasons, we are proposing to require, in § 1.506(d)(2) in the revised regulatory text, that when a SAHCODHA hazard in a food will be controlled by the foreign supplier, the importer must conduct (or obtain documentation of) initial and subsequent annual onsite auditing of the foreign suppler unless the importer determines that other supplier verification activities and/or less frequent onsite auditing are appropriate to provide adequate assurances regarding the safety of a particular food and foreign supplier based on the risk evaluation conducted under § 1.505. This would provide importers with the certainty of knowing that use of initial and subsequent annual onsite auditing would satisfy the verification requirement when a SAHCODHA hazard is present in a food, while allowing importers to use an alternative verification mechanism(s) if they determine that such mechanism(s) provide adequate safety assurances.

We do not believe, as some comments suggest, that making onsite auditing mandatory when there is a SAHCODHA hazard in a food or, in the case of our revised proposal, establishing onsite auditing as the ''default'' verification activity in such circumstances, would result in importers failing to analyze audit results or consider whether additional verification activities are needed. Both the previous proposed rule (§ 1.506(g)(5) under Option 1) and the revised proposal (§ 1.506(d)(6) in the revised regulatory text) would require importers to promptly review the results of their verification activities and, if necessary, take appropriate corrective action. In addition, under both the previous proposed rule (§ 1.506(g)(1) under Option 1) and the revised proposal (§ 1.506(d)(3) in the revised regulatory text), even when an importer conducts an onsite audit or obtains an onsite audit report to verify control of a SAHCODHA hazard in a food, it might be necessary in some circumstances for the importer to conduct some additional verification.

We also do not believe that purported uncertainty about the SAHCODHA standard would make it difficult for importers to comply with this provision. FDA's Reportable Food Registry Questions and Answers document discusses the types of violative products that should be addressed through a Class I recall, which uses the SAHCODHA standard. In addition, the Agency's weekly FDA Enforcement Report, which is available at FDA's Web site (*http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm*), provides more information about foods that have been the subject of a Class I recall and the reasons for the recall. We will consider providing additional guidance to industry to help clarify what food hazards constitute SAHCODHA hazards under the FSVP regulations.

We acknowledge that there may be concerns that the revised proposed approach to foreign supplier verification activity requirements could lead some importers to rely on verification activities that might be inadequate to provide sufficient assurances about the safety of the imported food. We believe that there are some circumstances, such as when a SAHCODHA hazard is present in a food, in which onsite auditing on an annual basis likely would be needed to ensure proper verification of suppliers. However, in some cases, including even when a SAHCODHA hazard is present, we believe it is possible that alternative supplier verification activities would provide adequate assurances of food safety. An importer who chose to conduct such an alternative activity would need to maintain documentation that the activity provides adequate assurances of safety; this documentation would be available for FDA review during any inspection of the importer. To address concerns that the revised proposal may allow too much discretion, and to assist importers in meeting the verification requirements, we anticipate that we will provide guidance to industry on the circumstances (incorporating both food and supplier risks) under which onsite auditing of foreign suppliers and/or other supplier verification approaches are appropriate for providing adequate assurances regarding the safety of the food produced by a foreign supplier.

6. Food From Farms That Are Not Covered Farms Under the Proposed Produce Safety Regulations

In addition to the just-discussed revisions concerning supplier verification activities, we are proposing to include a revision regarding food from foreign suppliers that are farms but not ''covered farms'' subject to the produce safety regulations. We are making this change to reflect the different treatment of food from such farms under the proposed produce

safety regulations and to be consistent with the potential requirement for a supplier program in the proposed preventive controls regulations.

Under § 1.506(d)(4) in the revised regulatory text, if a foreign supplier of a food is a farm that is not subject to the requirements in part 112 (the produce safety regulations) in accordance with § 112.4 regarding the food being imported, the importer would not be subject to the FSVP supplier verification activity requirements in revised § 1.506(d)(1) and (d)(2) if the importer:

- Documented, at the end of each calendar year, that the food provided by the foreign supplier was not subject to part 112; and
- obtained written assurance, at least every 2 years, that the foreign supplier was producing the food in compliance with the FD&C Act.

These alternative verification requirements would apply to importers of food from the following:

- Farms that do not grow and harvest ''produce,'' as defined in § 112.3(c) of the proposed produce safety regulations. For example, because food grains are not produce, the alternative verification requirements would apply to importers of food grain.
- Farms that grow and harvest produce that is not covered by the proposed produce safety regulations in accordance with proposed § 112.1. Such ''non-covered produce'' includes produce that is rarely consumed raw, produce that is produced for personal consumption or for consumption on the farm or another farm under the same ownership, and produce that is not a RAC.
- Farms that are not ''covered farms'' because they produce an average annual monetary value of produce of no more than $25,000 (see proposed § 112.4(a)).
- Farms that are not covered farms because they satisfy the requirements for a qualified exemption from the proposed produce safety regulations under proposed § 112.5 (including requirements concerning direct sale to qualified end-users) and the exemption has not been withdrawn.

Because FDA has determined that these farms either: (1) Should not be subject to the produce safety regulations or (2) should not be required to comply with the ''standard'' requirements applicable to covered activities conducted for covered produce, we tentatively conclude that it is appropriate to similarly not require importers of food from such farms to conduct the ''standard'' supplier verification activities. We request comment on the proposed alternative method of supplier verification of obtaining written assurance of compliance with the FD&C Act by these farms.

7. Documentation of Foreign Supplier Verification Activities

The proposed rule does not specify what documentation of onsite audits of foreign suppliers importers must maintain. At the public meetings on the FSVP proposed rule and in other meetings with stakeholders, we invited comment on what documentation of onsite audits importers should be required to have. We also stated that for onsite audits conducted for FSVP purposes, importers would not be required to obtain a regulatory audit report as required for audits conducted by accredited auditors/certification bodies under FDA's proposed rule on ''Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (78 FR 45782, July 29, 2013).

With respect to documentation of sampling and testing of an imported food, the proposed rule (§ 1.506(g)(2)(ii) under Option 1) specified a certificate of analysis (COA) containing the results of testing as an example of appropriate documentation but did not require a particular form or forms of documentation. The preamble to the proposed rule suggested certain information that might be included in a COA (78 FR 45730 at 45757). Similarly, the proposed rule (§ 1.506(g)(2)(iii) under Option 1) included records of a foreign supplier's audit of its supplier's hazard control activities as an example of appropriate documentation of review of a foreign supplier's food safety records but did not require a specific form of documentation. The preamble to the proposed rule states that food safety records are records documenting that the hazard control procedures established by the supplier are being followed and are adequately controlling the hazards (78 FR 45730 at 45756). The proposed rule provided no example of appropriate documentation of other verification procedures determined by the importer to be appropriate.

a. Comments

Several comments state that importers should not be required to share foreign supplier audit reports with FDA. The comments state that because such reports often include confidential business information and findings of flaws in safety systems, requiring that the reports be made available to the Agency might make suppliers less likely to allow audits or result in less robust audits. Some comments suggest that importers be required to maintain documentation that an audit was conducted (the date of the audit and the name of the auditor) and documentation of the completion of any corrective actions in response to significant deficiencies.

Regarding documentation of sampling and testing, one comment encourages us not to specify requirements for the content of COAs because this could change over time and is better left to industry to determine.

b. Revisions Regarding Documentation of Supplier Verification Activities

We acknowledge the concerns about requiring importers to document onsite audits of foreign suppliers with the full reports of those audits. We do not believe that importers should be required to make full audit reports available to us in an FSVP inspection. We understand that a foreign supplier might be reluctant to submit to onsite auditing if the full report of the audit would be made available to us, and we do not believe that we need to review the full audit report to determine whether an appropriate audit was conducted and any significant problems were corrected. Accordingly, we now are revising the proposed provisions regarding onsite auditing of foreign suppliers to require importers to retain documentation of the following: The audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor (§ 1.506(d)(1)(i)(C) in the revised regulatory text). We tentatively conclude that this requirement would enable us to determine whether an appropriate audit of the foreign supplier was conducted and whether the importer used the audit results appropriately, while preserving the benefits of the confidentiality of the audit reports.

We also are proposing to specify documentation requirements for other supplier verification activities. The revised proposal (§ 1.506(d)(1)(ii)(B) in the revised regulatory text) states that documentation of an incidence of sampling and testing (which under § 1.506(d)(1)(ii)(A) may be conducted either by the importer or the foreign supplier) must include the following: Identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical methods(s) used), the date(s) on which the test(s) were conducted, the results of

the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing.

The revised proposal (§ 1.506(d)(1)(iii) in the revised regulatory text) states that documentation of each review of foreign supplier safety records must include the date(s) of review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

The revised proposal does not specify how importers must document other appropriate supplier verification activities that they conduct. We request comment on whether the regulations should specify the form of such documentation and, if so, what form such documentation should take.

8. Independence of Qualified Individuals Conducting Verification Activities

The previous proposed rule specifies that a qualified individual who conducts any of the supplier verification activities must not have a financial interest in the foreign supplier and payment of the qualified individual must not be related to the results of the activity (proposed § 1.506(g)(6) (under Option 1)). The proposal states that this requirement would not prohibit an importer or one of its employees from conducting the verification activity. In the preamble to the 2013 proposed rule, we requested comment on whether and, if so, how the regulations should specify what constitutes a financial interest (78 FR 45730 at 45759).

a. Comments

Many comments express support for prohibiting persons who conduct supplier verification activities from having a financial interest in the foreign supplier whose operations they are evaluating, as well as support for the ban on linking remuneration to the results of verification activity (i.e., payment for a favorable assessment). One comment states that we should specify what constitutes a financial interest to ensure that audits are not performed by persons with a financial interest in the foreign supplier, and requests that we provide a standard disclosure form regarding financial interests.

b. Request for Further Comment

At this time, we are not making any revisions to the proposed requirement that persons conducting supplier verification activities not have a financial interest in the foreign supplier and that payment to such a person must not be related to the results of the activity they have performed. However, in the Preventive Controls supplemental document, we are requesting comment on whether the potential supplier program requirements, should they be included in the final rule, include provisions to address the independence of persons who conduct supplier verification activities. We ask in that document whether such conflict of interest requirements should be directed to a subset of persons who conduct verification activities (such as auditors) or whether they should encompass all persons who conduct verification activities. We also ask whether requirements such as those in the FSVP proposed rule would be appropriate or whether we should instead adopt different requirements, such as a requirement that persons be free of conflicts of interest that are relevant to the outcome of the verification activity conducted. In addition, we ask what should constitute a financial interest, including whether owning stock in a company should constitute a financial interest.

In light of our statements in the Preventive Controls supplemental document, we renew our request for comment on the provisions in the FSVP proposed rule on the independence of qualified individuals conducting verification activities and invite comment (in the context of the FSVP regulations) on the additional conflict of interest issues raised in the Preventive Controls supplemental document.

D. Definitions of Very Small Importer and Very Small Foreign Supplier

The 2013 proposed rule specified certain modified FSVP requirements for very small importers and importers of food from very small foreign suppliers. Proposed § 1.500 defined a ''very small importer'' as an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation. Proposed § 1.500 defined a ''very small foreign supplier'' as a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation.

We stated in the preamble to the proposed rule that the limitation of $500,000 in annual food sales was consistent with the sales limitation in the definition of ''qualified facility'' in the Preventive Controls proposed rule and ''small business'' in the Produce Safety proposed rule. We requested comment on this proposed approach to the definitions of very small importer and very small foreign supplier (78 FR 45730 at 45744). We also requested comment on whether and, if so, how these definitions should take into account the proposed definition of ''very small business'' in the Preventive Controls proposed rule, for which we posed three alternative dollar-value ceilings: $250,000, $500,000, and $1 million.

1. Comments

Several comments oppose modified requirements for very small importers and importers of food from very small foreign suppliers regardless of the sales dollar-value ceiling. Reasons specified for such opposition include the following: Congress did not exempt very small importers from the FSVP requirements; smaller operations may be more likely than larger ones to lack adequate verification or control systems because they have fewer resources; the effect of the FSVP regulations could be undermined if importers and foreign suppliers tried to manipulate their facilities or operations to avoid the ''standard'' requirements; and many small foreign suppliers would already be exempt from the preventive controls or produce safety regulations and should not benefit from an exemption from verification for their U.S. importers.

Several comments support the proposed $500,000 annual food sales ceiling as a reasonable limit on eligibility for the ''very small'' modified FSVP requirements. Other comments maintain that a $1 million ceiling would better reflect the types of very small importers and foreign suppliers operating today. One comment proposes that FDA set the annual sales ceiling at $2 million to be consistent with how ''small companies'' are defined in Japan.

Some comments state that other factors, either instead of, or in addition to, the monetary value of food sales, should be considered in defining very small importers and very small foreign suppliers. Some comments maintain that a more appropriate eligibility standard would be volume of food handled or sold, reflecting the fact that sales revenues vary by type of food, origin, quantity, price, and inflation rates. One comment states that a very

small foreign supplier should be defined as one that has fewer than 100 employees, contending that use of a monetary value ceiling would provide an unfair advantage to foreign firms because many foreign suppliers are located in countries with currencies valued lower than the U.S. dollar.

Several comments state that the definitions of very small importer and very small foreign supplier should align with the definition of very small business under the preventive controls regulations. The comments state that such alignment is needed to reduce unnecessary confusion, help FDA achieve its stated goal of aligning the FSVP provisions with the supplier verification provisions in the preventive controls regulations, and ensure that the regulations are consistent with U.S. international trade obligations.

2. Revisions Regarding Definitions of Very Small Importer and Very Small Foreign Supplier

We are revising the proposed definitions of very small importer and very small foreign supplier by increasing the annual food sales ceiling from $500,000 to $1 million, consistent with the revised proposed definition of very small business set forth in the Preventive Controls supplemental document published elsewhere in this issue of the **Federal Register**. The preamble to the Preventive Controls supplemental document states that defining a very small business as a business that has less than $1 million in total annual sales of human food adjusted for inflation would simplify a food facility's determination of whether it is a qualified facility under the preventive controls regulations because the facility would only need to calculate its total sales of human food rather than determine how much food was sold to qualified end users. The preamble to the Preventive Controls supplemental document also notes that FDA estimates that businesses with less than $1 million in total annual food sales produce less than one percent of the dollar value of food that is produced in the United States that would be covered by the preventive controls regulations in the absence of special provisions for very small businesses. The preamble further states that we are not basing the proposed definition of very small business on the number of employees or the volume of food sold because the statutory criteria for qualified facilities (of which very small businesses are a subset) focus on monetary value of sales, rather than volume of sales or number of employees.

To more appropriately reflect the risk to public health posed by the volume of food imported by very small importers and importers of food from very small foreign suppliers, as well as to align the proposed FSVP regulations with the proposed preventive controls regulations, we tentatively conclude that the monetary value ceiling in the definitions of very small importer and very small foreign supplier should be $1 million, adjusted for inflation. Consistency with the monetary value ceiling in the proposed definition of very small business under the proposed Preventive Controls for Human Food regulations, rather than the monetary value ceiling in the so-called Tester Amendment criteria for the definition of qualified facility (under section 418(l)(1) of the FD&C Act, is appropriate because use of the $1 million ceiling (instead of, for example, a ceiling of $250,000) means that any facility with sales below the ceiling would meet the definition of a qualified facility. We request comment on whether the revised proposed monetary value ceiling of $1 million, adjusted for inflation, for very small importers and very small foreign suppliers is appropriate, as well as on whether it is appropriate that the ceiling be the same as that specified in the definition of very small business under the preventive controls regulations.

As previously noted, the produce safety proposed rule includes provisions applicable to ''small businesses,'' which are defined as having annual produce sales of no more than $500,000; the proposed rule also includes provisions for ''very small businesses,'' which are defined as having annual produce sales of no more than $250,000. In addition, farms with produce sales of no more than $25,000 would not be covered under the proposed produce safety regulations. We also note that the revised proposed regulations on preventive controls for food for animals define ''very small business'' as having annual sales of animal food of less than $2,500,000. We request comment on whether and, if so, how the FSVP regulations should take into account these definitions and provisions applicable to smaller entities under the regulations on produce safety and preventive controls for animal food.

As with all other matters not specifically addressed in this supplemental notice of proposed rulemaking, we are still considering the comments that we have received concerning other aspects of the proposed modified provisions for very small importers and importers of food from very small foreign suppliers. These issues include, but are not limited to, whether the regulations should include any such modified provisions and, if so, what the modified requirements should be and whether the food sales to be considered for determination of eligibility should be limited to sales in or to the United States, rather than all food sales of an importer or foreign supplier. We will address comments on these issues and finalize any requirements for very small importers and importers of food from very small foreign suppliers in the FSVP final rule.

E. Other Related Revisions

We are making other revisions to the proposed rule to incorporate the changes that we are making regarding food and foreign supplier risk evaluations and supplier verification activities.

1. FSVP Reassessments

We are revising the proposed requirement in § 1.508 of the previous proposal for importers to reassess the effectiveness of their FSVPs to be consistent with our amended proposal requiring importers to evaluate food and foreign supplier risks. Section 1.508(a)(2) in the revised regulatory text would require an importer to promptly reassess the effectiveness of its FSVP for a food when it becomes aware of new information about potential risks associated with the food or foreign supplier of the food, instead of when the importer becomes aware of information about potential food hazards, as under previous § 1.508(a)(2).

Similarly, § 1.508(b) in the revised regulatory text would require that, in conducting an FSVP reassessment, an importer update its risk evaluation for a food and foreign supplier rather than, as under previous § 1.508(b), updating only the hazard analysis the importer conducted. If the reassessment led to a change in the identified risks, the importer would need to determine whether it needed to change its verification activities.

2. Records

We are revising the proposed recordkeeping requirements to reflect the previously discussed proposed amendments regarding: (1) Importers whose customers are in compliance with the supplier program requirements of the preventive controls regulations, (2) importers whose customers are controlling a significant hazard in a food, and (3) documentation requirements for supplier verification activities. Under previous § 1.510(d)(2), importers would have been required to maintain for at least 2 years (after the records were created or obtained)

records of certain supplier verification activities, investigations and corrective actions, FSVP reassessments, food subject to certain dietary supplement CGMP regulations, and food imported from a country with an officially recognized or equivalent food safety system (except that records of changes to FSVPs in accordance with the corrective actions or reassessment provisions would have had to be maintained until at least 2 years after their use was discontinued).

Under § 1.510(d)(2) in the revised regulatory text, importers would be required to maintain for at least 2 years (after the records were created or obtained) records of, among other things, written assurances from their customers that are in compliance with the supplier program requirements of the preventive controls regulations and documentation of supplier verification activities that importers conduct. Also subject to this requirement would be written assurances from importers' customers that the customer has established and is following procedures that will significantly minimize or prevent a hazard. With respect to records concerning the importation of dietary supplements, § 1.510(d)(2) in the revised regulatory text makes clear that this 2-year requirement would apply to written assurances of compliance with the dietary supplement CGMPs obtained from importers' customers and documentation of supplier verification activities conducted by importers of dietary supplements (discussed in section II.E.3).

3. Dietary Supplements

We are revising the proposed modified FSVP requirements for importers of dietary supplements in § 1.511 of the proposed rule to reflect previously discussed revisions to the proposed rule. We are revising previously proposed § 1.511(a) and (b) to specify that importers of dietary supplements and dietary supplement components that are subject to certain dietary supplement CGMP regulations in part 111 (21 CFR part 111) (or whose customers are subject to those regulations) would not be required to comply with revised § 1.506(a), concerning the requirement to establish and follow written procedures to ensure the use of approved suppliers (which replaces the previously proposed requirement to maintain a written list of foreign suppliers). This change is appropriate because these importers would not be required to conduct risk evaluations, which provide the basis for supplier approval. However, we request comment on whether some other requirement concerning identification of foreign suppliers would be appropriate for these importers, such as a requirement, as originally proposed, to maintain a list of the foreign suppliers of the dietary supplements and dietary supplement components they import.

We also are revising several of the provisions in previously proposed § 1.511(c) regarding importers of dietary supplements that will not be further processed. First, we are revising § 1.511(c)(1) to specify that although importers of these ''finished'' dietary supplements would not be required to analyze the hazards in the dietary supplements they import, they would be required to evaluate the other food safety risks set forth in § 1.505(a) in the revised regulatory text. Second, under § 1.511(c)(2) in the revised regulatory text, importers of these dietary supplements would be required to establish and follow written procedures to ensure that foods are imported only from approved suppliers (except in the limited circumstances when unapproved suppliers may be used), rather than having to maintain a list of their foreign suppliers. Third, § 1.511(c)(4) in the revised regulatory text now specifies that the purpose of supplier verification activities with respect to these dietary supplements is to provide assurances that the supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111. Finally, in § 1.511(c)(5)(i) through (c)(5)(iv) in the revised regulatory text, we are proposing requirements for documentation of foreign supplier verification activities by these importers that match those discussed in section II.C.5.

4. Very Small Importers and Importers of Food From Very Small Foreign Suppliers

We are revising, in § 1.512 in the revised regulatory text, the proposed modified FSVP requirements for very small importers and importers of food from very small foreign suppliers by deleting the proposed requirement to maintain a list of foreign suppliers. Consistent with our approach to requirements for very small businesses under the potential supplier program provisions in the preventive controls proposed rule, we are not proposing to require very small importers and importers of food from very small foreign suppliers to institute procedures to verify receipt of food from approved foreign suppliers.

5. Food From Countries With Officially Recognized or Equivalent Food Safety Systems

We are revising, in § 1.513 in the revised regulatory text, the proposed modified FSVP requirements for importers of food from foreign suppliers in countries whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States by renumbering references to sections of the regulations and by deleting the requirement to maintain a list of foreign suppliers. We tentatively conclude that, given the nature of the food that may be imported in accordance with these modified provisions (e.g., that the food is from a foreign supplier in good compliance standing with the food safety authority in a country with a comparable or equivalent food safety system), it is not necessary to apply a requirement to establish a procedure to verify receipt of food from approved suppliers to importers of such food.

6. Qualified Individuals

We are revising previously proposed § 1.503, ''Who must develop my FSVP and perform FSVP activities?'', to revise a reference to proposed § 1.512, regarding the modified requirements for very small importers and importers of food from very small foreign suppliers. Previously proposed § 1.503 states that except with respect to the requirements in §§ 1.506(a), 1.509, 1.510, 1.511(c)(2), and 1.512(b)(3) and (b)(6), a qualified individual must develop their FSVP and perform each of the activities required under the subpart. Previously proposed § 1.512(b)(3) stated the proposed requirement to maintain a written list of foreign suppliers, a requirement that is being deleted by this supplemental document. Previously proposed § 1.512(b)(6) referred to records requirements, which have been renumbered as § 1.512(b)(5) in the revised regulatory text. Therefore, § 1.503 should be modified to refer only to § 1.512(b)(5).

III. Preliminary Regulatory Impact Analysis

As explained in the 2013 FSVP proposed rule, we performed the necessary analyses to examine the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the PRA (44 U.S.C. 3501–3520). We provided a preliminary regulatory impact analysis (PRIA) of the proposed rule (see Ref. 13 of the

proposed rule) for public input (78 FR 45730 at 45770).

We performed additional analyses to examine the impacts of the revised proposed provisions described in this **Federal Register** document under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act of 1995, and the PRA. We present our additional analyses, including the total estimated costs and benefits of the FSVP proposed rule as revised, in our supplemental PRIA for this proposed rule (Ref. 3). We seek comment on our additional analyses.

IV. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to review by the OMB under the PRA (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section with an estimate of the annual reporting, recordkeeping, and third-party disclosure 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: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.

Description: FDA is revising its proposed regulations on FSVPs for food for humans and animals. The proposed regulations are intended to help ensure that food imported into the United States is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as the processes and procedures required for production of food in compliance with section 418 or 419 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g or 350h), if either is applicable, and in compliance with sections 402 and 403(w) of the FD&C Act (21 U.S.C. 342 and 343(w)). The revisions to the proposed rule include the following: (1) Specifying a revised approach to proposed requirements for supplier verification activities (the previous proposal contained two alternative approaches); (2) stating that importers who are in compliance with the potential supplier program provisions of the preventive controls regulations would be deemed in compliance with most of the FSVP requirements; (3) deleting the proposed requirement that importers conduct a food and foreign supplier compliance status review but adding a proposed requirement that importers consider, in addition to the hazards in the food they import, certain factors related to supplier risks; (4) proposing to require importers to follow written procedures for ensuring the use of suppliers that they have approved based on their evaluation of supplier risks, rather than require importers to maintain a list of suppliers; (5) proposing to require importers of food from farms not subject to the produce safety regulations to obtain written assurance of compliance from their suppliers rather than conduct standard verification activities; and (6) revising the definitions of very small importer and very small foreign supplier by increasing the annual food sales limit from $500,000 to $1 million.

Description of Respondents: Generally, persons who import food into the United States. We estimate that there are approximately 56,800 persons who meet the definition of importer set forth in the proposed rule. However, the proposed rule would exempt from the FSVP requirements the importation of certain foods, including certain juice and seafood products, food for research or evaluation (exempt but subject to a third-party disclosure requirement), food for personal consumption, certain alcoholic beverages, food that is transshipped, and food that is imported for further processing and future export. The proposed rule also would specify that importers who are in compliance with any supplier program provisions that the preventive controls final regulations may include would be deemed in compliance with most of the FSVP requirements.

Certain exceptions to the standard FSVP requirements would apply to importers of food for which the importer or its customer controls the hazards and to importers of food from farms not subject to the produce safety regulations. In addition, the proposed rule would establish modified FSVP requirements for importers of dietary supplements, very small importers, importers of food from very small foreign suppliers, and importers of food from suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

The information collection estimate for the FSVP proposed rule has decreased due to revisions to the proposed rule requirements. The information collection burden was previously estimated to be 3,303,988 hours; the revised estimate is 2,917,603 hours, a reduction of 386,385 hours. For more information on the original calculation of the information burden estimate, refer to the PRA for the previous proposed rule (Docket No. FDA–2011–N–0143).

Information Collection Burden Estimate

Supplemental Notice of Proposed Rulemaking Burden

FDA estimates the burden for this information collection as follows:

A. Reporting Burden

1. Exemption for Food for Research or Evaluation

Under proposed § 1.501(c), the FSVP regulations would not apply to food that is imported for research or evaluation purposes, provided that:

- The food is not intended for retail sale and is not sold or distributed to the public.
- The food is labeled with the statement ''Food for research or evaluation use.''
- When filing entry for the food with U.S. Customs and Border Protection (CBP), the customs broker or filer for the food provides an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

As shown in table 1, we estimate that annually there will be 36,360 persons for whom a declaration that a food will be used for research or evaluation purposes will be submitted, and that about 40 declarations will be submitted for each such person annually. We further estimate that submission of this declaration should take approximately 0.083 hours, resulting in a total annual burden of 120,715 hours. There is no change from the previous estimated burden.

2. Importer Identification at Entry

Proposed § 1.509(c) would require importers to ensure that, for each line entry of food product offered for importation into the United States, its name and Dun and Bradstreet Data

Universal Numbering System (DUNS) number is provided electronically when filing entry with CBP. As shown in table 1, we estimate that each of the estimated 56,800 importers would need to ensure that this information is provided for an average of 157 line entries each year. We further estimate that each such submission would require 0.02 hours, resulting in a total annual burden of 178,352 hours. There is no change from the previous estimated burden.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food for research 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
DUNS number for filing with CBP 1.509(c), 1.511(c), 1.512(b)(2).	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total					299,067

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

B. Recordkeeping Burden

1. Documentation of Production of Low-Acid Canned Foods in Accordance With 21 CFR Part 113

Proposed § 1.502(b) would require importers of thermally processed low-acid canned foods (LACF) packaged in hermetically sealed containers to verify and document that, with respect to microbiological hazards that are controlled under part 113 (21 CFR part 113), the food was produced in accordance with those regulations, and for all matters not controlled under part 113, to have an FSVP as specified in § 1.502(a). As shown in table 2, we estimate that there are 2,443 importers of LACF importing an estimated 4 LACF products annually. We further estimate that it would take each LACF importer 1 hour to document that a food was produced in accordance with part 113. This results in a total annual burden of 9,772 hours. There is no change from the previous estimated burden.

2. Hazard Analysis

Revised proposed § 1.504(a) would require importers, for each food they import or offer for import, to have a written hazard analysis. We estimate that 13,389 importers would need to spend an average of 10.5 hours each determining and documenting hazard analyses for imported foods, resulting in an estimated burden of 140,584.5 hours (46,862 hours annualized).

Revised proposed § 1.504(d) would permit importers to identify the hazards that are reasonably likely to occur with a food by reviewing and evaluating the hazard analysis conducted by the foreign supplier of the food. If the importer selects this approach to hazard analysis it must document the determination it makes based on its review and evaluation of the foreign supplier's hazard analysis. As shown in table 2, we estimate that 13,389 importers would take this approach to hazard analysis for about 7 products each, and that evaluating the supplier's hazard analysis and documenting each evaluation would require about 1 hour on average. This results in a total burden of 93,723 hours (30,929 hours annualized).

3. Risk Evaluation

Revised proposed § 1.505(a)(2) would require importers to document their evaluation of food and supplier risks. As shown in table 2, we estimate that it will take 12 hours for each of an estimated 13,389 importers to conduct and document their risk evaluation and approval of suppliers, resulting in a total burden of 160,668 hours (53,556 hours annualized). In addition, revised proposed § 1.505(b) requires that the importer reevaluate risk factors associated with suppliers when the importer becomes aware of new information. Recognizing that some importers may choose to spend more time less often, we estimate it would take about 15 minutes per day to maintain and follow these procedures by reviewing information regarding hazards and suppliers. This results in a burden of 1,221,746 hours annually.

4. Foreign Supplier Verification and Related Activities

Under revised proposed § 1.506(a), importers must establish and follow adequate written procedures to ensure that they import foods only from foreign suppliers that they have approved based on the risk evaluation they conduct under § 1.505 or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods importers subject to adequate verification activities before distributing, and document the use of those procedures. As shown in table 2, we estimate that it would take each of 13,389 importers 8 hours to establish procedures resulting in a burden of 107,112 hours (35,749 hours annualized) and 4 hours annually to document the use of such procedures resulting in an annual burden of 53,556 hours for a grand total of 89,305 hours annually.

Under revised proposed § 1.506(b), importers must establish and follow adequate written procedures for conducting foreign supplier verification activities. As shown in table 2, we estimate that it would take each of 13,389 importers 2 hours to establish procedures for about 4 hazards/products per importer resulting in a total annual burden of 107,112 hours (35,883 hours annualized).

Revised proposed § 1.506(d) would require importers to determine and document which supplier verification activities are appropriate in order to provide adequate assurances that the foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419, as applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. Under revised proposed § 1.506(d)(1)(i), an importer may conduct (and document) or obtain documentation of a periodic onsite audit of the foreign supplier. As shown in table 2, we estimate that 2,369 such audits would be conducted or documentation obtained for, with each audit requiring an average of 14 hours each, resulting in a total annual burden of 33,166 hours.

Under revised proposed § 1.506(d)(1)(ii), an importer may conduct (and document) or obtain documentation from a foreign supplier of lot-by-lot or periodic sampling and testing of a food for a hazard. As shown in table 2, we estimate that 11,396 importers each year would determine that this approach to verification is

appropriate an average of 5 times per year. We further estimate that each incidence of sampling and testing and corresponding documentation will require 4 hours. This results in a total annual burden of 227,920 hours.

Under revised proposed § 1.506(d)(1)(iii), an importer may conduct (and document) or obtain documentation of a review of its foreign supplier's food safety records to verify control of a hazard. As shown in table 2, we estimate that 11,396 importers each year would determine that this approach to verification is appropriate an average of 5 times per year. We further estimate that documentation of food safety record review would require 1.6 hours, resulting in a total annual burden of 91,168 hours.

Under revised proposed § 1.506(d)(1)(iv), an importer may use a different verification procedure that it has established as being appropriate based on the risk associated with the food and foreign supplier; the importer must document such use. We have not identified any alternative verification procedure nor included such costs in the PRIA; therefore, we do not identify any associated burden here for revised proposed § 1.506(d)(1)(iv).

Revised proposed § 1.506(d)(4) requires that if a foreign supplier of a food is a farm that is not subject to the requirements in part 112, the importer need only to: (1) Document, at the end of each calendar year, that the food from the foreign supplier is not subject to the produce safety regulations and (2) obtain written assurance, at least every 2 years, that the foreign supplier is producing the food in compliance with the FD&C Act. We estimate that these requirements would affect 22,333 importers annually and that each importer would need to conduct this documentation for 8 such suppliers each year, with documentation of each determination requiring, on average, 0.75 hours. This would result in a total annual burden of 133,998 hours.

Revised proposed § 1.506(d)(5) would allow an importer, instead of conducting an onsite audit, to rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. We do not estimate a PRA burden associated with this option because FDA has only officially recognized one country's food safety system to date and the Agency inspects only a small percentage of foreign food facilities each year.

5. Review of Complaints, Investigations, and Corrective Actions

Proposed § 1.507(b) would require an importer, if it became aware that an article of food that it imported was adulterated or misbranded, to promptly investigate the cause or causes of such adulteration or misbranding and to document any such investigation. As shown in table 2, we estimate that 10,658 importers would need to conduct 1 such investigation each year, and that conducting and documenting an investigation will require 14 hours. This would result in a total annual burden of 149,212 hours. There is no change from the previous estimated burden.

Revised proposed § 1.507(c) would require an importer to take corrective actions if it determines that one of its foreign suppliers of a food does not produce the food in compliance with the requirements of section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act. Such corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. In the PRIA we postulated that most importers probably already take some type of corrective actions if they determine that a food they import is not in compliance with appropriate regulations and that they probably document those corrective actions. Therefore, because we assume that most importers already take these types of corrective actions, we did not estimate the cost of additional corrective actions in the PRIA nor calculate a burden associated with corrective actions in the PRA.

Revised proposed § 1.507(d) would require an importer, if it determines by means other than its verification activities conducted under § 1.506 or § 1.511(c) or its FSVP reassessment conducted under § 1.508, that one of its foreign suppliers does not produce food in compliance with the requirements of section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act, to promptly investigate to determine whether the importer's FSVP is adequate and, when appropriate, to modify the FSVP. This provision also would require importers to document any such investigations and FSVP changes. As shown in table 2, we estimate that, on average, 10,658 importers will need to conduct an investigation once a year to determine the adequacy of their FSVP in accordance with proposed § 1.507(d) and that conducting and documenting the investigation will require 5 hours. This would result in a total annual burden of 53,290 hours. There is no change from the previous estimated burden.

6. FSVP Reassessment

Revised proposed § 1.508(b) would require an importer to document each reassessment of its FSVP that it conducts under § 1.508 and any resulting changes to the FSVP. Reassessment would be required every 3 years or more frequently if an importer becomes aware of new information about potential risks associated with a food or foreign supplier. We did not estimate a cost for reassessing an importer's FSVP under this requirement in the PRIA because we have already incorporated the costs of reassessment into the costs for maintaining the various elements of the FSVP in other provisions. Therefore we do not calculate an associated PRA burden here.

7. Food Subject to Certain Dietary Supplement CGMP Regulations

Revised proposed § 1.511 sets forth modified FSVP requirements for food that is subject to certain dietary supplement CGMP regulations. Under revised proposed § 1.511(a), importers who are required to establish specifications under § 111.70(b), (d), or (f) (21 CFR 111.70(b), (d), or (f)) with respect to a food, and are in compliance with the requirements of part 111 applicable to determining whether those specifications are met, must comply with the requirements in proposed §§ 1.509 and 1.510, but are not required to comply with the requirements of proposed §§ 1.502 through 1.508. These importers are included in the estimated reporting burden for proposed § 1.509(c).

Under revised proposed § 1.511(b), if an importer's customer is required to establish specifications under § 111.70(b), (d), or (f) with respect to a food, the customer is in compliance with the requirements of part 111 applicable to determining whether those specifications are met, and the importer annually obtains from its customer written assurance that the customer is in compliance with those requirements, then for that food the importer must comply with the requirements in §§ 1.509 and 1.510, but is not required

to comply with the requirements of §§ 1.502 through 1.508. As shown in table 2, we estimate that 5,574 importers would need to obtain written assurance from an average of 6 customers in accordance with revised § 1.511(b) and that documentation of each assurance would take 2.25 hours, resulting in a total annual burden of 75,249 hours. In addition, these importers are included in the estimated annual reporting burden for proposed § 1.509(c).

Under revised proposed § 1.511(c), importers of ''finished'' dietary supplements (i.e., packaged and labeled dietary supplements that are not subject to further processing) would be subject to different FSVP requirements. Revised proposed § 1.511(c)(2) would require importers of finished dietary supplements to establish and follow written procedures to ensure that food is imported only from foreign suppliers that have been approved for use based on the risk evaluation conducted under § 1.505. This burden to importers of ''finished'' dietary supplements is captured in the burden calculated for proposed § 1.506(a). Proposed § 1.511(c)(3) would require importers of finished dietary supplements to establish and follow procedures for conducting foreign supplier verification activities. This burden is included in the burden of revised proposed § 1.506(b).

Revised proposed § 1.511(c)(5) would require importers of finished dietary supplements to determine and document which appropriate verification activities should be conducted, and the frequency with which they should be conducted. As shown in table 2, we estimate that this provision would affect 1,822 importers annually and that each importer would need to make and document about 2 determinations (regarding both the appropriate verification activity and its frequency) each year, with making and documenting of each determination requiring 2.5 hours. This would result in a total annual burden of 9,110 hours. There is no change from the previous estimated burden.

For each ''finished'' dietary supplement imported, the importer would need to conduct one or more of the verification activities listed in proposed § 1.511(c)(5)(i) through (c)(5)(iv) before using or distributing the dietary supplement and periodically thereafter. The estimates associated with these activities are included in the burdens presented in table 2 for § 1.506(d)(1)(i) through (d)(1)(iv), respectively.

Revised proposed § 1.511(c) also would require importers of finished dietary supplements to conduct risk evaluations, conduct investigations and corrective actions, reassess the effectiveness of their FSVP, and ensure that information identifying them as the importer is provided at entry. These importers have been included in the estimated recordkeeping and reporting burdens for these activities under proposed §§ 1.505, 1.507(b), 1.508(b), and 1.509(c), respectively. We do not estimate any specific burden associated with corrective actions (§ 1.507(c)) as previously discussed.

8. Food Imported by Very Small Importers and From Very Small Foreign Suppliers

Revised proposed § 1.512 sets forth modified proposed FSVP requirements for very small importers (i.e., importers with annual food sales of not more than $1 million) and food from very small foreign suppliers (i.e., foreign suppliers with annual food sales of not more than $1 million).

Under proposed § 1.512(b)(1), if a very small importer or an importer of food from a very small foreign supplier chooses to comply with the requirements in § 1.512, the importer would be required to document, at the end of each calendar year, that it meets the definition of very small importer in § 1.500 or that the foreign supplier meets the definition of very small foreign supplier in § 1.500, whichever is applicable. As shown in table 2, we estimate that 56,800 importers would need to document eligibility each year (either that they are a very small importer or that they are obtaining food from a very small foreign supplier) and that such documentation would require 1 hour. While very small importers would only need to document this once per year, importers importing from very small suppliers may need to do it more than once, so we use an average of 1.79 records per importer, resulting in a total annual burden of 101,770 hours.

Under revised proposed § 1.512(b)(3), each very small importer or importer of food from a very small foreign supplier would need to obtain written assurance, before importing the food and at least every 2 years thereafter, that its foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as that required under section 418 or 419 of the FD&C Act, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. As shown in table 2, we estimate that 56,800 importers would need to obtain an average of 2 such written assurances each year and that documentation of each assurance would require 2.25 hours, resulting in a total annual burden of 255,600 hours.

Revised proposed § 1.512(b)(4) also would require very small importers and importers of food from very small foreign suppliers to document corrective actions; as previously stated, we do not estimate any specific burden associated with corrective actions.

9. Food Imported From a Country With an Officially Recognized or Equivalent Food Safety System

Revised proposed § 1.513 would establish modified FSVP requirements for importers of food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States. If such importers met certain conditions or requirements, they would not be required to comply with the requirements in proposed §§ 1.503 through 1.508, but they would be required to comply with §§ 1.509 and 1.510.

Proposed § 1.513(b)(1) would require an importer, before importing a food from the foreign supplier and annually thereafter, to document that the foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent and that the food is within the scope of FDA's official recognition or equivalency determination regarding the food safety authority of the country in which the foreign supplier is located.

Proposed § 1.513(b)(2) would require an importer, before importing a food from the foreign supplier, to determine and document whether the foreign supplier of the food is in good compliance standing, as defined in proposed § 1.500, with the food safety authority of the country in which the foreign supplier is located. The importer would be required to continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicated that food safety hazards associated with the food were not being adequately controlled, the importer would be required to take prompt corrective action and to document any such action.

FDA has officially recognized New Zealand as having a food safety system that is comparable to that of the United States; we have not yet determined any food safety systems to be equivalent. Because we have only recently entered into a systems recognition arrangement with New Zealand, we have not been

able to assess the effect of the arrangement on the importation of food from that country. Therefore, we have not included estimates for the recordkeeping burdens associated with proposed § 1.513. There is no change from the previous estimated burden.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours	Total operating and maintenance costs
Controls for LACF 1.502(b)	2,443	4	9,772	1	9,772	
Determine and document hazards 1.504(a)	13,389	1	13,389	3.5	46,862	
Review hazard analysis 1.504(d)	13,389	7	93,723	0.33	30,929	
Risk evaluation 1.505(a) and (b), 1.511(c)(2)	13,389	1	13,389	4	53,556	
Reevaluation of risks 1.505(c)	13,389	365	4,886,985	0.25	1,221,746	
Written procedures for use of approved foreign suppliers 1.506(a), 1.511(c)(2)	13,389	1	13,389	6.67	89,305	
Written procedures for conducting verification activities 1.506(b), 1.511(c)(3)	13,389	4	53,556	0.67	35,883	
Conduct/review audits 1.506(d)(1)(i), 1.511(c)(5)(i)	2,369	1	2,369	14	33,166	$1,480,625
Conduct periodic sampling/testing 1.506(d)(1)(ii), 1.511(c)(5)(ii)	11,396	5	56,980	4	227,920	$75,954,340
Review records 1.506(d)(1)(iii), 1.511(c)(5)(iii)	11,396	5	56,890	1.6	91,168	
Written assurances from foreign suppliers 1.506(d)(4)	22,333	8	178,664	0.75	133,998	
Investigate adulteration or misbranding 1.507(b), 1.511(c)(1)	10,658	1	10,658	14	149,212	$6,661,250
Investigate and determine FSVP adequacy 1.507(d), 1.511(c)(1)	10,658	1	10,658	5	53,290	
Written assurances for food produced under dietary supplement CGMPs 1.511(b)	5,574	6	33,444	2.25	75,249	
Determine and document verification activities for importers of dietary supplements 1.511(c)(5)	1,822	2	3,644	2.50	9,110	
Document very small importer/very small foreign supplier status 1.512(b)(1)	56,800	1.79	101,770	1	101,770	
Written assurances associated with very small importer/very small foreign supplier 1.512(b)(3)	56,800	2	113,600	2.25	255,600	
Total					2,618,536	$84,096,215

[1] There are no capital costs associated with this collection of information.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. Interested persons are requested to send comments regarding information collection by December 15, 2014 to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.''

V. Analysis of Environmental Impact

We did not prepare an environmental assessment or an environmental impact statement for the 2013 FSVP proposed rule because we 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. Because we have reached the same determination with respect to these revisions to the proposed rule included in this supplemental notice of proposed rulemaking, neither an environmental assessment nor an environmental impact statement is required for this document.

VI. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

VII. 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. These references are also available electronically at *http://regulations.gov.* We have verified the Web site addresses in this section, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.

1. FDA, Statement from FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers, December 19, 2013 (*http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm379397.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery*).
2. FDA, Proposed 21 Code of Federal Regulations, Part 1, Subpart L—Foreign Supplier Verification Programs for Food Importers (indicating revisions proposed in supplemental notice of proposed rulemaking), 2014.
3. FDA, ''Supplemental Preliminary Regulatory Impact Analysis,'' Docket Nos. FDA–2011–N–0143, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, and FDA–2011–N–0146, Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 2014 (*http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*).

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1, as proposed to be added on July 29, 2013 (78 FR 45730), be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 384a, 393; 42 U.S.C. 216, 241, 243, 262, 264.

Subpart L—[Amended]

■ 2. In § 1.500, remove the definition for ''Hazard reasonably likely to occur,'' add in alphabetical order definitions for ''Environmental pathogen,'' ''Facility,'' ''Known or reasonably foreseeable hazard,'' ''Pathogen,'' ''Qualified auditor,'' and ''Significant hazard,'' and revise the definitions for ''Hazard,'' ''Very small foreign supplier,'' and ''Very small importer'' to read as follows:

§ 1.500 What definitions apply to this subpart?

* * * * *

Environmental pathogen means a pathogen that is capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize or prevent the environmental pathogen. Environmental pathogen does not include the spores of pathogenic sporeformers.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of subpart H of this part.

* * * * *

Hazard means any biological, chemical (including radiological), or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

* * * * *

Known or reasonably foreseeable hazard means a potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with a food or the facility in which it is manufactured/processed.

* * * * *

Pathogen means a microorganism of public health significance.

Qualified auditor means a person who is a qualified individual as defined in this section and has technical expertise obtained by a combination of training and experience appropriate to perform the auditing function. A foreign government employee could be a qualified auditor.

* * * * *

Significant hazard means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

* * * * *

Very small foreign supplier means a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million, adjusted for inflation.

Very small importer means an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million, adjusted for inflation.

* * * * *

■ 3. In § 1.502, add paragraphs (c) and (d) to read as follows:

§ 1.502 What foreign supplier verification program (FSVP) must I have?

* * * * *

(c) *Importers subject to section 418 of the Federal Food, Drug, and Cosmetic Act.* If you are required to establish and implement a risk-based supplier program under § 117.136 or § 507.43 of this chapter for a food you import and you are in compliance with that section, then you are deemed to be in compliance with the requirements of this subpart, except for the requirements in § 1.509.

(d) *Importers whose customer is subject to section 418 of the Federal Food, Drug, and Cosmetic Act.* If your customer is required to establish and implement a risk-based supplier program under § 117.136 or § 507.43 of this chapter for a food you import, and you annually obtain from your customer written assurance that it is in compliance with that section, then you are deemed to be in compliance with the requirements of this subpart, except for the requirements in §§ 1.509 and 1.510.

■ 4. Revise § 1.503 to read as follows:

§ 1.503 Who must develop my FSVP and perform FSVP activities?

Except with respect to the requirements in §§ 1.506(a), 1.509, 1.510, 1.511(c)(2), and 1.512(b)(5), a qualified individual must develop your FSVP and perform each of the activities required under this subpart.

■ 5. Revise § 1.504 to read as follows:

§ 1.504 What hazard analysis must I conduct?

(a) *Requirement for a hazard analysis.* You must identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each food you import to determine whether there are any significant

hazards. Your hazard analysis must be written.

(b) *Hazard identification.* (1) Your analysis of the known or reasonably foreseeable hazards in each food must include the following types of hazards:

(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

(ii) Chemical hazards, including radiological hazards, pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

(iii) Physical hazards.

(2) Your analysis must include hazards that may be present in a food for any of the following reasons:

(i) The hazard occurs naturally;

(ii) The hazard may be unintentionally introduced;

(iii) The hazard may be intentionally introduced for purposes of economic gain.

(c) *Hazard evaluation.* (1) Your hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the probability that the hazard will occur in the absence of controls and the severity of the illness or injury if the hazard were to occur.

(2) The hazard evaluation required by paragraph (c)(1) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment before packaging and the packaged food does not receive a treatment that would significantly minimize the pathogen.

(3) Your hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;

(ii) The condition, function, and design of the foreign supplier's establishment and equipment;

(iii) Raw materials and ingredients;

(iv) Transportation practices;

(v) Harvesting, raising, manufacturing, processing, and packing procedures;

(vi) Packaging and labeling activities;

(vii) Storage and distribution;

(viii) Intended or reasonably foreseeable use;

(ix) Sanitation, including employee hygiene; and

(x) Any other relevant factors.

(d) *Review of the foreign supplier's hazard analysis.* If your foreign supplier has analyzed the known or reasonably foreseeable hazards for the food to determine whether there are any significant hazards, you may meet your requirement to determine whether there are any significant hazards in a food by reviewing and assessing the analysis conducted by the foreign supplier.

(e) *Microbiological hazards in raw agricultural commodities that are fruits or vegetables.* If you are importing a raw agricultural commodity that is a fruit or vegetable, you are not required to determine whether there are any significant microbiological hazards in such food.

(f) *No significant hazards.* If you evaluate the known and reasonably foreseeable hazards in a food and determine that there are no significant hazards, you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. This paragraph (f) does not apply if the food is a raw agricultural commodity that is a fruit or vegetable and that is subject to part 112 of this chapter.

(g) *Significant hazards controlled by you and/or your customer.* If the preventive controls that you and/or your customer implement in accordance with subpart C of part 117 of this chapter are adequate to significantly minimize or prevent all significant hazards in a food you import, you are not required to determine what foreign supplier verification and related activities you must conduct under § 1.505 and you are not required to conduct such activities under § 1.506. If your customer controls one or more such hazards, you must annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

■ 6. Revise § 1.505 to read as follows:

§ 1.505 What risk evaluation must I conduct?

(a) *Evaluation of food and supplier risks.* (1) In determining the appropriate supplier verification and related activities that you must conduct, you must consider the following:

(i) The hazard analysis that you conduct in accordance with § 1.504, including the nature of the hazard.

(ii) The entity that will be applying controls for the hazards analyzed under § 1.504, such as the foreign supplier or the foreign supplier's raw material or ingredient supplier.

(iii) The foreign supplier's procedures, processes, and practices related to the safety of the food.

(iv) Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert.

(v) The foreign supplier's food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food, and the supplier's record of correcting problems.

(vi) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) You must document your evaluation of risks.

(b) *Reevaluation of risk factors.* You must promptly reevaluate the risk factors specified in paragraph (a)(1) of this section associated with a food or foreign supplier when you become aware of new information about these factors. If you determine that it is appropriate to continue to import the food from the foreign supplier, you must document the reevaluation and your determination.

■ 7. Revise § 1.506 to read as follows:

§ 1.506 What foreign supplier verification and related activities must I conduct?

(a) *Use of approved foreign suppliers.* You must establish and follow written procedures to ensure that you import foods only from foreign suppliers you have approved based on the risk evaluation you conduct under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before using or distributing). You must document your use of these procedures.

(b) *Foreign supplier verification procedures.* You must establish and follow adequate written procedures for conducting foreign supplier verification activities with respect to the foods you import.

(c) *Purpose of supplier verification.* Your foreign supplier verification activities must provide adequate assurances that the foreign supplier produces the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g, 350h, 342, and 343(w)).

(d) *Foreign supplier verification activities.* (1) Except as provided in paragraphs (d)(2) and (4) of this section, you must conduct and document one or more of the supplier verification activities listed in paragraphs (d)(1)(i) through (iv) of this section for each foreign supplier before using or distributing the food and periodically thereafter. You must determine and

document which verification activity or activities are appropriate, as well as the frequency with which the activities must be conducted, based on the risk evaluation you conduct for the food and the foreign supplier under § 1.505.

(i) *Onsite audit of the foreign supplier.* (A) An onsite audit of a supplier must be performed by a qualified auditor.

(B) If the food is subject to one or more FDA food safety regulations, an onsite audit of the foreign supplier must consider such regulations and include a review of the supplier's written food safety plan for the food, if any, including its implementation.

(C) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(ii) *Sampling and testing of the food.* (A) Sampling and testing of a food may be conducted by either the importer or the foreign supplier.

(B) You must retain documentation of each sampling and testing of a food, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical methods(s) used), the date(s) on which the test(s) were conducted, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing.

(iii) *Review of the foreign supplier's relevant food safety records.* You must retain documentation of each record review, including the date(s) of review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) *Other appropriate activity.* You may conduct other supplier verification activities that are appropriate based on the risk associated with the food and the foreign supplier. You must document each performance of such verification activity.

(2) When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, you must conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless you document your determination that, instead of such initial and annual onsite auditing, other supplier verification activities as set forth in paragraph (d)(1) of this section and/or less frequent onsite auditing are appropriate to provide adequate assurances in accordance with paragraph (c) of this section for the food and foreign supplier based on the determination you made under § 1.505.

(3) Based on the risk evaluation you conduct, it might be necessary, under paragraph (d)(1) or (2) of this section, to conduct more than one supplier verification activity to address an individual hazard or risk factor or multiple hazards or risk factors.

(4) If a foreign supplier of a food is a farm that is not subject to the requirements in part 112 of this chapter in accordance with § 112.4 regarding the food being imported, the importer need not comply with paragraphs (d)(1) and (2) of this section if the importer:

(i) Documents, at the end of each calendar year, that the food provided by the foreign supplier is not subject to part 112 of this chapter; and

(ii) Obtains written assurance, at least every 2 years, that the foreign supplier is producing the food in compliance with the Federal Food, Drug, and Cosmetic Act.

(5) *Substitution of inspection by FDA or an officially recognized or equivalent food safety authority.* (i) Instead of an onsite audit conducted under paragraph (d)(1) or (2) of this section, an importer may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. You must document the inspection results on which you rely.

(ii) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(6) *Review of results of verification activities.* You must promptly review the results of the verification activities that you conduct or obtain documentation of under paragraph (d) of this section. If the results show that the risks for the food or foreign supplier identified in the determination you made under § 1.505 are not adequately controlled, you must take appropriate action in accordance with § 1.507(c).

(7) *Independence of qualified individuals.* A qualified individual who conducts any of the verification activities set forth in paragraph (d) of this section must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees from conducting the verification activity.

■ 8. Amend § 1.508 by revising paragraphs (a)(2) and (b) to read as follows:

§ 1.508 How must I reassess the effectiveness of my FSVP?

(a) * * *

(2) You must promptly reassess the effectiveness of your FSVP for a food you import when you become aware of new information about potential risks associated with the food or foreign supplier of the food.

(b) *Reassessment and implementation of changes.* In conducting a reassessment of your FSVP as required by paragraph (a) of this section, you must update your risk evaluation for the food and foreign supplier in accordance with § 1.505. If the risks you previously identified change as a result of the reassessment, you must promptly determine whether the verification activities you conduct under § 1.506 or § 1.511(c) need to be changed to comply with that section, and you must promptly implement any such changes. You must document each reassessment you conduct and any resulting changes to your FSVP.

■ 9. Amend § 1.510 by revising paragraph (d)(2) to read as follows:

§ 1.510 How must I maintain records of my FSVP?

* * * * *

(d) *Record retention.* * * *

(2) You must maintain records required under §§ 1.502(d) and 1.504(g) (customer assurances), § 1.506(d)(1)(i)(C), (d)(1)(ii)(B), (d)(1)(iii), and (d)(1)(iv) (certain verification activities), § 1.507 (investigations and corrective actions), § 1.508 (FSVP reassessments), § 1.511(b) (assurances from customers subject to certain dietary supplement current good manufacturing practice regulations), § 1.511(c)(5)(i)(C), (c)(5)(ii)(B), (c)(5)(iii), and (c)(5)(iv) (certain verification activities for importers of certain dietary supplements), and § 1.513(b) (food imported from a country with an officially recognized or equivalent food safety system) for a period of at least 2

years after the records were created or obtained, except that you must maintain records of any changes to your FSVP in accordance with § 1.507(d) or § 1.508(b) until at least 2 years after their use is discontinued.

■ 10. Amend § 1.511 by:

■ a. Revising the first sentence of paragraph (a);

■ b. Revising paragraph (b);

■ c. Revising paragraphs (c)(1), (2), and (4);

■ d. Revising the second sentence of paragraph (c)(5) introductory text;

■ e. Revising paragraphs (c)(5)(i) through (iv), (6), (7), and (8); and

■ f. Removing paragraph (c)(9).

The revisions read as follows:

§ 1.511 What FSVP must I have if I am importing a food subject to certain dietary supplement current good manufacturing practice regulations?

(a) *Importers subject to certain dietary supplement current good manufacturing practice regulations.* If you are required to establish specifications under § 111.70(b), (d), or (f) of this chapter with respect to a food you import and you are in compliance with the requirements of part 111 of this chapter applicable to determining whether the specifications you established are met for such food, then for that food you must comply with the requirements in §§ 1.509 and 1.510, but you are not required to comply with the requirements in §§ 1.502 through 1.508. * * *

(b) *Importers whose customer is subject to certain dietary supplement current good manufacturing practice regulations.* If your customer is required to establish specifications under § 111.70(b), (d), or (f) of this chapter with respect to a food you import, your customer is in compliance with the requirements of part 111 of this chapter applicable to determining whether the specifications it established are met for such food, and you annually obtain from your customer written assurance that it is in compliance with those requirements, then for that food you must comply with the requirements in §§ 1.509 and 1.510, but you are not required to comply with the requirements in §§ 1.502 through 1.508.

(c) *Other importers of dietary supplements.* (1) *General.* If the food you import is a dietary supplement and neither paragraph (a) or (b) of this section is applicable, you must comply with paragraph (c) of this section and the requirements in §§ 1.503, 1.505(a)(2) through (a)(6) and (b), and 1.507 through 1.510, but you are not required to comply with the requirements in §§ 1.504 and 1.505(a)(1). This requirement does not limit your obligations with respect to part 111 of this chapter or any other laws enforced by FDA.

(2) *Use of approved foreign suppliers.* You must establish and follow written procedures to ensure that you import foods only from foreign suppliers that you have approved based on the risk evaluation you conduct under § 1.505 (or, when necessary and appropriate, on a temporary basis from unapproved foreign suppliers whose foods you subject to adequate verification activities before using or distributing). You must document your use of these procedures.

* * * * *

(4) *Purpose of supplier verification.* Your foreign supplier verification activities must provide adequate assurances that your supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under part 111 of this chapter.

(5) *Supplier verification activities.* * * * You must determine and document which verification activity or activities are appropriate to provide adequate assurances in accordance with paragraph (c)(4) of this section. * * *

(i) *Periodic onsite auditing.* You conduct (and document) or obtain documentation of a periodic onsite audit of your foreign supplier.

(A) An onsite audit of a supplier must be performed by a qualified auditor.

(B) The onsite audit must consider the requirements of part 111 of this chapter and must include a review of the foreign supplier's written food safety plan, if any, and the supplier's implementation of such plan.

(C) You must retain documentation of each onsite audit, including the audit procedures, the dates the audit was conducted, the conclusions of the audit, any corrective actions taken in response to significant deficiencies identified during the audit, and documentation that the audit was conducted by a qualified auditor.

(ii) *Periodic or lot-by-lot sampling and testing of the food.* (A) Sampling and testing of the dietary supplement may be conducted by you or the foreign supplier.

(B) You must retain documentation of each sampling and testing of a dietary supplement, including identification of the food tested (including lot number, as appropriate), the number of samples tested, the test(s) conducted (including the analytical method(s) used), the date(s) on which the test(s) were conducted, the results of the testing, any corrective actions taken in response to detection of hazards, and information identifying the laboratory conducting the testing.

(iii) *Periodic review of the foreign supplier's food safety records.* You must retain documentation of each record review, including the date(s) of review, any corrective actions taken in response to significant deficiencies identified during the review, and documentation that the review was conducted by a qualified individual.

(iv) *Other appropriate activity.* You may conduct other supplier verification activities that are appropriate based on the risks associated with the food and the foreign supplier. You must document each performance of such verification activity.

(6) *Substitution of inspection by FDA or an officially recognized or equivalent food safety authority.* Instead of an onsite audit conducted under paragraph (c)(5)(i) of this section, an importer may rely on the results of an inspection of the foreign supplier conducted by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. You must document the inspection results on which you rely. For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(7) *Review of results of verification activities.* You must promptly review the results of the verification activities that you conduct or obtain documentation of under paragraph (c)(5) of this section. If the results show that the foreign supplier does not meet the standard in paragraph (c)(4) of this section, you must take appropriate action in accordance with § 1.507(c).

(8) *Independence of qualified individuals conducting verification activities.* A qualified individual who conducts any of the verification activities set forth in paragraph (c)(5) of this section must not have a financial interest in the foreign supplier and payment must not be related to the results of the activity. This does not prohibit you or one of your employees

from conducting the verification activity.

■ 11. Amend § 1.512 by:

■ a. Revising paragraph (b)(2);

■ b. Removing paragraph (b)(3);

■ c. Redesignating paragraphs (b)(4) and (5) as paragraphs (b)(3) and (4), respectively;

■ d. Revising newly redesignated paragraph (b)(4); and

■ e. Removing paragraph (b)(6).

The revisions read as follows:

§ 1.512 What FSVP may I have if I am a very small importer or I am importing food from a very small supplier?

* * * * *

(b) *Applicable requirements.* * * *

(2) *Additional requirements.* If this section applies and you choose to comply with the requirements in paragraph (b) of this section, you also are required to comply with the requirements in §§ 1.502, 1.503, and 1.509, but you are not required to comply with the requirements in §§ 1.504 through 1.508 or § 1.510.

* * * * *

(4) *Corrective actions.* You must promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 or 419 of the Federal Food, Drug, and Cosmetic Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. The appropriate corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed. You must document any corrective actions you take in accordance with this paragraph (b)(4). This paragraph (b)(4) does not limit your obligations with respect to other laws enforced by FDA, such as those relating to product recalls.

■ 12. Amend § 1.513 by revising paragraph (a) to read as follows:

§ 1.513 What FSVP may I have if I am importing a food from a country with an officially recognized or equivalent food safety system?

(a) *General.* If you meet the conditions and requirements of paragraph (b) of this section for a food you are importing, then you are not required to comply with the requirements in §§ 1.503 through 1.508. You would still be required to comply with the requirements in §§ 1.509 and 1.510.

* * * * *

Dated: September 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–22448 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL REGISTER

Vol. 79 Monday,

No. 188 September 29, 2014

Part VI

Department of Defense

Office of the Secretary

32 CFR Part 232

Limitations on Terms of Consumer Credit Extended to Service Members and Dependents; Proposed Rule

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 232

[DOD–2013–OS–0133]

RIN 0790–AJ10

Limitations on Terms of Consumer Credit Extended to Service Members and Dependents

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense.

ACTION: Proposed rule.

SUMMARY: The Department of Defense (''Department'') proposes to amend its regulation that implements the Military Lending Act, herein referred to as the ''MLA''. Among other protections for Service members, the MLA limits the amount of interest that a creditor may charge on ''consumer credit'' to a maximum annual percentage rate of 36 percent. The Department is proposing to amend its existing regulation primarily for the purpose of extending the protections of the MLA to a broader range of closed-end and open-end credit products, rather than the limited credit products currently defined as consumer credit. In addition, the Department is proposing to amend its existing regulation to amend the provisions governing a tool a creditor may use in assessing whether a consumer is a ''covered borrower,'' modify the disclosures that a creditor must provide to a covered borrower, implement the enforcement provisions of the MLA, as amended, and for other purposes.

DATES: Comments must be submitted not later than November 28, 2014.

ADDRESSES: You may submit comments, identified by docket number and or Regulatory Information Number (RIN) and title, by any of the following methods;

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, 2nd Floor, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Marcus Beauregard, 571–372–5357.

SUPPLEMENTARY INFORMATION:

Retrospective Review

This rule is part of DoD's retrospective plan, completed in August 2011, under Executive Order 13563, ''Improving Regulation and Regulatory Review.'' DoD's full plan and updates can be accessed at: *http://www.regulations.gov/#!docketDetail;dct=FR+PR+N+O+SR;rpp=10;po=0;D=DOD-2011-OS-0036.*

I. Executive Summary

A. Purpose of the Regulatory Action

The Department is proposing to amend its existing regulation primarily for the purpose of extending the protections of 10 U.S.C. 987 to a broader range of closed-end and open-end credit products, rather than the limited credit products currently defined as consumer credit. More specifically, the Department proposes to amend its regulation so that, in general, consumer credit covered under the MLA [1] would be defined consistently with credit that for decades has been subject to the protections under the Truth in Lending Act (TILA), namely: Credit offered or extended to a covered borrower primarily for personal, family, or household purposes, and that is (i) subject to a finance charge or (ii) payable by a written agreement in more than four installments.[2]

After observing the effects of its existing regulation during the past six years and based on its review of information provided by a wide variety of persons and entities, the Department believes that this proposal to amend the regulation is appropriate in order to address a wider range of credit products that currently fall outside the scope of the regulation implementing the MLA, streamline the information that a creditor would be required to provide to a covered borrower when consummating a transaction involving consumer credit, and provide a more straightforward mechanism for a creditor to assess whether a consumer-applicant is a covered borrower. In this regard, the Department is aware of misuses of the covered borrower identification statement whereby a Service member (or covered dependent) falsely declares that he or she is not a covered borrower. The Department believes that, if a creditor unilaterally conducts a covered-borrower check by using the MLA Database, a Service member or his or her dependent would be relieved from making any statement regarding his or her status as a covered borrower.

The Department is provided authority in 10 U.S.C 987(h) to establish regulations to implement the MLA. As described in 10 U.S.C. 987(h)(3) the Department, at a minimum, must consult with other Federal agencies ''not less often than once every two years'' with a view towards revising the regulation implementing the MLA.

B. Summary of the Major Provisions of the Department's Regulatory Action

The MLA, as implemented by the Department's regulation as well as under this proposed regulation, provides two broad classes of requirements applicable to a creditor: first, the creditor may not impose a Military Annual Percentage Rate (MAPR) greater than 36 percent in connection with an extension of consumer credit to a covered borrower (''interest-rate limit''); second, when extending consumer credit, the creditor must satisfy certain other terms and conditions, such as providing certain information (*e.g.,* a statement of the MAPR), both orally and in a form the borrower can keep, before or at the time the borrower becomes obligated on the transaction or establishes the account, by refraining from requiring the borrower to submit to arbitration in the case of a dispute involving the consumer credit, and by refraining from charging a penalty fee if the borrower prepays all or part of the consumer credit (collectively, ''other MLA conditions'').

C. Costs and Benefits

The Department anticipates that its regulation, if adopted as proposed, might impose costs of approximately $96 million during the first year, as creditors adapt their systems to comply with the requirements of the MLA and the Department's regulation. However, after the first year and on an ongoing basis, the annual effect on the economy is expected to be between approximately $13 to $137 million. The Department has estimated the potential savings that could result if the rule reduces the involuntary separations of Service members due to financial distress in sensitivity analyses; at some points in the range of estimates the

[1] The forms of ''consumer credit'' that may be covered by the MLA are subject to certain exceptions, notably for a residential mortgage. 10 U.S.C. 987(i)(6)(A) and 987(i)(6)(B).

[2] *See* 12 CFR 1026.1(c)(1)(iii) (limiting the coverage of the regulation, in relevant part, to credit that is subject to a finance charge or is payable by a written agreement in more than four installments).

Department has used to assess the proposal, these savings are estimated to exceed the compliance costs that would be borne by creditors.

FIGURE 1—SUMMARY OF ESTIMATED EFFECTS OF PROPOSED RULE

[2013 dollars in millions]

		First year	Annual, ongoing	PV 10-year, 7% discount rate	PV 10-year, 3% discount rate
Sensitivity Analysis: Benefits to the Department	Low	$0	$13	$96	$128
	High	0	137	970	1,304
Primary Analysis: Costs to Creditors of Compliance		96	20	144	194
Primary Analysis: Transfer Payments	Low	NA	101	717	958
	High	NA	120	856	1,139

II. Background

A. Overview of the Proposal

The Department proposes to amend its regulation [3] that implements 10 U.S.C. 987, which was enacted in section 670 of the John Warner National Defense Authorization Act for Fiscal Year 2007,[4] and amended by sections 661–663 of the National Defense Authorization Act for Fiscal Year 2013 (''2013 Act'').[5]

The 2013 Act amended several provisions of 10 U.S.C. 987. In particular, the 2013 Act added provisions that would permit a covered borrower to recover damages from a creditor who violates a requirement of the MLA,[6] and authorizes the agencies ''specified in section 108 of the Truth in Lending Act'' [''TILA''] to enforce the requirements of the MLA ''in the manner set forth in that section [of TILA] or under any other applicable authorities available to such agencies by law.'' [7] Section 663 of the 2013 Act modified the definition of ''dependent'' in order to make the meaning of that term consistent with parts of the definition that applies in the context of eligibility of a Service member's dependent for military medical care.[8] In addition, section 661 of the 2013 Act amended the MLA to require the Department to consult—''not less often than once every two years''—with the Board of Governors of the Federal Reserve System, the Consumer Financial Protection Bureau (''Bureau''), the Department of the Treasury, the Federal Deposit Insurance Corporation, the Federal Trade Commission, the National Credit Union Administration, and the Office of the Comptroller of the Currency (collectively, ''Federal Agencies'') with a view towards revising the regulation implementing the MLA.

In August 2007, the Department published its regulation to implement the MLA.[9] When initially determining the extent to which the protections of the MLA should apply, the Department ''focus[ed] on three problematic credit products that the Department identified in its August 2006 *Report to Congress on the Impact of Predatory Lending Practices on Members of the Armed Forces and Their Dependents* [(''2006 Report'')] [10]: Payday loans, vehicle title loans, and refund anticipation loans.'' [11] The Department elected, at that time, to define the scope of ''consumer credit'' covered by the regulation as a narrow band of products within these three categories of credit; for example, the rule defines a ''payday loan,'' in relevant part, as ''[c]losed-end credit with a term of 91 days or fewer in which the amount financed does not exceed $2,000.'' [12]

After observing the effects of its existing regulation, the Department believes that a wider range of credit products offered or extended to Service members reasonably could—and should—be subject to the protections of the MLA, and that the extremely narrow definition of ''consumer credit'' permits creditors to structure credit products in order to reduce or avoid altogether the obligations of the MLA. For example, if a creditor wishes to market a ''payday loan'' to a Service member without regard to the 36-percent interest-rate limit under the MLA, the creditor simply needs to adjust the terms or conditions so that the loan is (i) not closed-end credit, (ii) for a term longer than 91 days, *or* (iii) for an amount of more than $2,000. Making any of these elementary adjustments to a credit product marketed as a ''payday loan'' is not illegal, however, the effect is clear: a Service-member borrower would obtain the credit without the protections afforded under the MLA. The Department's proposal aims to amend the regulation to curb this unfortunate consequence, of which there is ample evidence in the credit markets in which Service members are active participants.[13]

The Department proposes to amend its regulation so that, in general, consumer credit covered under the MLA [14] would be defined consistently with credit that for decades has been subject to the protections under TILA, namely: credit offered or extended to a covered borrower primarily for personal, family, or household purposes, and that is (i) subject to a finance charge or (ii) payable by a written agreement in more than four installments.[15] In general, under the Department's proposal, any charge that is a ''finance charge'' under Regulation Z,[16] adopted by the Bureau, as well as certain other charges that would be covered as ''interest'' under 10 U.S.C. 987(i)(3), must be included in the calculation of the MAPR, as applicable to the transaction for consumer credit. However, the Department also proposes to provide a broad exclusion that would allow a creditor who offers consumer credit through a credit card account to

[3] 32 CFR part 232 (2013).

[4] Public Law 109–364, 120 Stat. 2266.

[5] Public Law 112–239, 126 Stat. 1785.

[6] *Id. See* section 662(a) of the 2013 Act.

[7] 126 Stat. 1786. *See* section 662(b) of the 2013 Act.

[8] 126 Stat. 1786 (defining ''dependent'' to be a person described in subparagraph (A), (D), (E), or (I) of 10 U.S.C. 1072(2)).

[9] Limitations on Terms of Consumer Credit Extended to Service Members and Dependents, 72 FR 50580 (Aug. 31, 2007).

[10] Department of Defense, *Report On Predatory Lending Practices Directed at Members of the Armed Forces and Their Dependents* (August 9, 2006), available at *http://www.defense.gov/pubs/pdfs/Report_to_Congress_final.pdf.*

[11] 72 FR at 50585.

[12] 32 CFR 232.3(b)(1)(i) (definition of ''consumer credit'').

[13] *See, e.g.,* section III.A.1 (describing information submitted by various persons in response to the Department's June 2013 advance notice of proposed rulemaking).

[14] The forms of ''consumer credit'' that may be covered by the MLA are subject to certain exceptions, notably for a residential mortgage. 10 U.S.C. 987(i)(6)(A) and 987(i)(6)(B).

[15] *See* 12 CFR 1026.1(c)(1)(iii) (limiting the coverage of the regulation, in relevant part, to credit that is subject to a finance charge or is payable by a written agreement in more than four installments).

[16] 12 CFR part 1026 (2013).

exclude from the MAPR any ''bona fide'' fee charged to a credit card account, as discussed more fully in this proposal. The chief consequence of the proposed exclusion from the MAPR for bona fide fees is that a creditor who, for its credit card product(s), currently charges a periodic interest rate of less than the interest-rate limit under 10 U.S.C. 987(b) coupled with one or more fees that carry reasonable costs tied to specific products or services should be able to continue to offer the same product(s) without any adjustments to those price terms. Under the proposal, that creditor would need to confirm that its fees are bona fide, reasonable and customary, and if so, it should be able to continue to offer the same credit card product(s) to covered borrowers by making limited adjustments only to the ''statement of the MAPR,'' which would be permitted simply to be added to its credit card agreement(s) (and not required to be provided in any advertisement), as discussed below.

In addition, the Department is proposing to revise its regulation to provide a creditor with a more straightforward mechanism to assist in assessing the status of a consumer as a covered borrower, in order that the creditor may have ''some degree of certainty in determining that the loans [the creditor makes] are in compliance with [the MLA] as implemented by Part 232.'' [17] The Department believes that a covered-borrower check could be conducted unilaterally by a creditor by checking the database maintained by the Department and without relying on the borrower (as currently required), akin to the process a creditor currently uses to obtain a consumer report when assessing the creditworthiness of a consumer. Accordingly, the Department proposes to amend the regulation to allow a creditor to access the Department's online database (the MLA Database) to assess the status of a consumer-applicant for consumer credit and, as discussed below, thereby provide a clearer mechanism for a creditor to obtain the protection of a safe harbor when determining whether a consumer is a covered borrower.

Consistent with the Department's longstanding policy in administering 10 U.S.C. 987, the Department intends to develop this regulation so that its provisions are true to the intent of the MLA without creating a system that unduly impedes the availability of credit that is beneficial to Service members or is so burdensome that the creditor cannot comply.[18]

The Department seeks comment on all aspects of this proposal. The Department also solicits information and data regarding the nature, scope, and prevalence of credit products offered or extended to Service members and their families.

In particular, the Department seeks comment on the following alternative:

1. Refining the Department's current rule for payday loans, vehicle title loans and refund anticipation loans—and the associated benefits and costs;

2. Refining the Department's current rule and adding all payday loans—and the associated benefits and costs; and

3. Adoption of Regulation Z for consumer credit products—and the associated benefits and costs;

As required by 10 U.S.C. 987(h)(3), in developing this proposal the Department has consulted with the Federal Agencies. The Department will continue to consult with these agencies throughout the process of considering revisions to the regulation implementing the MLA.

B. Financial Status of Enlisted Service Members

In the 2006 Report, the Department provided perspective on why the issue of maintaining the financial stability of Service members and their families is critical to sustaining the all-volunteer force and maintaining its readiness. These concerns remain relevant today.

Service members still represent a predominantly young group with 43 percent of Service members aged 25 years old or younger.[19] The junior enlisted ranks (E1–E4) comprise 44 percent of the military force.[20] Thirty five percent of E1s–E4s are married [21] and 20 percent of them have children or other legal dependents.[22] Considering only 11.7 percent of young people in the United States who are out of the military are married at a comparative age, Service members tend to take on relatively more household responsibilities than their civilian counterparts.[23]

Forty-one percent of enlisted Service members (46% of E1s–E4s) said they had used one or more sources of small dollar lending in the past 12 months. These sources included payday loans, vehicle title loans, bank deposit advance loans, pawn shop loans, cash advances on credit cards, overdraft loans, overdraft lines of credit, overdraft protection from other accounts, relief society loans, and loans from friends and family.[24] About 62% of enlisted Service members selected responses indicating that they were able to make ends meet without difficulty. Twelve percent selected the responses ''tough to make ends meet but keeping your head above water,'' or ''in over your head'' to describe their financial condition.[25] About 26% selected the response ''occasionally have some difficulty making ends meet.''

When asked about their savings habits, 14% of enlisted Service members selected the option ''spend all the income received and don't save'' and 4% selected the option ''don't know.'' Forty-four percent selected the option ''regularly set aside money in savings.'' The remaining 39% selected the option ''save whatever is left at the end of the month.'' When asked about their savings, about 57% of enlisted Service members indicated that they had at least $500 in savings that would be available for emergencies. Eight percent indicated that they have less than $100 and 17% indicated that they have no emergency savings.[26]

When asked about experiencing any shortfalls in finances, 47% of enlisted Service members reported having problems in the past 12 months. Specifically, 9% said they had been more than 60 days late in paying mortgage or other debts, 17% reported that they were unable to use bank credit card(s) because the credit limit was reached, 44% reported that they were short cash between paychecks and 12% indicated that they were unable to pay

[17] 72 FR at 50588.

[18] Limitations on Terms of Consumer Credit Extended to Service Members and Dependents, 72 FR 18157, 18165 (April 11, 2007) (in the context of disclosure requirements, explaining one of the policies for the Department's proposed regulation implementing the MLA).

[19] U.S. Dep't of Def., 2012 Demographics Profile of the Military Community, at 36. Available at *http://www.militaryonesource.mil/12038/MOS/Reports/2012_Demographics_Report.pdf.*

[20] *Id.* at 17.

[21] *Id.* at 44.

[22] *Id.* at 128.

[23] U.S. Census Bureau, U.S. Dep't of Commerce, Statistical Abstract of the United States 2012 table 57 (131st ed. 2011) (11.7 percent of individuals aged 18 through 24 who are not in the military are married).

[24] Defense Manpower Data Center (DMDC) QuickCompass of Financial Issues, 2013, Question 30: Have [you][your and/or your spouse][you and/or your significant other] used any of the following financial products or services to cover expenses in the past 12 months?''

[25] *Id.,* Question 13: ''Which of the following best describes [your financial condition][the financial condition of you and your spouse][the financial condition of you and your partner or significant other]?''

[26] *Id.,* Question 15: ''Which of the following best describes [your saving habits][the savings habits of you and your spouse][the savings habits of you and your partner or significant other]? I[We]:''

monthly bills.[27] When asked about how many months in the past 12 were they short on cash, unable to use a credit card because of the credit limit was reached, or unable to pay bills or other debts, 12% said 5 to 7 months and 11% said 8 or more months. The average response was 3.4 months in a 12-month period.[28]

The results of the Defense Manpower Data Center (''DMDC'') QuickCompass on Financial Issues tends to indicate that most Service members report sufficient access to safe, low-cost credit, report few problems managing their finances, and report little use of or impact by high-cost credit products on their financial lives. Nevertheless, the DMDC survey results also tend to indicate that a substantial minority of Service members continue to report difficulty managing their finances, and little access to safe, low-cost credit options. While the relative size of these two groups varies across the different types of financial indicators surveyed, the Department estimates that between 12 and 25% of enlisted Service members may face emergency financial short-falls and indicate difficulties managing their finances and avoiding problems with credit.

C. Financial Stability and Readiness

The Department makes a significant investment in recruiting, training and retaining highly qualified Service members. The Department expects these Service members to maintain personal readiness standards, including paying their debts and maintaining their ability to attend to the financial needs of their families.[29] Losing qualified Service members due to personal issues, such as financial instability, causes loss of mission capability and drives significant replacement costs. The Department estimates that each separation costs the Department $57,333.[30] Losing an experienced mid-grade noncommissioned officer (NCO), who may be in a leadership position or key technical position, may be considerably more expensive in terms of replacement costs and in terms of the degradation of mission effectiveness resulting from a loss of personal reliability for deployment and availability for duty. A study of the potential impact of the use of payday loans on enlisted members in the Air Force found ''significant average declines in overall job performance and retention, and significant increases in severely poor readiness,'' as a result of using payday loans.[31] Additionally, financial concerns detract from mission focus and often times require attention from commanding officers and senior NCOs to resolve outstanding debts and other credit issues.

D. Financial Readiness Program

As young people with steady pay checks and personal responsibilities which emerge earlier than their contemporaries, junior enlisted Service members need to have a commensurate level of financial acumen and maturity to succeed. Junior enlisted Service members are generally high school graduates who may have started college.[32] Prior to entering the military they may have had limited exposure to financial literacy programs within high school, but they are generally unprepared for their financial responsibilities.[33] The Department has established the Financial Readiness Program to assist Service members in dealing with financial concerns, by providing messaging, education, and assistance. Throughout each year, the Department provides key messages on personal finance to the military community as part of a strategic communications plan that includes press releases, news articles, interviews, Web sites and social media. The Department has the assistance of nonprofit organizations in delivering messages and programs to promote savings and sound money management. The Department annually promotes the ''Military Saves Campaign,'' which occurs at the end of February each year as part of ''America Saves,'' sponsored by the Consumer Federation of America. The campaign asks Service members and their families to pledge towards their own savings goals, and the campaigns are supported by banks and credit unions on military installations. Initiated in 2007, the campaign has signed up 31,527 savers through 2013.[34] Additionally, the Financial Institutions National Regulatory Authority (FINRA) Foundation sponsors the ''Save and Invest Program'' that has provided forums at military installations (33,000 participants), fellowships for 1,200 military spouses to earn a financial counselor credential and give back to the community through 355,000 practicum hours, assistance to wounded warriors (17,000 guides distributed), 800,000 booklets on managing money during military moves and deployments, and access to no cost on-line tools to assist 150,000 military families with managing credit.[35]

The Department has established policy requiring Service members to receive financial education throughout their military careers, commencing with an initial course provided within 3 months of having arrived at their first duty station. As Service members assume supervision of others, they are also provided information on policies and practices designed to protect junior military members.[36] Each of the Military Services manages its own educational program to fulfill this requirement, based on regulations from the Military Departments. For Fiscal Year 2012, the Military Services reported providing 34,867 briefings to 872,187 participants.[37] In addition, the National Guard and Reserve Commands conducted 8,912 sessions, hosted at unit events lasting one-to-three days, attended by 13,480 participants.[38]

[27] *Id.,* Question 28: ''During the past 12 months, did any of the following happen to [you][you and your spouse][you and your partner or significant other]? [I was][We were] . . .''

[28] *Id.,* Question 29: ''In how many of the past 12 months were [you][you and your spouse][you and your significant other] short on cash, unable to use a credit card because of the credit limit was reached, or unable to pay bills or other debts?''

[29] U.S. Dep't of Def., Instruction 1344.09, Indebtedness of Military Personnel (2008) (''Members of the Military Services are expected to pay their just financial obligations in a proper and timely manner [to include alimony and child support]. A Service member's failure to pay a just financial obligation may result in disciplinary action under the Uniform Code of Military Justice [10 U.S.C. 801–940] or a claim pursuant to Article 139 of [10 U.S.C. 801–940].'').

[30] U.S. Gov't Accountability Office, GAO–11–170, *Military Personnel: Personnel and Cost Data Associated with Implementing DOD's Homosexual Conduct Policy* (January 20, 2011) (estimating that each separation costs the Department $52,800 in 2009 dollars). The cost of $57,272 is calculated in 2013 dollars (through November 2013), using the U.S. Dep't of Labor, Bureau of Labor Statistics, Consumer Price Index, All Urban Consumers (CPI–U), available at *ftp://ftp.bls.gov/pub/special.requests/cpi/cpiai.txt.*

[31] Scott Carrell and Jonathan Zinman, ''In Harm's Way? Payday Lending and Military Personnel Performance,'' August 2008, Abstract.

[32] DMDC Survey, question 20: 39% of E1–E4s have a high school diploma, 22% have less than one year of college, 24% have one or more years of college, but no degree.

[33] Average score for high school seniors was 48.3% and 62.2% for college students on a financial literacy test measuring (1) Income; (2) money management; (3) saving and investing; and (4) spending and credit. Jump$tart Coalition survey of high school seniors and college students, 2008, page 8. *www.jumpstart.org/assets/files/2008SurveyBook.pdf.*

[34] Military Saves 2013 Report, page 2, *http://www.militarysaves.org/in-the-newsroom/military-saves-week-reports.*

[35] ''*Military Financial Readiness Program—Accomplishments To Date,'' SaveandInvest.org, About the Program, http://www.saveandinvest.org/MilitaryCenter/About/P124822.*

[36] DoD Instruction 1342.22, Family Readiness Program, July 3, 2012, page 12, *http://www.dtic.mil/whs/directives/corres/pdf/134222p.pdf.*

[37] ''Fiscal Year 2012 Annual Report on Family Readiness Programs'' (internal DoD report), which reflects activities of installation-based Military and Family Support Centers/Reserve Family Program Sites.]

[38] Military OneSource internal report for Fiscal Year 2012.

Department policy also requires the Military Services to provide one-on-one counseling to help a Service member determine appropriate short and long term actions to alleviate debt and achieve financial goals. The Military Services employ at least one certified financial counselor (civil service or contractor) at each military installation and have developed Military Service-specific programs to extend counseling into the military units through designated approved financial educators. For example, the Department of the Navy directs Navy and Marine Corps units to designate and train a Command Financial Specialist (E6 or above) who delivers financial education, conducts basic counseling and makes referrals to certified counselors. The Military Services reported 1,828,299 brief counseling contacts and 161,992 extended counseling contacts for Fiscal Year 2012.[39] To supplement the counseling services provided by the Military Services, the Department employs contract counselors through Military One Source to conduct over-the-phone counseling (available 24/7) and 12 in-person sessions for each military client (in a 12 month period). These counselors provided 32,000 in-person sessions for 35,000 Service members and spouses in Fiscal Year 2012.[40]

To provide monetary support to Service members and their families with financial hardships, the Military Services have partnered with nonprofit charitable organizations chartered to provide relief services to Service members and their families. The four relief societies for the Military Services (Army Emergency Relief, Navy-Marine Corps Relief Society, Air Force Aid Society and Coast Guard Mutual Assistance) (collectively, the ''Relief Societies'') provide no-interest loans, grants, and scholarships, and fund other support programs for active-duty military communities. Each of these Relief Societies traditionally has provided no-interest loans and grants for shortfalls in household expenses (*e.g.,* rent, mortgage, or utilities) and for unforeseen emergencies (*e.g.,* auto repair, funeral, or family emergency). Since 2007, each of the Relief Societies also has offered small-dollar loans, which can be drawn without counseling.[41] In total for 2012, the Relief Societies provided $142.2 million in no-interest loans and grants to 159,745 clients.[42]

E. Regulation in Support of Financial Readiness

The Department continues to believe that, consistent with the MLA, there may be a need to limit access to high-cost borrowing, even with the Department's emphasis on delivering messages to save and control debt, education to support managing finances wisely, counseling resources to aid Service members, and financial resources to help Service members cover unforeseen shortfalls and emergencies. As initially stated, the Department expects Service members to manage their resources to cover their just debts and to take care of the needs of their families. Additionally, as messaging and education programs make clear, the Department expects Service members to seek out assistance rather than continue attempting by themselves to manage high-cost debt.

In the House Report 112–705 accompanying the 2013 Act, the Department was asked ''to determine if changes to rules implementing [the MLA] are necessary to protect covered borrowers from continuing and evolving predatory lending practices.'' The Department responded to the request of the House Report by issuing a report in April 2014 (''April 2014 Report'').[43] The April 2014 Report presents data submitted by many sources, including anecdotal information, that assisted in responding to the request of the House Report. The Department recognizes that information submitted for the April 2014 Report was provided by numerous sources, including some surveys conducted by the Department, and the information does not yield definitive results; rather, as the April 2014 Report states, the data ''tend to indicate'' some findings[44] and, for many issues, raise important questions that might involve further examination. The April 2014 Report states—specifically in light only of the research and consultation in preparing that Report—that ''the definitions of [consumer credit] in the implementing regulation for the MLA do need to be updated and expanded to ensure that the MLA continues to provide protections to Service members and their families.''[45] While observing that certain conditions ''appear'' to warrant revising the definition of ''consumer credit,''[46] the Department has drawn no conclusions regarding the scope or terms of its regulation implementing the MLA. Rather, the April 2014 Report expressly states that ''the Department is working on [a more] comprehensive approach in its redrafting of the implementing regulation for the MLA.''[47] The Department is committed to an open and transparent process as its work continues on any potential amendment to its regulation, and, as stated above, invites comment on all aspects of this proposal, particularly data regarding the nature, scope, and prevalence of credit products offered or extended to Service members and their families.

The majority of Service members have access to reasonably priced (as well as low-cost) credit, and, as long as they wisely use those resources, they are likely not to need high-cost loans to fulfill their credit needs. In the event that a Service member overwhelms his or her credit, or has not established credit for an emergency, the Department and the Relief Societies are prepared to assist that person in order that he or she might resolve the immediate difficulties and continue to manage his or her income and expenses to a point where he or she can develop a sound financial basis. In circumstances where Service members have taken high-cost loans because no other alternatives appeared to be available, Department counselors and the Relief Societies have found that the existing high-cost debt makes intervention more difficult; these service providers would rather have had the opportunity to have helped resolve issues sooner.

III. Key Aspects of the Department's Proposal

A. Proposal To Amend the Scope of ''Consumer Credit''

The Department proposes to revise the scope of the definition of ''consumer

[39] ''Fiscal Year 2012 Annual Report on Family Readiness Programs'' (internal DoD report), which reflects activities of installation-based Military and Family Support Centers/Reserve Family Program Sites.]

[40] Military OneSource internal report for Fiscal Year 2012.

[41] *See* Army Emergency Relief, Soldiers Helping Soldiers: Army Emergency Relief 2012 Annual Report, at 13 (2013) (in 2012, Army Emergency Relief provided $19.1 million in ''Commander Referral Loans''); Air Force Aid Soc'y, Air Force Aid Society 2012 Annual Report, at 6 (2013) (in 2012, the Air Force Aid Society provided half of its $10.1 million in emergency assistance ''Falcon Loans''); Coast Guard Mut. Assistance, 2012 Annual Report, at 2 (2013) (in 2012, Coast Guard Mutual Assistance provided $212,000 in quick loans).

[42] *See* Army Emergency Relief, Soldiers Helping Soldiers: Army Emergency Relief 2012 Annual Report, at 13 (2013); Navy-Marine Corps Relief Society, 2012 Annual Report, at 11 (2013); Air Force Aid Soc'y, Air Force Aid Society 2012 Annual Report, at 6 (2013); Coast Guard Mut. Assistance, 2012 Annual Report, at 2 (2013).

[43] Dep't of Defense, *Report: Enhancement of Protections on Consumer Credit for Members of the Armed Forces and Their Dependents,* April 2014.

[44] *See, e.g.,* April 2014 Report, at 2.

[45] April 2014 Report, at 2.

[46] *Id.*

[47] *Id.*

credit'' to cover a broader range of closed-end and open-end credit products, to be generally consistent with the credit products that for decades have been subject to the requirements of the Bureau's Regulation Z. When adopting its initial regulation in 2007, the Department focused on three narrowly defined types of products that the Department believed, at that time, most directly acted as sources of the ''debt trap'' for Service members and their families.[48] In addition, the Department expressed its concern about the ''potential for unintended consequences that could adversely affect credit availability if it were to adopt a broadly applicable regulation.'' [49] At the same time, the Department was careful to avoid engendering any reliance interests in the narrow scope of its initial rule, and, in this regard, expressly stated that ''[t]he Department maintains the ability to issue additional rules in the future .. . . '' [50] When the Department adopted its initial regulation, financial-institution creditors, Service members, and others who have an interest in the administration of the MLA were appropriately cautioned that the Department had committed itself to review various sources of data, including ''input from regulatory agencies, consumer protection groups and the credit industry to assess the level of protection provided by the final rule,'' in order to determine whether ''further revisions [to its regulation] are needed.'' [51]

The Department continues to believe that certain payday loans, vehicle title loans, and refund anticipation loans present the most severe risks to Service members and their families, and remains mindful that more broadly defining the ''consumer credit'' that would be subject to 10 U.S.C. 987 may present unintended consequences, including a reduction in ''credit availability.'' At the same time, however, the Department recognizes—particularly in light of its experiences administering the existing regulation—that a broader range of closed-end and open-end credit products carry high costs, many of which far exceed the interest-rate limit established in 10 U.S.C. 987(b), and thereby pose the risks to Service members and their families that the Department has long sought to significantly reduce or eliminate.

Consistent with the Department's stated policy to monitor market developments that affect Service members, since adopting its initial regulation in 2007 the Department informally has gathered information from regulatory agencies, consumer protection groups, and participants in the credit industry to assess whether, and in which respects, the Department should consider revising its regulation implementing the MLA.[52] As described above in section II.E., information was submitted for the April 2014 Report issued in response to the House Report. In this regard, the April 2014 Report describes various sources of information, including results from a DMDC QuickCompass survey [53] and a questionnaire the Department distributed to financial counselors and legal assistance attorneys, which mostly requested narrative responses.[54]

More importantly, and directly to support the Department's rulemaking process, in June 2013 the Department published an advance notice of proposed rulemaking (''ANPR'') soliciting comment on several issues relating to its existing regulation.[55] In particular, the Department asked whether there is a need to revise the regulation, ''with special attention to the scope of the definition of 'consumer credit.' '' [56]

1. The Department's June 2013 ANPR

The Department received 37 comments in response to the ANPR. Most of the comments were submitted by state agencies, including state attorneys general,[57] and consumer protection groups. Several participants in the credit industry submitted comments,[58] as did several individuals. In addition, comments were submitted relating to whether the Department should consider revising its regulation in order to address rent-to-own transactions.

Generally, commenters responding to the ANPR urge the Department to take one of three actions relating to the definition of consumer credit: (1) leave untouched the current definition as three enumerated products, as well as the particular definition for each of those products; (2) extend the definition by covering certain additional products, such as overdraft services, rent-to-own transactions, and/or all payday loans; or (3) extend the definition by incorporating the definition of consumer credit in the Bureau's Regulation Z. Other commenters raise general concerns regarding the narrow scope of the existing definition of consumer credit and urge the Department to adopt a more comprehensive definition, but have not recommended a particular definition.

One commenter states that the Department's current rule has ''significant gaps and loopholes, which lenders exploit to target military borrowers with high interest loans well above the MLA's [36 percent] rate cap,'' and is ''particularly concerned with [a] multiple-payment or installment loan[ ]'' that is not covered by the rule, because the loan has a term of over 91 days or exceeds $2,000.[59] This commenter states, more specifically, that ''[i]n Texas, high cost multiple-payment loans with rates often exceeding [600 percent] APR are increasingly offered by payday lenders.'' [60] In support of its claims regarding the effects of the loopholes in the Department's current rule, this commenter describes its ''[s]tore visits'' in Killeen, Texas, in July 2013, where the commenter found companies that had changed their loan products to offer ''high-cost multiple-payment products to [Service] members,'' [61] and cited as an example particular loan products

[48] *See* 72 FR at 50582 (observing that ''[t]he combination of little-to-no regard for the borrower's ability to repay the loan, unrealistic payment schedule, high fees, and interest and the opportunity to roll over the loan instead of repaying it can create a cycle of debt for financially overburdened Service members and their families.'').

[49] 72 FR at 50584.

[50] 72 FR at 50585. In this context, the Department drew attention to its ''ability'' to issue additional rules. There can be no doubt, especially in light of section 661(b) of the 2013 Act, that the Department has the authority to amend the regulation implementing the protections of the MLA. 10 U.S.C. 987(h)(3) (requiring the Department, at a minimum, to consult with other Federal agencies ''not less often than once every two years'' with a view towards revising the regulation implementing the MLA).

[51] 72 FR at 50585.

[52] *See* 72 FR at 50585 (''The Department maintains the ability to issue additional rules in the future and the Department plans to continue surveying Service members and will obtain a variety of inputs from regulatory agencies, consumer protection groups and the credit industry to assess the level of protection provided by the final rule.'').

[53] *See, e.g.,* April 2014 Report, at 2.

[54] April 2014 Report, app. A.

[55] 78 FR 36134 (June 17, 2013).

[56] *Id.*

[57] California Attorney General, et al., DOD–2013–OS–0133–0002. References herein to the comments note the name of the commenter and the docket number of the submission, available at *http://www.regulations.gov.*

[58] *See, e.g.,* American Bankers Assoc. et al., DOD–2013–OS–0133–0022.

[59] Texas Appleseed, DOD–2013–OS–0133–0016, at 1–2; *see also* State of Colorado, DOD–2013–OS–0133–0034, at 1 (explaining how lenders can circumvent the Military Lending Act by ''offering 92 day loans, loans for $2001, or by structuring the loans as open-end credit''); *but see* Credit Union National Association and Defense Credit Union Council, DOD–2013–OS–0133–0032, at 2 (arguing that the current rule has been an ''effective tool'' and that the 91-day limit for payday loans should not be changed).

[60] Texas Appleseed, DOD–2013–OS–0133–0016, at 2.

[61] *Id.* at 3.

offered by a national payday lender with two locations in Killeen.[62]

Another commenter states that under the Department's current rule, ''lenders have easily circumvented the purpose and protections intended by the MLA.'' [63] For example, the commenter describes the ''structure of [the] payday loan law'' [64] in Colorado, which requires ''a minimum loan term of six months.'' [65] Because of the extended duration of the loan, ''the MLA rate cap of 36 percent does not apply,'' [66] allowing lenders ''to make loans to service members with an approximate 200 percent annual percentage rate.'' [67] The commenter urges the Department to revise the rule so that it does not ''contain limits that lenders may use to avoid regulation.'' [68] Specifically, the commenter recommends that the Department incorporate the definition of consumer credit under TILA, ''so that regardless of the consumer credit transaction amount, structure, or duration, it is subject to MLA's 36 percent cap on interest rates.'' [69]

Similarly, another commenter states that the Department's current rule has ''large loopholes that permit lenders to fashion abusive or predatory transactions that avoid the MLA's protections.'' [70] The commenter, more specifically, states that lenders can evade protections under the current rule ''by requiring that payday loans be a minimum of $2,001, or have a minimum period of 92 days'' or by offering ''[a]ny open-ended or revolving payday loan; [a]ny auto title loan for more than 181 days; [a]ny bank loan that is secured by funds on deposit, such as overdraft loans; and [a]ny retail sales credit loan or other similar rent-to-own transaction.'' [71] ''[T]o protect military borrowers from predatory lenders who purposefully structure loan transactions so as to avoid the strictures of the MLA,'' the commenter urges the Department to make the MLA protections ''apply uniformly to the full range of consumer credit loans that present dangers similar to those already covered, including rent-to-own transactions and overdraft loans.'' [72]

One commenter notes that ''inappropriate loans and exorbitant interest payments force many members of the military and their families to forgo other necessities, such as housing or grocery bills.'' [73] Financial strain ''negatively affects [service member] morale and puts their ability to do their job . . . at risk.'' [74] The commenter raises a concern about the ''narrow definition of consumer credit'' and urges the Department to ''modify the definition of consumer credit to ensure that Service Members in all states are protected from all forms of high-cost credit.'' [75]

One commenter expresses concern that ''the rules initially promulgated by the Department contained gaps in the definition of consumer credit.'' [76] These gaps ''have been taken advantage of by certain lenders'' to offer ''predatory loan products at exorbitant triple digit effective interest rates and loan products that do not include the additional protections envisioned by the law.'' [77] The commenter notes that ''the Department was given the authority and has inherent flexibility provided under the law'' to revise the rule to establish a more ''expansive'' definition of consumer credit to which the protections in the law would apply.[78] The commenter urges the Department to include within the scope of the rule ''payday and vehicle title loans of any duration, whether open or closed-ended,'' ''tax refund anticipation loans of any duration,'' as well as to ''consider extending the 36 [percent] APR cap to unsecured installment loans targeted at the military and all other forms of consumer credit.'' [79] The commenter states that ''[s]ervice members and their families deserve the strongest possible protections and swift action to ensure that all forms of credit offered to members of our armed forces are safe and sound.'' [80]

A group of industry commenters states the Department's current rule ''is working as intended to protect members of the armed forces and their dependents.'' [81] These commenters argue that the current rule strikes the correct balance between access to credit and protecting consumers from predatory lending practices. They point to several aspects of the MLA that, in their view, would prevent creditors from offering products to Service members if the current rule's definition is expanded to encompass other products. Specific concerns under the MLA include: Harsh penalties for non-compliance; duplicative and confusing disclosure requirements; oral disclosure requirements that are inconvenient for various technologies; inability to refinance or reprice debt; ban on arbitration clauses common to many loan contracts; and difficulties identifying all covered borrowers.[82] The same commenters specifically request that the rule continue to incorporate definitions provided under the TILA because ''[a]dding separate and disparate definitions undermines the ability of consumers to understand credit products and should be avoided.

[62] *Id.* at 3–4.

[63] State of Colorado, DOD–2013–OS–0133–0034, at 1; *see also* California Attorney General, et al., DOD–2013–OS–0133–0002, at 2 (''[T]he narrow categories and definitions create large loopholes that permit lenders to fashion abusive or predatory transactions that avoid the MLA's protections.''); *but see* Missouri Credit Union Association, DOD–2013–OS–0133–0801, at 1 (arguing that the rule's objective has been accomplished ''primarily by limiting the impact of the rule to those creditors that offer certain loans which are closed-end credit'').

[64] State of Colorado, DOD–2013–OS–0133–0034, at 1.

[65] *Id.*

[66] *Id.* at 2.

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] California Attorney General, et al., DOD–2013–OS–0133–0002, at 2; *see also,* Members of the U.S. Senate, DOD–2013–OS–0133–0036, at 1 (arguing that gaps in the rules ''have been taken advantage of by certain lenders'' who offer ''predatory loan products at exorbitant triple digit effective interest rates and loan products that do not include the additional protections envisioned by the law'').

[71] California Attorney General, et al., DOD–2013–OS–0133–0002, at 2.

[72] *Id.; but see* Ohio Credit Union League, DOD–2013–OS–0133–0027, at 2 (arguing that the current rule is effective and that the Department should protect Service members by ''reviewing and identifying those lending practices that are or can be predatory or abusive on a case by case basis'').

[73] Members of the U.S. House of Representatives, DOD–2013–OS–0133–0035, at 1.

[74] *Id.*

[75] *Id.* at 1–2. *See also* Washington Department of Veterans Affairs, DOD–2013–OS–0133–0004, at 2 (requesting that the Department ''modify the definition of consumer credit to ensure that service members are protected from all forms of high-cost credit, regardless of the duration or structure of the loan''); *but see* American Bankers Assoc., et al., DOD–2013–OS–0133–0022, at 1 (arguing that the Military Lending Act is working as intended and that ''[i]mposing additional requirements on lending to servicemembers would have adverse consequences for members of the armed forces and military families.'').

[76] Members of the U.S. Senate, DOD–2013–OS–0133–0036, at 1; *see also* Texas Appleseed, DOD–2013–OS–0133–0016, at 1 (stating that the current rule has ''significant gaps and loopholes''); *but see* American Bankers Assoc., et al., DOD–2013–0133–0022, at 4 (''The rule adopted in 2007 was structured carefully and struck the proper balance between protecting servicemembers and their families while still ensuring they had access to beneficial products and services.'').

[77] Members of the U.S. Senate, DOD–2013–OS–0133–0036, at 1.

[78] *Id.* at 1–2.

[79] *Id.* at 2.

[80] *Id.*

[81] American Bankers Assoc. et al., DOD–2013–OS–0133–0022, at 1; *see also* Missouri Credit Union Association, DOD–2013–OS–0133–0026, at 1 (''[T]he rule's objective has been accomplished primarily by limiting the impact of the rule to those creditors that offer certain loans which are closed-end credit in the form of payday loans, vehicle title loans, and tax refund anticipation loans.''); *but see* State of Colorado, DOD–2013–OS–0133–0034, at 1 (arguing that ''lenders have easily circumvented the purpose and protections intended by MLA'').

[82] American Bankers Assoc. et al., DOD–2013–OS–0133–0022, at 1, at 4–5.

It would be a step backwards to disconnect the MLA and TILA.'' [83]

One commenter expressed concern that the current rule ''includes limitations which reduce the [MLA's] effectiveness.'' [84] This commenter states that ''[a]pproximately one out of every ten veterans reported having more than $40,000 in unsecured debt. For many veterans, some of this debt is acquired while on active duty, often from high-cost lenders that frequently target military bases.'' [85] The commenter states that in at least eleven states, the current rule ''does not apply to all forms of payday lending permitted under state law, and in at least thirteen the rule does not apply to all forms of vehicle title lending.'' [86] The commenter requests that the Department align consumer credit under the rule with the definition of consumer credit under TILA. The commenter states that ''[t]his inclusive definition will ensure that all service members are covered by the consumer protections envisioned by Congress in 2007 and protect veterans from the long-term effects of predatory lending as they return to civilian life.'' [87]

One commenter states that the Department should ''not lose sight of [a] payday lender's demonstrated capacity for creative evasion.'' [88] In particular, the commenter states that he has seen lenders disguise closed-end transactions as open-end, thereby evading requirements of the MLA. The commenter states that some lenders disguise short-term loans as check cashing services and others disguise loans and loan fees using the sale of phone cards or other ''trinkets'' at inflated prices combined with the delayed presentment of checks. The commenter also states that rent-to-own transactions should be included as consumer credit under the Department's regulation because ''[i]f evaluated as interest, these extra costs amount to extraordinarily high interest, far in excess of that authorized by the MLA.'' [89] The commenter also states that the rule should prohibit unreasonable choice-of-venue provisions in a loan contract, specifically pointing to one creditor who requires all lawsuits be brought in Virginia while all the parties and transactions at issue are typically located in North Carolina. Finally, the commenter states that the Department should amend the rule to cover all payday, rent-to-own, installment, and vehicle title loans without respect to the duration of the loan.

One commenter states that the Department correctly ''left [rent-to-own] out'' of the current rule.[90] In support of its assertion that the Department properly did not include rent-to-own transactions within the scope of the current rule, the commenter states that ''the [rent-to-own] business model is not extending credit and is, instead, a personal property leasing model.'' [91] To support this point, the commenter describes a typical rent-to-own transaction where the consumer ''[does] not assume any debt'' [92] and instead enters into ''weekly, bi-weekly, semi-monthly, or monthly rental agreements for consumer durables.'' [93] The commenter further notes that because rent-to-own transactions are not included in the current rule, ''there was no reason for the industry to modify its practices to escape coverage.'' [94]

One commenter states ''there is no need at this time to revise the rule as it relates to credit unions.'' [95] Another commenter states that the Department should review and identify ''those lending practices that are or can be predatory or abusive on a case by case basis.'' [96] This commenter states that a ''one issue approach could have negative unintended consequences for credit unions and other lenders that adhere to fair and equitable lending practices'' and that such an approach could limit access to beneficial credit for Service members.[97]

One commenter requesting that the current rule should not be changed states that of over 40,000 complaints in the Better Business Bureau's complaint database in 2011, only 37 were filed against online military installment lenders.[98] The commenter states that installment lending should not be covered by the regulation because it ''provides access to affordable, repayable consumer credit'' and is ''the safest form of small-dollar lending'' because it is self-amortizing and thereby protects borrowers from becoming trapped in a cycle of debt.[99]

[83] *Id.* at 11.

[84] Idaho Division of Veterans Services, DOD–2013–OS–0133–0038, at 2; *see also* State of Colorado, DOD–2013–OS–0133–0034, at 2 (''[T]he definition of consumer credit should be as broad as possible and should not contain limits that lenders may use to avoid regulation.''); *but see* American Bankers Assoc. et al., DOD–2013–OS–0133–0022, at 3 (noting that Service members also benefit from many other consumer protections that are not occupation-specific).

[85] *Id.* at 1 (citing Eric Elbogen, Sally Johnson, Ryan Wagner, Virginia Newton, and Jean Beckham, ''Financial Well-Being and Postdeployment Adjustment Among Iraq and Afghanistan War Veterans,'' *Military Medicine* 177 (June 2012).

[86] Idaho Division of Veterans Services, DOD–2013–OS–0133–0038, at 2.

[87] *Id.*

[88] Michael S. Archer, DOD–2013–OS–0133–0007, at 3; *see also* State of Colorado, DOD–2013–OS–0133–0034, at 1 (stating that lenders are easily able to circumvent the current rule's ''purpose and protections'').

[89] Michael S. Archer, DOD–2013–OS–0133–0007, at 4. With regard to rent-to-own transactions, the commenter states that the Department should specifically prohibit sellers from tracking consumers' activity on computers and other electronics. The commenter states that the Department should prohibit contact with commanding officers and other third parties in the debt collection context unless the service member has given written consent after default. *But see* Rent-A-Center, DOD–2013–OS–0133–0010 (arguing that rent-to-own transactions should not be defined as consumer credit due to the nature of those transactions and legislative and regulatory history).

[90] Association of Progressive Rental Organizations, DOD–2013–OS–0133–0012, at 1; *see also* Aaron's, Inc., DOD–2013–OS–0133–0028, at 2 (''[A]ny attempt to include the [rent-to-own] transaction] under [the] definition of consumer credit would not be consistent with federal and state laws.''); *but see* Shriver Center, DOD–2013–OS–0133–0009, at 2 (''[R]ent-to-own transactions are consumer credit sales and should be protected as consumer credit under the MLA.'').

[91] Association of Progressive Rental Organizations, DOD–2013–OS–0133–0012, at 2. *See also* Aaron's, Inc., DOD–2013–OS–0133–0028. In this regard, the Department is cognizant of the consumer protection issues that may arise during rent-to-own transactions. However, consistent with the Department's determination when adopting the initial regulation in 2007, 72 FR at 50582, rent-to-own products usually are not considered credit for purposes of TILA. Accordingly, rent-to-own transactions typically would not be ''consumer credit,'' as that term is proposed in § 232.3(e).

[92] Association of Progressive Rental Organizations, DOD–2013–OS–0133–0012, at 2.

[93] *Id.*

[94] *Id.* at 1–2.

[95] Missouri Credit Union Association, DOD–2013–OS–0133–0026, at 1; *see also* Michigan Credit Union League & Affiliates, DOD–2013–OS–0133–0021, at 1 (''Because of credit unions' unique structure and the products and services offered to assist Service members, the MCUL does not believe revisions to the rules as they relate to credit unions are necessary or desirable at this time.'').

[96] Ohio Credit Union League, DOD–2013–OS–0133–0027, at 2; *but see* Woodstock Institute, DOD–2013–OS–0133–0025, at 2 (''In order to beset protect all service members, the Department of Defense should eliminate its narrow product definitions and apply the 36 percent Military APR limit, and additional protections, to all consumer credit products covered by the Truth in Lending Act.'').

[97] Ohio Credit Union League, DOD–2013–OS–0133–0027, at 2.

[98] American Financial Service Association, DOD–2013–OS–0133–0020 at 2 (citing Jean Ann Fox, *The Military Lending Act Five Years Later: Impact On Servicemembers, the High-Cost Small Dollar Loan Market, and the Campaign against Predatory Lending,* Consumer Federation of America, (May 29, 2012)).

[99] *Id.* at 2; *see also* National Installment Lenders Association, DOD–2013–OS–0133–0014, at 1 (arguing that the Department of Defense should instruct Base commanders to ''place off limits to service members any business they find objectionable or predatory'' instead of amending the rule to cover installment lending); *but see* Shriver Center, DOD–2013–OS–0133–0009, at 2 (arguing that installment loans can ''have many of the same harmful features the MLA prohibits such as high interest rates, automatic access to a bank account, payment by military allotment, and repeated refinances with no benefit to the consumer'').

2. Proposal To Amend the Scope of ''Consumer Credit''

As several commenters state and as the Department itself has observed, a creditor currently may lawfully provide a wide range of closed-end and open-end credit products to a Service member that carry inordinately high costs, and many of these credit products can be offered without meaningfully applying underwriting measures that consider the borrower's ability to repay or with unrealistic payment schedules—precisely the types of risks to Service members that the Department consistently has aimed to diminish.

The Department believes that the narrowly defined parameters of the credit products regulated as ''consumer credit'' under the existing regulation do not effectively provide the protections intended to be afforded to Service members and their families under the MLA. Accordingly, the Department proposes to amend the regulation, in § 232.3(e), so that, in general, consumer credit would be defined consistently with certain credit that long has been subject to the protections under TILA, namely: Credit offered or extended to a covered borrower primarily for personal, family, or household purposes, and that is (i) subject to a finance charge or (ii) payable by a written agreement in more than four installments.[100]

The Department proposes amendments so that, in general, its rule may rely on the provisions and jurisprudence of the Bureau's Regulation Z because that regulation substantially regulates the central components of the framework of the MLA, particularly the types of charges that should be included as ''interest'' [101] and the methods for calculating the annual percentage rate of interest for consumer credit.[102] The Department believes that, even as consumer credit may be revised to apply to a broad range of credit products, aligning the key aspects of the framework under the MLA with the terms and standards that have been developed under Regulation Z will greatly facilitate a creditor's ability to comply with the Department's regulation. More specifically, the Department proposes, in §§ 232.3(*l*) and 232.4(c), that any charge that is a ''finance charge'' under Regulation Z, as well as certain other charges that would be covered as ''interest'' under 10 U.S.C. 987(i)(3), must be included in the calculation of the MAPR (as applicable to the transaction), and would be subject to the interest-rate limit under 10 U.S.C. 987(b).

QUESTION 1: The Department solicits comment on whether an approach should be taken that would define ''consumer credit'' consistently with certain credit regulated under TILA, and invites suggestions on alternative approaches.

QUESTION 2: If the Department were to adopt a regulation as proposed, to what extent, and in what manner, would the Department's regulation affect the availability of consumer credit to Service members and their dependents or have other consequences?

QUESTION 3: If the Department were to adopt a regulation as proposed, to what extent would a creditor, as a practical matter, need to develop separate classes of credit products, namely, one class of products for covered borrowers and other classes for other consumers?

QUESTION 4: If the Department continues to pursue an approach that defines ''consumer credit'' to be generally consistent with certain credit regulated under TILA, should the Department consider a limited or complete exemption for an insured depository institution or insured credit union? What legitimate basis could there be for any exemption for an insured depository institution or insured credit union from the requirements of the MLA, particularly if under this approach other financial institutions would be subject to the Department's regulation? What other protections relating to credit products already are afforded to—or could be improved for—Service members and their dependents?

QUESTION 5: If the Department continues to pursue an approach that defines ''consumer credit'' to be generally consistent with certain credit regulated under TILA, should the Department consider including one or more exemptions for certain types of credit products, such as student loans? What legitimate basis could there be for any particular exemptions for certain credit products?

QUESTION 6: Apart from the conditional exclusion proposed for a credit card account that charges bona fide fees, as discussed below, should the Department consider providing one or more exceptions from the charges that must be included in the MAPR for de minimis bona fide fees associated with an open-end credit line? If so, should that type of exception be limited to an open-end line of credit connected to a deposit account? If so, please specifically describe which fees on these accounts would be bona fide fees eligible for such an exception. What would be the appropriate cost limit of a de minimis fee? If the Department does provide for such an exception to open-end credit (other than for credit card accounts), what parameters should the Department use to limit the exception to prevent evasion of the protections under the MLA?

B. Proposed Conditional Exclusion for Credit Card Accounts

Even though the Department believes that the consumer credit regulated under the MLA generally should track the scope of credit regulated under Regulation Z, the Department recognizes that imposing the interest-rate limit of 10 U.S.C. 987(b) on credit card products likely would result in dramatic changes to the terms, conditions, and availability of those products to Service members and their families. The important protections Congress intends to provide to Service members and their families under the MLA should be made relevant to a broader range of credit products without unduly impeding the availability of credit that is benign or beneficial to Service members and their families.[103] Unlike the vast majority of credit products that are amenable to straightforward pricing mechanisms relating to the cost of the funds borrowed (such as solely on the basis of a fixed or variable interest rate applied for a term or on a periodic basis), credit provided through a credit card account can be provided subject to pricing mechanisms that, in part, account for the value of products or services delivered through the cardholder's use of the card itself. In this regard, many creditors offer credit card products that, from a consumer's perspective, generally are subject to periodic interest-rate charges (*i.e.,* the cost of the funds borrowed), plus participation fees and transaction-based fees that may vary, depending on the consumer's use of the card.

The Department believes that most creditors impose bona fide fees expressly tied to specific products or services connected to using the credit card itself and segregable from the cost

[100] *See* 12 CFR 1026.1(c)(1)(iii) (limiting the coverage of the regulation, in relevant part, to credit that is subject to a finance charge or is payable by a written agreement in more than four installments).

[101] *See* 10 U.S.C. 987(i)(3) (broadly defining ''interest'').

[102] *See* 10 U.S.C. 987(h)(2) (granting discretion to the Department to prescribe rules regarding ''[t]he method for calculating the applicable annual percentage rate of interest on [consumer credit] obligations'').

[103] *See* 72 FR at 50585 (''The intent of the statute is clearly to restrict or limit credit practices that have a negative impact on Service members without impeding the availability of credit that is benign or beneficial to Service members and their families.'').

of funds borrowed, such as a foreign transaction fee that applies only when the cardholder tenders the card for a purchase made outside of the United States. Even though some of these fees might appear to be relatively high under certain circumstances, the Department believes that credit card products represent a form of consumer credit that, in general, is beneficial to Service members,[104] especially insofar as the costs of bona fide fees expressly tied to specific products or services may be imposed only upon the Service member's own choices regarding the use of the card. If the interest-rate limit of 10 U.S.C. 987(b) were to be flatly imposed on credit card products, then creditors likely would be required to significantly re-structure their current products, services, and pricing mechanisms when providing credit cards to Service members and their families—without a corresponding benefit to the Service members and their families. Flatly applying the interest-rate limit of 10 U.S.C. 987(b) to credit card products could result in unusually adverse consequences to both creditors and Service members, especially insofar as some creditors might elect to stop offering these products altogether or suspend certain functions of the card (*i.e.,* use of a card to make purchases in a foreign country) to Service members.

The Department also believes that credit card products may warrant special consideration under the MLA because comparable protections for consumers who use these products separately apply under the Credit Card Accountability Responsibility and Disclosure Act of 2009 (''CARD Act''). For example, the CARD Act, as implemented by the Bureau's Regulation Z, limits penalty fees on credit cards, including late-payment and over-the-limit fees, to those fees that are ''reasonable and proportional'' to the omission or violation that triggered the fee.[105] Regulation Z provides safe harbor fee ranges designed to facilitate compliance with these requirements of the CARD Act. The CARD Act also limits the total amount of fees that may be charged on an account in its first year: In general, a creditor may not impose fees for a credit card account during the first year that exceed 25 percent of the available line of credit in effect when the account is opened.[106]

In an effort to balance the interests of limiting credit practices that have an adverse impact on Service members without unduly impeding the availability of credit that is benign or beneficial to Service members and their families, the Department has considered proposing a complete exemption from the definition of ''consumer credit'' for credit extended to a covered borrower under a credit card account. However, the Department believes that certain creditors could take advantage of an opportunity to exploit a complete exemption for credit cards by transforming high-cost, open-end credit products (which otherwise would be covered as ''consumer credit'') into credit card products.

The Department similarly has considered whether exclusions from the MAPR for certain types of fees, such as an application fee or participation fee, should be proposed for credit card accounts in order to preserve current levels of access to those products for Service members and their dependents; however, the Department believes that unqualified exclusions from the MAPR for certain fees, or all non-periodic fees, likewise could be exploited by a creditor who would be allowed to preserve a high-cost, open-end credit product by offering a relatively lower periodic rate coupled with a high application fee, participation fee, or other fee (as described in the exclusion), subject to the restrictions under the CARD Act.

To avoid creating clear regulatory gaps in the framework for 10 U.S.C. 987, the Department believes that consumer credit under the MLA should include credit extended to a covered borrower under a credit card account under an open-end (not home-secured) consumer credit plan, except that this form of consumer credit may be subject to a qualified exclusion for bona fide application fees, participation fees, transaction-based fees, and similar fees connected to the use of the credit card.[107] Proposed § 232.4(d) would allow a creditor to exclude from the MAPR a bona fide fee—other than a periodic rate—only to the extent that the charge by the creditor is (i) a bona fide fee and (ii) reasonable and customary for that type of fee. Proposed § 232.4(d)(2) would clarify that certain charges—namely, ''any credit insurance premium, including charges for single premium credit insurance, fees for debt cancellation or debt suspension agreements, or to any fees for credit-related ancillary products sold in connection with and either at or before consummation of the credit transaction or upon account opening''—may not be excluded as bona fide fees because these charges are expressly included in the definition of ''interest'' in 10 U.S.C. 987(i)(3).

Proposed Standards for Exclusion for Bona Fide Fees

The Department believes that the proposed conditions for excluding a bona fide fee from the MAPR—namely, that the fee must be ''reasonable'' and ''customary''—would fairly allow Service members and their families to continue to have access to credit card products *and* limit the opportunity for a creditor to exploit the exclusion for those products. Unlike a complete or targeted exemption for credit card products, the proposed conditional exclusion would not allow a creditor to transform high-cost, open-end credit products into credit card accounts by offering a relatively lower periodic rate coupled with a high application fee, participation fee, or other fee. Under the proposal, a creditor who imposes an unreasonable (in any respect) fee or a fee that is not, in every respect, customary (such as in the manner of the charge or the basis for the computation) in a credit card account for a Service member must include the total amount of the fees—including any fee(s) that otherwise may be eligible for the exclusion—in the MAPR. The ''reasonable and customary'' conditions for a bona fide fee, as proposed, are intended to be applied flexibly so that, in general, creditors may continue to offer a wide range of credit card products that carry reasonable costs expressly tied to specific products or services and which vary depending upon the Service member's own choices regarding the use of the card.

Proposed §§ 232.4(d)(3)(i)–(v) would provide standards to guide determinations regarding whether a bona fide fee—other than a periodic rate—for a credit card account may be excluded from the calculation of the MAPR as ''reasonable and customary.''

Like-kind fees. Proposed § 232.4(d)(3)(i) would provide that the bona fide fee must be compared to ''fees typically imposed by other creditors for the same or a substantially similar

[104] In this regard, the Department notes that approximately 68 percent of American families have at least one credit card. *See* Federal Reserve Board's Survey of Consumer Finances (2010), available at *http://www.federalreserve.gov/pubs/bulletin/2012/pdf/scf12.pdf* p. 67.

[105] 15 U.S.C. 1665d; 12 CFR 1026.52.

[106] 15 U.S.C. 1637(n)(1); 12 CFR 1026.52(a).

[107] The Department maintains that 10 U.S.C. 987(i)(6) grants broad latitude to the Department to ''define which types of consumer credit transactions shall be covered by the law, provided that they do not include the two listed exemptions.'' 72 FR at 50585. Furthermore, 10 U.S.C. 987(h) grants to the Department discretion to ''prescribe regulations to carry out [the MLA],'' and, in particular, to prescribe rules relating to ''[t]he method for calculating the applicable annual percentage rate of interest'' and the ''types of fees'' that are subject to the restrictions of the MLA. 10 U.S.C. 987(h)(2)(B) and (h)(2)(C).

product or service.'' The Department believes that this elementary like-kind standard would be appropriate because a creditor should not be required to assess a fee for, say, a balance-transfer service based on the fees that other creditors charge for cash-advance services.

Safe harbor. Proposed § 232.4(d)(3)(ii) is designed to provide a firm, yet flexibly adaptable standard for a ''reasonable'' amount of a bona fide fee. Under this provision, a creditor may compare the amount of the bona fide fee to ''an average amount for a substantially similar fee charged by 5 or more creditors each with at least $3 billion in outstanding loans on U.S. credit card accounts at any time during the 3-year period preceding the time such average is computed.'' The Department believes that the standard for a ''reasonable'' amount of a bona fide fee should be sufficiently flexible to allow for changing conditions in the marketplace for products and services provided through credit card accounts, and thus proposes language in the provision (''an average'' of an amount charged by ''5 or more creditors'') that would allow a creditor to select any group of 5 or more credit card issuers who each have the qualifying amount of outstanding credit card loans in order to make a determination. The Department believes that using a pool of 5 or more of these qualifying creditors is reasonable because these creditors, taken together, would represent a significant portion of the market for credit card products.[108]

In order for a creditor to use the fee(s) charged by a credit card issuer when computing an average, the credit card issuer must have had the qualifying amount of loans at any time during the 3-year period preceding the date when the creditor computes the average. If the amount of the creditor's own bona fide fee is less than or equal to the average of the amount charged by those 5 or more credit card issuers who each have the qualifying amount of outstanding credit card loans, then the creditor's bona fide fee would be reasonable for the purposes of the exclusion.

Proposed § 232.4(d)(3)(ii) would set a threshold of $3 billion in outstanding credit card loans on U.S. credit card accounts held by a credit card issuer in order for that issuer's fees to be eligible for inclusion in an average calculated for the purposes of compliance with the ''reasonable'' condition of § 232.4(d)(1). The Department proposes the use of a minimum of 5 credit card issuers, each of whom meet the threshold of $3 billion in outstanding credit card loans on U.S. credit card accounts, in order to facilitate a creditor's ability to compute an average under the safe-harbor provision in light of a very manageable, yet fairly representative, sample of fees in the marketplace for credit card products. The Department believes a threshold of $3 billion of outstanding credit card loans is reasonable because that threshold would include a significant number of credit card issuers, whose credit card products make up the majority of the products in the current credit card market. Moreover, the credit card issuers who hold more than $3 billion in outstanding credit card loans on U.S. credit card accounts offer credit card products that are typical in that marketplace. The Department is aware that many credit card issuers who hold less than $3 billion in outstanding credit card loans on U.S. credit card accounts may offer credit card products with lower or similar fees (relative to issuers who hold more than $3 billion in outstanding credit card loans); these issuers would benefit in a straightforward manner from the proposed method of computing an average for the purposes of the safe-harbor proposed in § 232.4(d)(3)(ii). The Department believes that establishing this threshold would prevent a niche issuer charging unreasonable credit card fees from benefiting from the safe harbor, in a manner that evades the intent of the rule, by comparing its fees only to the fees of other niche issuers, rather than a more representative sample of the marketplace.

The Department also proposes a rolling 3-year look-back period to facilitate a creditor's ability to establish that a credit card issuer meets the asset-size standard. This 3-year period should facilitate the process for calculating, and relying on, an average amount for one or more relevant fees because, for example, when a creditor uses information from the past year to establish that a credit card issuer meets the asset-size threshold, the creditor could rely on the fee information relating to that credit card issuer's credit card products for the next two years. At the same time, the proposed 3-year period could provide stability to the safe-harbor determination, particularly if credit card loan holdings of credit card issuers shift significantly in response to market conditions or otherwise. Furthermore, a 3-year period could provide adequate time for the Department to amend the proposed threshold or safe harbor, as may be necessary.[109]

The Department believes that all creditors who offer credit card products to Service members and their dependents could readily calculate whether each type of fee associated with those products may fit within the safe harbor because data relating to the fees imposed by other credit card issuers, as well as the amount of credit card loans outstanding, is widely available. With regard to credit card fees, most credit card issuers, particularly all of the largest issuers, make complete contract terms on their current offerings freely available on their Web sites as part of solicitations and applications for their products.[110] With regard to the amount of outstanding credit card loans held by a credit card issuer, issuers provide this information in both filings to the Securities and Exchange Commission (SEC filings) and Consolidated Reports of Condition and Income (Call Reports). Both SEC filings [111] and Call Reports [112] are available online without charge. In addition, the Department recognizes that data collected from these and other information sources is compiled in commercially available databases regularly used by financial institutions to track the marketplace for credit card products and services, and the Department believes that creditors should be permitted to reasonably rely upon those industry-specific databases when computing an average fee under proposed § 232.4(d)(3)(ii).

For example, a creditor seeking to determine whether another credit card issuer could qualify as one of the 5

[108] The Department is aware of at least 16 creditors who hold loans above the proposed asset threshold. *See* The Nilson Report, Issue 1,025 (Sept. 2013) at 10 (listing 14 MasterCard and Visa issuers with above $3 billion in outstanding loans mid-year 2013); Discover Bank, Consolidated Reports on Condition and Income for A Bank with Domestic Offices Only—FFEIC 041 (July 30, 2013) at 17 (indicating that Discover held more than $49 billion in such loans); and American Express Company, Consolidated Statements of Income (July 17, 2013) at 13 (indicating that American Express held $54.6 billion in cardmember loans. These 16 creditors (who are not the only creditors above the $3 billion threshold) hold over $582 billion in credit card loans or greater than 87 percent of the market in 2013.

[109] In this regard, 10 U.S.C. 987(h)(3) requires the Department, at a minimum, to consult with other Federal agencies ''not less often than once every two years'' with a view towards revising the regulation implementing the MLA.

[110] *See, e.g.,* the solicitations available at *https://creditcards.chase.com.*

[111] The SEC makes public filings available through its Electronic Data Gathering, Analysis, and Retrieval (EDGAR) system. Information on this system is available at *http://www.sec.gov/edgar/aboutedgar.htm.*

[112] Call Reports for institutions insured by the Federal Deposit Insurance Corporation can be found on the Federal Financial Institutions Examination Council's Web site, available at *https://cdr.ffiec.gov/public/.* Call Reports for credit unions are available online through the National Credit Union Administration's Web site, available at *http://researchcu.ncua.gov/Views/FindCreditUnions.aspx.*

creditors for determining the average fee under proposed § 232.4(d)(3)(ii) could download a recent Call Report for an issuer and review Schedule RC–C Part I line 6(a) that provides credit card ''[l]oans to individuals for household, family, and other personal expenditures'' held by the institution. If that credit card issuer indicated that it held more than $3 billion in outstanding credit card loans, then the creditor could include any fee charged by that credit card issuer in the creditor's safe-harbor calculation under proposed § 232.4(d)(3)(ii). The creditor could find the amounts of the relevant fees for that credit card issuer disclosed on the issuer's current offerings, as available through a variety of sources, such as the issuer's Web site.

The following example is provided for additional guidance on how a creditor could determine whether its own fees for a credit card account would fit within the safe harbor under proposed § 232.4(d)(3)(ii). Creditor Bank regularly offers a credit card product called the ''Creditor Bank Card.'' The Creditor Bank Card carries an annual fee of $25, a cash advance fee of 3 percent of a transaction or $5, whichever is greater, and no other fees.[113] Creditor Bank is aware of 5 large credit card issuers: Bank A, Bank B, Bank C, Bank D, and Bank E. Creditor Bank consults the SEC filings for each of these 5 banks and finds that all 5 held U.S. credit card loans in excess of $3 billion at some time in the preceding year. Next, Creditor Bank reviews the fees charged on various credit card products issued by those 5 banks. Bank A charges an annual fee of $100 on one credit card product and a $0 annual fee on another credit card product. Bank A charges a cash advance fee of 4 percent of a transaction or $10, whichever is greater, on both of its card products. Bank B charges a $50 annual fee on one credit card product and a $0 annual fee on another credit card product. Bank B charges a cash advance fee of 2 percent of the transaction or $5, whichever is greater, on both its credit card products. Bank C, Bank D, and Bank E each offers one credit card product that carries a $50 annual fee, and a cash advance fee of 3 percent of the transaction or $5, whichever is greater.

Under proposed § 232.4(d)(3)(ii), Creditor Bank may choose to calculate an average using the highest annual fees charged by each of these other 5 banks. In this case, Creditor Bank could calculate an average fee for the annual participation fee of $60 (the sum of $100 for Bank A, plus $50 for each of Bank B, Bank C, Bank D, and Bank E; divided by 5). Because the Creditor Bank Card's $25 annual fee falls below the $60 average of fees charged by 5 other banks, Creditor Bank would meet the safe harbor for that fee. Creditor Bank could then undertake the same analysis for cash advance fees, and would be required to consider whether its fee is ''reasonable'' under the safe harbor with respect to both the percentage charged and the minimum fee. In this case, Creditor Bank could calculate an average cash advance percentage fee of 3 percent and an average cash advance minimum fee of $6. Because the Creditor Bank Card's percentage fee and minimum fee fall below these averages, Creditor Bank may exclude these bona fide fees from the MAPR under proposed § 232.4(d)(3)(ii). We seek comment on the feasibility of performing this calculation and the associated costs.

Reasonable fee. Proposed § 232.4(d)(3)(iii) is designed to clarify that a bona fide fee still may be ''reasonable'' for the purposes of the exclusion even if that fee is higher than an average amount as calculated under proposed § 232.4(d)(3)(ii). In particular, the Department recognizes that, due to several factors in the marketplace for credit cards, the prices of certain fees could drop from current levels, including to zero, and yet the Department believes that a creditor who charges a reasonable fee still should be permitted to avail itself of the exclusion in paragraph (d)(1) of this section. Accordingly, the Department proposes a provision that expressly states that ''[a] bona fide fee charged by a creditor is not unreasonable solely because other creditors do not charge a fee for the same or a substantially similar product or service.''

Customary. Proposed § 232.4(d)(3)(iv) would provide a standard to assess whether a bona fide fee is ''customary'' for the purposes of the exclusion. The touchstone for assessing whether a creditor's bona fide fee is ''customary'' is whether ''other creditors typically compute, or customarily have computed,'' that fee in the manner by which that creditor does so. Nevertheless, the condition that a bona fide fee be ''customary'' for that type of fee should not be interpreted so as to require creditors to move in lockstep in order to satisfy this condition. The Department intends the standard for a ''customary'' condition to be applied with sufficient flexibility that a creditor who imposes a bona fide fee in a given manner, such as a fixed amount per transaction, may continue to do so, ''even if substantially all other creditors compute that fee on a percentage basis.''

Reasonableness for a participation fee. Consistent with the Department's proposal that the conditions of ''reasonable and customary'' be applied flexibly, proposed § 232.4(d)(3)(v) would provide a standard in the particular case of a participation fee. The Department recognizes that creditors who issue credit cards provide a range of benefits and services to Service members and their dependents who are cardholders, and some cards may charge a participation fee in lieu of (or in light of lower) transaction-based fees. For example, a creditor may offer a credit card that carries a relatively higher participation fee, yet does not charge a foreign transaction fee. Accordingly, proposed § 232.4(d)(3)(v) would provide a standard stating that ''[a]n amount of a bona fide fee for participation in a credit card account may be reasonable and customary . . . if that amount reasonably and customarily corresponds to the credit limit in effect or credit made available when the fee is imposed, to the services offered under the credit card account, or to other factors relating to the credit card account.''

QUESTION 7: If the Department continues to pursue an approach that defines ''consumer credit'' to be generally consistent with certain credit regulated under TILA, should the Department consider including an exemption specifically for a credit card account under an open-end (not home-secured) consumer credit plan? Would the consumer protection under TILA be sufficient to be consistent with the requirements of MLA? How would an exemption for consumer credit offered through a credit card account be articulated?

QUESTION 8: The Department solicits comment on potential operational issues with applying the regulation under the MLA to credit card products offered in retail sales locations, particularly at the point of sale. How should the Department address any such potential issues in a final rule that may cover some or all credit card products extended to covered borrowers?

QUESTION 9: Do the proposed standards appropriately describe

[113] For the sake of simplicity, only two fees are considered in this example. Under proposed § 232.4(d)(1), each bona fide fee must be ''reasonable and customary,'' and accordingly, a creditor seeking to determine whether all of its bona fide fees fit within the safe harbor under proposed § 232.4(d)(3)(ii) must conduct a separate analysis for each fee. Similarly, the example uses bank cards only for the sake of simplicity. The proposed regulation does not distinguish among types of credit cards (*e.g.,* private label, bank, or retail store cards) or types of creditors.

whether a bona fide fee may be excluded from the calculation of the MAPR as ''reasonable and customary?'' If not, please specifically describe the language the Department should use to clarify when a bona fide fee is not required to be included in the MAPR.

QUESTION 10: Does the threshold of $3 billion in outstanding credit card loans on U.S. credit card accounts appropriately allow an assessment of whether a bona fide fee is ''reasonable,'' in light of the fees charged by credit card issuers whose credit card products are typical in the marketplace? If not, what measure(s) should be used to facilitate a creditor's own assessment of its bona fide fees, for the purposes of complying with conditions proposed in § 232.4(d)(1), while also preventing other creditors who offer credit card products that carry unreasonable fees from benefitting from the safe harbor? Is a pool of 5 or more creditors reasonably large for computing an average fee for the purposes of § 232.4(d)(1)? Does a period of 3 years provide sufficient stability for measuring whether a credit card issuer meets the asset-size standard? If not, what period should be used?

C. Proposal To Revise Provisions Governing Assessment of a Covered Borrower

When adopting its initial regulation in 2007, the Department explained that the provisions governing the assessment of a ''covered borrower'' should balance protections for a covered borrower while also addressing a creditor's need to have ''some degree of certainty in determining that the loans [the creditor makes] are in compliance with [the MLA] as implemented by Part 232.'' [114] The Department's existing regulation seeks to balance these interests by providing a ''safe harbor'' from the requirements of the regulation for a creditor who, with respect to a consumer credit transaction: first, provides a consumer a prescribed form, the ''covered borrower identification statement,'' declaring whether he or she is a covered borrower, and the consumer signs the form indicating that he or she is not a covered borrower; and, second, has not determined, using certain optional verification procedures, that the consumer is a covered borrower.[115] The Department is proposing to revise these provisions governing the assessment of a covered borrower for two reasons.

First, the Department has become aware of misuses of the covered borrower identification statement whereby a Service member (or covered dependent) falsely declares that he or she is not a covered borrower. The Department is concerned that a Service member seeking a credit product that is subject to the MLA falsely states—either on his or her own initiative or complicit with the creditor in the course of the application process—that he or she is not a covered borrower so that the institution offers the credit product unencumbered by the interest-rate limit and other restrictions of the MLA. While the Department intended the provision of the covered borrower identification statement to afford protections for Service members and their dependents, in actual transactions the dynamic between creditors and individual borrowers has led to widespread misuses of the statement, often resulting in extensions of credit that violate the MLA—plus, adverse effects on Service members or their dependents who make false statements. Furthermore, and benignly, some spouses of active duty Service members may not understand that they are ''dependents'' covered under the MLA and might unwittingly incorrectly complete the covered borrower identification statement. Accordingly, the Department believes that this section of the regulation should be revised to relieve a Service member or his or her dependent from making any statement regarding his or her status as a covered borrower [116] in the course of a transaction involving consumer credit.

Second, the Department believes that the current framework of providing the covered borrower identification statement—which allows the consumer to state either that ''I AM'' or ''I AM NOT'' a covered borrower—could be unduly cumbersome for some creditors to administer. In particular, the Department is concerned that, in light of the proposal to cover a broader range of products as consumer credit under the MLA, a creditor should be afforded a more straightforward mechanism to have ''some degree of certainty in determining that the loans [the creditor makes] are in compliance with [the MLA] as implemented by Part 232.'' [117] The Department believes that a covered-borrower check could be conducted unilaterally by a creditor by checking the Department's database, akin to the unilateral process a creditor currently uses to obtain a consumer report when assessing the creditworthiness of a consumer and to ascertain the consumer's identity. Accordingly, the Department proposes to revise this section of the regulation in order to provide a clearer mechanism for a creditor to obtain the protection of a safe harbor when assessing whether a consumer is a covered borrower.

The Department currently provides an online database, available at *https://www.dmdc.osd.mil/appj/mla/index.jsp,* that allows a creditor to determine whether a consumer is a covered borrower under the MLA (the MLA Database). Proposed § 232.5 would provide a conclusive mechanism for a creditor to unilaterally assess the status of a consumer who applies for consumer credit if: first, the creditor checks the MLA Database to determine that consumer-applicant's status when the creditor enters into a transaction or establishes an account for consumer credit; second, the consumer-applicant does (or does not) appear in the MLA Database; and, third, the creditor retains a record of the information obtained from the MLA Database.

The Department anticipates that commercial information-services providers, such as consumer reporting agencies, may choose to supply information products to financial institutions that would include covered-borrower checks as part of those products used to process loan applications. As the Department may determine to be appropriate, the structure, as well as the terms and conditions for use, of the MLA Database could be developed to permit a commercial information-services provider to access the MLA Database for the purposes of obtaining and reselling a search record regarding a consumer. Contemplating that such developments could be made, if appropriate, nothing in proposed § 232.5 would prohibit or otherwise restrict a creditor from using a commercially provided information product to conduct a covered-borrower check, so long as the MLA Database is the underlying source of the data relied on by that creditor.

QUESTION 11: If the Department makes appropriate adjustments to the MLA Database, should the Department modify the language of § 232.5 to clarify that a creditor may take advantage of the

[114] 72 FR at 50588.

[115] 32 CFR 232.5(a)(1)–(2). However, the Department also issued an important ''caveat'' to this provision, stating that a creditor may not fit within the safe harbor if the ''creditor obtains documentation as part of the credit transaction reflecting that the applicant is a covered borrower'' (notwithstanding the signed declaration). 72 FR at 50588.

[116] In this regard, the Department notes that even under the elective verification method, an activated member of the National Guard or Reserves is required to provide a copy of the military orders calling the covered member to military service, upon request of the creditor. 32 CFR 232.5(b).

[117] 72 FR at 50588.

safe harbor by conducting a covered-borrower check using a commercially provided information product whose underlying data is derived from the MLA Database? If so, please specifically describe the language the Department should use to clarify this aspect of § 232.5.

If the vast majority of transactions are amenable to covered-borrower checks conducted solely through information obtained from the MLA Database, the actual status of the consumer as a covered borrower could be material to a consumer credit transaction or account if the creditor has actual knowledge of that consumer's status. Consistent with the policy underlying the caveat to the existing § 232.5(a), the Department believes that a creditor who has actual knowledge that a consumer is a covered borrower should not be entitled to the safe harbor when entering into a transaction or establishing an account for consumer credit for that borrower. For example, if as part of the creditor's application or underwriting process, the creditor collects from a covered borrower a copy of the borrower's current military identification card or other record of the borrower's status, the creditor would obtain actual knowledge of that borrower's status, regardless of whether the creditor checks the MLA Database. Proposed § 232.5(c) reflects this policy and provides that the creditor must ''treat the consumer as a covered borrower notwithstanding any determination by that creditor based on information obtained from the [MLA Database].'' The Department intends for this exception to the safe harbor in proposed § 232.5(b) to apply so that a creditor may not take advantage of an obvious error in the MLA Database when the creditor knows otherwise, and the Department expects these circumstances to be rare.

If a creditor conducts a covered-borrower check in reliance on information obtained (including, potentially, indirectly) from the MLA Database, and determines at the outset that a consumer-applicant is not a covered borrower, proposed § 232.5(b)(2) generally would provide a safe harbor from liability under the MLA in the event that the consumer, in fact, is a covered borrower. This situation could occur, for example, in the case that a consumer married to an active duty service member (and, therefore who is a covered borrower himself or herself) has not registered for any military benefits in the Defense Enrollment Eligibility Reporting System which provides the underlying data for the MLA Database. The Department believes a creditor who checks a consumer against the MLA Database has undertaken the best efforts under the circumstances to comply with the MLA and should receive, therefore, protection from liability if the database had contained incorrect information about that consumer. Moreover, a creditor who satisfies the conditions for the safe harbor provided under proposed § 232.5(b)(2) would be free from liability under the MLA at the outset of establishing an account for credit—and throughout the lifespan of that particular account—relating to that consumer.

The Department believes the consumer protections of the MLA will be most effectively provided if creditors extending consumer credit with an MAPR exceeding the 36 percent interest-rate limit check the MLA Database before extending that credit to consumers. In order to benefit from the safe-harbor provision under proposed § 232.5(b), a creditor must check the MLA Database whenever a consumer applies for a new consumer credit product or establishes a new account for consumer credit, including a new line of consumer credit that might be associated with a pre-existing transactional account held by the borrower. For example, if a consumer initially opens a checking account with a bank, and then, later, applies for an overdraft line of credit associated with that checking account and which carries a cost in excess of the interest-rate limit, in order to receive the benefit of the safe harbor for purposes of that new line of consumer credit, the bank must check the MLA Database when the consumer applies for the overdraft line of credit, even if the bank previously had checked the MLA Database at the time he or she established the checking account and did not find the consumer in the database.

QUESTION 12: If the Department were to adopt a framework for a creditor to conduct a covered-borrower check as proposed in § 232.5, should the Department also adopt an exception from the safe harbor that addresses the situation when the creditor has actual knowledge that a consumer is a covered borrower? What are the likely costs associated with conducting covered-borrower checks as proposed in § 232.5? What alternatives should the Department consider for creditors to conduct covered-borrower checks? Should the Department consider alternative safe harbor provisions for certain types of creditors or certain types of consumer credit, such as credit extended at retail sales locations? Please provide specific language for provisions that would implement these alternatives.

QUESTION 13: Should the Department retain a safe harbor for use of the covered borrower identification statement? The Department solicits comment on whether the use of the statement would be unduly cumbersome if the Department expands coverage of the regulation to additional types of credit products?

QUESTION 14: Should the Department provide a fallback provision to protect a creditor from liability in the case that the creditor is temporarily or permanently unable to access the internet at the time of conducting a transaction or establishing an account for consumer credit? Should the Department provide protection from liability from the MLA in the case that a creditor can demonstrate that the MLA Database was not operational at the time the creditor attempted to search the database? If so, should the Department address how the creditor may establish that the MLA Database was not operational at the time the creditor attempted the search?

IV. Section-by-Section Description of the Proposed Regulation

Section 232.1 Authority, purpose, and coverage

The Department proposes minor revisions to this section, mainly for the sake of clarity and consistency with provisions of the regulation.

Section 232.2 Applicability

The Department proposes to amend this section in two respects.

First, in the new proposed subsection (a), the Department would add a provision stating: ''Nothing in this part applies to a credit transaction or account relating to a consumer who is not a covered borrower at the time he or she becomes obligated on a credit transaction or establishes an account for credit.'' This proposed provision is designed to clarify the Department's longstanding policy that the requirements under 10 U.S.C. 987, as implemented in the regulation, apply only to a consumer who is a covered borrower ''at the time he or she becomes obligated on a consumer credit transaction covered by this part.'' [118]

The Department believes that defining the scope of the regulation to apply only to a covered borrower when he or she enters into a transaction or establishes an account for consumer credit is consistent with the language and

[118] *See* 32 CFR 232.3(c) (defining a ''covered borrower'').

structure of 10 U.S.C. 987.[119] In this regard, the Department believes that 10 U.S.C. 987 should not be interpreted so as to impose restrictions on an existing agreement between a creditor and a consumer involving a credit transaction primarily for personal, family, or household purposes that spring to life when the consumer becomes a covered borrower when he or she begins active duty service in the military. Interpreting 10 U.S.C. 987 as applying only to a covered borrower who holds that status when he or she agrees to obtain the consumer credit is fair to the creditor who, at the outset of the transaction, should be in a position to know the status of its counterparty to the agreement. Moreover, the Department's longstanding policy regarding this aspect of the scope of 10 U.S.C. 987 is consistent with the provision set forth in § 987(f)(3),[120] which makes any credit contract that is prohibited under 10 U.S.C. 987 ''void from the inception of such contract.'' Section § 987(f)(3) would operate unjustly if a consumer, upon obtaining the status of a covered borrower, could sue the creditor to void an existing credit contract on the grounds that the contract—which may have been entirely lawful when originally entered into with the consumer—violates one or more provisions of 10 U.S.C. 987. One practical consequence of the Department's longstanding policy is that a creditor is not required to constantly monitor the status of each consumer who has obtained credit or holds an account for credit to assess whether the consumer is a ''covered borrower;'' rather, the creditor may conduct that assessment, as the creditor may so elect, only at the outset of the transaction or when establishing the account for consumer credit. The Department proposes to adopt corresponding revisions to the language of certain other provisions of the regulation, notably §§ 232.3(f) and 232.5(b)(2), for the sake of clarity and consistency with this policy.

Second, the Department proposes to add a new subsection (b) stating: ''The examples in this part are not exclusive. To the extent that an example in this part implicates a term or provision of Regulation Z (12 CFR part 1026), issued by the Consumer Financial Protection Bureau to implement the Truth in Lending Act, Regulation Z shall control the meaning of that term or provision.''

Section 232.3 Definitions

(a) Affiliate. The Department proposes a definition of ''affiliate'' to accompany the definition of ''creditor.'' This new proposed definition is designed to prevent evasion of the rule, specifically with respect to an entity that would not, when considered alone, qualify as a creditor, but, when considered together with its affiliates, would be engaged in extending credit, as described in § 232.3(i)(3) of the proposed rule.

(b) Billing cycle. The Department proposes to define the term consistent with the meaning of this term in Regulation Z.

(c) Bureau. The Department proposes to define the term for the Consumer Financial Protection Bureau.

(d) Closed-end credit. The Department proposes to define the term consistent with the meaning of this term in Regulation Z.

(e) Consumer. The Department proposes to define this term as a natural person.

(f) Consumer credit. As discussed above, the Department proposes to define ''consumer credit'' consistent with the relevant provisions of the Bureau's Regulation Z. Proposed § 232.3(f)(2) would provide exceptions to ''consumer credit'' that, in general, track the exceptions in 10 U.S.C. 987(i)(6).

Certain credit products may, or may not, be covered under the Department's proposed definition of ''consumer credit,'' depending, for example, on whether the particular credit product is subject to a ''finance charge,'' which the Department likewise proposes to define consistent with the meaning of that term in Regulation Z. Most, if not all, ''deposit advance'' products would (when offered to a covered borrower) be covered as consumer credit because this type of product typically involves credit extended by a creditor primarily for personal, family, or household purposes for which the borrower pays any fee or charge that is, or is expected to be, repaid from funds available in the borrower's asset account held by that creditor. Likewise, consistent with Regulation Z,[121] an overdraft line of credit with a finance charge would (when offered to a covered borrower) be covered as consumer credit to the extent that product consists of credit extended by a creditor primarily for personal, family, or household purposes to pay an item that overdraws an asset account and for which the borrower pays any fee or charge, but only if (A) the extension of credit for such an item and (B) the imposition of the fee or charge were previously agreed upon in writing. On the other hand, an overdraft service typically would not be covered as consumer credit because Regulation Z excludes from ''finance charge'' any charge imposed by a creditor for credit extended to pay an item that overdraws an asset account and for which the borrower pays any fee or charge, unless the payment of such an item and the imposition of the fee or charge were previously agreed upon in writing.[122]

Consistent with the Department's existing regulation, proposed § 232.3(f)(2)(iv) would exclude from the scope of ''consumer credit'' any credit transaction that is an exempt transaction for the purposes of Regulation Z (other than a transaction exempt under 12 CFR 1026.29) [123] or otherwise is not subject to disclosure requirements under Regulation Z. The Department believes, at this time, that the exclusions in proposed § 232.3(f)(2)(iv) are appropriate limitations to the consumer credit that is subject to 10 U.S.C. 987 because these types of exempted credit do not pose risks to Service members and their dependents, and a creditor who already complies with Regulation Z should not be required to independently assess whether certain types of credit exempt under that rule could be subject to the requirements of the MLA.

In this regard, this section of the proposed rule would remove the provision in the Department's existing regulation that provides an exclusion for ''credit secured by a qualified retirement account as defined in the Internal Revenue Code.'' [124] The Department believes that the intent of this exclusion is sufficiently captured by the exception for any credit transaction that is an exempt transaction for the purposes of Regulation Z, as described in proposed § 232.4(c)(1)(iv). Under § 1026.3(g) of Regulation Z, credit extended to a participant in certain retirement plans is

[119] *See, e.g.,* 10 U.S.C. 987(a) (imposing conditions on ''[a] creditor who *extends* consumer credit''); 10 U.S.C. 987(c) (requiring certain information to be provided to a covered borrower ''before the issuance of credit''); 10 U.S.C. 987(e) (declaring that ''[i]t shall be unlawful for any creditor *to extend* consumer credit to a [covered borrower]'' that involves certain restrictions or conduct) (emphases added).

[120] 10 U.S.C. 987(f)(3) (''Any credit agreement, promissory note, or other contract prohibited under this section is void from the inception of such contract.'').

[121] *See* 12 CFR 1026.4(c)(3) (imposing certain conditions on a charge for overdraft services that, if not satisfied, would make that charge a ''finance charge'').

[122] *See* 12 CFR 1026.4(c)(3).

[123] *See* 12 CFR 1026.29, regarding state application for Bureau exemption of a class of transactions within the state.

[124] 32 CFR 232.3(b)(2)(iv). In addition, the Department now believes that this provision represents a drafting error because, upon closer review, the Department could not locate a reference in the Internal Revenue Code to a ''qualified retirement account,'' as described in this provision.

not subject to the requirements of Regulation Z.

(g) Covered borrower. The Department proposes to revise the definition of ''covered borrower'' to provide greater clarity and more closely reflect the language of the MLA. Consistent with the plain language of 10 U.S.C. 987(i)(1), the proposed rule would refer to the ''armed forces.'' This proposed provision also would clarify that the protections provided to members of the armed forces on active duty apply to Service members called or ordered to active duty under titles 10 or 14 of the United States Code, or Service members on active Guard and Reserve duty under title 32. Additionally, the Department proposes to revise the definition of ''dependent'' to reflect the plain language of the statute, as amended by § 663 of the 2013 Act. The Department believes that the proposed definition of ''dependent,'' consistent with the term used to establish eligibility for military medical care, would appropriately carry out the intent to simplify the process for determining which family members are covered under 10 U.S.C. 987.

QUESTION 15: Does the revised definition of covered borrower appropriately cover active duty Service members and their dependents?

(h) Credit. The proposed definition of ''credit'' is not changed from the Department's existing regulation.[125]

(i) Creditor. The Department proposes to define ''creditor'' to more closely track the language in the definition of the term in 10 U.S.C. 987(i)(5). In addition, in paragraph (i)(3), the Department proposes to interpret the statutory provision of ''engaged in the business of extending consumer credit'' [126] consistent with the corresponding provision of the Department's existing regulation, which refers to the definition of ''creditor'' in Regulation Z.[127]

(j) Department. The Department proposes to define the term for the Department of Defense.

(k) Dwelling. The proposed definition of ''dwelling'' is not changed from the Department's existing regulation.[128]

(l) Electronic fund transfer. The Department proposes to amend the definition of ''electronic fund transfer'' to have the same meaning as in the regulation issued by the Bureau to implement the Electronic Fund Transfer Act (''EFTA''), as amended from time to time (12 CFR part 1005).[129] In the context of this provision—which relates only to an exception that would be contained in proposed § 232.8(e)—the Department believes that there is no need to account for the authority of the Board of Governors of the Federal Reserve System under EFTA.

(m) Finance charge. The Department proposes to define the term consistent with the meaning of this term in Regulation Z.

(n) Military annual percentage rate (MAPR). The Department proposes to define the term as the cost of credit expressed as an annual rate, and requires the MAPR to be calculated in accordance with proposed § 232.4(c).

(o) Open-end credit. The Department proposes to define the term consistent with the meaning of this term in Regulation Z.

(p) Person. The Department proposes to define the term consistent with the definition of ''person'' in the Department's existing regulation.[130]

(q) Regulation Z. The Department proposes to define the term consistent with the definition of ''Regulation Z'' in the Department's existing regulation,[131] except that, first, the Department would delete the phrase ''or contract'' and, second, the Department would include a provision relating to the authority of the Board of Governors of the Federal Reserve System under TILA.

Section 232.4 Terms of Consumer Credit Extended to Covered Borrowers

Proposed § 232.4(a) is intended to track the restrictions under 10 U.S.C. 987(a). Relative to the language of this provision in the Department's existing rule, which describes a ''creditor'' and an ''assignee,'' the Department is proposing to modify this provision to track the language of the statute and proposed § 232.3(i)(2), which includes an ''assignee'' within the definition of creditor.

Proposed § 232.4(a)(2) would track the restriction under 10 U.S.C. 987(a)(2), which provides that a creditor who extends consumer credit to a covered borrower shall not require the borrower to ''pay interest with respect to the extension of such credit, except as . . . authorized by applicable State or Federal law.'' The Department understands that this condition on an extension of consumer credit possibly could be interpreted to restrict a financial institution, such as a national bank, based in one state from charging interest to covered borrowers residing in another state, which imposes a limit on the interest rate that may be charged, ''except as . . . authorized by [that other] State.'' The Department believes nothing in 10 U.S.C. 987 or this regulation should be construed so as to affect the Federal law governing the interest rate a financial institution may charge.[132]

Proposed § 232.4(b) is intended to track the interest-rate limit of 10 U.S.C. 987(b).

Proposed § 232.4(c) provides the framework for calculating the MAPR by: First, in § 232.4(c)(1), describing each of the charges that must be included in the MAPR; and second, in § 232.4(c)(2), prescribing the rules for computing the MAPR based on those charges.

Proposed § 232.4(c)(1)(i)–(ii) is intended to reflect the charges that must be included as ''interest'' under 10 U.S.C. 987(i)(3). Relative to the corresponding provisions of the Department's existing rule,[133] the language of these proposed provisions would be amended to reflect the broader scope of consumer credit subject to the regulation, such as by referring to ''the credit transaction for *closed-end credit or upon account opening for open-end credit*'' (emphasis added). The proposed exception for a bona fide fee (other than a periodic rate) charged to a credit card account would not apply to the charges set forth in proposed § 232.4(c)(1)(i)–(ii).

At this time, the Department proposes to maintain (in proposed § 232.4(c)(1)(ii)) the language of § 232.3(h)(1)(iii), which requires a creditor to include in the MAPR ''fees for credit-related ancillary products sold in connection with and either at or before consummation of the [consumer credit].'' When adopted in 2007, including in the MAPR only the ''credit-related ancillary products'' sold ''either at or before consummation of the credit transaction'' [134] was designed to be consistent with the scope of consumer credit, which covers only a narrow band of closed-end credit products. However, nothing in the MLA necessarily limits the inclusion in the MAPR of these charges only to those that are sold at the outset of the credit transaction. Particularly insofar as consumer credit would cover open-end credit products, as proposed, the MLA reasonably could

[125] 32 CFR 232.3(d).

[126] 10 U.S.C. 987(i)(5)(A)(i).

[127] 32 CFR 232.3(e) (''*Creditor* means a person who . . . and who otherwise meets the definition of 'creditor' for purposes of Regulation Z.'').

[128] 32 CFR 232.3(f).

[129] Currently the term ''electronic fund transfer'' is defined in section 1005.3(b) of the Bureau's Regulation E. 12 CFR 1005.3(f).

[130] 32 CFR 232.3(e) (defining ''person'' for the purposes of § 232.3 as including a ''natural person, organization, corporation, partnership, proprietorship, association, cooperation, estate, [and] trust.''

[131] 32 CFR 232.3(i).

[132] In the case of a national bank, for example, *see* 12 U.S.C. 85; 12 CFR 74001.

[133] 32 CFR 232.3(h)(1)(ii)–(iii).

[134] 32 CFR 232.3(h)(1)(iii).

be interpreted to require a creditor to include in the MAPR the fee for any ancillary product ''sold with any extension of credit to a [covered borrower]'' so long as that ancillary product was ''associated with the extension of credit'' [135]—which could arise at any time in an ongoing, open-end account for consumer credit. The Department has considered whether to amend the language of proposed § 232.4(c)(1)(ii) to require the inclusion in the MAPR of any fees for credit-related ancillary products, with respect to open-end credit, sold either upon account opening or at any time during the existence of the account, so long as the consumer was a covered borrower at the time the account was established.[136]

QUESTION 16: Should the Department consider eliminating the timing condition of § 232.4(c)(1)(ii) to require the inclusion in the MAPR of any fees for credit-related ancillary products sold either upon account opening or at any time during the existence of an account for open-end consumer credit? If so, please specifically describe the scope of an amended § 232.4(c)(1)(ii). For example, how should the Department define a ''credit-related ancillary product?'' How should the Department define the seller whose charge for a credit-related ancillary product would be subject to inclusion in the MAPR (*i.e.,* ''sold by the creditor'' or ''sold by the creditor or any affiliate of the creditor'')?

Proposed § 232.4(c)(1)(iii) is intended to describe the charges that must be included in the MAPR in light of the definition of consumer credit, which would chiefly consist of ''[f]inance charges,'' consistent with Regulation Z. In general, a charge that is excluded as a ''finance charge'' under Regulation Z also would be excluded from the charges that must be included when calculating the MAPR. As a result, whereas the Department's existing regulation provides exclusions from the MAPR for late payment fees [137] and taxes required to be paid,[138] proposed § 232.4(c) omits these provisions because these charges (as well as other charges) are not finance charges under Regulation Z.[139]

However, the Department recognizes that, under Regulation Z, a wide range of charges that a creditor may impose in connection with a credit product are excluded as ''finance charges,'' particularly an application fee and a participation fee.[140] If these exclusions from the definition of finance charge were to be maintained in the context of consumer credit covered under the MLA, a creditor would have a strong incentive to evade the interest-rate limit of 10 U.S.C. 987(b) by shifting the costs of a credit product by lowering the interest rate and imposing (or increasing) one or more of these excluded fees. To guard against this obvious result, the Department proposes to specifically include any application fee and any participation fee as charges that generally must be included in the MAPR.[141] The exception for a bona fide fee (other than a periodic rate) charged to a credit card account would apply to the charges set forth in proposed § 232.4(c)(1)(iii).

Proposed § 232.4(c)(1)(iv) is intended to clarify that, even if a charge set forth in paragraphs (c)(1)(i)–(iii) of this section would be excluded from the finance charge under Regulation Z, that charge nevertheless must be included in the calculation of the MAPR.

QUESTION 17: Would this approach to include any application fee or participation fee in the calculation of the MAPR be reasonable to implement the statutory provision of ''interest,'' which covers ''any other charge or premium with respect to the extension of consumer credit?'' [142]

1. Computing the MAPR

The proposed rule contains two provisions for computing the MAPR,[143] both of which track the methods already established in Regulation Z.

First, for closed-end credit, the proposed rule would require a creditor to follow ''the rules for calculating and disclosing the 'Annual Percentage Rate (APR)' for credit transactions under Regulation Z,'' based on the charges required for the MAPR, as set forth in proposed § 232.4(c)(1). In general, the requirements for calculating the APR for closed-end credit under Regulation Z are found in § 1026.22(a)(1), and include the explanations and instructions for computing the APR set forth in appendix J to part 1026.

For example, the MAPR for single advance, single payment transactions, such as some types of deposit advance loans, must be computed in accordance with the rules in Regulation Z, such as by following the instructions described in paragraph (c)(5) of appendix J. Based on the formula provided in paragraph (c)(5) of appendix J, in the case of a single advance, single payment transaction loan extended to a covered borrower for a period of 45 days, and for which the advance is $500 and the single payment required consists of the principal amount plus a finance charge of $28.44, for a total payment of $528.44, the MAPR would be 46.14 percent. In this example, the resultant MAPR would exceed the interest-rate limit imposed by 10 U.S.C. 987(b), as set forth in proposed § 232.4(b) of the regulation.

Second, for open-end credit, a creditor generally would be required to calculate the MAPR using the methods prescribed in § 1026.14(c)–(d) of Regulation Z, which relates to the ''effective annual percentage rate.'' [144] Section 1026.14(c) of Regulation Z provides for the methods of computing the annual percentage rate under three scenarios: (1) When the finance charge is determined solely by applying one or more periodic rates; (2) when the finance charge includes a fixed charge that is not due to application of a periodic rate, other than a charge with respect to a specific transaction; and (3) when the finance charge includes a charge relating to a specific transaction during the billing cycle.

[135] 10 U.S.C. 987(i)(3) (defining '' 'interest''' generally as including ''all cost elements associated with the extension of credit'').

[136] Amending the scope of § 232.4(c)(1)(ii) by eliminating the timing condition would be consistent with the scope of § 232.4(c)(1)(i) (which tracks § 232.3(h)(1)(ii) of the existing regulation), which does not impose a condition based on the timing of a sale or charge for a credit insurance premium.

[137] 32 CFR 232.3(h)(2)(i) (excluding from the MAPR ''[f]ees or charges imposed for actual unanticipated late payment, default, delinquency, or similar occurrence'').

[138] 32 CFR 232.3(h)(2)(ii) (excluding from the MAPR ''[t]axes or fees prescribed by law that actually are or will be paid to public officials for determining the existence of, or for perfecting, releasing, or satisfying a security interest'').

[139] *See* 12 CFR 1026.4(c).

[140] *See* 12 CFR 1026.4(c)(1) and (c)(4).

[141] *See also* 72 FR at 50587 (explaining the need to define the MAPR so that covered credit products ''cannot evade the 36 percent [interest-rate] limit by including low interest rates with high fees associated with origination, membership, administration, or other cost that may not be captured in the TILA definition of APR'').

[142] 10 U.S.C. 987(i)(3).

[143] 10 U.S.C. 987(h)(1) (authorizing the Department to prescribe regulations to carry out the MLA); 10 U.S.C. 987(h)(2)(B) (authorizing the Department to establish ''[t]he method for calculating the applicable annual percentage rate of interest on such obligations, in accordance with the limit established under [the MLA]'').

[144] A creditor subject to § 1026.40 of Regulation Z is not required to comply with § 1026.14(c) (''[that type of] creditor may, at its option, disclose an effective annual percentage rate pursuant to § 1026.7(a)(7) and compute the effective annual percentage [in accordance with the subparagraphs of § 1026.14(c)]''). However, for the purposes of complying with the Department's proposed rule when computing a MAPR for open-end credit, any creditor subject to the Department's regulation would be required to comply with that proposed § 1026.14(c), subject to the proposed § 232.4(c)(2)(ii)(B) (in the event that there is no balance during a billing cycle).

For example, suppose a creditor offers a line of credit to a covered borrower primarily for personal, family, or household purposes (commonly referred to as a ''personal line of credit''), and permits the borrower to repay on a monthly basis. Upon establishing the personal line of credit, the covered borrower borrows $500. The creditor charges a periodic rate of 0.006875 (which corresponds to an annual rate of 8.25 percent), plus a fee of $25, charged when the account is established and annually thereafter. Under these circumstances, pursuant to § 1026.14(c)(2) of Regulation Z the creditor would calculate the MAPR as follows: ''Dividing the total amount of the finance charge for the billing cycle''—which is $3.44 (corresponding to (0.006875) × ($500)), plus $25—''by the amount of the balance to which it is applicable''—$500—and multiplying the quotient (expressed as a percentage) by the number of billing cycles in a year''—12 (since the creditor allows the borrower to repay monthly), which is 68.26 percent. In this example, even though the periodic rate (0.006875) would comply with the interest-rate limit under proposed § 232.4(b), the resultant MAPR would be in excess of that limit because the amount borrowed is low at the time the annual fee is imposed. If the covered borrower instead borrows a higher amount, then the creditor still could impose the $25 annual fee and comply with proposed § 232.4(b); for example, if the amount initially borrowed is $1,400, then the resultant MAPR would be 24.73, well below the 36 percent limit.

In the case of open-end credit extended through a credit card account, a creditor likewise would be required to calculate the MAPR using the methods prescribed in § 1026.14(c)–(d) of Regulation Z. For example, if a creditor extends credit to a covered borrower through a credit card account and the borrower incurs a finance charge relating to a specific transaction, such as a cash advance transaction, during the billing cycle, then the creditor would calculate the MAPR under the instructions set forth in § 1026.14(c)(3) of Regulation Z. However, in the case of a credit card account the creditor may exclude, pursuant to proposed § 232.4(c)(1)(iii), any bona fide fee (as described in proposed § 232.4(d)) from the finance charges that otherwise must be accounted for; thus, if a charge for the cash advance transaction fits within the exclusion for a bona fide fee under proposed § 232.4(d), then that charge would not be included when computing the MAPR for that billing cycle.

Under certain circumstances, a creditor might not know at the outset of a billing cycle whether the borrower's use of an open-end line of credit will lead to a finance charge that—through a combination of rates and fees—exceeds the interest-rate limit of the MLA. However, at the end of a billing cycle the creditor would be able to calculate the total charges included in the MAPR and waive an amount necessary to comply with the 36-percent limit of § 232.4(b).

QUESTION 18: Are there operational issues with the use of the effective APR methodology for open-end credit products that the Department should consider? If so, are there alternative methods for calculating the MAPR for these products that would be consistent with 10 U.S.C. 987 and that would address the operational issues?

Proposed § 232.4(c)(2)(ii)(B) generally would prohibit a creditor from imposing a charge in an open-end credit plan for any billing cycle during which there is no balance. However, this provision would include an exception for a participation fee (which otherwise would be required to be included under proposed § 232.4(c)(1)(iii)(B)) because the Department believes that there might be circumstances in which a creditor should be allowed to charge a bona fide fee for maintaining an open-end line of credit for a covered borrower. Still, recognizing that a creditor could structure a high-cost, open-end line of credit to fit within this exception by substantially increasing the participation fee, the Department proposes to limit that fee to $100 per annum, regardless of the billing cycle in which the participation fee is imposed. The Department believes that $100 is the highest reasonable amount that a creditor could charge as a bona fide participation fee, during a billing cycle in which there is no balance, for the purposes of keeping the line of credit open to the covered borrower. Furthermore, proposed § 232.4(c)(2)(ii)(B) would contain a provision to clarify that the $100-per annum limitation on the amount of the participation fee does not apply to a bona fide participation fee charged to a credit card account that would be eligible for the exclusion under proposed § 232.4(d). We seek comment on whether the limit on a participation fee to $100 per annum is reasonable and economically justifiable.

2. Conditional Exclusion From the MAPR for Bona Fide Fees Charged to a Credit Card Account

The Department believes that credit card products may warrant special consideration under the MLA. As discussed above, proposed § 232.4(d) would provide the conditional exclusion, including standards relating to the conditions, that allows a creditor to exclude bona fide fees charged to a credit card account from the MAPR. The Department believes that the proposed conditions for excluding a bona fide fee from the MAPR—namely, that the fee must be ''reasonable'' and ''customary''—would fairly allow Service members and their dependents to continue to have access to credit card products *and* limit the opportunity for a creditor to exploit the exclusion for those products.

However, as set forth in proposed § 232.4(d)(4), a creditor who imposes any fee that is not a bona fide fee or that fails to meet the conditions of being ''reasonable and customary'' must include the total amount of those fees, including any bona fide fees, in the MAPR. Thus, if a creditor charges one unreasonable fee or a fee that is not customary in a credit card account for a covered borrower, the creditor must include the total amount of the fees—including any fee(s) that otherwise may be eligible for the exclusion—in the MAPR. As discussed above, the ''reasonable and customary'' conditions for a bona fide fee, as proposed, are intended to be applied flexibly so that, in general, creditors may continue to offer a wide range of credit card products that carry reasonable costs expressly tied to specific products or services and which vary depending upon the covered borrower's own choices regarding the use of the card.

Section 232.5 Identification of Covered Borrowers

As discussed above and except as provided in § 232.5(c), proposed § 232.5 would provide a mechanism for a creditor to unilaterally assess the status of a consumer who applies for consumer credit if: First, the creditor checks the MLA Database to determine that consumer-applicant's status when the creditor enters into a transaction or establishes an account for consumer credit; second, the consumer-applicant does (or does not) appear in the MLA Database; and, third, the creditor retains a record of the information obtained from the MLA Database. In addition, proposed § 232.5(a) would expressly provide that a creditor is permitted to use other methods, as the creditor may elect, to assess whether a consumer is a covered borrower.

Proposed § 232.5(c)(1) would provide that a creditor who has actual knowledge that a consumer is a covered borrower must ''treat the consumer as a

covered borrower notwithstanding any determination by that creditor based on information obtained from the [MLA Database].'' The Department intends for this exception to the safe harbor in proposed § 232.5(b) to apply so that a creditor may not take advantage of an obvious error in the MLA Database when the creditor knows otherwise, and the Department expects these circumstances to be rare.

Proposed § 232.5(c)(2) would state that ''actual knowledge'' of the status of a consumer as a covered borrower may be established ''only on the basis of a record (including any electronic record) collected by the creditor prior to entering into a transaction or establishing an account for consumer credit and maintained in any system used by the creditor that relates to the consumer credit involving that consumer.'' This proposed paragraph (c)(2) is intended to provide an evidentiary standard to establish whether a creditor might have ''actual knowledge'' with respect to a consumer's status relating to a consumer credit transaction or account. Depending on the circumstances, actual knowledge may be established based on the presence of one or more records maintained in the relevant system the creditor uses for the consumer credit transaction or account; under proposed § 232.5(c)(2), actual knowledge may not be established solely on the basis of other kinds of evidence, such as solely on testimony from a borrower that, during the application process, the borrower told the creditor's employee that the borrower is a Service member on active duty.

QUESTION 19: What alternatives should the Department consider for the evidentiary standard articulated in proposed § 232.5(c)(2)? Please provide specific language for provisions that would implement these alternatives.

Section 232.6 Mandatory Loan Disclosures

The Department proposes to amend § 232.6 of the regulation to simplify the information that a creditor must provide to a covered borrower when issuing consumer credit, consistent with the requirements of 10 U.S.C. 987(c). In particular, the Department is proposing, first, to eliminate the current requirement for information to be provided ''clearly and conspicuously'' and, second, to require a creditor to provide a ''statement'' of the MAPR that describes the charges the creditor may impose, instead of the periodic rate of the MAPR itself ''and the total amount of all charges included in the MAPR,'' as the existing regulation currently requires.

Proposed § 232.6(a) would require a creditor to provide four categories of information to a covered borrower at the time the borrower becomes obligated on the transaction or establishes an account for the consumer credit. namely:

- A statement of the MAPR applicable to the extension of consumer credit;
- Any disclosure required by Regulation Z, which shall be provided only in accordance with the requirements of Regulation Z that apply to that disclosure;
- A clear description of the payment obligation of the covered borrower, as applicable. A payment schedule (in the case of closed-end credit) or account-opening disclosure (in the case of open-end credit) provided pursuant to paragraph (a)(2) of this section satisfies this requirement; and
- A statement [describing the protections afforded to Service members and their dependents under the MLA].''

1. Clear and Conspicuous Requirement

The Department's existing regulation requires each of these categories of information to be provided ''clearly and conspicuously'' to a covered borrower.[145] There might be some benefits to covered borrowers by requiring certain information to be provided in a manner that, relative to other terms and conditions relating to the extension of or account for consumer credit, makes that information clear and conspicuous.[146] However, nothing in 10 U.S.C. 987(c) requires information to be provided ''clearly and conspicuously.'' In addition, Regulation Z independently generally requires disclosures regarding the costs of credit to be provided ''clearly and conspicuously,''[147] and requires a creditor to present some types of information in those disclosures in certain formats.[148] The Department believes that—particularly in light of the proposal to extend the protections of the MLA to a broader range of transactions of and accounts for consumer credit—a creditor should be relieved from the obligation to present the categories of information required under 10 U.S.C. 987(c)(1)(A) and 987(c)(1)(C) in a manner that is clear and conspicuous. However, the Department continues to intend that the information which would be required to be provided to a covered borrower must be provided consistent with the format and other requirements of Regulation Z.[149]

QUESTION 20: If the Department were to adopt a regulation as proposed, to what extent, and in what manner, would the elimination of the clear-and-conspicuous requirement affect the presentation of the categories of information required under 10 U.S.C. 987(c)(1)(A) and 987(c)(1)(C)?

2. Statement of the MAPR

Proposed § 232.6(a)(1) would require a creditor to provide a ''statement'' of the MAPR, instead of ''[t]he MAPR applicable to the extension of consumer credit, and the total dollar amount of all charges included in the MAPR,'' as required under § 232.6(a)(1) of the existing regulation. When adopting this requirement in 2007, the Department recognized that the disclosure of the figures relating to the MAPR would apply only to the discrete forms of closed-end credit defined as ''consumer credit,'' and therefore interpreted the language of 10 U.S.C. 987(c)(1)(A) to require an annual percentage rate of interest. Nonetheless, the Department then recognized ''the potential confusion inherent in mandating the disclosure of two differing annual percentage rates (the MAPR required by [its] regulation and the APR required by TILA).''[150] The Department now believes that this same ''potential confusion'' would be significantly magnified in the context of a wider range of closed-end and open-end credit products that, under this proposal, would be covered under the MLA.

Section 987(c)(1)(A) of the MLA does not, by its terms, require the disclosure of a particular annual percentage rate or the ''amount of all charges'' applicable to the extension of consumer credit. Rather, 10 U.S.C. 987(c)(1)(A) requires a ''*statement* of the annual percent rate of interest applicable to the extension of credit'' (emphasis added), and 10 U.S.C. 987(c)(2) independently requires ''[s]uch disclosures [to] be presented in accordance with terms prescribed by the regulations . . . to implement the [TILA].''[151] Taken singly and in

[145] 32 CFR 232.6(a).

[146] When adopting its rule in 2007, the Department addressed the disclosure requirements of Regulation Z, *see, e.g.,* 72 FR at 50588, but did not address the purposes of imposing a clear-and-conspicuous requirement under 10 U.S.C. 987(c).

[147] 12 CFR 1026.5(a)(1)(i) and 1026.17(a)(1).

[148] *See, e.g.,* 12 CFR 1026(a)(3)(iii) (requiring ''[c]ertain account-opening disclosures [to] be provided in a tabular format''); *see also, e.g.,* 12 CFR 1026.17(a)(1) (prescribing the format of the TILA disclosures for closed-end credit transactions to be ''grouped together, [and] segregated from everything else'').

[149] *See* 72 FR at 50588. Accordingly, the information required under the MLA should not be interspersed with the TILA disclosures.

[150] 72 FR at 50589.

[151] 10 U.S.C. 987(c)(2). As enacted, the MLA refers in this section to regulations ''issued by the

conjunction with each other, these provisions of § 987(c) reasonably should be interpreted as requiring a ''statement'' regarding the MAPR and, separately, disclosures regarding the particular costs of credit relating to a transaction of or account established for consumer credit that are ''in accordance with the terms'' of Regulation Z.

In addition, section 987(i)(4) of the MLA provides that the term '' 'annual percentage rate' has the same meaning as in section 107 of [TILA], as implemented by regulations of the [Bureau].'' That term also includes ''all fees and charges,'' including certain charges that may be exempt from the term ''finance charge'' under Regulation Z.[152] The Department believes that, in light of section 987(i)(4) (''' annual percentage rate' has the same meaning as in section 107 of [TILA], as implemented by the [Bureau]''), section 987(c)(1)(A) of the MLA (''A statement of the annual percentage rate of interest'') should not be interpreted to require a creditor to calculate and disclose to a covered borrower a definitive figure for the ''annual percentage rate'' of interest applicable to the consumer credit that could include additional charges that must be counted as ''interest,'' and thereby would be materially different from the figure the creditor is required (under section 987(c)(1)(B) of the MLA) to compute and disclose under TILA. Instead, the Department believes that the appropriate approach to interpret the tension between sections 987(i)(4), 987(c)(1)(A), and 987(c)(1)(B) is to subject a creditor to one set of requirements for calculating and disclosing the costs of the extension of credit, namely, the requirements under TILA. One clear and beneficial consequence of interpreting these ambiguous provisions of the MLA under this approach is that a creditor would not be required to provide to a covered borrower two different numerical disclosures, which inevitably would lead to confusion.[153]

In light of the scope of the proposed definition of consumer credit, which would encompass open-end credit products, the Department proposes to exercise its discretion under the MLA[154] to interpret 10 U.S.C. 987(c)(1)(A) more straightforwardly to require, in § 232.6(c), a creditor to provide a description of ''the charges the creditor may impose, in accordance with this part and subject to the terms and conditions of the agreement relating to the consumer credit to calculate the MAPR.'' This proposed section also would clarify that a creditor would *not* be required to ''describe the MAPR as a numerical value or to describe the total dollar amount of all charges in the MAPR that apply to the extension of consumer credit.'' The Department believes that the disclosure of the items relating to the costs of consumer credit (*e.g.,* a periodic rate and other finance charges) that apply to a particular transaction or account, including the format of those items, should be governed under Regulation Z, consistent with the provisions of 10 U.S.C. 987(c)(1)(B) and 987(c)(2). Accordingly, under the Department's proposal, a creditor should be able to streamline its compliance with these requirements under 10 U.S.C. 987(c) by providing to a covered borrower the same disclosures the creditor must (in any event) provide to a consumer under Regulation Z, plus a statement of the MAPR. In order to facilitate compliance with that latter requirement, proposed § 232.6(c)(3) provides a model statement that a creditor could use.

Proposed § 232.6(c)(2) provides that a creditor may include a statement of the MAPR in its agreement with the covered borrower for the transaction of or account established for consumer credit. Consistent with the Department's interpretation of its existing regulation,[155] proposed § 232.6(c)(2) would expressly provide that the statement of the MAPR is not required in any advertisement relating to consumer credit.

QUESTION 21: If the Department were to adopt a regulation as proposed, to what extent, and in what manner, would the requirement to provide a description of ''the charges the creditor may impose, in accordance with this part and subject to the terms and conditions of the agreement relating to the consumer credit to calculate the MAPR,'' instead of a definitive figure for the ''annual percentage rate'' of interest applicable to the consumer credit, affect the offering or provision of that credit to a covered borrower?

3. One-Time Delivery of Information; Methods of Delivery; Refinancing a Covered Loan

Proposed § 232.6(b) would establish rules relating to transactions involving a creditor and assignee or multiple creditors. More specifically, proposed § 232.6(b)(1) would provide that the information required under the MLA is ''not required to be provided to a covered borrower more than once for the transaction or the account established for consumer credit with respect to that borrower.'' (However, the disclosures required by Regulation Z, described in proposed § 232.6(a)(2), would remain subject to Regulation Z, and not the one-time delivery provision in proposed § 232.6(b)(1).) Proposed § 232.6(b)(2) would require multiple creditors to agree among themselves as to how to provide the information required under the MLA.

Proposed § 232.6(d) would establish rules relating to the methods of delivery, which are substantively similar to the rules under the existing regulation. Under proposed § 232.6(d)(1), a creditor would be required to provide the information required under the MLA ''in writing in a form the covered borrower can keep.'' And under proposed § 232.6(d)(2), consistent with the structure and intent of the existing regulation,[156] a creditor would be required to orally provide the information required under the MLA, or provide a method for the covered borrower to obtain oral disclosures when the borrower engages in a mail transaction, an internet transaction, or a credit transaction conducted at the point-of-sale in connection with the sale of a nonfinancial product or service. In this regard, the Department recognizes that its proposal to extend the scope of consumer credit to apply to a broader range of closed-end and open-end credit products would encompass credit offered at retail locations for nonfinancial products or services; similar to the treatment of a mail or internet transaction under the existing

Board of Governors of the Federal Reserve System'' (Board) to implement TILA. Subject to certain exceptions, notably under section 1029(c) of the Consumer Financial Protection Act of 2010, 12 U.S.C. 5519(c), the Board's authorities to prescribe rules implementing the federal consumer financial laws have been transferred to the Bureau. 12 U.S.C. 5581. Accordingly, the Department now generally looks to the rules prescribed by the Bureau implementing TILA, except with respect to certain creditors. *See* proposed § 232.3(p) (describing the application of the Board's Regulation Z, 12 CFR part 226, to certain creditors).

[152] *See* 12 U.S.C. 1026(c).

[153] In this regard, the Department also recognizes that many creditors likely would adopt disclosures and contract documents that would be designed to be provided to both consumers who are not entitled to the protections under the MLA and to covered borrowers. The Department's proposed interpretation of sections 987(i)(4), 987(c)(1)(A), and 987(c)(1)(B) of the MLA, which would require a creditor to provide the cost disclosures only required by TILA, would reduce the general confusion to *non*-covered borrowers assessing the costs of credit products that are not covered by the MLA.

[154] 10 U.S.C. 987(h)(1) (authorizing the Department to prescribe regulations to carry out the MLA); 10 U.S.C. 987(h)(2)(A) (authorizing the Department to prescribe regulations establishing ''[d]isclosures required of any creditor that extends consumer credit to a [covered borrower]'').

[155] 72 at 50589.

[156] *See* 10 U.S.C. 987(c)(1) (requiring information to be provided ''orally'').

regulation, the Department believes that, because a creditor is not present to interact orally with a covered borrower, the creditor should be permitted to provide a toll-free telephone number on or with the written disclosures so that the borrower may obtain the oral disclosures when obtaining consumer credit at the point-of-sale for a nonfinancial product or service.

Proposed § 232.6(e) would keep intact the current provision, currently found in § 232.6(c) of the Department's regulation, that requires ''a new statement''—to correspond with the statement of the MAPR under proposed § 232.6(a)(1)—and ''disclosures under this section only when the transaction for that credit would be considered a new transaction that requires disclosures under Regulation Z.''

4. Proposal To Eliminate Disclosure Under § 232.6(a)(4)

Under the Department's existing regulation (as well as this proposed regulation), § 232.6(a)(4) requires a creditor to provide to a covered borrower a specific statement regarding protections for Service members and their dependents under Federal law and resources that may be available to assist them with financial matters (''Statement of Federal Protections''). Consistent with the Department's stance when proposing its initial regulation in 2007,[157] the Department intends to develop this regulation so that its provisions are true to the intent of the MLA without creating a system that is so burdensome that the creditor cannot comply. If the Department were to adopt in the final rule the provisions relating to the statement of the MAPR, including the model statement set forth in proposed § 232.6(c)(3), and maintain the general statement regarding the protections under the MLA, under § 232.6(a)(4), a creditor effectively would be required to provide two, potentially overlapping items of information before or at the time the covered borrower becomes obligated on the transaction or establishes an account for the consumer credit. The Department recognizes that, whereas a ''statement'' of the MAPR is required by 10 U.S.C. 987(c)(1)(A), the Statement of Federal Protections under § 232.6(a)(4) is solely a function of the Department's discretion to require a creditor to provide certain disclosures.[158] In light of other aspects of the Department's proposal, the Department is concerned that these two, potentially duplicative disclosure requirements could create a system that would be relatively burdensome for a creditor to comply with. The Department recognizes the need to consider balancing Service members' and their dependents' interests in receiving useful information with creditors' compliance burdens; thus, the Department could take certain steps to reduce the overall amount of and simplify the information relating to extensions of consumer credit. Accordingly, the Department is considering whether to eliminate § 232.6(a)(4) that requires a creditor to provide the Statement of Federal Protections.

QUESTION 22: Please specifically describe the benefits currently provided to a covered borrower by requiring a creditor to provide a specific statement describing the protections afforded to Service members and their dependents under the MLA, as set forth in § 232.6(a)(4). What would be the likely costs or benefits of eliminating the requirement in § 232.6(a)(4) to provide this specific statement?

QUESTION 23: The Department solicits comment on whether the proposal adequately addresses compliance challenges involving the provision of oral disclosures required by the MLA. The Department invites comment on alternatives that would balance the informational needs of covered borrowers with the compliance burden of creditors.

Section 232.7 Preemption

Proposed § 232.7 would revise the corresponding section of the Department's existing regulation to reflect amendments to 10 U.S.C. 987(d)(2) enacted in section 661(a)(1) of the 2013 Act. In particular, § 232.7(b)(1) would be amended to reflect the prohibition against a state to authorize creditors to charge covered borrowers rates of interest for ''*any consumer credit or* loans'' that are higher than the legal limit for residents of the state (emphasis added). To mirror the language in 10 U.S.C. 987(d)(2), proposed § 232.7(b)(1) also would revise the term ''rates of interest'' to ''annual percentage rates of interest.'' Additionally, § 232.7(b)(2) would be amended to clarify that the prohibition against a state to permit a violation or waiver of any state law protections on the basis of a covered borrower's nonresident or military status to protections ''covering consumer credit,'' consistent with the amendment in section 661(a)(2) of the 2013 Act.

Section 232.8 Limitations

When the Department adopted its initial regulation in 2007, § 232.8(a) provided an exception from the prohibition, set forth in 10 U.S.C. 987(e)(1), against rolling over, renewing, or refinancing consumer credit that had been extended to a covered borrower by the same creditor. The exception allows the same creditor to renew or refinance consumer credit to the covered borrower if ''the new transaction results in more favorable terms to the covered borrower, such as a lower MAPR.''[159] Commenters on the Department's initial proposal expressed concerns that the more-favorable-terms standard was ''too subjective and would create uncertainty about what terms are 'more beneficial,' '' and ''suggested that financial institutions might err on the side of caution and forego entering transactions that could benefit the borrower in order to avoid any potential liability.''[160] Whereas the existing exception had been adopted in the context of a narrow band of products within the three categories initially defined as consumer credit, this proposal to extend the scope of consumer credit increases the potential risks associated with any perceived ambiguity in the more-favorable-terms standard.

Proposed § 232.8(a) would track the language of the refinancing prohibition of 10 U.S.C. 987(e)(1),[161] but would limit the application of that prohibition to a relatively narrow group of creditors. More specifically, the Department would exercise its discretion to define a creditor for the purposes of 10 U.S.C. 987[162] by defining—only for the purposes of § 232.8(a)—the term ''creditor'' to mean ''a person engaged in the business of extending consumer credit subject to applicable law to engage in deferred presentment transactions or similar payday loan transactions (as described in the

[157] When proposing its initial regulation in April 2007, the Department addressed the disclosure requirements under § 232.6(a) and stated: ''As with other aspects of the statute, the Department's intention has been to develop a regulation that is true to the intent of the statute without creating a system that is so burdensome that the creditor cannot comply.'' 72 FR at 18165.

[158] 10 U.S.C. 987(h)(2)(A).

[159] 32 CFR 232.8(a)(1).

[160] 72 FR at 50589.

[161] In addition, the Department proposes to substantially preserve the provision which currently states: ''This part shall not apply to a transaction permitted by this paragraph when the same creditor extends consumer credit to a covered borrower to refinance or renew an extension of credit that was not covered by this part because the consumer was not a covered borrower at the time of the original transaction.''

[162] 10 U.S.C. 987(h)(1) (authorizing the Department to prescribe regulations to carry out the MLA); 10 U.S.C. 987(i)(5)(A)(ii) (authorizing the Department to establish ''additional criteria [for the definition of creditor] as are specified for such purpose in regulations prescribed under [the MLA]'').

relevant law), *provided however,* that the term does not include a person that is chartered or licensed under Federal or State law as a bank, savings association, or credit union.'' Restricting the application of the refinancing prohibition to creditors who are engaged in the business of ''deferred presentment transactions or similar payday loan transactions (as described in the relevant law)'' would be consistent with the structure, language, and intent of the prohibition, which is designed to apply to a creditor who rolls over, renews, repays, refinances, or consolidates consumer credit that the creditor itself already extended to a covered borrower, thereby ensnaring the borrower in the debt trap that the Department described in its 2006 Report.[163] The Department believes that payday lenders commonly engage in these transactions. Moreover, the Department believes that restricting the application of the refinancing prohibition to that specified class of creditors would permit most creditors, including a wide range of banks, thrifts, and credit unions, to offer beneficial forms of consumer credit, such as workout loans and other favorable refinancing transactions, to their covered-borrower customers.

Proposed § 232.8(e) generally would track the language of § 232.8(a)(5) of the existing regulation.

Proposed § 232.8(f) would track the language of the prohibition of 10 U.S.C. 987(e)(6), but would provide an exemption for a unique class of creditors. More specifically, the Department would exercise its discretion to define a creditor for the purposes of 10 U.S.C. 987 [164] by excluding—only for the purposes of § 232.8(f)—from the term ''creditor'' military welfare societies and the service relief societies, as described in 10 U.S.C. 1033(b)(2) and 37 U.S.C. 1007(h)(4) and: Army Emergency Relief, the Air Force Aid Society, the Navy-Marine Corps Relief Society, and the Coast Guard Mutual Assistance. Federal law provides that a loan to a Service member from one of these specified Relief Societies may be repaid through deductions from the pay of the borrowing Service member.[165]

In the Department's experience, the specified Relief Societies provide essential emergency financial assistance to Service members. The specified Relief Societies make low- and no-cost loans, as well as grants, to Service members repayable through an allotment of military pay.[166] Recognizing the unique and important role of the specified Relief Societies, and the long history of the specified Relief Societies in supporting the welfare of Service members and their families, the Department encourages Service members facing financial need to utilize the services provided by the specified Relief Societies.

In light of the specialized operations of each of the specified Relief Societies, which currently depend crucially on the use of an allotment from a Service-member borrower's pay, and consistent with the Department's regulations on deductions from pay under 37 U.S.C. 1007, the Department proposes to exclude the Relief Societies specified in 10 U.S.C. 1033(b)(2) and 37 U.S.C. 1007(h)(4) from the definition of ''creditor'' only for the purposes of the prohibition in § 232.8(f).

In all other respects, proposed § 232.8 would substantially preserve the language of the existing provisions of § 232.8. However, the Department proposes to amend the structure of § 232.8 by eliminating subsection § 232.8(b) (and make other conforming amendments) because the definition of ''creditor,'' in proposed § 232.3(i)(2), would include an assignee of a covered creditor.

QUESTION 24: What would be the likely costs or benefits of revising the refinancing prohibition in 10 U.S.C. 987(e)(1) to apply only to a specific type of creditor who is ''engaged in the business of extending consumer credit subject to applicable law to engage in deferred presentment transactions or similar payday loan transactions (as described in the relevant law),'' and to not include a creditor that is ''chartered or licensed under Federal or State law as a bank, savings association, or credit union?''

QUESTION 25: What would be the likely costs or benefits of amending the prohibition in 10 U.S.C. 987(e)(5) to apply to creditors other than a creditor who is ''chartered or licensed under Federal or State law as a bank, savings association, or credit union?''

QUESTION 26: Should the Department consider a broader exemption from the term ''creditor'' for the military welfare societies and the service Relief Societies specified in 10 U.S.C. 1033(b)(2) and 37 U.S.C. 1007(h)(4)?

Section 232.9 Penalties and Remedies

Proposed § 232.9(a)–(d) would preserve the language of those provisions of the existing regulation. The Department proposes to add a new § 232.9(e) to reflect (with conforming changes to the language) the civil-liability provisions of the MLA enacted in section 662(a) of the 2013 Act.

Section 232.10 Administrative Enforcement

The Department proposes to add a new § 232.10 to reflect (with conforming changes to the language) the administrative-enforcement provisions of the MLA enacted in section 662(b) of the 2013 Act.

Section 232.11 Servicemembers Civil Relief Act Provisions Unaffected

As a consequence of adding a new section for the administrative-enforcement provisions, the existing § 232.10 would be re-numbered to § 232.11, without any change to the language of that section.

Section 232.12 Effective Dates

The Department proposes to amend the section relating to the effective dates of the regulation, now § 232.12, particularly to reflect the effective dates of amendments to the MLA enacted in the 2013 Act.

Proposed § 232.12(a) would amend the language of § 232.11 of the existing regulation to reflect the amendments that would be adopted in the Department's forthcoming final rule. Consistent with the current § 232.11, consumer credit extended to a covered borrower any time on or after October 1, 2007, and up to the effective date of the Department's forthcoming final rule

[163] *See* 2006 Report, at 14. *See also* Consumer Financial Protection Bureau, *Payday Loans and Deposit Advance Products* 24–25 (April 2013), available at *http://files.consumerfinance.gov/f/201304_cfpb_payday-dap-whitepaper.pdf* (discussing the sustained use of payday loans, and stating that for consumers who conducted at least seven payday loan transactions in a year, the majority of those transactions ''were taken on a nearly continuous basis.'').

[164] 10 U.S.C. 987(h)(1) (authorizing the Department to prescribe regulations to carry out the MLA); 10 U.S.C. 987(i)(5)(A)(ii) (authorizing the Department to establish ''additional criteria [for the definition of creditor] as are specified for such purpose in regulations prescribed under [the MLA]'').

[165] 37 U.S.C. 1007(h).

[166] *See* Army Emergency Relief: *http://www.aerhq.org/dnn563/Portals/0/AERAnnualReport2012.pdf,* ''[i]n 2012, AER provided more than $68.6 million in no-interest loans and grants to 55,342 Soldiers and Families and their Families;'' Air Force Aid Society: *http://www.afas.org/file/documents/2012-Annual-Report.pdf,* ''2012 direct assistance totaled nearly $18 million, and includes more than 40,000 assists to Airmen and their families;'' Navy-Marine Corps Relief Society *http://b.3cdn.net/nmcrs/45f955f5204f8ca1df_mlbruu7ib.pdf,* ''FY12 63,392 Clients received financial assistance, $41.8 million;'' Coast Guard Mutual Aid: *http://www.cgmahq.org/Financial/AnnualReports/2012.pdf,* ''[o]verall in 2012, CGMA distributed more than $4.27 million in direct financial assistance to over 5,900 Coast Guard individuals and their families.''

would be subject to the requirements of the Department's existing rule.

Proposed § 232.12(b) generally would apply the requirements of the Department's forthcoming final rule only to new transactions or accounts involving consumer credit that are consummated or established after the effective date of the final rule. The Department believes that this provision would be equitable, particularly to avoid the potential injustice and operational difficulties that could arise if new requirements under the amended regulation were to apply to pre-existing transactions or accounts involving consumer credit to covered borrowers. However, proposed § 232.12(b) would provide exceptions to allow certain provisions of § 232.7(b) and § 232.9(e), as discussed below, to become effective prior to the effective date of the Department's forthcoming final rule.

Proposed § 232.12(c) would provide that ''the amendments to 10 U.S.C. 987(d)(2) enacted in section 661(a) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239, 126 Stat. 1785), as reflected in § 232.7(b), shall take effect on January 2, 2014.'' Section 661(c)(2)(A) of the 2013 Act provides, in relevant part, that the amendments enacted in section 661(a) of that Act shall take effect on ''the date that is one year after the date of enactment of this Act.'' [167] As a result, only the amendments made in § 232.7(b)(1)—adding the phrase ''any consumer credit'' before ''loans''—and § 232.7(b)(2)—adding the phrase ''covering consumer credit'' after ''State consumer lending protections''—would be effective on January 2, 2014.

Proposed § 232.12(d) would provide that civil-liability provisions adopted in § 232.9(e) ''shall apply with respect to consumer credit extended on or after January 2, 2013.'' This subsection reflects the effective date, established in section 662(c) of the 2013 Act, of the civil-liability provisions enacted in section 662(a) of that Act.

V. Regulatory Analyses

A. Analysis Under Executive Orders 12866 and 13563

In accordance with the requirements of Executive Orders 12866 [168] and 13563 [169] (''EO 12866'' and ''EO 13563''), the Department has assessed the expected costs associated with the proposal to amend its regulation to extend the protections of 10 U.S.C. 987 to a broader range of closed-end and open-end credit products offered or extended to covered borrowers. In addition, the Department has provided a sensitivity analysis that examines potential benefits.

1. Executive Summary

EO 12866 and EO 13563 direct executive agencies, including the Department, to assess the anticipated present and future benefits and costs of available regulatory alternatives—including both quantitative measures and qualitative measures—using the best available techniques. A determination has been made that this proposed regulation is a significant regulatory action, as defined in EO 12866 and as supplemented by EO 13563, in that this regulation, if adopted as proposed, might have an annual effect on the economy of $100 million or more. Accordingly, this proposed regulation has been reviewed by the Office of Management and Budget (''OMB''). The regulatory impact assessment prepared by the Department for this proposed regulation is provided below.

The Department anticipates that its regulation, if adopted as proposed, might impose costs of approximately $96 million during the first year, as creditors adapt their systems to comply with the requirements of the MLA and the Department's regulation. After the first year and on an ongoing basis, the annual cost to the economy is expected to be approximately $20 million. The Department provides a sensitivity analysis examining scenarios in which the proposed rule would, if adopted, reduce the incidence of involuntary separation of Service members due to financial distress; the benefits under these scenarios range from $13 million to $137 million annually.

The MLA, as implemented by the Department's regulation as well as under this proposed regulation, provides two broad classes of requirements applicable to a creditor: first, the creditor may not impose an MAPR greater than 36 percent in connection with an extension of consumer credit to a covered borrower (''interest-rate limit''); second, when extending consumer credit, the creditor must satisfy certain other terms and conditions, such as providing certain information (*e.g.,* a statement of the MAPR), both orally and in a form the borrower can keep, before or at the time the borrower becomes obligated on the transaction or establishes the account, by refraining from requiring the borrower to submit to arbitration in the case of a dispute involving the consumer credit, and by refraining from charging a penalty fee if the borrower prepays all or part of the consumer credit (collectively, ''other MLA conditions'').

The interest-rate limit results in a transfer payment because the amount of interest revenue to be foregone by a creditor—that is, the amount of interest revenue that a creditor otherwise could receive by imposing an MAPR of greater than 36 percent—necessarily corresponds to the amount saved by the covered borrower.

The Department recognizes that the other MLA conditions of the proposed regulation could lead to various types of compliance costs for creditors, and the estimated cumulative amount of those quantified costs on an ongoing, annual basis is approximately $20 million. The other MLA conditions are anticipated to impose direct financial costs on a creditor that are not reasonably expected to be offset by any quantifiable, financial benefit to a covered borrower. For example, the Department believes that, for the purposes of conducting this assessment under EO 12866 and EO 13563, the estimated costs on creditors associated with the requirement to provide to covered borrowers a statement of the MAPR is not offset by any financial benefit to the borrowers, even though borrowers generally do obtain some non-quantifiable benefits from receiving the statement. Similarly, the Department expects that creditors will face compliance costs when using the Department's MLA Database to assess whether consumer-applicants are covered borrowers and maintaining records of that information, as provided in proposed § 232.5(b), and consumers reasonably can be assumed to be indifferent to the functions associated with conducting covered-borrower checks through the MLA Database and not receive any readily quantifiable, financial benefits thereof. The Department believes, as discussed above in section III.C., there are benefits to a system for conducting a covered-borrower check that minimizes, or eliminates, the opportunity for a covered borrower to make a false statement regarding his or her status when applying for consumer credit. Likewise, the Department recognizes that the proposal could impose certain types of costs on covered borrowers, including a potential reduction in access to available credit. Nevertheless, as discussed above in section II.E., the majority of Service members have access to reasonably priced (as well as low-cost) credit, and, as long as they wisely use those resources, they are

[167] 10 U.S.C. 987 note.

[168] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[169] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).

likely not to need high-cost loans to fulfill their credit needs.

The scenario analysis that examines the potential benefit of the Department's proposal are the savings attributable to lower recruiting and training expenses associated with the reduction in involuntary separation of Service members due to financial distress. Each separation of a Service member is estimated to cost the Department $57,333, and the Department estimates that each year approximately 4,703 to 7,957 Service members are involuntarily separated due to financial distress. If the Department's proposed regulation could reduce the annual number of involuntary separations due to financial distress from between five to 30 percent, the savings to the Department are expected to be in the range of approximately $13.47 million to $136.85 million each year.

Figure 1 (which also appears in the Executive Summary, in section I.C.) provides a summary of the anticipated benefits and (costs) of the Department's proposed regulation,[170] and the estimates are provided for the first year, on an annual (ongoing basis), and for a ten-year period, applying discount rates of both 7 percent and 3 percent, consistent with guidance issued by OMB.[171] Nevertheless, the Department has assessed the amounts of value that potentially may be involved in the transfer payments due to the interest-rate limit, and those amounts are summarized in Figure 2.

FIGURE 1—SUMMARY OF ESTIMATED EFFECTS OF PROPOSED RULE

[2013 dollars in millions]

		First year	Annual, ongoing	PV 10-year, 7% discount rate	PV 10-year, 3% discount rate
Sensitivity Analysis:					
Benefits to the Department	Low	$0	$13	$96	$128
	High	0	137	970	1,304
Primary Analysis:					
Costs to Creditors of Compliance		96	20	144	194
Primary Analysis:					
Transfer Payments	Low	NA	101	717	958
	High	NA	120	856	1,139

FIGURE 2—ESTIMATED VALUE OF TRANSFER PAYMENTS UNDER THE PROPOSED RULE

[2013 dollars in millions]

	Annual, ongoing	10-year, 7% discount rate	10-year, 3% discount rate
Transfer Payments:			
Low	$101	$716	$957
High	120	856	1,139

2. Need for the Regulation and Consideration of Alternatives

The Department is proposing to amend its existing regulation primarily for the purpose of extending the protections of 10 U.S.C. 987 to a broader range of closed-end and open-end credit products, rather than the limited credit products currently defined as consumer credit. More specifically, as discussed above, the Department proposes to amend its regulation so that, in general, consumer credit covered under the MLA[172] would be defined consistently with credit that for decades has been subject to the protections under TILA, namely: credit offered or extended to a covered borrower primarily for personal, family, or household purposes, and that is (i) subject to a finance charge or (ii) payable by a written agreement in more than four installments.[173]

In developing this proposal, the Department has consulted with the Federal Agencies (pursuant to 10 U.S.C. 987(h)(3)), and in the course of that process has considered a range of alternatives to the provisions contained in this proposal. For example, as discussed above in section III.B., in developing the provisions for the conditional exclusion for credit card accounts, the Department has considered proposing a complete exemption from the definition of ''consumer credit'' for credit extended to a covered borrower under a credit card account. The Department similarly has considered whether exclusions from the MAPR for certain types of fees, such as an application fee or participation fee, should be proposed for credit card accounts in order to preserve current levels of access to those products for Service members and their dependents. The Department also has considered alternative mechanisms and thresholds for the provision in proposed § 232.4(d)(3)(ii) would set a threshold of $3 billion in outstanding credit card loans on U.S. credit card accounts held by a credit card issuer in order for that issuer's fees to be eligible for inclusion in an average calculated for the purposes of compliance with the ''reasonable'' condition of § 232.4(d)(1).

Similarly, in developing the provisions relating to a creditor's assessment of a covered borrower, the Department has considered alternatives to the creditor's use of the MLA Database in order to obtain the benefit

[170] For the sake of brevity and clarity, the estimated savings to creditors, as discussed below, are not included in the computations represented in Figure 1.

[171] *See* OMB Circular A–4 (Regulatory Planning and Review), at 31–34 (recommending, for regulatory analysis, providing estimates of net benefits using discount rates of both 3 percent and 7 percent), available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*.

[172] The forms of ''consumer credit'' that may be covered by the MLA are subject to certain exceptions, notably for a residential mortgage. 10 U.S.C. 987(i)(6)(A) and 987(i)(6)(B).

[173] *See* 12 CFR 1026.1(c)(1)(iii) (limiting the coverage of the regulation, in relevant part, to credit that is subject to a finance charge or is payable by a written agreement in more than four installments).

of a safe harbor under proposed § 232.5(b)(2). In this regard, the Department has considered whether to retain a safe harbor for a creditor's use of the covered borrower identification statement, and explicitly seeks comment on that alternative.[174] Likewise, the Department has considered alternative provisions relating to a creditor's use of the MLA Database via commercial information-services providers, such as consumer reporting agencies, and seeks comment on that approach.[175]

In light of the data and other information available to the Department at this time, the Department has considered alternative approaches to the provisions of the proposal and, as appropriate, explicitly solicits comments on the alternatives the Department should consider.[176]

After observing the effects of its existing regulation during the past six years and based on its review of information provided by a wide variety of persons and entities, the Department believes that this proposal to amend the regulation is appropriate in order to address a wider range of credit products that currently fall outside the scope of the MLA, streamline the information that a creditor would be required to provide to a covered borrower when consummating a transaction involving consumer credit, and provide a more straightforward mechanism for a creditor to conclusively assess whether a consumer-applicant is a covered borrower. In this regard, as discussed above in section III.C., the Department is aware of misuses of the covered borrower identification statement whereby a Service member (or covered dependent) falsely declares that he or she is not a covered borrower. The Department believes that, if a creditor unilaterally conducts a covered-borrower check by using the MLA Database, a Service member or his or her dependent would be relieved from making any statement regarding his or her status as a covered borrower.

3. Estimate of Anticipated Costs Associated With Other MLA Conditions

The other MLA conditions that would apply to creditors who offer consumer credit products that would be subject to the proposed regulation might present several types of compliance costs to those creditors. For example, if a creditor extends consumer credit to a covered borrower only in the form of a credit card product (and who thus currently is not subject to the MLA), the creditor might encounter various costs associated with complying with requirements for: adjustment of computer systems and software to provide for calculation of the MAPR (pursuant to § 232.4(b)); the use of the MLA Database and the retention of records relating to its covered-borrower determinations (under proposed § 232.5(b)); the mandatory loan disclosures (under proposed § 232.6); and each of the statutory limitations applicable to consumer credit (under proposed § 232.8).

The Department believes that some of the compliance costs due to the other MLA conditions are not material to the quantifiable aspects of this regulatory impact assessment because some costs are minimal (relative to the creditor's other compliance costs or the creditor's overall costs of operations when providing consumer credit) or not amenable to measurement.[177] Accordingly, for the purposes of this regulatory impact assessment, the Department has focused its quantitative assessment of costs on two areas that, based on the Department's experience, are reasonably likely to impose costs: First, the disclosures required by the MLA to be provided by a creditor to a covered borrower (under proposed § 232.6); and, second, the use of the MLA Database and the retention of records for covered-borrower determinations (under proposed § 232.5(b)). In addition, for the purposes of this regulatory impact assessment, the Department addresses the potential costs associated with the prohibition against requiring a covered borrower to submit to arbitration in the case of a dispute involving an extension of consumer credit (under proposed § 232.8(c)).

The Department recognizes that this assessment does not capture all possible compliance costs associated with the proposed regulation. Indeed, the Department anticipates that a creditor who chooses to extend credit with a cost that may exceed the interest-rate limit or implicate the limitations in proposed § 232.8 might need to adjust its computer and software systems to calculate the MAPR, develop new policies and procedures, and train staff on new procedures for identifying covered borrowers and taking advantage of the proposed safe harbor under proposed § 232.5. Further, creditors likely would select different techniques for meeting compliance obligations under the proposal. The cost burden on each creditor could vary depending on the business decisions made by that creditor. Acknowledging the limits of the assessment and pursuant to the directive of EO 12866 and EO 13563, the Department has sought to quantify the important potential costs of the proposal and to identify important non-quantified potential costs and benefits.[178]

As the Department assesses whether to amend its regulation, as proposed, the Department will further consider the potential benefits and costs of extending the protections of the MLA to a broader range of closed-end and open-end credit products. There are several areas where additional information could assist the Department in better estimating the potential benefits, costs, and effects of amending its regulation. The Department requests interested parties to provide specific data relating to the benefits and costs of amending the regulation, as proposed, including costs to implement measures to adjust computer systems and to train personnel. The Department seeks comments on whether all anticipated costs have been adequately captured in the analysis. Please provide information on the type of costs and the magnitude of costs by providing relevant data and studies.

Disclosures. Under the Department's existing regulation (''status quo alternative''), a creditor who extends to a covered borrower one or more of the three consumer credit products covered by the regulation must ''clearly and conspicuously'' disclose: (i) A

[174] *See* section III.C., question 13.

[175] *See* section III.C., question 11.

[176] *See, e.g.,* section III.B., question 10.

[177] For example, the Department believes that the costs associated with the prohibition against requiring a covered borrower to waive his or her rights under any otherwise applicable provision of law (as provided in proposed § 232.8(b)) is not material to this regulatory impact assessment because the potential costs of this prohibition are negligible. Moreover, there is no reasonable basis for the Department to estimate the potential costs associated with this prohibition, in part because the Department believes so few—if any—creditors currently require, as part of their standard agreements in credit products, a consumer to waive rights under applicable provisions of State or Federal law.

[178] In considering the costs associated with updating computer programs, the Department relies on analysis from the Government Accountability Office (GAO) examining the costs of implementing changes to minimum payment disclosures for credit card accounts. There, GAO found that credit card issuers were unable to provide precise estimates of, among others, the cost of computer programming to provide the revised disclosures. GAO found that estimates of the computer programming cost varied widely, from $5,000 to $1 million. For large issuers, GAO concluded that these one-time costs would be very small when compared with large issuers' net income. For smaller issuers, GAO concluded that work to implement changes would be done largely by third-party processors, accustomed to reprogramming required to managing cardholder data and processing billing statements. U.S. Gov't Accountability Office, GAO–06–434, *Credit Cards: Customized Minimum Payment Disclosures Would Provide More Information to Consumers, but Impact Could Vary* (April 2006).

numerical value for the MAPR applicable to the extension of credit, including the total dollar amount of all charges included in the MAPR; (ii) any disclosures required by Regulation Z; (iii) a clear description of the payment obligation (which may be satisfied by a payment schedule provided pursuant to Regulation Z); and (iv) a Statement of Federal Protections. A creditor must provide the information orally and in writing prior to consummation of the credit transactions. For mail and internet transactions, the creditor may provide, with the written disclosures, a toll-free telephone number that the borrower may use to obtain the oral disclosures.

Section 232.6 of the proposed rule would amend the provisions relating to the information required by the MLA to simplify the information that a creditor must provide to a covered borrower when extending consumer credit. The proposal would relieve a creditor of the obligation to disclose ''clearly and conspicuously'' the information required by the MLA. Additionally, the Department would eliminate the requirement that a creditor disclose a numerical value for the MAPR or ''the total dollar amount of all charges,'' and instead would require a creditor to provide a description of the charges that the creditor may impose. Thus, in general, the proposal would permit a creditor to streamline compliance with the disclosure requirements under 10 U.S.C. 987(c) by providing to a covered borrower the same information the creditor must provide to a consumer under Regulation Z, plus a statement of the MAPR. In order to facilitate compliance, the proposed regulation provides a model statement that a creditor could use. Consistent with the Department's interpretation of its existing regulation, the proposal expressly provides that the statement of the MAPR would not be required in any advertisement relating to consumer credit.

The Department estimates that there are approximately 191 million transactions each year in which creditors would provide the required information,[179] generally included as part of their standard credit agreements. The Department assumes that all creditors, other than creditors who offer only residential mortgage loans or loans expressly to finance the purchase of personal property (neither of which loans is consumer credit), will provide these disclosures, and believes that, based on these assumptions, approximately 40,000 creditors would be subject to the proposed regulation.[180] The Department seeks comments on whether the estimate of 40,000 creditors is reasonable. Please provide data and studies that support the comment.

(a) Statement of the MAPR

For creditors who currently provide disclosures to covered borrowers (under the status quo alternative), the proposed rule is expected to reduce some of their compliance costs by eliminating the requirement to disclose a numerical value for the MAPR. The Department estimates that eliminating the requirement under the status quo to disclose a numerical value for the MAPR would reduce the compliance costs for creditors who currently offer forms of consumer credit by $71,900 per year. Over ten years, the Department estimates that the total savings to this class of creditors would be between $0.58 million (at a 7 percent discount rate) and $0.69 million (at a 3 percent discount rate).

The proposal to require the provision of a statement of the MAPR, which may be satisfied through the use of a model statement, is anticipated to cost all creditors approximately $19 million during the first year, principally due to the costs of modifying the documents given to covered borrowers (such as a contract for consumer credit).[181] The Department estimates that, on an ongoing basis, providing the statement of the MAPR would add approximately 50 seconds to each transaction when provided orally and require one-quarter of a printed page when included in standard account disclosures. To estimate the cost of providing the statement of the MAPR orally, the Department assumes that this statement is provided by a creditor's teller or sales person, provided only to covered borrowers, and that there are approximately 2 million covered borrowers, each opening two credit accounts per year.[182] The Department estimates that the ongoing cost to creditors for the additional transaction time in orally providing the statement of MAPR will be approximately $0.69 million per year.[183] Over ten years, the total costs to creditors of providing a statement of the MAPR orally during in-person transactions would be between $4.88 million (at a 7 percent discount rate) and $6.57 million (at a 3 percent discount rate).

The Department further assumes that creditors will update standard account disclosures for all consumer credit accounts and that the printing and paper costs are five cents per page.[184] The Department estimates that the ongoing costs for additional printing would be approximately $2.39 million per year.[185] Over ten years, the total

[179] To estimate the number of consumer credit transactions each year, the Department relies on data from the Federal Reserve Bank of New York's Consumer Credit Panel. *See* Federal Reserve Bank of New York, *Quarterly Report on Household Debt and Credit* (August 2013). For the six months prior to the second quarter of 2013, there were approximately 159 million credit inquiries. The Department assumes that 60 percent of these inquiries were for credit accounts that would be consumer credit under proposed § 232.3(f). This estimate does not differentiate between credit applications and credit accounts opened. If most creditors only supply the required information as part of their account agreements which are provided at the time of account opening, then the overall number of transactions involving the provision of that information would be lower than is estimated here.

[180] The Department bases this estimate on relevant numbers of establishments published by the Bureau of Labor Statistics, the FDIC, and NCUA. *See* BLS, Quarterly Census of Employment and Wages, NAICS 522291 Consumer Lending, NAICS 522298 All Other Nondepository Credit Intermediation (2012) (the annual average number of establishments for consumer lending is 14,544; the annual average number of all other nondepository establishments for credit intermediation is 8,963); FDIC Institution Directory, available at *http://www2.fdic.gov/IDASP/* (reporting 6,812 insured institutions) (accessed January 2014); and NCUA Annual Report 145 (2012), available at *http://www.ncua.gov/Legal/Documents/Reports/AR2012.pdf* (reporting 9,369 credit unions) (accessed January 2014).

[181] The Department estimates that set-up for the statement of the MAPR will take 20 hours, and that staff time for the set-up of the proposed disclosure will be 50 percent data entry and information processing workers, 40 percent supervisors of office and administrative support workers, and 10 percent legal counsel. U.S. Dep't of Labor, Bureau of Labor and Statistics, Occupational Employment and Wages 2012, Table 1 (mean hourly wage for data entry and information processing workers is $15.11; mean hourly wage for supervisors of office and administrative support workers is $25.40; mean hourly wage for legal counsel is $62.93), available at *http://www.bls.gov/news.release/ocwage.t01.htm.* The Department calculates the total estimated cost by multiplying the mean hourly wage by the portion of time for each classification of worker expected to be involved in modifying the documents.

[182] In this regard, the Department has estimated the potential costs only for in-person transactions. These figures do not relate to applications involving the use of the creditor-supplied telephone number for the oral delivery of the required information.

[183] The Department reaches this estimate by computing the cost of the additional transaction time, calculated by multiplying the number of transactions (4 million) by the mean hourly wage for financial tellers ($12.40) and the portion of hour that the disclosure will take in a typical transaction (1/72nd of an hour). U.S. Dep't of Labor, Bureau of Labor and Statistics, Occupational Employment and Wage Table 1 (May 2012) (mean hourly wage for financial tellers is $12.40).

[184] The Department relies on estimates of paper and printing costs recently published by the Department of Labor. Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure,77 FR 5632, 5654 (Feb. 3, 2012).

[185] The Department reaches this estimate by computing the cost of the additional printing and paper for the disclosure, calculated by multiplying the number of transactions (191 million) by the cost

Continued

costs to creditors of providing a printed statement of the MAPR would be between $16.93 million (at a 7 percent discount rate) and $22.75 million (at a 3 percent discount rate).

Taking the additional transaction time for oral disclosure and the additional printing and paper expenses for written disclosure together, the Department estimates that the total costs to all creditors of providing the statement of the MAPR would be $3.08 million each year. Over ten years, the Department estimates that the total costs to all creditors of providing the statement of the MAPR would be between $21.81 million (at a 7 percent discount rate) and $29.32 million (at a 3 percent discount rate).

Additionally, creditors may experience some increase in call volume and costs associated with providing oral disclosures if borrowers engage in consumer credit transactions by mail, internet, or at the point of sale in association with the sale of a nonfinancial product or service. The Department seeks comment, as well as data (as may be appropriate), on its supposition regarding the costs associated with these sales channels. Due to the lack of readily available data, the Department has not quantified the potential costs of any increase in this call volume; however, the Department has sought to streamline and minimize the compliance burden associated with all disclosures, including the requirement to orally provide the required information. Proposed § 232.6(d)(2) reflects the Department's effort to minimize the burden on creditors while retaining the structure and intent of the current regulation. The Department seeks comment on the assumptions invoked in this section. Please provide comment on the reasonableness of the assumptions and likelihood of the associated costs. Please provide data and studies that support the comment.

(b) Statement of Federal Protections

Under the proposal, like the status quo alternative, a creditor still must provide to a covered borrower the Statement of Federal Protections. However, because the proposal would apply the protections of 10 U.S.C. 987 to a broader scope of credit transactions, an additional 20,000 creditors would provide the Statement of Federal Protections, as required by proposed § 232.6(a)(4). The Department estimates that incorporating the 111 words in the required Statement of Federal Protections into existing disclosures or contract documents would cost newly obligated creditors approximately $9.60 million in set-up costs during the first year.[186]

On an ongoing basis, the Department estimates that providing the Statement of Federal Protections would add approximately 50 seconds to each transaction when the disclosure is provided orally and require one-quarter of a printed page when included in standard account disclosures. To estimate the cost of orally providing the Statement of Federal Protections, the Department assumes that this statement is provided by a creditor's teller or sales person, provided only to covered borrowers, and that there are approximately 2 million covered borrowers, each opening two credit accounts per year. The Department estimates that the cost to creditors of providing the Statement of Federal Protections orally will be approximately $0.69 million per year.[187] Over ten years, the total costs to creditors of providing the Statement of Federal Protections orally during in-person transactions would be between $4.88 million (at a 7 percent discount rate) and $6.57 million (at a 3 percent discount rate).

The Department further assumes that creditors will update standard account disclosures for all credit accounts and that the printing and paper costs are five cents per page.[188] The Department estimates that the ongoing costs for additional printing would be approximately $2.39 million per year.[189] Over ten years, the total costs to creditors of providing the Statement of Federal Protections in account agreements would be between $16.93 million (at a 7 percent discount rate) and $22.75 million (at a 3 percent discount rate).

Taking the additional transaction time for oral disclosure and the additional printing and paper expenses for written disclosure together, the Department estimates that the total costs to all creditors of providing the Statement of Federal Protections would be $3.08 million each year. Over ten years, the Department estimates that the total costs to all creditors of providing the Statement of Federal Protections would be between $21.81 million (at a 7 percent discount rate) and $29.32 million (at a 3 percent discount rate). Because some creditors obligated under the current rule may provide the Statement of Federal Protections to covered borrowers, the actual additional cost of the proposal over the status quo alternative could be lower than the Department's estimate.

Additionally, as with the statement of the MAPR, the Department realizes that creditors might experience some increase in call volume and costs associated with providing oral disclosures if borrowers engage in consumer credit transactions by mail, internet, or at the point of sale in association with the sale of a nonfinancial product or service. The Department has not quantified the potential costs of any increase in this call volume; however, the Department has sought to streamline and minimize the compliance burden associated with all disclosures, including the MLA's oral disclosure requirement. Proposed § 232.6(d)(2) reflects the Department's effort to minimize the burden on creditors while retaining the structure and intent of the current regulation.

Figure 3a provides a summary of the anticipated benefits and (costs) associated with the disclosures under the Department's proposed regulation.

per page ($.05) and the portion of the page used for the disclosure (0.25 page).

[186] The Department estimates that set-up for the Statement will take 20 hours and that staff time for the set-up of proposed disclosures will be 50 percent data entry and information processing workers, 40 percent supervisors of office and administrative support workers, and 10 percent legal counsel. U.S. Dep't of Labor, Bureau of Labor and Statistics, Occupational Employment and Wages Table 1 (2012) (mean hourly wage for data entry and information processing workers is $15.11; mean hourly wage for supervisors of office and administrative support workers is $25.40; mean hourly wage for legal counsel is $62.93). *http://www.bls.gov/news.release/ocwage.t01.htm.* The Department calculates the total estimated cost by multiplying the mean hourly wage by the portion of time for each classification of worker expected to be involved in modifying the documents.

[187] The Department reaches this estimate by computing the cost of the additional transaction time, calculated by multiplying the number of transactions (4 million) by the mean hourly wage for financial tellers ($12.40) and the portion of hour that the disclosure will take in a typical transaction (1/72nd of an hour). U.S. Dep't of Labor, Bureau of Labor and Statistics, Occupational Employment and Wage Table 1 (May 2012) (mean hourly wage for financial tellers is $12.40).

[188] U.S. Dep't of Labor, Bureau of Labor and Statistics, Occupational Employment and Wages Table 1 (May 2012). *See also* Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure, 77 FR 5632, 5654 (Feb. 3, 2012) (estimating costs of printing and paper).

[189] The Department reaches this estimate by computing the cost of the additional printing and paper for the disclosure, calculated by multiplying the number of transactions (191 million) by the cost per page ($.05) and the portion of the page used for the disclosure (0.25 page).

FIGURE 3A—ESTIMATED BENEFITS AND COSTS OF DISCLOSURES UNDER THE PROPOSED RULE

[2013 dollars in millions]

	First year	Annual, ongoing	PV 10-year, 7% discount rate	PV 10-year, 3% discount rate
Benefits of eliminating requirement to disclose numerical MAPR	$0.00	$0.07	$0.58	$0.69
Set up costs of Proposed Statement of the MAPR	19	n/a	n/a	n/a
Ongoing costs of Proposed Statement of the MAPR (oral and printed)	0.00	3	22	29
Set up costs of Statement of Federal Protections (additional creditors)	10	n/a	n/a	n/a
Ongoing costs of Statement of Federal Protections (oral and printed)	0.00	3	22	29
Total Net Costs	29	6	43	58

Department seeks comment on the assumptions invoked in this section. Please provide comment on the reasonableness of these assumptions and likelihood of the associated costs. Please provide data and studies that support the comment.

Identification of Covered Borrowers. Under the status quo, the Department believes that a creditor who offers a covered payday loan, vehicle title loan, or refund anticipation loan typically assesses the status of a consumer-applicant by providing a self-certification form which is completed by the applicant, as provided in § 232.5.

The Department proposes to modify the process for conducting a covered-borrower check so that a creditor may unilaterally assess the status of a consumer-applicant, rather than relying on the applicant to complete a self-declaration form. Proposed § 232.5(b), if adopted, would allow a creditor to access the MLA Database to assess the status of a consumer-applicant for consumer credit, and would provide a safe harbor from liability under the MLA for a creditor who uses the MLA Database (except when a creditor has actual knowledge about the status of the consumer-applicant), finds that the consumer is not a covered borrower, and maintains a record of the information obtained from the database.

The Department assumes that all creditors, other than creditors who offer only residential mortgage loans or loans expressly to finance the purchase of personal property (neither of which loans is consumer credit), will establish processes for querying the MLA Database and retaining records of covered-borrower checks. As described above, the Department believes that, based on these assumptions, approximately 40,000 creditors would be subject to the proposed regulation. The Department believes that setting up the process to use the MLA Database and retain records of queries will take each creditor 70 hours of labor time. Based on these assumptions, the Department estimates that the total costs relating to setting up the processes to use the MLA Database and take advantage of the safe harbor in proposed § 232.5(b) would be $67.22 million.[190]

The Department has observed that, in general, creditors who currently offer consumer credit products, as defined by the Department's existing regulation, require all consumer-applicants to complete the self-declaration form. For the purposes of this analysis, the Department assumes that a creditor requests the consumer-applicant to complete the self-declaration form only once. For a creditor who currently offers a form of consumer credit, as defined by the Department's existing rule, replacing the self-declaration form with a process to use the MLA Database is estimated to result in a savings from transaction time, printing and paper costs, as well as a reduction in legal risks. Further, the Department assumes that creditors choosing to avail themselves of the MLA Database and the safe harbor in proposed § 232.5(b) will retain a record of the result of the database query in electronic form.

According to the FDIC, approximately 2 million households report using a payday loan, and 1.45 million households report using a refund anticipation loan in the past year.[191] In a comment letter submitted to the Bureau, the auto title lending industry association reports having 1 million customers.[192] The Department assumes that there is one transaction per household, and further assumes that processing each self-certification form costs five cents (conservatively assuming only the costs per page for printing and paper). Given these assumptions of volume and cost—4.45 million transactions involving a printed self-declaration form—the Department estimates that for those creditors who currently offer consumer credit products, the savings on printing and paper will be $222,500 per year; over ten years, the Department estimates a savings of between $1.58 million (at a 7 percent discount rate) and $2.12 million (at a 3 percent discount rate). The Department has not quantified the expected savings for creditors with respect to the potential reduction in transaction time or legal risk.

The Department expects that proposed § 232.5(b), if adopted, would prompt all creditors who offer consumer credit with an MAPR of more than 36 percent (which would include some creditors who offer credit products with credit insurance premiums or fees for credit-related ancillary products sold in connection with the consumer credit) to assess the status of consumer-applicants as potential covered borrowers. Depository institutions or credit unions that offer open-end lines of credit, such as deposit advance loans, might choose to use the MLA Database before offering or extending those types of loans, and thereby take advantage of the safe harbor in the proposed § 232.5(b), to identify potential covered borrowers within their respective account portfolios. In addition, other creditors may choose to query the database, regardless of the terms of their credit products, particularly through batch processing of their customer accounts.

The Department estimates that of the estimated 191 million covered credit

[190] The Department estimates that staff time to set up access to the MLA Database and the processes to record and retain information will be 50 percent data entry and information processing workers, 40 percent supervisors of office and administrative support workers, and 10 percent legal counsel. U.S. Dep't of Labor, Bureau of Labor and Statistics, Occupational Employment and Wages Table 1 (2012) (mean hourly wage for data entry and information processing workers is $15.11; mean hourly wage for supervisors of office and administrative support workers is $25.40; mean hourly wage for legal counsel is $62.93).

[191] Federal Deposit Insurance Corp., *Addendum to the FDIC National Survey of Unbanked and Underbanked Households* (June 2013).

[192] American Association of Responsible Auto Lenders (AARAL), Comment letter to Consumer Financial Protection Bureau (CFPB Docket No. CFPB–HQ–2011–2) (2011).

applications each year,[193] there will be approximately 70 million applications when creditors choose to query the MLA Database as a single-record check. For each of these single-record checks, the inquiry and record retention is expected to add approximately 60 seconds to each new consumer credit transaction. The Department estimates that the total cost to creditors for using the database and retaining records relating to consumer-applicants would be approximately $14.47 million per year;[194] over ten years, the total cost of using the MLA Database would be between $102.56 million (at a 7 percent discount rate) and $137.87 million (at a 3 percent discount rate).

Because modern credit applications, whether conducted online or in person, involve highly automated systems for underwriting, the Department expects that many creditors who issue credit cards and other creditors will choose to develop systems that make the marginal increase in time for querying the MLA Database negligible. The Department has not sought to estimate the potential costs associated with computer programming or including a covered-borrower check in automated underwriting.[195]

Figure 3b provides a summary of the anticipated benefits and (costs) associated with the covered-borrower checks under the Department's proposed regulation.

FIGURE 3B—ESTIMATED BENEFITS AND COSTS OF COVERED-BORROWER CHECKS UNDER THE PROPOSED RULE

[2013 dollars in millions]

	First year	Annual	PV 10-year, 7% discount rate	PV 10-year, 3% discount rate
Benefits of Eliminating Printing and Paper Costs for Self-Certification	$0.00	$0.22	$2	$2
Set-up Costs to Use MLA Database	67	n/a	n/a	n/a
Covered-Borrower Checks	0.00	14	103	138
Total	67	14	101	136

Department seeks comment on the assumptions invoked in this section. Please provide comment on the reasonableness of these assumptions and the likelihood of the associated costs. Please provide data and studies that support the comment.

Prohibition on Requiring Arbitration. The MLA prohibits a creditor from ''requir[ing] a covered borrower to submit to arbitration or impos[ing] onerous legal notice provisions in the case of a dispute'' relating to an extension of consumer credit,[196] and this restriction is reflected in proposed § 232.8(c). Under the status quo, the prohibition against requiring a covered borrower to submit to arbitration applies only to certain payday loans, vehicle title loans, and refund anticipation loans. If the Department adopts the regulation as proposed, then the prohibition against requiring arbitration (in proposed § 232.8(c)) would apply to agreements for a significantly broader range of credit products, such as credit cards and deposit advance loans. The Department recognizes that extending the application of the prohibition in proposed § 232.8(c) likely would lead to costs, primarily as a result of the significantly broader range of creditors affected by that prohibition. Nevertheless, the Department has not endeavored to quantify the costs of the restriction itself, such as the costs that might be associated with making modifications to standard agreements or potentially increased exposures to disputes litigated in courts.

The Department seeks comment on the potential costs to creditors, across a variety of contracts implicated by the prohibition in proposed § 232.8(c), who offer forms of consumer credit that could be affected by the prohibition against requiring arbitration.

4. Sensitivity Analysis on Potential Benefits

Each year, thousands of well-trained Service members are compelled to leave military service because they experience financial distress that leads to the revocation of their security clearances. The Department has direct experience with this process of involuntary separation, which generally involves a Service member becoming over-extended in debt—which occurs due to a wide range of factors—defaulting on one or more credit agreements (either by making late payments or by failing to make payments), and experiencing a deterioration in the credit score or credit history prepared by a consumer reporting agency for that individual. The individual's deteriorating creditworthiness presents an exposure to the Department that the individual poses a security risk, which ultimately warrants separation.

As discussed in sections II.C and II.D, the Department makes a significant investment in recruiting, training, and progressing each qualified Service member. Losing a qualified soldier, sailor, airman, or Marine can cause a loss of mission capability, and there are substantial costs associated with replacing that Service member. Even though, for the purposes of this regulatory impact assessment under EO 12866 and EO 13563, the most direct effect of the interest-rate limit is a transfer payment, a secondary—yet no less direct—effect is the reduction in the

[193] The Department estimates 191 million relying on data from the Federal Reserve Bank of New York's Consumer Credit Panel. *See,* Federal Reserve Bank of New Year, *Quarterly Report on Household Debt and Credit* (August 2013). For the six months prior to the second quarter of 2013, there were about 159 million credit inquiries. The Department assumes that 60 percent of these inquiries were for credit accounts that would be consumer credit under proposed § 232.3(f).

[194] The Department calculates the estimated cost by multiplying the expected number of transactions involving a covered borrower check (70 million) by the mean hourly wage for financial tellers ($12.40) and the additional transaction time expected (1/60th of an hour).

[195] In considering the costs associated with updating computer programs, the Department relies on analysis from GAO examining the costs of implementing changes to minimum payment disclosures for credit card accounts. There, GAO found that credit card issuers were unable to provide precise estimates of, among others, the cost of computer programming to provide the revised disclosures. GAO found that estimates of the computer programming cost varied widely, from $5,000 to $1 million. For large issuers, GAO concluded that these one-time costs would be very small when compared with large issuers' net income. For smaller issuers, GAO concluded that work to implement changes would be done largely by third-party processors, accustomed to reprogramming required to managing cardholder data and processing billing statements. U.S. Gov't Accountability Office, GAO–06–434, *Credit Cards: Customized Minimum Payment Disclosures Would Provide More Information to Consumers, but Impact Could Vary* (April 2006).

[196] 10 U.S.C. 987(e)(3).

overall amount of debt owed to creditors by covered borrowers. The Department believes if the interest-rate limit were to apply to a broader range of credit products, the overall amount of debt owed to creditors would be reduced; as a result, regardless of the original occasions for incurring debts, Service members reasonably may be expected to have a lower incidence of financial distress, and a correspondingly lower incidence of involuntary separation. Thus, the Department believes that the savings of the Department's costs associated with replacing Service members who are involuntarily separated constitute benefits for the purposes of this regulatory impact assessment—entirely independently of the transfer payment flowing from the interest-rate limit—and are amenable to being quantified. More generally, the anticipated improvements in military readiness and Service-member retention lie at the core of 10 U.S.C. 987.

Military Readiness and Service Member Retention. The most substantial—as well as meaningfully quantifiable—benefit of the Department's proposed regulation, if adopted, would be the reduction in involuntary separations among Service members due to financial distress. The Department also anticipates that the proposed regulation would entail non-quantifiable benefits, reducing stress for Service members or their families, which currently affects approximately two-thirds of military families who report experiencing stress related to their financial condition.[197]

The Department estimates that each separation costs the Department $57,333.[198] The Department estimates the potential impact of adopting the proposed regulation by using two alternative approximations of the current number of separations attributable to financial distress.

(a) Estimate One

For the years 2003 through 2011, there was an average of 55,036 involuntary separations per year. Of those involuntary separations that were due to legal or standard-of-conduct issues—an average of 19,893 per year—the Department estimates that approximately half are attributable to a loss of security clearance, and, of these, 80 percent are due to financial distress.[199] Based on this data and these assumptions, the Department estimates that, going forward, there would be approximately 7,957 separations each year due to financial distress.

(b) Estimate Two

In 2005, there were 1,999 revocations of security clearances in the Navy and Marine Corps, representing 8.5 percent of involuntary separations.[200] Approximately 80 percent of the revocations of security clearances are due to financial distress.[201] The Department conservatively estimates the number of separations due to financial distress at 25 percent, rather than attempt to identify separations not triggered by a loss of security clearance.[202] Based on this data and these assumptions, the Department estimates that, going forward, there would be approximately 4,703 separations each year due to financial distress.[203]

The Department estimates that the 10-year cost of involuntary separations due to financial distress is between $1.912 billion and $4.348 billion. However, the Department believes that these calculations significantly underestimate the impact of involuntary separations due to financial distress on Service-member retention and military readiness, primarily because the loss of security clearance is only one way that financial distress leads to separation from military service. Furthermore, involuntary separation is only one of the ways to detect the impact of financial distress on military readiness; excessive debt—which is less manageable at higher rates of interest—likewise can impair a Service member's eligibility to deploy or to reenlist.

The Department acknowledges that the proposed regulation, if adopted as proposed, would not entirely eliminate financial distress among Service members. However, the Department expects that extending the protections of 10 U.S.C. 987 to a broader range of credit products would significantly reduce the incidence of derogatory items in the credit files of Service members (maintained by consumer reporting agencies), and thereby improve the Service members' respective capacities to manage and pay debts.

The Department estimates that the proposal, if adopted, would reduce the separations associated with financial distress. To assess the anticipated savings reasonably attributable to a reduction in involuntary separations, the Department has used three estimates of the possible reduction in involuntary separations: 5 percent,[204] 17.5 percent,[205] and 30 percent.[206] The Department believes that estimating between 5 percent and 30 percent reduction in the total number of these separations is reasonable in light of the conservative assumptions relating to the separations due to financial distress. The Department seeks comment on the reasonableness of these estimates. Please provide data and studies that support the comment.

The Department estimates that the proposed regulation, if adopted, would result in savings from involuntary separations due to financial distress of between $13.47 million and $136.85

[197] Blue Star Families, *The 2013 Military Family Lifestyle Survey* 11 (May 2013).

[198] U.S. Gov't Accountability Office, GAO–11–170, *Military Personnel: Personnel and Cost Data Associated with Implementing DOD's Homosexual Conduct Policy* (January 20, 2011) (estimating that each separation costs the Department $52,800 in 2009 dollars). The cost of $57,333 is calculated in 2013 dollars (through December 2013), using the U.S. Dep't of Labor, Bureau of Labor Statistics, Consumer Price Index, All Urban Consumers (CPI–U), available at *ftp://ftp.bls.gov/pub/special.requests/cpi/cpiai.txt.*

[199] U.S. Dep't of Defense, *Report on Predatory Lending Practices Directed at Members of the Armed Forces and Their Dependents* 39 (August 9, 2006), available at *http://www.defense.gov/pubs/pdfs/Report_to_Congress_final.pdf.*

[200] Amy Klamper, ''Breakthrough,'' Navy League of the United States (October 2006).

[201] U.S. Dep't of Defense, *Report on Predatory Lending Practices Directed at Members of the Armed Forces and Their Dependents* 9 (August 9, 2006), available at *http://www.defense.gov/pubs/pdfs/Report_to_Congress_final.pdf.*

[202] Service members also could be separated in a number of other ways; for example, this number does not attempt to account for separations where a Service member is court-marshaled for failure to pay debts.

[203] Thus, in estimate two, the Department computes the total number of separations per year as follows: the approximate total number of revocations per year [(1,999)/(0.0850)] multiplied by 0.80, yields the revocations due to financial distress of 18,814; and 25 percent of that figure is 4,703.

[204] *See, generally,* Scott Carrell & Jonathan Zinman, *In Harm's Way? Payday Loan Access and Military Personnel Performance* (January 2013) (estimating a 5 percent increase in negative personnel outcomes for Service members with access to high-cost payday loans). The Department uses this study to estimate a low-end of the possible reduction in separations. This estimate likely is less reliable than other estimates of separations included in this analysis because the study does not directly measure the impact of high-cost loans on borrower personnel outcomes.

[205] *See, generally,* Department of Navy, Personnel Security Appeals Board, CY 2011 Activity Report at 7 (in 2011, 47 percent of denied appeals of revoked security clearances were due to financial problems) available at *www.ncis.navy.mil/securitypolicy/PSAB/PSAB%20Activity%20Reports/CY11%20PSAB%20Activity%20Report.pdf*); Consumer Federation of America, et al, DOD–2013–OS–0133–0030, at 3 (noting that for the Department of Navy the portion of denied appeals of revoked security clearances due to financial distress declined from 57 percent in 2006 to 47 percent in 2011). The Department uses the percentage of the decline (17.5) as a midpoint estimate.

[206] *See, generally,* Jean Ann Fox, *The Military Lending Act Five Years Later,* Consumer Federation of America (2012) at 16–17 (for the Department of the Navy, overall denied appeals of revoked security clearances declined by 30 percent from 2006 to 2010).

million per year. Over ten years, the proposal would save the Department between $95.52 million and $1.304 billion. Figure 4 provides a summary of the anticipated savings that reasonably could be attributable to reduction in involuntary separations due to financial distress.

FIGURE 4—SCENARIO ANALYSIS OF COSTS SAVINGS FROM REDUCTIONS IN SEPARATIONS

[2013 dollars in millions]

	Annual	10-year, 7% discount rate	10-year, 3% discount rate
Estimate One: 7,957 separations per year			
Separations Reduced by 30%	$137	$970	$1,304
Separations Reduced by 17.5%	80	567	763
Separations Reduced by 5%	23	162	217
Estimate Two: 4,703 separations per year			
Separations Reduced by 30%	81	574	771
Separations Reduced by 17.5%	47	335	451
Separations Reduced by 5%	13	96	128

In addition to reducing the quantifiable costs associated with separations due to financial distress, the Department believes that the proposed regulation, if adopted, would reduce non-quantifiable costs associated with financial strains on Service members. High-cost debt can detract from mission focus, reduce productivity, and require the attention of supervisors and commanders. Additionally, if the Department's proposed regulation is adopted, the protections afforded to covered borrowers under the MLA might, over time, improve the Department's capabilities to retain Service members. In this regard, one study found that access to extremely high-cost debt decreases military readiness by increasing the presence of unfavorable credit information in the files of consumer reporting agencies, and by producing a significant decline in job performance, reducing the overall eligibility of Service members for reenlistment.[207]

5. Estimate of Amount of Transfer Payments

The Department believes that the interest-rate limit and the corresponding provisions governing computation of the MAPR could entail some costs, particularly for creditors who might need to adjust their systems to compute the MAPR in accordance with the standards of the proposed regulation. The Department anticipates that the great majority of creditors should be able to compute the MAPR for their credit products without significantly redesigning their computing or accounting systems. However, there might be a relatively small number of creditors who offer credit insurance products or credit-related ancillary products with loans who might encounter costs to adjust their computing or accounting systems to comply with the new standards, if adopted as proposed. For example, credit card issuers whose fees fit within the bona fide fee safe harbor would not be required to calculate an effective APR cost element of the MAPR, provided that the periodic rate falls below 36 percent APR. The Department anticipates that only a small number of creditors would offer credit products requiring calculation of an effective APR cost element of the MAPR. For this limited class of creditors, the Department recognizes that adjustments to computing or accounting systems could entail some costs, however, there are no reliable data on how many creditors would pursue such product offerings nor data that would allow the Department to develop a quantifiable estimate of the potential costs associated with compliance with the interest-rate limit and the provisions governing computation of the MAPR. Thus, for the purposes of this analysis under EO 12866 and EO 13563, the Department has assessed the potential effects of the interest-rate limit only in terms of the amount of the transfer payments relating to certain consumer credit products.

Even though the interest-rate limit of 10 U.S.C. 987(b) results in transfer payments from various creditors to covered borrowers, and thus does not affect the benefits-cost analysis under EO 12866 and EO 13563, the Department has estimated the amounts involved in these payments. For the purposes of assessing the amounts involved in the transfer payments, the Department has considered estimates of the current cost of credit and usage rates for four types of consumer credit, namely: (i) Credit card products, (ii) payday loans, (iii) auto title loans, and (iv) installment loans.

In the credit card market, the Department believes that most creditors should be able to comply with the limitation on the MAPR by continuing to offer credit card products with minimal or no alternations to their current pricing practices. In this regard, few, if any, creditors who offer credit card products charge periodic rates that exceed the interest-rate limit of 10 U.S.C. 987(b) and proposed § 232.4(b). Taking into account the exclusion for bona fide fees under proposed § 232.4(d), the Department expects that nearly all of the amount of the transfer payments in credit card products will be due to revenues that would be foregone from credit insurance, debt cancellation, and credit-related ancillary products sold to covered borrowers.

The Department estimates the amount of the transfer payments by taking the difference of the cost of credit for a typical credit card with a credit insurance or debt cancellation product and 36 percent MAPR, less the payout rate on a credit insurance or debt protection product. To calculate the range of possible transfer payments associated with credit card products, the Department estimates an amount per account, and then makes a high- and low-end estimate of the number of Service members with credit cards who

[207] Scott Carrell & Jonathan Zinman, *In Harm's Way? Payday Loan Access and Military Personnel Performance* (January 2013) at 23, available at *http://www.econ.ucdavis.edu/faculty/scarrell/payday.pdf* ("Overall the results provide ammunition for the Pentagon's concern that payday borrowing has adverse effects on military readiness. We find that payday loan access produces a significant decline in overall job performance (as measured by a 3.9% increase in reenlistment ineligibility), and a concomitant decline in retention. We also find that a measure of severely poor readiness (the presence of an Unfavorable Information File) increases by 5.3%.").

also carry a credit insurance or debt cancellation product that would cause the MAPR to exceed the 36-percent threshold. In this regard, the Department's estimate is conservative because the data relate only to consumer credit obtained by Service members, and not to other categories of individuals who could be covered borrowers.

The Department is aware that there are other credit-related ancillary products that may be sold in connection with, and either at or before, the account opening. The Department has not estimated the amount of the transfer payments that might be associated with those credit-related ancillary products.

To estimate the amount of the transfer payment for each credit card account, the Department assumes that 78 percent of Service members have a credit card,[208] revolving an average balance of $5,000.[209] The Department further assumes that a typical debt-cancellation product costs $1.10 per $100 of balance and has a payout rate of 21 percent.[210] Assuming that a borrower makes only the minimum payment each month on this card while paying 28 percent APR, under the proposal, a creditor who offers a credit card with these terms could charge a fee for a credit insurance or debt cancellation product of no more than $0.67 per $100 of balance per month, a price of 8 percent interest per year. For a credit card with a credit insurance or debt cancellation product carrying standard prices, the amount transferred from a creditor to a covered borrower—that is, when the creditor complies with the 36-percent MAPR limit and foregoes revenue that the borrower thereby saves—would be $886 per card over ten years.[211]

Second, from an examination of credit card offers, the Department estimates that between 44 and 100 percent of the 78 percent of Service members who have a credit card account have a card with an APR sufficiently high that if the creditor also sells a credit insurance or debt cancellation product, the cost of credit could exceed the limit in 10 U.S.C. 987(b). The Department assumes that 7 percent of these accounts actually use credit insurance or debt cancellation; therefore the estimates are based on the assumption that between 3 percent and 7 percent of the 78 percent of Service members holding credit cards have a credit insurance or debt cancellation product.[212]

At the high-end, assuming that 78 percent of Service members have a credit card that, given typical costs, might exceed the interest-rate limit if the borrower purchases credit insurance or debt cancellation and pays a penalty APR, and that 7 percent of these borrowers actually do purchase such a product, the amount that would be transferred is estimated to be $6.75 million per year.[213] Over ten years, the discounted amount that would be transferred would be between $54.13 million (at a 7 percent discount rate) and $61.17 million (at a 3 percent discount rate).

At the low-end, assuming that 44 percent of Service members have a credit card that, given typical fees, might exceed the interest-rate limit if the borrower purchases credit insurance or debt cancellation and pays a penalty APR, and that 7 percent of these borrowers actually do purchase such a product, the amount that would be transferred is estimated to be $2.97 million per year.[214] Over ten years, the discounted amount that would be transferred would be between $23.82 million (at a 7 percent discount rate) and $26.91 million (at a 3 percent discount rate).

For non-credit card credit products that would be subject to the proposed regulation, the Department estimates the amount that would be transferred due to the interest-rate limit by considering three segments of that market for consumer credit: Payday loans, auto title loans, and non-purchase money installment loans. The Department assumes that approximately 12 percent of Service members use non-credit card credit products that would be covered under the Department's regulation, if adopted as proposed.[215] The prices associated with these credit products vary widely; for any given creditor, the amount that would be transferred as a result of compliance with the interest-rate limit depends on how much that creditor charges for credit extended under the status quo.

In order to estimate the amount that would be transferred, the Department assumes that between 7 percent and 4.9 percent of Service members use payday loans with a median APR of 391 percent and a median ten transactions per year, each borrowed for 14 days,[216] 0.3 percent of Service members use auto title loans with a median APR of 300 percent,[217] and 7 percent of Service members use installment loans with a median APR of 80 percent.[218]

Given typical prices of payday loans and borrowing patterns, the Department estimates that the value that would be

[208] Blue Star Families, *The 2013 Military Family Lifestyle Survey* 34 (May 2013).

[209] FINRA Investor Education Foundation, *Financial Capability in the United States, Military Survey* (October 2010).

[210] U.S. Gov't Accountability Office, GAO–11–311, *Credit Cards: Consumer Costs for Debt Protection Can be Substantial Relative to Benefits but Are Not a Focus of Regulatory Oversight* 9, 21 (March 2011).

[211] This calculation assumes a beginning balance of $5,000 and that the borrower pays only the minimum payment, calculated as 4 percent of the monthly balance. Under the status quo, the APR is 28 percent and the debt cancellation is $1.10 per $1,000 of outstanding balance, and the sum of payments over ten years is $12,696. Under the proposal, the APR is 28 percent and the debt cancellation is $.67 per $1,000 of outstanding balance, and the sum of payments over ten years is $11,810.

[212] U.S. Gov't Accountability Office, GAO–11–311, *Credit Cards: Consumer Costs for Debt Protection Can be Substantial Relative to Benefits but Are Not a Focus of Regulatory Oversight* 7 (March 2011).

[213] The Department calculates the estimated transfer amount by multiplying the number of active duty service members (1.4 million) by the percentage with a credit card account (78 percent), the percentage of accounts with costs that might exceed the interest rate limit if the borrower purchases add-on products (100 percent), the percentage of accounts where the borrower actually purchases add-on products (7 percent), and the amount transferred per card ($886).

[214] The Department calculates the estimated transfer amount by multiplying the number of active duty service members (1.4 million) by the percentage with a credit card account (78 percent), the percentage of accounts with costs that might exceed the interest rate limit if the borrower purchases add-on products (44 percent), the percentage of accounts where the borrower actually purchases add-on products (7 percent), and the amount transferred per card ($886).

[215] *See* Department of Defense, *Report On Predatory Lending Practices Directed at Members of the Armed Forces and Their Dependents* (August 9, 2006), available at *http://www.defense.gov/pubs/pdfs/Report_to_Congress_final.pdf;* Jean Ann Fox, *The Military Lending Act Five Years Later,* Consumer Federation of America (2012); U.S. Gov't Accountability Office, GAO–05–349, *Military Personnel: DOD's Tools for Curbing the Use and Effects of Predatory Lending Not Fully Utilized* (April 2005); The Pew Charitable Trusts, *Payday Lending in America: Who Borrowers, Where They Borrow, and Why* 4 (July 2012).

[216] *See* Department of Defense, *Report On Predatory Lending Practices Directed at Members of the Armed Forces and Their Dependents* (August 9, 2006), available at *http://www.defense.gov/pubs/pdfs/Report_to_Congress_final.pdf;* Jean Ann Fox, *The Military Lending Act Five Years Later,* Consumer Federation of America (2012); Consumer Financial Protection Bureau, *Payday Loans and Deposit Advance Products* 8 (April 2013). The Department further assumes that borrowers take a median of 10 loans per year, those loans are for $392 and carry an average 14-day term. *See* Consumer Financial Protection Bureau, *Payday Loans and Deposit Advance Products* (April 2013). Some, though not all, transactions involving these products are subject to the protections of 10 U.S.C. 987 under the current rule. *See, e.g.,* section II.A.

[217] Consumer Federation of America and Center for Responsible Lending, *Driven to Disaster: Car-Title Lending and Its Impact on Consumers* 3 (2013); U.S. Gov't Accountability Office, GAO–05–349, *Military Personnel: DOD's Tools for Curbing the Use and Effects of Predatory Lending Not Fully Utilized* (April 2005); Jean Ann Fox, *The Military Lending Act Five Years Later,* Consumer Federation of America (2012).

[218] *See* Jean Ann Fox, *The Military Lending Act Five Years Later,* Consumer Federation of America (2012).

transferred is $534 per borrower per year for payday loans.[219] Assuming that 4.9 percent of Service members use payday loans each year, the Department estimates that the proposed regulation would result in transfer payments of $36.74 million per year relating to the domestic payday lending industry.[220] Over ten years, the Department estimates that the amount of the transfer payments relating to the domestic payday lending industry would be between $260.45 million (at a 7 percent discount rate) and $350.11 million (at a 3 percent discount rate). Alternatively, assuming that 7 percent of Service members use payday loans each year, the Department estimates that the amount of transfer payments on the domestic payday lending industry would be $52.16 million per year.[221] Over ten years, the Department estimates that the transfer payments under the proposed regulation would be between $369.80 million (at a 7 percent discount rate) and $497.11 million (at a 3 percent discount rate).

Approximately 7 percent of volume in payday loans is done by online lenders based offshore.[222] The Department estimates that the transfer payments relating to these offshore creditors would be between $2.57 million and $3.65 million per year. Over ten years, the Department estimates that the total amount of the transfer payments relating to these offshore creditors would be between $18.23 million (at a 7 percent discount rate, assuming 4.9 percent usage) and $34.80 million (at a 3 percent discount rate, assuming 7 percent usage).

Assuming that 0.3 percent of Service members use auto title loans each year and that the average auto title loan carries an APR of 300 percent, the Department estimates that the interest-rate limit would lead to transfer payments relating to the auto title lending industry of $0.87 million per year.[223] Over ten years, the Department estimates that the total amount of the transfer payments relating to auto title lenders would be between $6.14 million (at a 7 percent discount rate) and $8.26 million (at a 3 percent discount rate).

Assuming that 7 percent of Service members use high-cost installment loans each year and that the average installment loan carries an APR of 80 percent, the Department estimates that the interest-rate limit would result in transfer payments relating to the domestic installment lending industry of $60.06 million per year.[224] Over ten years, the Department estimates that the total amount of transfer payments from installment-loan creditors would be between $425.77 million (at a 7 percent discount rate) and $572.35 million (at a 3 percent discount rate).

Approximately 7 percent of volume in the high-cost installment lending market is done by online lenders based offshore.[225] The Department estimates the proposed regulation would result in transfer payments relating to these offshore creditors of approximately $4.20 million per year. Over ten years, the total amount of transfer payments from these offshore creditors are estimated to be between $29.80 million (at a 7 percent discount rate) and $40.06 million (at a 3 percent discount rate).

Overall, the Department estimates that the total amount of transfer payments relating to these four categories of consumer credit products would be between $100.64 million and $119.84 million per year; over ten years, the overall amount of these transfer payments would be between $716.18 million (assuming lower usage rates and a 7 percent discount rate) and $1.139 billion (assuming higher usage rates and a 3 percent discount rate). Of these overall amounts, between $6.77 million and $7.85 million of the transfer payments would relate to offshore creditors, and between $48.03 million and $74.86 million over ten years. The transfer payments from domestic creditors would be between $93.87 million and $111.99 million per year; over ten years, these transfer payments would be between $668.15 million (assuming lower usage rates and a 7 percent discount rate) and $1.064 billion (assuming higher usage rates and a 3 percent discount rate). Figure 5 provides a summary of all of these figures for the transfer payments.

FIGURE 5—AMOUNT OF TRANSFER PAYMENTS RELATING TO THE INTEREST-RATE LIMIT

[2013 dollars in millions]

	Annual	PV 10-year, 7% discount rate	PV 10-year, 3% discount rate
Payday:			
(1) At 4.9% usage	$37	$260	$350
(2) At 7% usage	52	370	497
Auto title	0.87	6	8
Installment	60	426	572

[219] The Department assumes that the average loan amount is $392, ten loans of 14 days each are taken in a year, and the average APR is 391 percent. The Department calculates the transfer amount per borrower by finding the difference between the cost of a typical loan under the status quo, assuming that the loan falls outside the scope of the current rule ($588), and the permissible cost of a loan complying with the 36 percent interest rate limitation ($54).

[220] The Department calculates the estimated transfer amount by multiplying the number of active duty service members (1.4 million) by the percentage with a payday loan (4.9 percent), and the amount transferred per account ($534).

[221] The Department calculates the estimated transfer amount by multiplying the number of active duty service members (1.4 million) by the percentage with a payday loan (7 percent), and the amount transferred per account ($534).

[222] *See* Stephens Inc., *Forging Ahead: Growth, Opportunity and the Direction of the Alternative Financial Services Sector,* presentation to the Community Financial Services Association of America, March 7, 2013 (estimating that one-third of lending volume is online and that 20 percent of the online market is offshore).

[223] The Department assumes that the average principal borrowed is $951, average APR is 300 percent, and the average loan term is 30 days. The Department calculates the transfer amount per borrower by finding the difference between the cost of a typical loan under the status quo, assuming that the loan falls outside the scope of the current rule ($235), and the permissible cost of a loan complying with the 36 percent interest rate limitation ($28). *See* Susanna Montezemolo, *Car-Title Lending,* Center for Responsible Lending, July 2013, available at *http://www.responsiblelending.org/state-of-lending/reports/7-Car-Title-Loans.pdf. See* Consumer Federation of America, *Policy Brief: Gaps in the Military Lending Act Leave Many Service Members Vulnerable to Abusive Lending Practices,* July 2013, available at *http://www.consumerfed.org/pdfs/130725-policybrief-mla-cfa.pdf* (finding that a typical auto title loan has a 300 percent APR). The Department does not have data regarding auto-title creditors located offshore.

[224] The Department assumes that a typical loan is $1,000 and borrowed for two years. Under the status quo with an APR of 80 percent, the monthly payment is $85 per month, for a sum of payments of $2,032. Under the proposal with an APR of 36 percent, the monthly payment is $59, for a sum of payments of $1,417, a difference of $615. For information on typical military installment loans, *see* Jean Ann Fox, *The Military Lending Act Five Years Later,* Consumer Federation of America, May 2012.

[225] *See* Stephens Inc., *Forging Ahead: Growth, Opportunity and the Direction of the Alternative Financial Services Sector,* presentation to the Community Financial Services Association of America, March 7, 2013 (estimating that one-third of lending volume is online and that 20 percent of the online market is offshore).

FIGURE 5—AMOUNT OF TRANSFER PAYMENTS RELATING TO THE INTEREST-RATE LIMIT—Continued

[2013 dollars in millions]

	Annual	PV 10-year, 7% discount rate	PV 10-year, 3% discount rate
Credit Cards:			
(1) At 3% of cards	3	24	27
(2) At 7% of cards	7	54	61
TOTAL			
Low (4.9% payday, 3% cards)	101	716	958
High (7% payday, 7% cards)	120	856	1,139

Apart from the MLA, for active duty Service members who are materially affected by virtue of his or her military service, the Servicemembers Civil Relief Act (SCRA) limits the permissible rate of interest on outstanding pre-service balances at 6 percent APR.[226] To avail himself or herself of the protections of the SCRA, a Service member must make a written request to the creditor. Because data is unavailable on the extent to which creditors are reducing pre-service obligations for Service members, the Department is unable to adjust the estimated amount of the transfer payments relating to the interest-rate limit of the proposed regulation to account for the potential effects of the SCRA.

Furthermore, the Department does not expect that the interest rate limitation will have undesirable side-effects for Service members. The Department observes that numerous creditors currently supply credit to Service members in a manner that already should comply with the interest-rate limit. In the Department's experience, covered borrowers enjoy access to low- and no-cost credit. For example, to provide monetary support to Service members and their families with financial hardships, the Military Services have partnered with nonprofit charitable organizations chartered to provide relief services to Service members and their families. The four Relief Societies for the Military Services provide no-interest loans and grants for shortfalls in household expenses and unforeseen emergencies.

B. Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104–4)

The Department certifies that this proposed regulation does not contain a Federal mandate that may result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector of $100 million or more in any one year.[227]

C. Regulatory Flexibility Act

The Department certifies that this proposed regulation is not subject to the Regulatory Flexibility Act (''RFA'')[228] because the regulation, if adopted as proposed, would not have a significant economic impact on a substantial number of small entities.

The North American Industrial Classification (NAIC) codes for the affected businesses are the following:

(a) 522110—Commercial Banking
(b) 522130—Credit Unions
(c) 522210—Credit Card Issuing
(d) 522291—Consumer Lending

Pursuant to the Small Business Administration (SBA) Small Business Size Standards, a consumer lending business is a ''small business entity'' if it has less than $35.5 million in receipts. According to the 2007 Economic Census (the last year for which data is available), approximately 96 percent of firms in NAIC code 522291 are small business entities. For the other three potentially affected businesses, the SBA Small Business Size Standards considers any business with less than $500 million in assets to be a small business entity.

Approximately 81 percent of firms in NAIC code 522110 and 94 percent of firms in NAIC code 522130 are small business entities. Overwhelmingly, credit card products are issued by insured depository institutions and, therefore, small business entities issuing credit cards (included within NAIC code 522210) are covered by the previously described codes.

While a substantial portion of firms in each affected market are ''small business entities,'' Service members and their dependents make up only a small portion of the consumers for those businesses. Because only approximately 2.5 percent of households in the United States include an active duty Service member, the interest-rate limit and other MLA conditions of the proposed regulation would affect a small percentage of the consumers served by entities that could be creditors covered by this regulation. Thus, the Department concludes that—even though there appears to be a large percentage of small business entities in each affected class of business—the proposed regulation would not (for the purposes of the RFA) have a significant economic impact on a substantial number of small businesses because those businesses nonetheless have very few customers who are covered borrowers. The Department seeks comment, particularly from potentially affected small businesses themselves, on the possible impact of the proposed rule on small businesses. Please provide data and studies that support the comment.

D. Paperwork Reduction Act

Proposed §§ 232.5 and 232.6 contain information-collection requirements. The Department has submitted the following proposal to OMB under the provisions of the Paperwork Reduction Act.[229] Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents.

Title: Database Inquiry and Mandatory Loan Disclosures as Part of Limitations on Terms of Consumer Credit Extended to Service Members and Their Dependents.

[226] 50 App. USC 527(a).

[227] *See* analysis in section IV.A. for calculations. The Department expects expenditure by the private sector of approximately $96.03 million in the implementation year for setting up the required disclosures and optional database inquiry and record retention process. On an ongoing basis, the Department expects expenditure by the private sector of $20.34 million to comply with the required disclosures and optional database inquiry and record retention procedures during the course of credit transactions.

[228] 5 U.S.C. 601.

[229] 44 U.S.C. 3502, 3506–07.

Type of Request: Reinstatement with change.

Number of Respondents: 40,000.

Responses per Respondent: Varies by type of respondent.

Annual Responses: 191 million.

Average Burden per Response: Varies by type of response. On an ongoing basis, respondents likely will spend 1 minute (0.02 hours) for single-record borrower inquiry (70 million); 1.67 minutes (0.03 hours) for orally providing the required information to covered borrowers (4 million responses); and 0 minutes for printed disclosures included in all consumer credit contracts (191 million). In the first year, there is expected to be a one-time burden of 110 labor hours to set up the mandatory oral and printed disclosures, as well as a process for conducting covered-borrower checks and retaining records.

Annual Burden Hours: 4,000,000 set-up burden hours in the first year; 1,266,747 ongoing burden hours each year.

Needs and Uses: With respect to any extension of consumer credit to a covered borrower, a creditor would be required to provide to the borrower (a) a statement of the MAPR and (b) a Statement of Federal Protections. In approximately 4 million transactions, the required information would be provided orally as well as in a printed document; in approximately 191 million transactions, the required information would be included in standard account agreements. Additionally, a creditor may, at its discretion, identify the status of a consumer-applicant by querying the MLA Database and, in the event that the inquiry indicates that consumer-applicant is not a covered borrower, take advantage of a safe harbor from liability under 10 U.S.C. 987 by retaining a record of the information obtained from the database.

Affected Public: Creditors making loans that are subject to a finance charge or payable by a written agreement in more than four installments, except for loans that are mortgage loans and purchase-money financing for vehicles or other personal property.

Frequency: One set of disclosures for each transaction involving consumer credit; one database inquiry for each transaction involving consumer credit.

Respondents' Obligation: Mandatory loan disclosures; optional database inquiry and subsequent record retention.

OMB Desk Officer

Written comments and recommendations on the proposed information collection should be sent to Ms. Jasmeet Seehra at the Office of Management and Budget, DoD Desk Officer, Room 10102, New Executive Office Building, Washington, DC 20503, with a copy to the Office of the Deputy Assistant Secretary of Defense (Military Community and Family Policy), 4000 Defense Pentagon, Washington, DC 20301–4000. Comments can be received from 30 to 60 days after the date of this document, but comments to OMB will be most useful if received by OMB within 30 days after the date of this document.

You may also submit comments, identified by docket number and title, by the following method:

* Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Office of the Deputy Assistant Secretary of Defense (Military Community and Family Policy), 4000 Defense Pentagon, Washington, DC 20301–4000, Marcus Beauregard, 571–372–5357.

E. Executive Order 13132 Federalism

Executive Order 13132 (''EO 13132'') requires Executive departments and agencies, including the Department, to identify regulatory actions that have significant federalism implications. A regulation has federalism implications if it has substantial direct effects on the States, on the relationship or distribution of power between the Federal Government and the States, or on the distribution of power and responsibilities among various levels of government.

The provisions of this part, as required by 10 U.S.C. 987, override state statutes inconsistent with this part to the extent that these provisions provide different protections for covered borrowers than those provided to residents of that State. As discussed in the section-by-section description of the proposed regulation, in section III, the proposal would revise the corresponding section of the Department's existing regulation to reflect amendments to 10 U.S.C. 987(d)(2) enacted in section 661(a)(1) of the 2013 Act. This amendment clarifies the scope of state laws subject to preemption by 10 U.S.C. 987.

The proposed regulation, if adopted as proposed, would not affect in any manner the powers and authorities that any State may have or affect the distribution of power and responsibilities between Federal and State levels of government. Therefore, the Department has determined that the proposed regulation has no federalism implications that warrant the preparation of a Federalism Assessment in accordance with EO 13132.

List of Subjects in 32 CFR Part 232

Loan programs, Reporting and recordkeeping requirements, Service members.

For the reasons set forth in the preamble, chapter I of title 32, Code of Federal Regulations is proposed to be amended by revising part 232 to read as follows:

PART 232—LIMITATIONS ON TERMS OF CONSUMER CREDIT EXTENDED TO SERVICE MEMBERS AND DEPENDENTS

Sec.
232.1 Authority, purpose, and coverage.
232.2 Applicability; examples.
232.3 Definitions.
232.4 Terms of consumer credit extended to covered borrowers.
232.5 Identification of covered borrower.
232.6 Mandatory loan disclosures.
232.7 Preemption.
232.8 Limitations.
232.9 Penalties and remedies.
232.10 Administrative enforcement.
232.11 Servicemembers Civil Relief Act provisions unaffected.
232.12 Effective dates.

Authority: 10 U.S.C. 987.

§ 232.1 Authority, purpose, and coverage.

(a) *Authority.* This part is issued by the Department of Defense to implement 10 U.S.C. 987.

(b) *Purpose.* The purpose of this part is to impose limitations on the cost and terms of certain extensions of credit to Service members and their dependents, and to provide additional protections relating to such transactions in accordance with 10 U.S.C. 987.

(c) *Coverage.* This part defines the types of transactions involving ''consumer credit,'' a ''creditor,'' and a ''covered borrower'' that are subject to the regulation, consistent with the provisions of 10 U.S.C. 987. In addition, this part:

(1) Provides the maximum allowable amount of all charges, and the types of

charges, that may be associated with a covered extension of consumer credit;

(2) Requires a creditor to provide to a covered borrower a statement of the Military Annual Percentage Rate, or MAPR, before or at the time the borrower becomes obligated on the transaction or establishes an account for the consumer credit. The statement required by this part differs from and is in addition to the disclosures that must be provided to consumers under the Truth in Lending Act;

(3) Provides for the method a creditor must use in calculating the MAPR; and

(4) Contains such other criteria and limitations as the Secretary of Defense has determined appropriate, consistent with the provisions of 10 U.S.C. 987.

§ 232.2 Applicability; examples.

(a) *Applicability.* This part applies to consumer credit extended by a creditor to a covered borrower, as those terms are defined in this part. Nothing in this part applies to a credit transaction or account relating to a consumer who is not a covered borrower at the time he or she becomes obligated on a credit transaction or establishes an account for credit.

(b) *Examples.* The examples in this part are not exclusive. To the extent that an example in this part implicates a term or provision of Regulation Z (12 CFR part 1026), issued by the Consumer Financial Protection Bureau to implement the Truth in Lending Act, Regulation Z shall control the meaning of that term or provision.

§ 232.3 Definitions.

(a) *Affiliate* means any person that controls, is controlled by, or is under common control with another person.

(b) *Billing cycle* has the same meaning as ''billing cycle'' in Regulation Z.

(c) *Bureau* means the Consumer Financial Protection Bureau.

(d) *Closed-end credit* means consumer credit (but for the conditions applicable to consumer credit under this part) other than consumer credit that is ''open-end credit'' as that term is defined in Regulation Z.

(e) *Consumer* means a natural person.

(f)(1) *Consumer credit* means credit offered or extended to a covered borrower primarily for personal, family, or household purposes, and that is:

(i) Subject to a finance charge; or

(ii) Payable by a written agreement in more than four installments.

(2) *Exceptions.* Notwithstanding paragraph (f)(1) of this section, consumer credit does not mean:

(i) A residential mortgage, which is any credit transaction secured by an interest in the covered borrower's dwelling, including a transaction to finance the purchase or initial construction of a dwelling, any refinance transaction, home equity loan or line of credit, or reverse mortgage;

(ii) Any credit transaction that is expressly intended to finance the purchase of a motor vehicle when the credit is secured by the vehicle being purchased;

(iii) Any credit transaction that is expressly intended to finance the purchase of personal property when the credit is secured by the property being purchased; and

(iv) Any credit transaction that is an exempt transaction for the purposes of Regulation Z (other than a transaction exempt under 12 CFR 1026.29) or otherwise is not subject to disclosure requirements under Regulation Z.

(g) *Covered borrower* means a consumer who, at the time the consumer becomes obligated on a consumer credit transaction or establishes an account for consumer credit, is a covered member (as defined in this paragraph) or a dependent (as defined in this paragraph) of a covered member.

(1) The term ''covered member'' means a member of the armed forces who is serving on—

(i) Active duty pursuant to title 10, title 14, or title 32, United States Code, under a call or order that does not specify a period of 30 days or fewer, or

(ii) Active Guard and Reserve duty, as that term is defined in 10 U.S.C. 101(d)(6).

(2) The term ''dependent'' with respect to a covered member means a person described in subparagraph (A), (D), (E), or (I) of 10 U.S.C. 1072(2).

(h) *Credit* means the right granted to a consumer by a creditor to defer payment of debt or to incur debt and defer its payment.

(i) *Creditor,* except as provided in § 232.8(a) and § 232.8(f), means a person who is:

(1) Engaged in the business of extending consumer credit; or

(2) An assignee of a person described in paragraph (i)(1) of this section with respect to any consumer credit extended.

(3) For the purposes of this definition, a creditor is engaged in the business of extending consumer credit if the creditor considered by itself and together with its affiliates meets the transaction standard for a ''creditor'' under Regulation Z with respect to extensions of consumer credit to covered borrowers.

(j) *Department* means the Department of Defense.

(k) *Dwelling* means a residential structure that contains one to four units, whether or not the structure is attached to real property. The term includes an individual condominium unit, cooperative unit, mobile home, and manufactured home.

(*l*) *Electronic fund transfer* has the same meaning as in the regulation issued by the Bureau to implement the Electronic Fund Transfer Act, as amended from time to time (12 CFR part 1005).

(m) *Finance charge* has the same meaning as ''finance charge'' in Regulation Z.

(n) *Military annual percentage rate (MAPR).* The MAPR is the cost of the consumer credit expressed as an annual rate, and shall be calculated in accordance with § 232.4(c).

(o) *Open-end credit* means consumer credit that (but for the conditions applicable to consumer credit under this part) is ''open-end credit'' under Regulation Z.

(p) *Person* means a natural person or organization, including any corporation, partnership, proprietorship, association, cooperative, estate, trust, or government unit.

(q) *Regulation Z* means any rules, or interpretations thereof, issued by the Bureau to implement the Truth in Lending Act, as amended from time to time, including any interpretation or approval issued by an official or employee duly authorized by the Bureau to issue such interpretations or approvals. However, for any provision of this part requiring a creditor to comply with Regulation Z, a creditor who is subject to Regulation Z (12 CFR part 226) issued by the Board of Governors of the Federal Reserve System must continue to comply with 12 CFR part 226. Words that are not defined in this rule have the same meanings given to them in Regulation Z (12 CFR part 1026) issued by the Bureau, as amended from time to time, including any interpretation thereof by the Bureau or an official or employee of the Bureau duly authorized by the Bureau to issue such interpretations. Words that are not defined in this part or Regulation Z, or any interpretation thereof, have the meanings given to them by State or Federal law.

§ 232.4 Terms of consumer credit extended to covered borrowers.

(a) *General conditions.* A creditor who extends consumer credit to a covered borrower may not require the covered borrower to pay an MAPR for the credit with respect to such extension of credit, except as:

(1) Agreed to under the terms of the credit agreement or promissory note;

(2) Authorized by applicable State or Federal law; and

(3) Not specifically prohibited by this part.

(b) *Limit on cost of consumer credit.* A creditor may not impose an MAPR greater than 36 percent in connection with an extension of consumer credit that is closed-end credit or in any billing cycle for open-end credit.

(c) *Calculation of the MAPR.*

(1) *Charges included in the MAPR.* The charges for the MAPR shall include, as applicable to the extension of consumer credit:

(i) Credit insurance premiums, including charges for single premium credit insurance, fees for debt cancellation or debt suspension agreements;

(ii) Fees for credit-related ancillary products sold in connection with and either at or before consummation of the credit transaction for closed-end credit or upon account opening for open-end credit; and

(iii) Except for a bona fide fee (other than a periodic rate) which may be excluded under paragraph (d) of this section:

(A) Finance charges associated with the consumer credit;

(B) Any application fee charged to a covered borrower who applies for consumer credit; and

(C) Any fee imposed for participation in any plan or arrangement for consumer credit, subject to paragraph (c)(2)(ii)(B) of this section.

(iv) *Certain exclusions of Regulation Z inapplicable.* Any charge set forth in paragraphs (c)(1)(i)–(iii) of this section shall be included in the calculation of the MAPR even if that charge would be excluded from the finance charge under Regulation Z.

(2) *Computing the MAPR*—(i) *Closed-end credit.* For closed-end credit, the MAPR shall be calculated following the rules for calculating and disclosing the ''Annual Percentage Rate (APR)'' for credit transactions under Regulation Z based on the charges set forth in paragraph (c)(1) of this section.

(ii) *Open-end credit*—(A) *In general.* Except as provided in paragraph (c)(2)(ii)(B) of this section, for open-end credit, the MAPR shall be calculated following the rules for calculating the effective annual percentage rate for a billing cycle as set forth in § 1026.14(c)–(d) of Regulation Z (as if a creditor must comply with that section) based on the charges set forth in paragraph (c)(1) of this section. Notwithstanding § 1026.14(c)–(d) of Regulation Z, the amount of charges related to opening, renewing, or continuing an account must be included in the calculation of the MAPR to the extent those charges are set forth in paragraph (c)(1) of this section.

(B) *No balance during a billing cycle.* For open-end credit, if the MAPR cannot be calculated in a billing cycle because there is no balance in the billing cycle, a creditor may not impose any fee or charge during that billing cycle, except that the creditor may impose a fee for participation in any plan or arrangement for that open-end credit so long as the participation fee does not exceed $100 per annum, regardless of the billing cycle in which the participation fee is imposed; *provided, however,* that the $100-per annum limitation on the amount of the participation fee does not apply to a bona fide participation fee imposed in accordance with paragraph (d) of this section.

(d) *Bona fide fee charged to a credit card account*—(1) *In general.* For consumer credit extended in a credit card account under an open-end (not home-secured) consumer credit plan, a bona fide fee, other than a periodic rate, is not a charge required to be included in the MAPR pursuant to paragraph (c)(1) of this section. The exclusion provided for any bona fide fee under this paragraph applies only to the extent that the charge by the creditor is a bona fide fee, and must be reasonable and customary for that type of fee.

(2) *Ineligible items.* The exclusion for bona fide fees in paragraph (d)(1) of this section does not apply to any credit insurance premium, including charges for single premium credit insurance, fees for debt cancellation or debt suspension agreements, or to any fees for credit-related ancillary products sold in connection with and either at or before consummation of the credit transaction or upon account opening.

(3) *Standards relating to bona fide fees*—(i) *Like-kind fees.* To assess whether a bona fide fee is reasonable and customary under paragraph (d)(1) of this section, the fee must be compared to fees typically imposed by other creditors for the same or a substantially similar product or service. For example, when assessing a bona fide cash advance fee, that fee must be compared to fees charged by other creditors for transactions in which consumers receive extensions of credit in the form of cash or its equivalent.

(ii) *Safe harbor.* A bona fide fee is reasonable under paragraph (d)(1) of this section if the amount of the fee is less than or equal to an average amount of a fee for the same or a substantially similar product or service charged by 5 or more creditors each with at least $3 billion in outstanding loans on U.S. credit card accounts at any time during the 3-year period preceding the time such average is computed.

(iii) *Reasonable fee.* A bona fide fee that is higher than an average amount, as calculated under paragraph (d)(3)(ii) of this section, also may be reasonable under paragraph (d)(1) of this section depending on other factors relating to the credit card account. A bona fide fee charged by a creditor is not unreasonable solely because other creditors do not charge a fee for the same or a substantially similar product or service.

(iv) *Customary.* A bona fide fee computed as a percentage of the amount of a transaction is customary under paragraph (d)(1) of this section so long as other creditors typically compute, or customarily have computed, that fee for the same or a substantially similar product or service on a percentage basis. Nothing in this paragraph (d)(3)(iv) shall prohibit a bona fide fee that is a fixed amount from being customary for the purpose of meeting the condition set forth in paragraph (d)(1) of this section, even if substantially all other creditors currently compute that fee on a percentage basis. Nothing in this paragraph (d)(3)(iv) shall prohibit a bona fide fee that is charged on a percentage basis from being customary for the purpose of meeting the condition set forth in paragraph (d)(1) of this section, even if substantially all other creditors currently charge a fixed amount.

(v) *Indicia of reasonableness for a participation fee.* An amount of a bona fide fee for participation in a credit card account may be reasonable and customary under paragraph (d)(1) of this section if that amount reasonably and customarily corresponds to the credit limit in effect or credit made available when the fee is imposed, to the services offered under the credit card account, or to other factors relating to the credit card account. For example, even if other creditors typically charge $100 per annum for participation in credit card accounts, a $400 fee nevertheless may be reasonable and customary if (relative to other accounts carrying participation fees) the credit made available to the covered borrower is significantly higher or additional services or other benefits are offered under that account.

(4) If a creditor imposes any fee (other than a periodic rate) that is not a bona fide fee and imposes a finance charge to a covered borrower, the total amount of those fees, including any bona fide fees, and other finance charges shall be

included in the MAPR pursuant to paragraph (c) of this section.

(5) *Rule of construction.* Nothing in paragraph (d)(1) of this section authorizes the imposition of fees or charges otherwise prohibited by this part or by other applicable State or Federal law.

§ 232.5 Identification of covered borrower.

(a) *In general.* A creditor may conclusively determine whether credit is offered or extended to a covered borrower, and thus may be subject to 10 U.S.C. 987 and the requirements of this part, by assessing the status of a consumer in accordance with this section. A creditor also is permitted to assess whether a consumer is a covered borrower by using other methods, as the creditor may elect.

(b) *Safe harbor*—(1) *Department database.* To determine whether a consumer is a covered borrower, a creditor may verify the status of a consumer by accessing the information relating to that consumer, if any, in the database maintained by the Department, available at *http://www.dmdc.osd.mil/mla/owa/home.* A search of the Department's database requires the entry of the consumer's last name, date of birth, and Social Security number.

(2) *Determination and recordkeeping.* Except as provided in paragraph (c) of this section, when a creditor enters into a transaction or establishes an account for consumer credit, a determination by a creditor regarding the status of a consumer based on information obtained from the Department's database shall be deemed to be conclusive with respect to that transaction or account involving consumer credit between the creditor and that consumer, so long as that creditor maintains a record of the information so obtained.

(c) *Actual knowledge.* (1) If at the time a creditor enters into a transaction or establishes an account for consumer credit the creditor has actual knowledge that a consumer is a covered borrower, the creditor shall treat the consumer as a covered borrower notwithstanding any determination by that creditor based on information obtained from the Department's database. Actual knowledge that a consumer is a covered borrower obtained after a creditor has entered into a transaction or established an account for consumer credit shall not affect that transaction or account if the prior determination by that creditor was based solely on information obtained from the Department's database.

(2) For the purposes of this section, actual knowledge of the status of a consumer as a covered borrower may be established only on the basis of a record (including any electronic record) collected by the creditor prior to entering into a transaction or establishing an account for consumer credit and maintained in any system used by the creditor that relates to the consumer credit involving that consumer.

§ 232.6 Mandatory loan disclosures.

(a) *Required information.* With respect to any extension of consumer credit (including any consumer credit originated or extended through the internet) to a covered borrower, a creditor shall provide to the covered borrower the following information before or at the time the borrower becomes obligated on the transaction or establishes an account for the consumer credit:

(1) A statement of the MAPR applicable to the extension of consumer credit;

(2) Any disclosure required by Regulation Z, which shall be provided only in accordance with the requirements of Regulation Z that apply to that disclosure;

(3) A clear description of the payment obligation of the covered borrower, as applicable. A payment schedule (in the case of closed-end credit) or account-opening disclosure (in the case of open-end credit) provided pursuant to paragraph (a)(2) of this section satisfies this requirement; and

(4) A statement that ''Federal law provides important protections to regular or reserve members of the Army, Navy, Marine Corps, Air Force, or Coast Guard, serving on active duty under a call or order that does not specify a period of 30 days or fewer, and their dependents. Members of the Armed Forces and their dependents may be able to obtain financial assistance from Army Emergency Relief, Navy and Marine Corps Relief Society, the Air Force Aid Society, or Coast Guard Mutual Aid. Members of the Armed Forces and their dependents may request free legal advice regarding an application for credit from a service legal assistance office or financial counseling from a consumer credit counselor.''

(b) *One-time delivery; multiple creditors.* (1) The information described in paragraphs (a)(1), (a)(3), and (a)(4) of this section are not required to be provided to a covered borrower more than once for the transaction or the account established for consumer credit with respect to that borrower.

(2) *Multiple creditors.* If a transaction involves more than one creditor, the creditors shall agree among themselves which creditor must provide the information described in paragraphs (a)(1), (a)(3), and (a)(4) of this section.

(c) *Statement of the MAPR*—(1) *In general.* A creditor may satisfy the requirement of paragraph (a)(1) of this section by describing the charges the creditor may impose, in accordance with this part and subject to the terms and conditions of the agreement relating to the consumer credit to calculate the MAPR. Paragraph (a)(1) of this section shall not be construed as requiring a creditor to describe the MAPR as a numerical value or to describe the total dollar amount of all charges in the MAPR that apply to the extension of consumer credit.

(2) *Method of providing a statement regarding the MAPR.* A creditor may include a statement of the MAPR applicable to the consumer credit in the agreement with the covered borrower involving the consumer credit transaction. Paragraph (a)(1) of this section shall not be construed as requiring a creditor to include a statement of the MAPR applicable to an extension of consumer credit in any advertisement relating to the credit.

(3) *Model statement.* A statement substantially similar to the following statement may be used for the purpose of paragraph (a)(1) of this section: ''Federal law provides important protections to members of the Armed Forces and their dependents relating to extensions of consumer credit. In general, the cost of consumer credit to a member of the Armed Forces and his or her dependent may not exceed an annual percentage rate of 36 percent. This rate must include, as applicable to the credit transaction or account: the costs associated with credit insurance premiums; fees for ancillary products sold in connection with the credit transaction; any application fee charged (other than certain application fees for a credit card account); and any participation fee charged (other than certain participation fees for a credit card account).''

(d) *Methods of delivery*—(1) *Written disclosures.* The creditor shall provide the information required by paragraphs (a)(1), (a)(3), and (a)(4) of this section in writing in a form the covered borrower can keep.

(2) *Oral disclosures.* The creditor also shall orally provide the information required by paragraphs (a)(1), (a)(3), and (a)(4) of this section. In mail transactions, internet transactions, and transactions conducted at the point-of-sale in connection with the sale of a nonfinancial product or service, the creditor satisfies this requirement if it provides a toll-free telephone number

on or with the written disclosures that a covered borrower may use to obtain oral disclosures and the creditor provides oral disclosures when the covered borrower contacts the creditor for this purpose.

(e) *When disclosures are required for refinancing or renewal of covered loan.* The refinancing or renewal of consumer credit requires new disclosures under this section only when the transaction for that credit would be considered a new transaction that requires disclosures under Regulation Z.

§ 232.7 Preemption.

(a) *Inconsistent laws.* 10 U.S.C. 987 as implemented by this part preempts any State or Federal law, rule or regulation, including any State usury law, to the extent such law, rule or regulation is inconsistent with this part, except that any such law, rule or regulation is not preempted by this part to the extent that it provides protection to a covered borrower greater than those protections provided by 10 U.S.C. 987 and this part.

(b) *Different treatment under State law of covered borrowers is prohibited.* A State may not:

(1) Authorize creditors to charge covered borrowers rates of interest for any consumer credit or loans that are higher than the legal limit for residents of the State, or

(2) Permit the violation or waiver of any State consumer lending protection covering consumer credit that is for the benefit of residents of the State on the basis of the covered borrower's nonresident or military status, regardless of the covered borrower's domicile or permanent home of record, provided that the protection would otherwise apply to the covered borrower.

§ 232.8 Limitations.

Title 10 U.S.C. 987 makes it unlawful for any creditor to extend consumer credit to a covered borrower with respect to which:

(a) The creditor rolls over, renews, repays, refinances, or consolidates any consumer credit extended to the covered borrower by the same creditor with the proceeds of other consumer credit extended by that creditor to the same covered borrower. This paragraph shall not apply to a transaction when the same creditor extends consumer credit to a covered borrower to refinance or renew an extension of credit that was not covered by this paragraph because the consumer was not a covered borrower at the time of the original transaction. For the purposes of this paragraph only, the term ''creditor'' means a person engaged in the business of extending consumer credit subject to applicable law to engage in deferred presentment transactions or similar payday loan transactions (as described in the relevant law), *provided however,* that the term does not include a person that is chartered or licensed under Federal or State law as a bank, savings association, or credit union.

(b) The covered borrower is required to waive the covered borrower's right to legal recourse under any otherwise applicable provision of State or Federal law, including any provision of the Servicemembers Civil Relief Act (50 U.S.C. App. 501 et seq.).

(c) The creditor requires the covered borrower to submit to arbitration or imposes other onerous legal notice provisions in the case of a dispute.

(d) The creditor demands unreasonable notice from the covered borrower as a condition for legal action.

(e) The creditor uses a check or other method of access to a deposit, savings, or other financial account maintained by the covered borrower, except that, in connection with a consumer credit transaction with an MAPR consistent with § 232.4(b), the creditor may:

(1) Require an electronic fund transfer to repay a consumer credit transaction, unless otherwise prohibited by law;

(2) Require direct deposit of the consumer's salary as a condition of eligibility for consumer credit, unless otherwise prohibited by law; or

(3) If not otherwise prohibited by applicable law, take a security interest in funds deposited after the extension of credit in an account established in connection with the consumer credit transaction.

(f) The creditor requires as a condition for the extension of consumer credit that the covered borrower establish an allotment to repay the obligation. For the purposes of this paragraph only, the term ''creditor'' shall not include a ''military welfare society,'' as defined in 10 U.S.C. 1033(b)(2), or a ''service relief society,'' as defined in 37 U.S.C. 1007(h)(4).

(g) The covered borrower is prohibited from prepaying the consumer credit or is charged a penalty fee for prepaying all or part of the consumer credit.

§ 232.9 Penalties and remedies.

(a) *Misdemeanor.* A creditor who knowingly violates 10 U.S.C. 987 as implemented by this part shall be fined as provided in title 18, United States Code, or imprisoned for not more than one year, or both.

(b) *Preservation of other remedies.* The remedies and rights provided under 10 U.S.C. 987 as implemented by this part are in addition to and do not preclude any remedy otherwise available under State or Federal law or regulation to the person claiming relief under the statute, including any award for consequential damages and punitive damages.

(c) *Contract void.* Any credit agreement, promissory note, or other contract with a covered borrower that fails to comply with 10 U.S.C. 987 as implemented by this part or which contains one or more provisions prohibited under 10 U.S.C. 987 as implemented by this part is void from the inception of the contract.

(d) *Arbitration.* Notwithstanding 9 U.S.C. 2, or any other Federal or State law, rule, or regulation, no agreement to arbitrate any dispute involving the extension of consumer credit to a covered borrower pursuant to this part shall be enforceable against any covered borrower, or any person who was a covered borrower when the agreement was made.

(e) *Civil liability*—(1) *In general.* A person who violates 10 U.S.C. 987 as implemented by this part with respect to any person is civilly liable to such person for:

(i) Any actual damage sustained as a result, but not less than $500 for each violation;

(ii) Appropriate punitive damages;

(iii) Appropriate equitable or declaratory relief; and

(iv) Any other relief provided by law.

(2) *Costs of the action.* In any successful action to enforce the civil liability described in paragraph (e)(1) of this section, the person who violated 10 U.S.C. 987 as implemented by this part is also liable for the costs of the action, together with reasonable attorney fees as determined by the court.

(3) *Effect of finding of bad faith and harassment.* In any successful action by a defendant under this section, if the court finds the action was brought in bad faith and for the purpose of harassment, the plaintiff is liable for the attorney fees of the defendant as determined by the court to be reasonable in relation to the work expended and costs incurred.

(4) *Defenses.* A person may not be held liable for civil liability under paragraph (e) of this section if the person shows by a preponderance of evidence that the violation was not intentional and resulted from a bona fide error notwithstanding the maintenance of procedures reasonably adapted to avoid any such error. Examples of a bona fide error include clerical, calculation, computer malfunction and programming, and printing errors, except that an error of

legal judgment with respect to a person's obligations under 10 U.S.C. 987 as implemented by this part is not a bona fide error.

(5) *Jurisdiction, venue, and statute of limitations.* An action for civil liability under paragraph (e) of this section may be brought in any appropriate United States district court, without regard to the amount in controversy, or in any other court of competent jurisdiction, not later than the earlier of:

(i) Two years after the date of discovery by the plaintiff of the violation that is the basis for such liability; or

(ii) Five years after the date on which the violation that is the basis for such liability occurs.

§ 232.10 Administrative enforcement.

The provisions of this part, other than § 232.9(a), shall be enforced by the agencies specified in section 108 of the Truth in Lending Act (15 U.S.C. 1607) in the manner set forth in that section or under any other applicable authorities available to such agencies by law.

§ 232.11 Servicemembers Civil Relief Act protections unaffected.

Nothing in this part may be construed to limit or otherwise affect the applicability of section 207 and any other provisions of the Servicemembers Civil Relief Act (50 U.S.C. App. 527).

§ 232.12 Effective dates.

(a) *Prior extensions of consumer credit.* Consumer credit that is extended to a covered borrower and consummated any time between October 1, 2007, and [EFFECTIVE DATE OF FINAL REGULATION, AS AMENDED], are subject to the requirements of this part as were established by the Department and effective on October 1, 2007.

(b) *New extensions of consumer credit.* Except as provided in paragraphs (c) and (d) of this section, the requirements of this part, as amended by the Department and effective as of [EFFECTIVE DATE OF FINAL REGULATION], shall apply only to a consumer credit transaction or account for consumer credit consummated or established on or after [EFFECTIVE DATE OF FINAL REGULATION].

(c) *Provisions of 10 U.S.C. 987(d)(2).* The amendments to 10 U.S.C. 987(d)(2) enacted in section 661(a) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239, 126 Stat. 1785), as reflected in § 232.7(b) of this part, shall take effect on January 2, 2014.

(d) *Civil liability remedies.* The provisions set forth in § 232.9(e) shall apply with respect to consumer credit extended on or after January 2, 2013.

Dated: September 22, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–22900 Filed 9–26–14; 8:45 am]

BILLING CODE 5001–06–P

FEDERAL REGISTER

Vol. 79 Monday,

No. 188 September 29, 2014

Part VII

The President

Proclamation 9173—Pacific Remote Islands Marine National Monument Expansion

Federal Register
Vol. 79, No. 188
Monday, September 29, 2014

Presidential Documents

Title 3—

The President

Proclamation 9173 of September 25, 2014

Pacific Remote Islands Marine National Monument Expansion

By the President of the United States of America

A Proclamation

Through Proclamation 8336 of January 6, 2009, the President established the Pacific Remote Islands Marine National Monument (''Monument'') to protect and preserve the marine environment around Wake, Baker, Howland, and Jarvis Islands, Johnston and Palmyra Atolls, and Kingman Reef for the care and management of the historic and scientific objects therein. The Monument is an important part of the most widespread collection of marine- and terrestrial-life protected areas on the planet, sustaining many endemic species including corals, fish, shellfish, marine mammals, seabirds, water birds, land birds, insects, and vegetation not found elsewhere. The Monument includes the lands, waters, and submerged and emergent lands of the seven Pacific Remote Islands to lines of latitude and longitude that lie approximately 50 nautical miles from the mean low water lines of those seven Pacific Remote Islands. The islands of Jarvis, Howland, and Baker were also the location of notable bravery and sacrifice by a small number of voluntary Hawaiian colonists, known as Hui Panalāʻau, who occupied the islands from 1935 to 1942 to help secure the U.S. territorial claim over the islands.

The area around the Monument includes the waters and submerged lands to the extent of the seaward limit of the United States Exclusive Economic Zone (''U.S. EEZ'') up to 200 nautical miles from the baseline from which the breadth of the territorial sea of these seven Pacific Remote Islands is measured. The U.S. EEZ areas adjacent to Wake and Jarvis Islands and Johnston Atoll (''adjacent areas'') contain significant objects of scientific interest that are part of this highly pristine deep sea and open ocean ecosystem with unique biodiversity. These adjacent areas hold a large number of undersea mountains (''seamounts'') that may provide habitat for colonies of deepwater corals many thousands of years old. These adjacent areas' pelagic environment provides habitat and forage for tunas, turtles, manta rays, sharks, cetaceans, and seabirds that have evolved with a foraging technique that depends on large marine predators.

A significant geological feature of the adjacent areas is the undersea mountains. A seamount is a mountain rising from the seabed that does not reach the sea surface. Most often seamounts occur in chains or clusters. Nearly all of the seamounts in the adjacent areas are volcanoes: some are still erupting actively, and others stopped erupting long ago. The Monument includes 33 seamounts; the adjacent areas include approximately 132 more. The additional seamounts provide important opportunities for scientific exploration and study. Estimates are that 15 to 44 percent of the species on a seamount or seamount group are found nowhere else on Earth. Roughly 5 to 10 percent of invertebrates found on each survey of a seamount are new to science. Some seamounts have pools of undiscovered species. The approximately 132 seamounts in the adjacent areas provide the opportunity for identification and discovery of many species not yet known to humans, with possibilities for research, medicines, and other important uses.

The adjacent areas also provide an important ecosystem for scientific study and research. The pristine waters provide a baseline comparison for important scientific research that monitors and evaluates impacts of global climate change, including benchmarking coral bleaching and ocean acidification. The scale of the adjacent areas significantly enhances opportunities for such scientific research beyond the Monument boundaries established in Proclamation 8336.

The available scientific information indicates that the adjacent areas include important deep-coral species. For example, sampling from the U.S. Line Islands has identified deep-sea coral species not previously recorded from the central Pacific. Tropical coral reefs and associated marine ecosystems are among the most vulnerable areas to the impacts of climate change and ocean acidification. Protection of the ecosystem in the adjacent areas will provide the scientific opportunity to identify and further study the important deep sea corals.

The adjacent areas provide significant habitat and range for species identified in Proclamation 8336. They include waters used by five species of protected turtles. In addition to the Green and Hawksbill turtles that use the near-shore waters of the Monument, the adjacent areas include waters used by the endangered leatherback, loggerhead, and Olive Ridley turtles. All five species use the adjacent areas for their migratory paths and feeding grounds.

The adjacent areas provide the foraging habitat for several of the world's largest remaining colonies of Sooty Terns, Lesser Frigatebirds, Red-footed Boobies, Red-tailed Tropicbirds, and other seabird species. Many of these wide-ranging species make foraging trips of 300 miles or more from their colonies on the Monument's islands, atolls, and reefs. For example, since the Monument was established, U.S. Fish and Wildlife Service biologists have documented the return of seabird populations once absent at Johnston Atoll, including Great Frigatebirds, Sooty Terns, Red-tailed Tropicbirds, and other species that are known to feed as much as 300 to 600 miles offshore. Jarvis Island alone has nearly three million nesting pairs of Sooty Terns, which forage more than 300 miles from shore even when rearing chicks on the island. These seabirds forage, in part, by seeking schools of tuna and other large marine predators that drive prey fish to the surface. Black-footed and Laysan Albatross, species that forage across the entire North Pacific, recently recolonized Wake Atoll, making it one of the few northern albatross colonies outside of the Hawaiian archipelago. At Jarvis Island, the Monument and its adjacent area provide an important undisturbed ecosystem that supports many rare seabird species, including the endangered White-throated Storm-petrel.

Manta rays are abundant around the Monument's reefs. Since the Monument was established, scientific research on manta ray movement has shown that manta rays frequently travel over 600 nautical miles away from the coastal environment, and well outside of the Monument boundaries established in Proclamation 8336. Scientific study of the multi-species ecological cycle at the Monument illustrates a very diverse and balanced habitat used by manta rays, many of which are found in the adjacent areas.

The ecosystem of the Monument and adjacent areas also is part of the larger Pacific ecosystem. The Monument land and atoll groups and the adjacent areas share geographic isolation, as well as climate, bathymetric, geologic, and wildlife characteristics that define them as individual biogeographic regions. However, the Pacific Remote Islands area, including the adjacent areas, is tied together by regional oceanographic currents that drive marine species larval transport and adult migrations that shape the broader Pacific ecosystem.

WHEREAS the waters and submerged lands surrounding Jarvis and Wake Islands and Johnston Atoll from the lines of latitude and longitude depicted on the maps accompanying Proclamation 8336 to the seaward limit of the U.S. EEZ of the three Pacific Remote Islands contain objects of historic

or scientific interest that are situated upon lands owned or controlled by the Government of the United States;

WHEREAS section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431) (the ''Antiquities Act''), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected;

WHEREAS it is in the public interest to preserve the marine environment, including the waters and submerged lands, in the U.S. EEZ adjacent to the Monument at Jarvis and Wake Islands and Johnston Atoll for the care and management of the historic and scientific objects therein;

WHEREAS the security of the United States, the prosperity of its citizens, and the protection of the ocean environment are complementary and reinforcing priorities; and the United States continues to act with due regard for the rights, freedoms, and lawful uses of the sea enjoyed by other nations under the law of the sea in managing the Pacific Remote Islands Marine National Monument and adjacent areas, and does not compromise the readiness, training, and global mobility of U.S. Armed Forces when establishing marine protected areas:

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by the authority vested in me by section 2 of the Antiquities Act, do hereby proclaim the objects identified above that are situated upon lands and interests in lands owned or controlled by the Government of the United States to be part of the Pacific Remote Islands Marine National Monument Expansion (''Monument Expansion'') and, for the purpose of protecting those objects, reserve as a part thereof all lands and interests in lands owned or controlled by the Government of the United States within the boundaries described on the accompanying maps entitled ''Pacific Remote Islands Marine National Monument Expansion'' attached hereto, which form a part of this proclamation. The Monument Expansion includes the waters and submerged lands of Jarvis and Wake Islands and Johnston Atoll that lie from the Pacific Remote Islands Marine National Monument boundary established in Proclamation 8336 to the seaward limit of the U.S. EEZ (as established in Proclamation 5030 of March 10, 1983) of Jarvis and Wake Islands and Johnston Atoll. The Federal lands and interests in lands reserved consist of approximately 308,316 square nautical miles, which is the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of the Monument Expansion are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, leasing, or other disposition under the public land laws to the extent that those laws apply. Lands and interests in lands within the Monument Expansion not owned or controlled by the United States shall be reserved as a part of the Monument Expansion upon acquisition of title or control by the United States.

Management of the Marine National Monument

Nothing in this proclamation shall change the management of the Pacific Remote Islands Marine National Monument as specified in Proclamation 8336. The Secretary of the Interior, in consultation with the Secretary of Commerce, shall have primary responsibility for management of the Monument Expansion pursuant to applicable legal authorities. The Secretary of Commerce, through the National Oceanic and Atmospheric Administration, and in consultation with the Secretary of the Interior, shall within the Monument Expansion have primary responsibility with respect to fishery-

related activities regulated pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and any other applicable legal authorities. The Secretaries of the Interior and Commerce shall not allow or permit any appropriation, injury, destruction, or removal of any object of the Monument Expansion except as provided for by this proclamation and shall prohibit commercial fishing within the boundaries of the Monument Expansion.

The Secretaries of the Interior and Commerce shall take appropriate action pursuant to their respective authorities under the Antiquities Act, the Magnuson-Stevens Fishery Conservation and Management Act, and such other authorities as may be available to implement this proclamation, to regulate fisheries, and to ensure proper care and management of the Monument Expansion.

The United States shall continue to preserve the freedom of the seas (i.e., all of the rights, freedoms, and lawful uses of the sea recognized in international law enjoyed by all nations, including the conduct of military activities, exercises, and surveys in or over the exclusive economic zone), and to protect the training, readiness, and global mobility of U.S. Armed Forces as U.S. national interests that are essential to the peace and prosperity of civilized nations.

The Secretary of Defense shall continue to manage Wake Island and Johnston Atoll as specified in Proclamation 8336.

Regulation of Scientific Exploration and Research

Subject to such terms and conditions as the Secretary of the Interior or Commerce, as appropriate, deems necessary for the care and management of the objects of the Monument and Monument Expansion, the Secretaries may permit scientific exploration and research within the Monument Expansion, including incidental appropriation, injury, destruction, or removal of features of the Monument Expansion for scientific study, and the Secretary of Commerce may permit fishing within the Monument Expansion for scientific exploration and research purposes to the extent authorized by the Magnuson-Stevens Fishery Conservation and Management Act. The prohibitions required by this proclamation shall not restrict scientific exploration or research activities by or for the Secretaries of the Interior or Commerce, and nothing in this proclamation shall be construed to require a permit or other authorization from the other Secretary for their respective scientific activities.

Regulation of Fishing and Management of Fishery Resources

The Secretaries of the Interior and Commerce may permit noncommercial fishing upon request, at specific locations in accordance with this proclamation and Proclamation 8336. The Secretaries shall provide a process to ensure that recreational fishing continues to be managed as a sustainable activity in the Monument and Monument Expansion, in accordance with this proclamation, Proclamation 8336, and consistent with Executive Order 12962 of June 7, 1995, as amended, and other applicable law.

Monument Management Planning

The Secretaries of the Interior and Commerce shall, within 2 years of the date of this proclamation, prepare management plans, using their respective authorities, for the Monument and Monument Expansion and promulgate implementing regulations that address any further specific actions necessary for the proper care and management of the objects and areas identified in this proclamation and those in Proclamation 8336. The Secretaries shall revise and update the management plans as necessary. In developing and implementing any management plans and any management rules and regulations, the Secretaries shall consult and designate and involve as cooperating agencies the agencies with jurisdiction or special expertise, including the Department of Defense and Department of State, in accordance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and its implementing regulations.

This proclamation shall be applied in accordance with international law. The management plans and their implementing regulations shall impose no restrictions on innocent passage in the territorial sea or otherwise restrict navigation and overflight and other internationally recognized lawful uses of the sea in the Monument and Monument Expansion and shall incorporate the provisions of this proclamation regarding Armed Forces actions and compliance with international law. No restrictions shall apply to or be enforced against a person who is not a citizen, national, or resident alien of the United States (including foreign flag vessels) unless in accordance with international law. Also, in accordance with international law, no restrictions shall apply to foreign warships, naval auxiliaries, and other vessels owned or operated by a state and used, for the time being, only on Government non-commercial service, in order to fully respect the sovereign immunity of such vessels under international law.

Emergencies, National Security, and Law Enforcement Activities

1. The prohibitions required by this proclamation shall not apply to activities necessary to respond to emergencies threatening life, property, or the environment, or to activities necessary for national security or law enforcement purposes.

2. Nothing in this proclamation shall limit agency actions to respond to emergencies posing an unacceptable threat to human health or safety or to the marine environment and admitting of no other feasible solution.

Armed Forces Actions

1. The prohibitions required by this proclamation shall not apply to activities and exercises of the Armed Forces (including those carried out by the United States Coast Guard).

2. The Armed Forces shall ensure, by the adoption of appropriate measures not impairing operations or operational capabilities, that its vessels and aircraft act in a manner consistent, so far as is reasonable and practicable, with this proclamation.

3. In the event of threatened or actual destruction of, loss of, or injury to a Monument Expansion resource or quality resulting from an incident, including but not limited to spills and groundings, caused by a component of the Department of Defense or the United States Coast Guard, the cognizant component shall promptly coordinate with the Secretary of the Interior or Commerce, as appropriate, for the purpose of taking appropriate actions to respond to and mitigate any actual harm and, if possible, restore or replace the Monument Expansion resource or quality.

4. Nothing in this proclamation or any regulation implementing it shall limit or otherwise affect the Armed Forces' discretion to use, maintain, improve, manage, or control any property under the administrative control of a Military Department or otherwise limit the availability of such property for military mission purposes, including, but not limited to, defensive areas and airspace reservations.

The establishment of this Monument Expansion is subject to valid existing rights.

This proclamation 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, or entities, its officers, employees, or agents, or any other person.

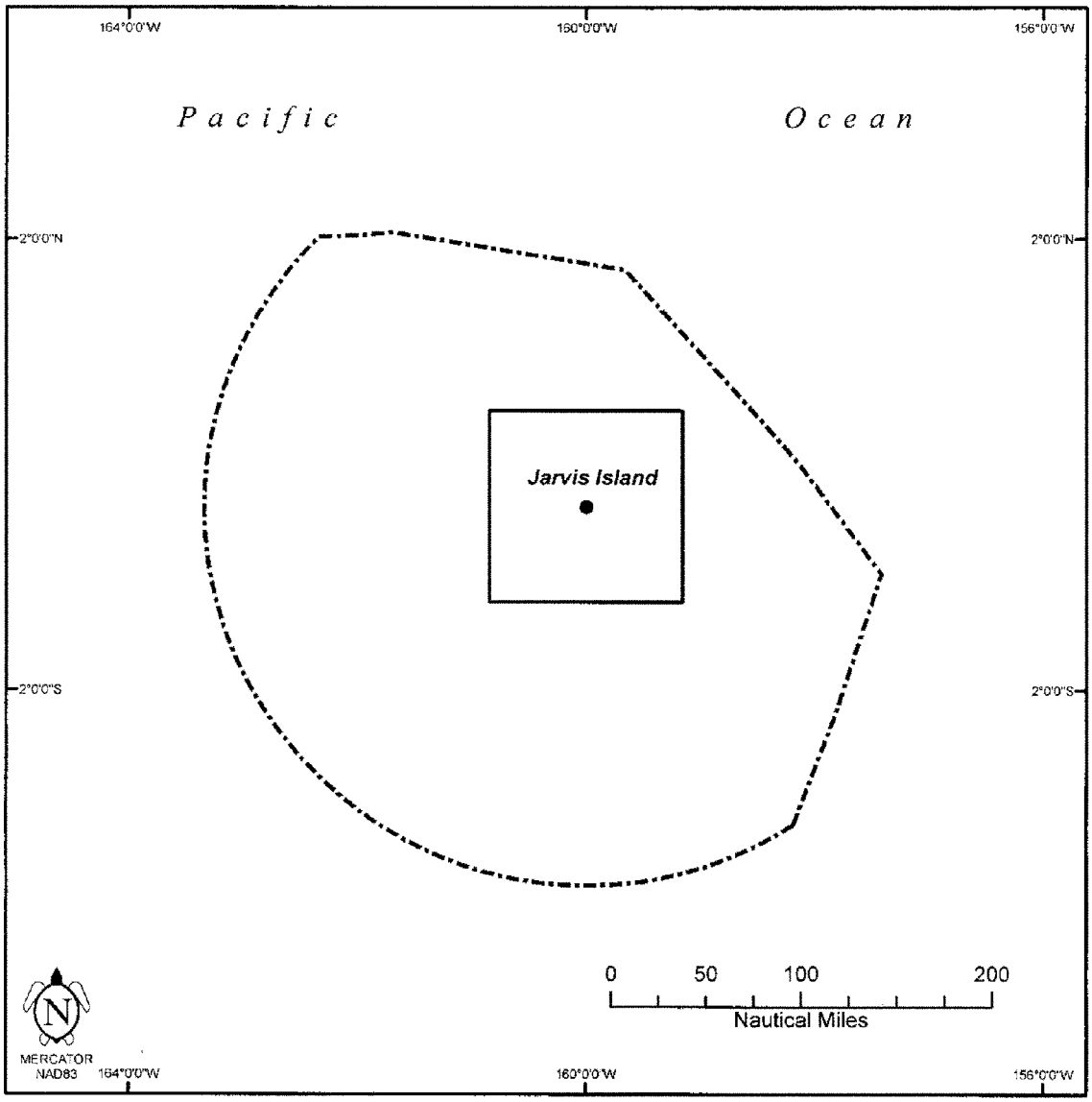
Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the Monument Expansion shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, excavate, injure, destroy, or remove any feature of this Monument Expansion and not to locate or settle upon any lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fifth day of September, in the year of our Lord two thousand fourteen, and of the Independence of the United States of America the two hundred and thirty-ninth.

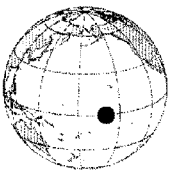
Billing code 3295–F4–P

Pacific Remote Islands Marine National Monument Expansion



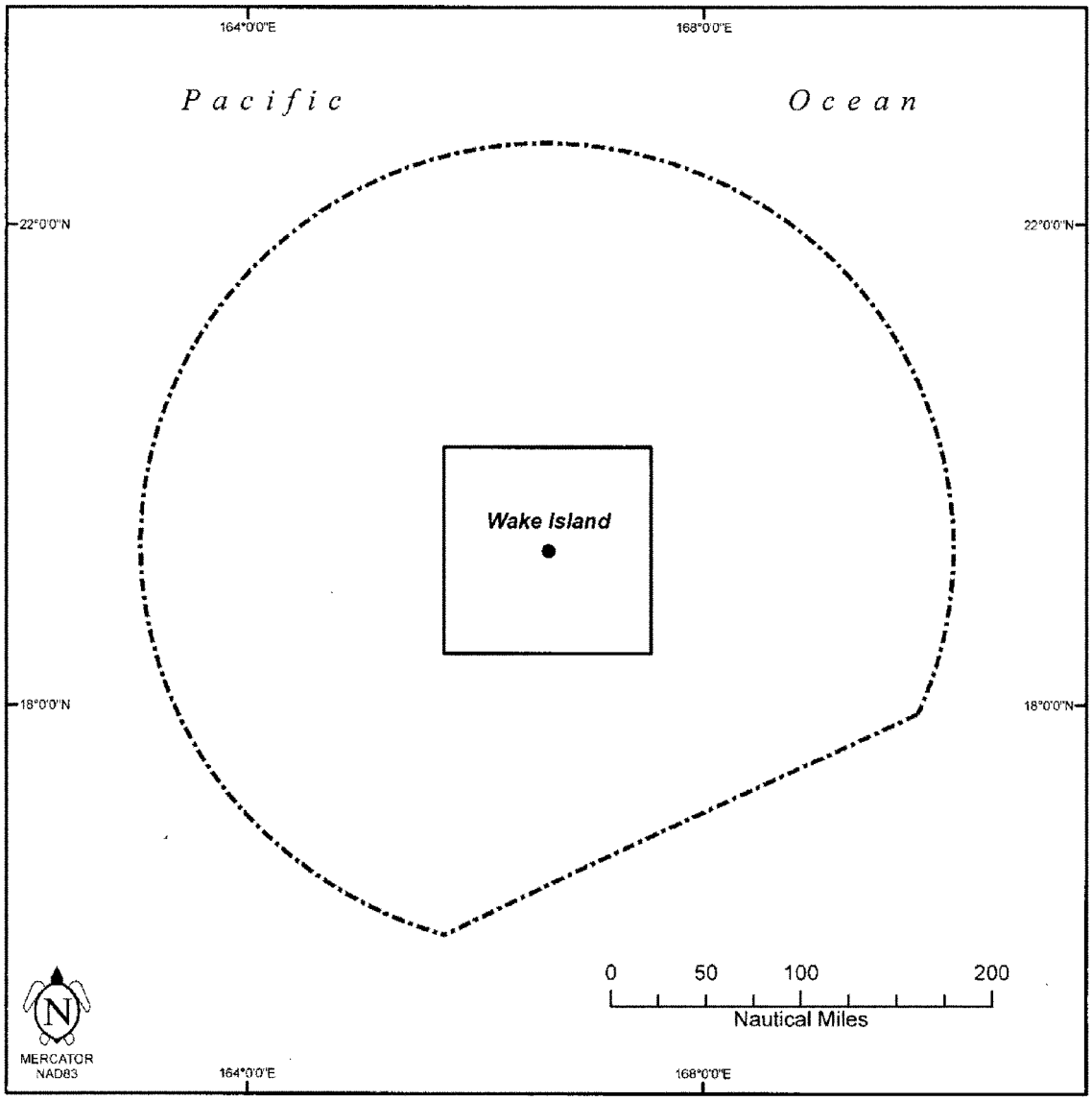
Pacific Remote Islands MNM Boundary Expanded - seaward limits of U.S. Exclusive Economic Zone

Pacific Remote Islands MNM Boundary - 50 nmi



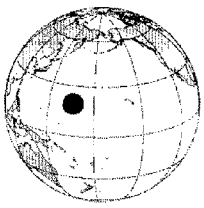
9/15/2014 FWS-R1-NWRS-RRI 14-096-11.MXD

Pacific Remote Islands Marine National Monument Expansion



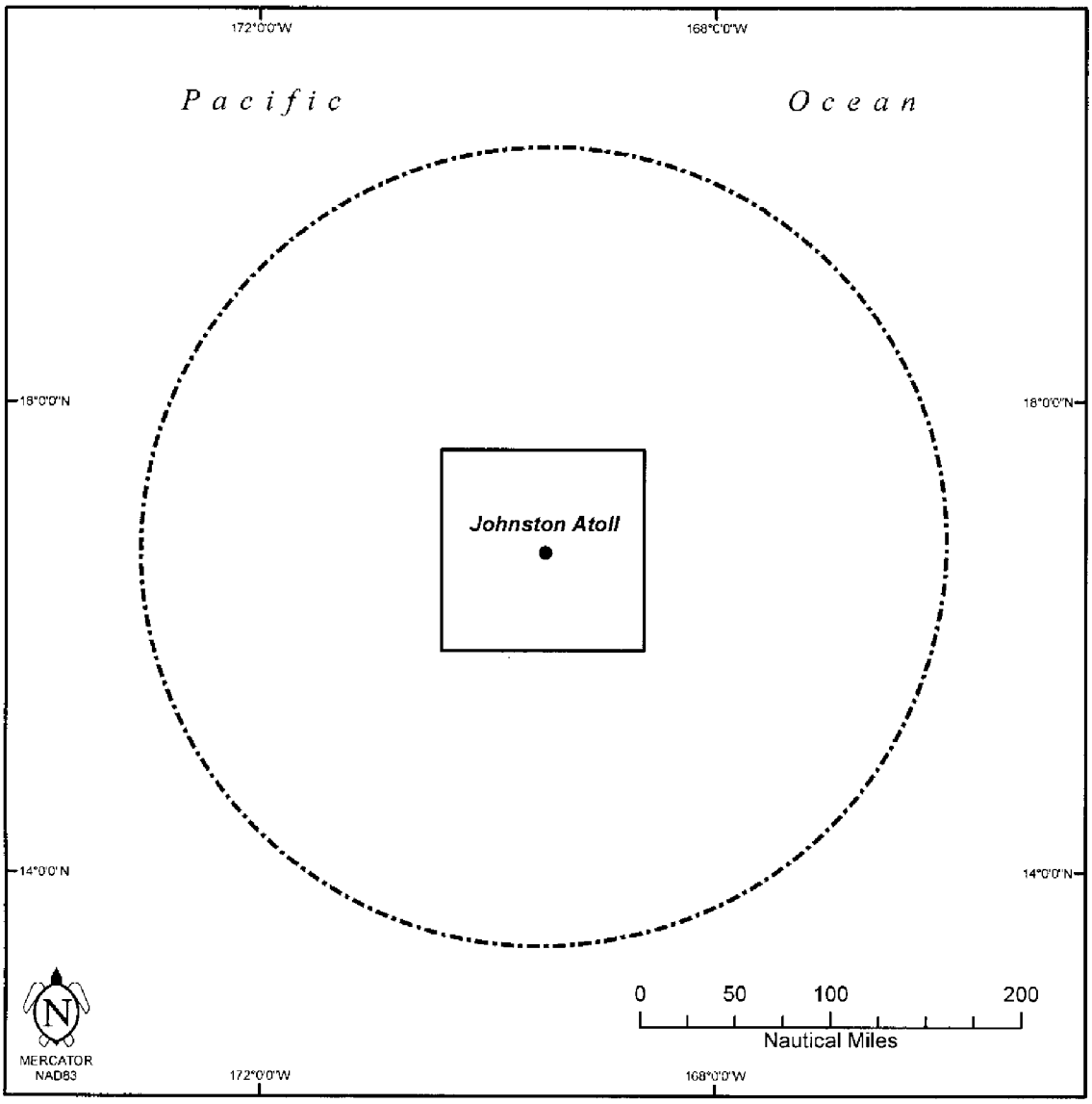
Pacific Remote Islands MNM Boundary Expanded - seaward limits of U.S. Exclusive Economic Zone

Pacific Remote Islands MNM Boundary - 50 nmi



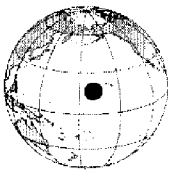
9/15/2014 FWS-R1-NWRS-RRI 14-096-8.MXD

Pacific Remote Islands Marine National Monument Expansion



Pacific Remote Islands MNM Boundary Expanded - seaward limits of U.S. Exclusive Economic Zone

Pacific Remote Islands MNM Boundary - 50 nmi



9/3/2014 FWS-R1-NWRS-RRI 14-096-9 MXD

[FR Doc. 2014–23319

Filed 9–26–14; 11:15 am]

Billing code 4310–10–C

Reader Aids

Federal Register

Vol. 79, No. 188

Monday, September 29, 2014

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: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: **www.ofr.gov.**

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 (or change 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.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, SEPTEMBER

51887–52164 2
52165–52542 3
52543–52952 4
52953–53126 5
53127–53280 8
53281–53600 9
53601–54184 10
54185–54566 11
54567–54886 12
54887–55350 15
55351–55602 16
55603–55962 17
55963–56216 18
56217–56476 19
56477–56630 22
56631–56936 23
56937–57428 24
57429–57698 25
57699–58240 26
58241–58654 29

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.

2 CFR

1882 56486

3 CFR

Proclamations:
9154 52937
9155 52939
9156 52941
9157 52943
9158 52945
9159 52947
9160 52949
9161 52951
9162 53599
9163 54181
9164 54885
9165 54887
9166 55959
9167 55961
9168 56473
9169 56929
9170 56937
9171 57425
9172 57427
9173 58645
Executive Orders:
13676 56931
13677 57699
Administrative Orders:
Memorandums:
Memorandum of September 10, 2014 56623
Memorandum of September 23, 2014 58237
Notices:
Notice of September 4, 2014 53279
Notice of September 17, 2014 56475
Presidential Determinations:
No. 2014–14 of September 5, 2014 54183
No. 2014–15 of September 15, 2014 56625
No. 2014–16 of September 18, 2014 57699

5 CFR

550 53601
1653 53603
Ch. XCIX 54567

7 CFR

63 55603
319 .....52543, 55963
718 57703
915 55351
944 55351
1220 53605
1412 57703
1416 57703
1940 .....55965, 56217
1942 55965
1944 55965
1948 55965
1980 55965
Proposed Rules:
27 53633
28 53633
29 53633
51 53633
52 53633
54 53633
56 53633
58 53633
62 53633
70 53633
75 53633
91 53633
318 53346
319 53346
761 52239
762 52239
763 52239
764 52239
765 52239
766 52239
767 52239
770 52239
772 52239
773 52239
774 52239
799 52239
1436 52239
1940 .....52239, 56020
1942 56020
1944 56020
1948 56020
1980 56020
4279 55316
4287 55316

8 CFR

214 58241
Proposed Rules:
1003 .....55659, 55662
1240 55662
1241 55662

9 CFR

77 53606
101 55968
113 55968
304 56220
327 56220
381 56220
391 56235
590 56220

10 CFR

51 ..... 56238, 56283
70 57721
72 53281
905 56477

Proposed Rules:

30 56524
32 56524
35 56524
70 57840
72 53352
73 56525
429 57842
430 ..... 54213, 58290
431 ..... 54215, 55538

12 CFR

3 57725
30 54518
168 54518
170 54518
213 56482
217 57725
226 56483
324 57725
652 53127
1005 55970
1013 56482
1026 56483
1090 56631

Proposed Rules:

45 57348
237 57348
349 57348
607 52814
614 52814
615 52814
620 52814
624 57348
628 52814
1221 57348
1263 54848
1282 ..... 54482, 57348

13 CFR

Proposed Rules:

121 ..... 53646, 54146

14 CFR

25 ..... 52165, 52169, 53128, 53129, 54571, 54572, 54574, 54576, 56485, 57429, 58243
29 54889
39 ..... 52172, 52174, 52177, 52181, 52184, 52187, 52190, 52545, 52953, 53285, 53288, 54577, 54579, 54891, 54893, 54895, 54897, 55604, 56264, 57751, 57753
71 ..... 51887, 52192, 52194, 52957, 54185, 54901, 55354, 55355, 55356, 55357, 55995, 55997, 56650, 57757, 57758
73 55606
91 57431
97 ..... 51888, 51891, 57432, 57436
1204 54902
1267 56486
1274 56486

Proposed Rules:

Ch. 1 52223
1 56288
39 ..... 52260, 52263, 52267, 52270, 52585, 52588, 54218, 54220, 54672, 54917, 54919, 54922, 54925, 55673, 55675, 56023, 56025, 56526, 56682, 58294
60 55407
71 ..... 51919, 51920, 53667, 53669, 57482, 57483
73 ..... 57484, 57486
121 ..... 53008, 56288
125 56288
135 56288
145 53008
234 57489
244 57489
250 57489
255 57489
256 57489
257 57489
259 57489
399 57489

15 CFR

30 54588
738 52958
740 52958
742 52958
744 ..... 52958, 55608, 55998
746 55608
772 52958
774 52958
801 53291
902 54590
922 52960

Proposed Rules:

Ch. VII 53355

16 CFR

240 58245
305 52549
435 55615

17 CFR

1 57767
229 57184
230 57184
232 ..... 55078, 57184
239 57184
240 ..... 55078, 57184
243 57184
249 ..... 55078, 57184
249b 55078

Proposed Rules:

230 ..... 54218, 54224
270 51922
274 51922

18 CFR

2 56939
38 56939

Proposed Rules:

806 57850

19 CFR

122 57782

21 CFR

310 ..... 53133, 53134
314 ..... 53133, 53134
329 ..... 53133, 53134
520 53134
522 53134
558 53134
600 ..... 53133, 53134
864 52195
866 ..... 53608, 56009
1300 53520
1301 53520
1304 53520
1305 53520
1307 53520
1317 53520

Proposed Rules:

1 ..... 58524, 58574
16 ..... 58476, 58524
112 58434
117 ..... 58476, 58524
172 51922
182 51922
507 58476
610 53670
680 53670
870 54927
872 56027
890 56532

22 CFR

22 52197
173 56488

23 CFR

627 52972
773 55381

Proposed Rules:

450 ..... 51922, 53673
771 53673
773 55381

24 CFR

5 ..... 54186, 55360
232 55360
500 51893
501 51893
502 51893
503 51893
504 51893
505 51893
506 51893
507 51893
508 51893
509 51893
510 51893
511 51893
572 51893
585 51893
590 51893
597 51893
598 51893
943 54186
982 54186
3285 53609
3286 53609

Proposed Rules:

Ch. IX 57489

25 CFR

Proposed Rules:

41 54936

26 CFR

1 ..... 56442, 56892
31 55362
51 ..... 57783, 57784
301 ..... 57784, 57785, 58256
602 57784

Proposed Rules:

1 ..... 56305, 56310
51 57785

27 CFR

73 52198

Proposed Rules:

9 52273

28 CFR

0 54187

Proposed Rules:

36 53146

29 CFR

1904 56130
1910 56955
1926 ..... 56955, 57785
4022 54904
4044 54904

30 CFR

Proposed Rules:

100 55408
250 57008

32 CFR

157 55622
706 52556

Proposed Rules:

199 56312
232 58602
238 55679
286 52500

33 CFR

100 ..... 51895, 52556, 53291, 54905, 54906, 57439, 57798, 57799
117 ..... 53294, 56268, 56651, 56654, 56655
147 ..... 51898, 52559
151 54907
165 ..... 52199, 52561, 53295, 53297, 54603, 54605, 54607, 56011, 56013, 56015, 56489, 57440, 57799, 57802
175 56491
181 56491

Proposed Rules:

100 ..... 53671, 56316
117 ..... 54241, 54244
165 ..... 52591, 54937, 55409, 56319, 58298

34 CFR

Proposed Rules:

Ch. II 53254, 57015
Ch. VI 52273

36 CFR

51 58261
1191 57804
1250 56500

Proposed Rules:

13 52595

37 CFR

201 ..... 55633, 56190
210 56190

Proposed Rules:

201 ..... 55687, 55694, 55696

38 CFR

3 ..... 52977, 54608, 57660
14 52977
17 ..... 54609, 57410, 57415
19 57660
20 ..... 52977, 57660
43 54609

Proposed Rules:

36 53146

39 CFR

111 54188
3001 54552
3020 53139
3035 54552

40 CFR

9 ....51899, 52563
52 ....51913, 52420, 52426, 52439, 52564, 53299, 54617, 54908, 54910, 55637, 55641, 55645, 56268, 56513, 56655, 57442, 57445, 58263
62 52201
81 ....52205, 55645, 56962
122 56274
131 57447
180 ....52210, 52215, 52985, 52990, 54620, 55653, 56275, 56963, 57450, 57805
271 52220
300 ....55657, 56515, 57458, 57459
721 ....51899, 52563
761 58266

Proposed Rules:

51 55412
52 ....51923, 52602, 53355, 54941, 55412, 55712, 55920, 56322, 56538, 56684, 57490, 57491, 58301, 58302, 58309
58 54356
60 ....55413, 57492
62 52275
81 53008
82 56331
180 53009
271 52275
300 56538

41 CFR

61–250 57463
61–300 57463
102–117 55363

Proposed Rules:

60–1 55712

42 CFR

37 55366
495 52910

43 CFR

2 51916
3000 57476

Proposed Rules:

2 51926

44 CFR

64 53618
67 ....54913, 54915

45 CFR

89 55367
146 52994
147 52994
148 52994
155 52994
156 52994
170 ....52910, 54430

46 CFR

1 58270
2 53621
4 58270
6 58270
10 58270
11 ....55657, 58270
12 58270
13 58270
14 58270
15 58270
24 ....53621, 58270
25 53621
27 58270
28 58270
30 ....53621, 58270
35 58270
38 58270
42 58270
44 58270
45 58270
52 58270
62 58270
67 58270
69 58270
70 ....53621, 58270
71 58270
72 58270
76 58270
77 58270
78 58270
90 ....53621, 58270
92 58270
95 58270
97 58270
105 58270
109 58270
111 58270
114 58270
115 58270
117 58270
119 58270
121 58270
122 58270
131 58270
150 58270
151 58270
153 58270
154 58270
159 58270
160 ....56491, 58270
161 58270
162 58270
163 58270
164 58270
167 58270
169 ....56491, 58270
171 58270
172 58270
174 58270
175 58270
176 58270
180 58270
181 58270
182 58270
185 58270
188 ....53621, 58270
189 58270
190 58270
194 58270
196 58270
197 58270
199 58270
515 56522

Proposed Rules:

401 52602
502 56546

47 CFR

0 56968
1 ....54190, 56968
15 ....56987, 56988
17 56968
20 55367
25 52224
64 53303
69 ....57810, 57811
73 ....52225, 53006, 53143, 54916
97 52226

Proposed Rules:

20 ....53356, 55413
32 54942
54 57853
69 57492
73 ....54674, 54675, 55742, 57493

48 CFR

204 56278
213 56278
217 56278
225 56278
249 56278
904 56279
952 56279
970 56279
1201 54626
1202 54626
3002 56661
3007 56661
3009 56661
3016 56661
3034 56661
3035 56661
3052 56661

Proposed Rules:

42 54949
217 56331
225 56333
515 54126
538 54126
552 54126
1809 57015
1815 57015
1816 57015
1817 57015
1819 57015
1823 57015
1827 57015
1828 57015
1831 57015
1832 57015
1837 57015
1842 57015
1849 57015
1852 57015

49 CFR

109 55403
171 55403
172 55403
173 ....55403, 56988, 56989
174 55403
175 55403
176 55403
177 55403
178 55403
179 55403
180 55403
264 55381
571 57829
593 56990
594 57002
622 55381
1511 56663

Proposed Rules:

105 54676
107 54676
171 ....54676, 57494
173 57494
219 57495
223 57856
232 53356
380 56547
383 56547
384 56547
594 54247
613 ....51922, 53673
622 53673

50 CFR

17 ....52567, 52576, 53303, 53315, 54627, 54635, 54782
20 ....52226, 56864, 57402, 58198
80 54668
223 53852
300 ....53631, 56017
622 ....53006, 53144, 54668, 55658, 57830
635 53344
648 ....51917, 52578, 56669, 57837
660 56670
679 ....52583, 54590, 54669, 56286, 56671, 57837, 57838

Proposed Rules:

17 ....53384, 55874, 56029, 56041, 56686, 56704, 56730, 57032
92 53120
Ch. II 53151
216 53013
223 ....51929, 52276
226 53384
259 57496
Ch. III 53151
Ch. IV 53151
Ch. V 53151
Ch. VI 53151
600 53386
635 ....54247, 54252, 56047
648 ....52293, 53386
660 ....53401, 54950, 56547
697 ....56553, 57041

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List September 24, 2014

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.