

Form #2

FILED

2014 MAY 15 A 10:18

OFFICE WEST VIRGINIA
SECRETARY OF STATE

ATTACH A BRIEF SUMMARY OF YOUR PROPOSAL

Brief Summary

The rules have been amended to incorporate by reference the Federal meat and poultry regulations which have been passed from March 1, 2013 to May 1, 2014. During this time period several changes were included such as an increase in the adjusted retail exemptions for meat and poultry products, guidance for HACCP systems validation, guidance for violative residues in livestock slaughter establishments, guidance for controlling the spread of *Salmonella* in hog slaughter facilities, guidance for prevention of allergens in meat and poultry products, guidance to assist livestock slaughter establishments in complying with the regulatory requirements for humane handling and slaughter of livestock, and changing of the *Salmonella* verification program in regards to the analysis of raw beef for shiga toxin-producing *Escherichia coli* and *Salmonella*. Parts 412 and 418 have been added to the federal regulations to cover label approvals and recalls.

Statement of Circumstances

This rule change adopts changes made through March 1, 2013 and May 1, 2014 to the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Federal Regulations into the State-Federal Cooperative Meat and Poultry Inspection Program and allows the Meat and Poultry Inspection Division of the West Virginia Department of Agriculture to maintain an "equal to" program and the Federal funding associated with that program.

Several changes have been made in regards to retail exemption limits, label approvals, and the use of guidance documents in enforcing regulations.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title:

Inspection of Meat and Poultry

Type of Rule:

☒ Legislative ☐ Interpretive ☐ Procedural

Agency:

West Virginia Department of Agriculture

Address:

1900 Kanawha Blvd. E.

Charleston, WV 25305

Phone Number:

304-558-2206

Email: rpitts@wvda.us**Fiscal Note Summary**

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

None

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "+")	Next Increase/Decrease (use "+")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Inspection of Meat and Poultry

Rule Title:

Rule Title: _____

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

N/A

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Inspection personnel currently employed will enforce additional regulations as required within their scheduled work times by adjusting their schedules with no additional time or equipment.

Date: May 15, 2014

Signature of Agency Head or Authorized Representative

Walt Helmer

TITLE 61
LEGISLATIVE RULE
DEPARTMENT OF AGRICULTURE

SERIES 16
INSPECTION OF MEAT AND POULTRY

FILED

2014 MAY 15 A 10:18

OFFICE WEST VIRGINIA
SECRETARY OF STATE**§61-16-1. General.**

1.1. Scope. -- This rule is established in order to implement the requirements of W. Va. Code §19-2B-1 et seq. Inspection of Meat and Poultry, and to maintain and administer an effective State-Federal Cooperative Meat and Poultry Inspection Program in the State of West Virginia by establishing requirements which equal those imposed by the applicable provisions of the Federal Meat Inspection Act (34 Stat. 1260) as amended by the Wholesome Meat Act (81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, U.S.C., Sec. 601 et seq.), and the Poultry Products Inspection Act (71 Stat. 441), as amended by the Wholesome Poultry Products Act (82 Stat. 791; U.S.C. 451 et seq.). This rule establishes general operating procedures, requirements and standards in the West Virginia Department of Agriculture, Meat and Poultry Inspection Division.

1.2. Authority. -- W. Va. Code §19-2B-3.

1.3. Filing Date. --

1.4. Effective Date. --

§61-16-2. Incorporation by Reference of Federal Meat and Poultry Inspection Regulations.

The Mandatory Meat Inspection Regulations (9 CFR, Parts 301 et seq.) the Mandatory Poultry Products Inspection Regulations (9 CFR, Part 381) and Regulatory Requirements Under the Federal Meat Inspection Act and the Poultry Products Inspection Act (9 CFR, Parts 412, 416, 417, 418, 424, 430, 441 and 442) of the United States Department of Agriculture, promulgated in the Federal Register prior to ~~March 1, 2013~~ May 1, 2014 are hereby adopted in their entirety with the exception of the deleted regulations specified in section 3 of this rule.

§61-16-3. Deleted Regulations.

The following sections of the Federal regulations governing the mandatory meat inspection (9 CFR, Part 301 et seq.) and the mandatory poultry products inspection (9 CFR, Part 381) of the United States Department of Agriculture incorporated by reference under section 2 of this rule are deleted and are not rules of the West Virginia Department of Agriculture: 302.2; 303.1 (c); 304; 305.2 (b); 307.5; 307.6; 312; 316.12; 316.13 (c); 317.7; 317.9; 318.8; 321; 322; 327; 329.6; 329.7; 329.8; 329.9; 331; 335; 381.16; 381.17; 381.30; 381.31; 381.38; 381.39; 381.96, 381.98, 381.104 through 381.112; 381.123 (b)(1) and (4); 381.179; 381.185; 381.186; 381.195 through 381.236.

In 9CFR 381.10(a) (3) and (4) the words "and the statement 'Exempt - P. L. 90-492'" are deleted.

In 9CFR 381.123(b) (2) the words "and accompanied by the prefix 'P' " are deleted.

§61-16-4. Definitions.

4.1. All terms used in this rule are those defined in W. Va. Code §19-2B-2, except for the terms defined in this section.

4.2. Definitions in the incorporated parts of the Federal regulations on mandatory meat inspection (9 CFR, Part 301 et seq.) and mandatory poultry products inspection (9 CFR, Part 381) of the United States Department of Agriculture are amended to read as follows:

4.2.a. "The Act" means W. Va. Code §19-2B-1 et seq.

4.2.b. "The United States Department of Agriculture" and "Department" means the West Virginia Department of Agriculture. For brevity, the acronym WVDA for the West Virginia Department of Agriculture is used in this rule.

4.2.c. "Secretary" means the Commissioner of Agriculture.

4.2.d. "Administrator", "Regional Director", and "Area Supervisor" mean the Director, Meat and Poultry Inspection Division, WVDA.

4.2.e. "Federal Meat Inspection", "Program", "Federal Inspection", "Federal Poultry Inspection", "Meat and Poultry Inspection Program", "Inspection Service", "Standards and Labeling Division", "Meat and Poultry Inspection", "Technical Services", and "Agency" mean the Meat and Poultry Inspection Division, WVDA.

4.2.f. "Federal" means State.

4.2.g. "Food Inspector", "Inspection Service Employee", "USDA Inspector", "USDA Program Official", and "Program Inspector" mean Inspector, Meat and Poultry Inspection Division, WVDA.

4.2.h. "Inspection Service Supervisor", "Veterinary Inspector", and "Circuit Supervisor" mean Veterinary Supervisor, Meat and Poultry Inspection Division, WVDA.

4.2.i. "Food Safety and Inspection Service" means the Meat and Poultry Inspection Division, WVDA.

4.2.j. "USDA Inspection Legend" and "Official Inspection Legend" mean WVDA Inspection Legend.

4.2.k. "Federally Inspected and Passed", "U.S. Inspected and Passed", "U.S. Inspected for Wholesomeness", and "Federally Inspected for Wholesomeness" mean WVDA Inspected and Passed.

4.2.l. "U.S. Passed for Cooking" means WVDA Passed for Cooking.

4.2.m. "U.S. Passed for Refrigeration" means WVDA Passed for Refrigeration.

4.2.n. "U.S. Inspected and Condemned" means WVDA Inspected and Condemned.

4.2.o. "U.S. Retained" or "U.S. Detained" means WVDA Retained.

4.2.p. "U.S. Rejected" means WVDA Rejected.

4.2.q. "U.S. Suspect" means WVDA Suspect.

4.2.r. "U.S. Condemned" means WVDA Condemned.

4.2.s. "U.S. Government Seals" means WVDA Seals.

4.3. Whenever an official form, certificate, or seal is designated by Federal regulations, the appropriate WVDA form, certificate, or seal shall be substituted.

§61-16-5. The United States Department of Agriculture's Guidelines and Procedures Applicable to the West Virginia Department of Agriculture.

The following publications prepared and approved by the United States Department of Agriculture are applicable to the West Virginia Department of Agriculture, as determined by the Commissioner of Agriculture:

5.1. "U.S. Inspected Meat and Poultry Packing Plants: A Guide to Construction and Layout", Agriculture Handbook 570;

5.2. "Standards and Labeling Policy Book"; and

5.3. Food Safety and Inspection Service's Directives, Notices, and Bulletins.

§61-16-6. Licensing.

6.1. Application for license and inspection. -- Every commercial slaughterer, custom slaughterer, commercial processor, custom processor, or distributor shall obtain a license from the Commissioner.

6.1.a. An applicant for a license shall make application on an official form furnished by the Commissioner and shall complete the application to include all information requested. Only the applicant named in the application may conduct operations at the establishment for which the license is granted.

6.1.b. The licensee shall apply for a new license when ownership or the location of the business changes.

6.2. Drawings and specification to be furnished.

6.2.a. Each applicant for the license shall submit to the Director, Meat and Poultry Inspection Division; WVDA;

6.2.a.1. Three (3) sets of complete drawings containing a plot plan showing the limits of the establishment's premises, locations in outline of buildings on the premises, cardinal points of the compass, and roads and railroads serving the establishment; the floor plans of the establishment for which inspection is requested, showing the locations of principal pieces of equipment, floor drains, principal drainage lines, handwashing basins and hose connections for cleanup purposes; and a room schedule showing the finish of walls, floors, and ceilings of all rooms in the establishments;

6.2.a.2. Three (3) sets of specifications which shall include statements, describing water supply, plumbing, drainage, refrigeration, equipment, lighting, and operations to be performed at the establishment; and

6.2.a.3. A current certificate from the local or state health authority certifying the water potability at the establishment and approval of the sewage disposal system of the establishment.

§61-16-7. Official Inspection Marks and Devices.

7.1. General. -- The inspection marks and devices, prescribed or referenced in this section are official marks and devices, for purposes of the W. Va. Code §19-2B-6 and shall be used in accordance

with the provisions of this section and the United States Department of Agriculture regulations governing meat and poultry inspection as incorporated in this rule.

7.2. The inspection marks shall be affixed by the establishment under the oversight of the inspectors of the Meat and Poultry Inspection Division, WVDA.

7.3. Inspection legends on animal carcasses and parts of carcasses.

7.3.a. The inspection legend to identify WV inspected and passed animal carcasses, primal cuts, beef livers, beef tongues, beef hearts, and smoked meats not in casings and for application to materials that enclose carcasses or parts of carcasses, is as shown in this subdivision. The establishment number shall be placed in the inspection legend by the establishment where the three zeros appear. The size of the inspection legend shall be 1-7/8"x2".



7.3.b. The inspection legend may be proportionally reduced in size, provided it shall not be smaller than 7/8"x1", for application to the loins and ribs of pork, beef tails, and sausages in animal casings.

7.4. Inspection legends on labels.

7.4.a. The inspection legend required to be shown on all labels for inspected and passed products of cattle, sheep, swine, goats, and poultry shall be in the form as shown in subdivision 7.3.a of this rule, except that it need not be of the size illustrated, provided that it is of a sufficient size and of such color as to be conspicuously displayed and readily legible and the same proportions of letter size and boldness are maintained. The establishment number shall be placed in the inspection legend where the three zeros appear, and it may be preceded by the abbreviation "EST."

7.4.b. The inspection legend shall be applied on labels by mechanical means and shall not be applied by a hand stamp.

7.4.c. The inspection legend described in subdivision 7.3.a of this section may also be used on shipping containers, band labels, artificial casings, and other articles with the approval of the Director, Meat and Poultry Inspection Division, WVDA.

7.5. Any brand, stamp, label, or other device approved by the Director, Meat and Poultry Inspection Division, WVDA, and bearing any inspection legend presented in this section is an official device for purposes of the W. Va. Code §19-2B-6.

7.6. Custom stamps and devices to identify custom slaughtered animals or custom prepared product.

7.6.a. An establishment licensed for custom slaughter, custom processing operations, or both shall identify all custom carcasses, carcass parts, and custom meats with:

7.6.a.1. A custom stamp as provided for in subdivision 7.6.b of this rule and a custom stamp with the words "NOT FOR SALE" in uppercase letters at least 3/8" in height applied to the animal carcass immediately after slaughter;

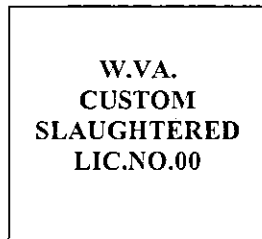
7.6.a.2. A custom stamp with the words "NOT FOR SALE" in uppercase letters at least 3/8" in height applied immediately upon receipt of a carcass or carcass parts which were slaughtered at a location other than the receiving licensed establishment;

7.6.a.3. A tag made from a material that is nontoxic and waterproof, that identifies the name of the owner or a number which identifies the owner of the meat, which must be placed on the carcass immediately after slaughter or on the carcass or carcass parts upon receipt. The tag may be omitted if the identification number is legibly applied directly on the meat or poultry by an approved marking pencil;

7.6.a.4. A stamp or legible printing or pressure sensitive tape with the words "NOT FOR SALE" in uppercase letters at least 3/8" in height on all custom wrapped or packaged meats or poultry immediately after final preparation. All custom meat or poultry must remain so identified while on the establishment's premises; and

7.6.a.5. A stamp, legible printing or pressure sensitive tape or tag attached with the words "NOT FOR SALE" in uppercase letters at least 3/8" in height on closed containers when utilized for packing unwrapped, wrapped, or packaged custom meats or poultry. All custom meat or poultry must remain so identified immediately after packing the containers and while on the establishment's premises.

7.6.b. The official custom stamp (brass faced) required to identify animal carcasses or parts of carcasses resulting from custom establishment slaughter is as shown in this subdivision. The size of the stamp shall be 2"X2" with uppercase letters 3/8" in height.



§61-16-8. Overtime and Holiday Inspection Service.

8.1. The management of a licensed establishment shall reimburse WVDA for the cost of inspection service furnished on any holiday as specified in subsection 8.3 of this Section, or for providing inspection services for more than eight (8) hours on any day or more than forty (40) hours in any administrative workweek, Saturday through Friday.

8.2. When a licensed establishment requires an inspection service on a holiday or for more than eight (8) hours on any other day, it shall request the veterinary supervisor to furnish inspection during that period. The request shall be made at least seven (7) days before the holiday and at least two (2) days in advance of planned overtime.

8.3. Holidays are those specified in W. Va. Code §2-2-1.

8.4. The Commissioner shall determine from time to time the rate for overtime and holiday services.

§61-16-9. Poultry Exemptions.

9.1. A poultry producer who otherwise meets the requirements of the exemption for poultry producers that slaughter or process 20,000 or fewer birds per calendar year under the federal Poultry Products Inspection Act, 21 U. S. C. 464 (c) (3), may not keep a poultry flock of more than 3,000 birds at any one time.

4:30 p.m., Monday through Friday (FSIS have verified the following Web site addresses, but FSIS is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Risk Assessment of the Public Health Impact from Foodborne *Listeria monocytogenes* in Some Ready-to-Eat Foods Sliced, Prepared, and/or Packaged in Retail Facilities; Request for Comments and for Scientific Data and Information. (74 FR 3617 (January 21, 2009)), Docket No. FDA-2008-N-0658, <http://www.fda.gov/OHRMS/DOCKETS/98fr/E9-938.pdf>.
2. Interagency Retail Listeria monocytogenes Risk Assessment: Notice of a Public Meeting. (74 FR 27276; June 9, 2009). Docket No. FSIS-2009-0012, <http://www.gpo.gov/fdsys/pkg/FR-2009-06-09/html/E9-13378.htm>.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_policies/Federal_Register_Notices/index.asp.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_Events/Email_Subscription/. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password-protect their accounts.

USDA Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information

(Braille, large print, or audiotape) should contact USDA's Target Center at (202) 720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Done at Washington, DC, on April 18, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-09508 Filed 4-22-13; 8:45 am]
BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2013-0013]

Retail Exemptions Adjusted Dollar Limitations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the dollar limitations on the amount of meat and meat food products, poultry, and poultry products that a retail store can sell to hotels, restaurants, and similar institutions without disqualifying itself for exemption from Federal inspection requirements. In accordance with FSIS's regulations, for calendar year 2013, the dollar limitation for meat and meat food products is being increased from \$67,300 to \$69,600 and for poultry products from \$51,700 to \$54,500. FSIS is changing the dollar limitations from calendar year 2012 based on price changes for these products evidenced by the Consumer Price Index.

DATES: *Effective Date:* This notice is effective April 23, 2013.

FOR FURTHER INFORMATION CONTACT: John O'Connell, Policy Issuances Division, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, Room 6083 South Building, 1400 Independence Avenue SW., Washington, DC 20250-3700; Telephone: (202) 720-0345.

SUPPLEMENTARY INFORMATION:

Background

The Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) provide a comprehensive statutory framework to ensure that meat,

meat food products, poultry, and poultry products prepared for commerce are wholesome, not adulterated, and properly labeled and packaged. Statutory provisions requiring inspection of the preparation or processing of meat, meat food, poultry, and poultry products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants when those operations are conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities (21 U.S.C. 661(c)(2) and 454(c)(2)). FSIS's regulations (9 CFR 303.1(d) and 381.10(d)) elaborate on the conditions under which requirements for inspection do not apply to retail operations involving the preparation of meat and meat food, and processing of poultry and poultry products.

Sales to Hotels, Restaurants, and Similar Institutions

Under these regulations, sales to hotels, restaurants, and similar institutions (other than household consumers) disqualify a store for exemption if the product sales exceed either of two maximum limits: 25 percent of the dollar value of total product sales or the calendar year dollar limitation set by the Administrator. The dollar limitation is adjusted automatically during the first quarter of the year if the Consumer Price Index (CPI), published by the Bureau of Labor Statistics, shows an increase or decrease of more than \$500 in the price of the same volume of product for the previous year. FSIS publishes a notice of the adjusted dollar limitations in the **Federal Register**. (See 9 CFR 303.1(d)(2)(iii)(b) and 381.10(d)(2)(iii)(b).)

The CPI for 2012 reveals an annual average price increase for meat and meat food products at 3.4 percent and for poultry products at 5.5 percent. When rounded to the nearest \$100, the dollar limitation for meat and meat food products increased by \$2,300 and the dollar limitation for poultry products increased by \$2,800. Because the dollar limitation of meat and meat food products and poultry products increased by more than \$500, FSIS is increasing the dollar limitation on sales to hotels, restaurants, and similar institutions to \$69,600 for meat and meat food products and to \$54,500 for poultry products for calendar year 2013, in accordance with 9 CFR 303.1(d)(2)(iii)(b) and 381.10(d)(2)(iii)(b).

USDA 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, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (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 TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_and_policies/Federal_Register_Notices/index.asp.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_and_Events/Email_Subscription/. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on April 18, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-09512 Filed 4-22-13; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE**Forest Service****Dixie Resource Advisory Committee**

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Dixie Resource Advisory Committee (RAC) will meet in Cedar City, Utah. The RAC is authorized under the Secure Rural Schools and Community Self-Determination Act of 2000, (the Act) (Public Law 110-343) and operates in compliance with the Federal Advisory Committee Act (FACA) (Public Law 92-463). The purpose of the RAC is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. The meeting is open to the public. The purpose of the meeting is to review proposals for forest projects and recommending funding.

DATES: The meeting will be held Thursday, May 9, 2013, at 1:00 p.m. (MDT)

ADDRESSES: The meeting will be held at the Dixie National Forest Supervisor's Office, 1789 North Wedgewood Lane, Cedar City, Utah 84721. Written comments may be submitted as described under Supplementary Information. All comments, including names and addresses when provided are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Dixie National Forest Headquarters Office, 1789 North Wedgewood Lane, Cedar City, Utah 84721. Please call ahead to Janice Minarik, RAC Coordinator by phone at (435) 865-3794 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Janice Minarik, RAC Coordinator, Dixie National Forests Headquarter at (435) 865-3794, or by email jminarik@fs.fed.us. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting agenda will focus on reviewing proposals for forest projects and recommending funding. Anyone who would like to bring related matters to the attention of the RAC may file written statements with the RAC staff before the meeting. Written comments and requests for time for oral comments

must be sent to Janice Minarik, RAC Coordinator, Dixie National Forests Headquarter by email to jminarik@fs.fed.us or via facsimile to (435) 865-3791.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility for proceedings by contacting the person listed under For Further Information Contact. All reasonable accommodation requests are managed on a case by case basis.

Dated: April 17, 2013.

Angelita S. Bulletts,

Forest Supervisor, Dixie National Forest.

[FR Doc. 2013-09493 Filed 4-22-13; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF COMMERCE**Census Bureau****Proposed Information Collection; Comment Request; Quarterly Summary of State and Local Government Tax Revenue**

AGENCY: U.S. Census Bureau.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration, written comments must be submitted on or before June 24, 2013.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the Internet at jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Cheryl Lee, Chief, State Finance and Tax Statistics Branch, Governments Division, U.S. Census Bureau, Headquarters: 6K041, Washington, DC, 20233; telephone: 301.763.5635; facsimile: 301.763.6833; email: cheryl.h.lee@census.gov

SUPPLEMENTARY INFORMATION:

in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Meredith C. Jones, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2289.

SUPPLEMENTARY INFORMATION:

Background

On January 30, 2013, we published in the *Federal Register* (78 FR 6222-6227, Docket No. APHIS-2012-0002), a proposal¹ to amend the fruits and vegetables regulations to allow the importation of avocados from continental Spain (excluding the Balearic Islands and Canary Islands) into the United States subject to a systems approach and treatment.

Comments on the proposed rule were required to be received on or before April 1, 2013. We are reopening the comment period on Docket No. APHIS-2012-0002 for an additional 15 days. This action will allow interested persons additional time to prepare and submit comments. We will also accept comments received between April 2, 2013 (the day after the close of the original comment period) and the date of this notice.

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

Done in Washington, DC, this 22nd day of May 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013-12679 Filed 5-28-13; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS-2011-0132]

RIN 0579-AD62

Importation of Fresh Apricots From Continental Spain

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would allow the importation into the United States of fresh apricots from continental Spain. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the proposed rule published January 30, 2013 (78 FR 6227) is reopened. We will consider all comments that we receive on or before June 13, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2011-0132-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2011-0132, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!documentDetail;D=APHIS-2011-0132> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Meredith C. Jones, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2289.

SUPPLEMENTARY INFORMATION: On January 30, 2013, we published in the *Federal Register* (78 FR 6227-6232, Docket No. APHIS-2011-0132) a

proposal¹ to amend the regulations concerning the importation of fruits and vegetables to allow the importation of fresh apricots from continental Spain into the United States subject to a systems approach jointly agreed upon in a bilateral workplan between APHIS and the national plant protection organization of Spain.

Comments on the proposed rule were required to be received on or before April 1, 2013. We are reopening the comment period on Docket No. APHIS-2011-0132 for an additional 15 days. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between April 2, 2013 (the day after the close of the original comment period) and the date of this notice.

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

Done in Washington, DC, this 22nd day of May 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013-12685 Filed 5-28-13; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR part 417

[Docket No. FSIS-2009-0019]

HACCP Systems Validation

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of updated guidance for Hazard Analysis Critical Control Point (HACCP) systems validation. In addition, FSIS is announcing that it will hold a public meeting on June 25, 2013, to review changes to the guidance announced in this notice and to take comments. The public meeting will also be available by teleconference.

Following the public meeting, the Agency will accept written comments until July 25, 2013. Given the extensive opportunity for comment on the guidance, however, the Agency believes

¹ To view the proposed rule, risk documents, and the comments we received, go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0002>.

¹ To view the proposed rule, risk documents, and the comments we received, go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2011-0132>.

that very few, if any, issues remain in this proceeding.

DATES: The public meeting will be held on June 25, 2013 from 8:30 a.m. to 12:30 p.m. On-site registration will begin at 8:00 a.m. Written comments may be submitted until July 25, 2013.

ADDRESSES: The public meeting will be held in the 1st Floor Auditorium of Patriots Plaza 3, 355 E Street SW., Washington, DC 20024.

FSIS will finalize the agenda by June 18, 2013 and post it on the FSIS Web page at: http://www.fsis.usda.gov/News_Events/meetings_events/index.asp.

Registration: Pre-registration is recommended. To pre-register, access the FSIS Web site at http://www.fsis.usda.gov/News_Events/meetings_events/index.asp. Call-in information will be provided via email to pre-registered participants. If you are interested in making a public comment during the teleconference, please indicate so on the registration form.

In addition to the public meeting, interested persons may submit comments using either of the following methods:

- **Federal eRulemaking Portal:** This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- **Mail, including CD-ROMs, etc.:** Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMS, Patriots Plaza 3, 1400 Independence Avenue SW., Mail Stop 3782, Room 8-163A, Washington, DC 20250-3700.

- **Hand- or Courier-Delivered Submittals:** Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20024.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2009-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: William K. Shaw, Jr., Ph.D., Office of Policy and Program Development, FSIS, USDA, 1400 Independence Avenue SW., Patriots Plaza 3, Mailstop 3782,

Room 8-142, Washington, DC 20250.
Telephone: (301) 504-0852 Fax:
(202)245-4792. E-Mail:
william.shaw@fsis.usda.gov.

Background

FSIS administers the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) to protect the health and welfare of consumers by preventing the distribution in commerce of meat or poultry products that are unwholesome, adulterated, or misbranded. To reduce the risk of foodborne illness from meat or poultry products, FSIS issued regulations on July 25, 1996, which require that federally inspected establishments adopt HACCP systems (61 FR 38806). These regulations require that federally inspected establishments adopt measures to prevent or control the occurrence of food safety hazards at each stage of the production process where such hazards are reasonably likely to occur.

In the May 9, 2012 *Federal Register* (77 FR 27135), FSIS issued a notice to clarify its requirements for validation by an establishment of its HACCP system and to announce the availability of the draft guidance on validation, which is discussed in more detail below. The HACCP regulations in 9 CFR part 417 require that establishments validate the HACCP plan's adequacy to control the food safety hazards identified by the hazard analysis (9 CFR 417.4(a)). These regulations prescribe requirements for the initial validation of an establishment's HACCP plan and require establishments to "conduct activities designed to determine that the HACCP plan is functioning as intended." During this initial validation period, establishments are to "repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions" prescribed in their HACCP plans (9 CFR 417.4(a)(1)). As FSIS explained in the May 9, 2012 *Federal Register*, validation under 9 CFR 417.4(a)(1) requires that establishments assemble two types of data: 1) the scientific or technical support for the judgments made in designing the HACCP system, and 2) evidence derived from the HACCP plan in operation to demonstrate that the establishment is able to implement the critical operational parameters necessary to achieve the results documented in the scientific or technical support.

The regulations also provide that "[v]alidation . . . encompasses reviews of the records themselves, routinely

generated by the HACCP system, in the context of other validation activities" (9 CFR 417.4(a)(1)). As FSIS explained in the May 9, 2012 *Federal Register*, if an establishment's supporting documentation for its hazard analysis includes records associated with a prerequisite program that provides for an intervention or process designed to prevent a hazard from being likely to occur, the establishment's validation records would need to include all documents associated with the prerequisite program. Thus, validation of the HACCP system involves validation of the critical control points in the HACCP plan, as well as of any interventions or processes used to support decisions in the hazard analysis.

Initial Draft Guidance

In March 2010, FSIS posted on its Web site an initial draft guidance document to assist the industry, particularly small and very small establishments, in complying with the requirements for HACCP systems, pursuant to 9 CFR 417.4.

On June 14, 2010, FSIS held a public meeting to discuss the initial draft HACCP validation guidance and received input from stakeholders. The transcript of the June 2010 public meeting is available on the FSIS Web site at: http://www.fsis.usda.gov/PDF/Transcripts_HACCP_Validation_061410.pdf.

FSIS received over 2,000 comments on the initial draft guidance, particularly with respect to the use of microbiological testing to validate the effectiveness of HACCP systems in controlling biological hazards. The Agency considered the issues raised by the comments received in response to the May 2010 *Federal Register* notice and at the June 2010 public meeting and developed updated second draft compliance guidance.

On September 22-23, 2011, FSIS shared a second draft of the HACCP validation guidance with the National Advisory Committee on Meat and Poultry Inspection (NACMPI). The Committee reviewed the draft and provided comments and suggestions to FSIS on how to improve the guidance. The NACMPI report is available on the FSIS Web site at: http://www.fsis.usda.gov/PDF/Validation_Issue_Paper_Final.pdf. The Agency made additional revisions to the draft guidance in response to the input from NACMPI.

In a May 9, 2012 *Federal Register* notice, FSIS announced the availability of, and requested comments on, the revised draft guidance document

(<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2009-0019.htm>). In the May 2012 Federal Register notice, the Agency also clarified its requirements for HACCP system validation and responded to the comments that it had received on the initial draft guidance. The May 2012 Federal Register notice explained that the Agency was soliciting comments on the revised draft, and that it would hold another public meeting before issuing final guidance for HACCP systems validation (77 FR 27135).

Comments on the Guidance

FSIS received fifty-one (51) comments on its May 2012 revised draft guidance on HACCP validation from small and very small meat or poultry processors, trade associations representing animal producers, small business owners, corporations, State Departments of Agriculture, and consumer advocacy organizations. FSIS has carefully considered the comments and has revised its draft guidance in light of these comments. The following is a brief summary and discussion of the major issues raised in the comments to the draft guidance document.

1. Concerns About Validation, Its Applicability, and Cost

Comment: Several commenters asked why the validation guidance or new FSIS enforcement of validation requirements is necessary, especially given the amount of time the HACCP regulations have been in place. These commenters stated that establishments should not have to "revalidate" their systems.

Response: The validation guidance is necessary because the Agency found that establishments have not adequately validated their systems. During the process of developing the draft guidance, FSIS added an appendix to the document that explains the need for validation and FSIS's experiences that led it to create the guidance document (e.g., FSIS's findings following a 2011 Lebanon bologna outbreak that the establishment's scientific support on file did not match the process the establishment was using to make the bologna; non-O157 positives in 2012 that FSIS concluded likely occurred because of improperly designed interventions; and the chicken pot pie outbreaks in 2007 that FSIS concluded may have occurred because of improperly validated cooking instructions).

Based on findings from FSIS's data analyses and outbreak investigations, the Agency recommends that establishments use the guidance document to ensure that their HACCP

systems are properly validated. On an annual basis, and whenever changes occur that affect the hazard analysis of the HACCP plan, the establishment should conduct a reassessment as required in 9 CFR 417.4(a)(3) (i.e., review records generated over the course of the previous year, or during the period the change occurred, that reflect how the HACCP system is performing as a whole and analyze them to determine whether food safety goals are being met).

If the reassessment shows that the HACCP system is effective and functioning as intended, the establishment can consider continuing on with the same system and the same monitoring and verification procedures and frequencies. If reassessment shows that either their HACCP system was not set up correctly, is not being implemented consistently, or is no longer effective, the establishment would make changes to its HACCP system (e.g., add another intervention) and then would, in most cases, be required to validate any changes to its HACCP system.

While most establishments have assembled the scientific or technical documentation needed to support their HACCP systems, many establishments have not gathered the necessary in-plant validation data demonstrating that their HACCP systems are functioning as intended, which is why the guidance document is necessary. As is explained below, in approximately six months from the time that FSIS issues the final validation guidance, FSIS intends to begin verifying that establishments comply with all validation requirements.

Comment: Several commenters expressed concern about the cost of validation, particularly for small establishments that have many different HACCP plans. One comment stated that if a very small establishment cannot afford to comply with validation requirements, it should have the option to return to "conventional" inspection instead of HACCP. Commenters were also concerned about the costs of obtaining in-plant microbial data and other costs associated with validation.

Response: HACCP was implemented in 1996 and has resulted in great improvements in food safety. The Agency is not going back to a command and control inspection approach because it would not provide establishments with the flexibility to design innovative systems that ensure food safety.

In the guidance, FSIS states that microbiological testing is needed for in-plant data in only limited circumstances

and has provided low cost ways in which establishments can validate their systems in place of microbiological testing, such as ensuring that they are meeting the critical operating parameters of the interventions as defined in the scientific support. Therefore, FSIS estimates that costs associated with meeting validation requirements will be minimal.

Comment: Several commenters stated that establishments should not have to validate their prerequisite programs because 9 CFR 417.4(a)(1) does not apply to prerequisite programs. One commenter recommended that, in the absence of a CCP, prerequisite programs referenced in the flow chart should be validated, but that otherwise, establishments should not be required to validate their prerequisite programs. The same commenter also requested that FSIS begin only reviewing validation for CCPs and then, at a later date, begin reviewing validation for prerequisite programs referenced in the flow chart. One commenter stated that only prerequisite programs that contain scientifically supported critical operating parameters (e.g., foreign material control, Good Manufacturing Practices, employee hygiene) should have to be validated. Several commenters stated that they needed guidance concerning how to validate pest control, employee hygiene, sanitation practices, and other processes.

Response: Validation is the process of demonstrating that the HACCP system, as designed, can adequately control identified hazards to produce a safe, unadulterated product. Prerequisite programs designed to support a decision in the hazard analysis are part of the HACCP system. When an establishment determines that a hazard is not reasonably likely to occur because the prerequisite program prevents the hazard, that prerequisite program becomes part of the HACCP system. Therefore, prerequisite programs designed to support decisions in the hazard analysis (e.g. Sanitation Standard Operating Procedures (Sanitation SOPs), purchase specifications, antimicrobial interventions) need to be validated to ensure that the overall system can operate effectively. Even though 9 CFR 417.4(a)(1) does not refer to Sanitation SOPs or other prerequisite programs, establishments' initial validation activities need to include employee hygiene and other similar prerequisite programs if they are used to support decisions in the hazard analysis. As explained in the guidance, in order to validate such programs, establishments

need to provide scientific documentation that supports that they will work as intended and to collect in-plant data to support that the programs can be implemented as designed.

Comment: Some commenters stated that establishments should not be required to validate cooking instructions because the cooking is performed by the consumer. One comment stated that discussion of validating the time and temperature combinations for cooking instructions should be removed from the guidance. Another commenter requested more guidance on how establishments should validate cooking instructions. Another commenter asked for confirmation that validated cooking instructions are not considered a CCP.

Response: An establishment must validate all measures that it relies upon to prevent or control the hazards that it has identified in its HACCP system, whether the measures are part of the HACCP plan itself or part of a program that includes measures that affect the hazard analysis. Thus, if an establishment's HACCP system includes cooking instructions as a measure to address a potential food safety hazard after entry into the establishment, the establishment must properly validate the instructions.

As we saw in the 2007 salmonellosis outbreak associated with chicken pot pies, providing cooking instructions on a package that cannot be repeated by the consumer represents an increased risk to the consumer. Had the establishment validated the cooking instructions on the pot pies to ensure they would achieve the desired endpoint temperature under actual consumer cooking conditions, these illnesses may have been prevented (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5747a3.htm>).

If an establishment's HACCP system includes placing cooking instructions on the product's label, the instructions must be validated to ensure that consumers who follow the instructions will achieve the endpoint time/temperature needed to ensure that the product is cooked and safe to consume. While validated cooking instructions may be used as a control to address hazards that may occur after the product has left the establishment, the establishment is still required to address food safety hazards that are reasonably likely to occur in the production process and identify the measures the establishment can apply to control those hazards (9 CFR 417.2(a)(1)). <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5747a3.htm>.

FSIS is in the process of developing a guidance document on validating

cooking instructions for mechanically tenderized beef product. FSIS has previously recommended validated cooking instructions for product that appears to be ready-to-eat, but its meat or poultry components have not received a sufficient lethality step or some other component has not received a lethality step. http://www.fsis.usda.gov/OPPDE/rdad/FSIS-Directives/10240.4/Resource_1.pdf Resource 1 for NRTE products that appear to be RTE (e.g., entrees, dinners, casseroles etc) http://www.fsis.usda.gov/PDF/Info_on_Validation_of_Labeled_Cooking_Instructions_Raw_or_Partially_Cooked_Poultry.pdf (validated cooking instructions) http://www.fsis.usda.gov/PDF/Labeling_Policy_Guidance_Uncooked_Breaded_Boneless_Poultry_Products.pdf (this link includes the background information and Q&As)

Comment: Several comments stated that establishments should not be required to collect in-plant data for more than one product in a HACCP process category. These commenters also requested guidance on how to select a product from within each HACCP category. Commenters noted that such in-plant data would include execution data for all CCPs, interventions, and prerequisite programs used to support decisions in the hazard analysis. One commenter questioned whether the establishment would need to validate the food safety system for each product if the only difference among products is a seasoning. Another commenter stated that it is possible to have in-plant data for product of one species within a HACCP category serve as in-plant data to validate the process for product from another species if there are no additional food safety concerns. Another commenter stated that FSIS's guidance should follow the NACMPI recommendations to group typical products into categories and select "worst case products" within the group.

Response: In the revised guidance, FSIS has clarified that establishments are not required to collect in-plant data for more than one product within a HACCP process category. The guidance now provides information concerning how establishments should select a product from within a HACCP category. The guidance also provides information on how establishments can develop a decision-making document concerning product choices for collecting in-plant data. The guidance provides examples of how to collect in-plant data to aid industry, but establishments will have the flexibility to develop their own criteria.

Comment: A few commenters requested confirmation that establishments would not have to conduct "initial" validation for all changes that result from reassessment. Several commenters asked whether the whole system would need to be validated or just a change following reassessment. One commenter stated that improved implementation of a HACCP system would not necessarily result in changes to the design of the system.

Response: Establishments do not need to conduct validation of the whole system for all changes that result from reassessment. Depending on the change, the establishment will likely only need to validate that the change is functioning as intended. For example, an establishment may change the thickness of a raw patty product and determine that it only needs to validate that the cooking instructions still achieve the desired endpoint temperature at the new product thickness. In this example, the establishment would not need to validate the entire HACCP system.

Comment: Several commenters stated that very small establishments that produce products infrequently cannot obtain 13 production days worth of records within 90 calendar days. One commenter suggested extending the validation period beyond 90 calendar days in order to obtain 13 days worth of records. Another commenter requested that the guidance document clarify that large establishments have the flexibility to determine whether there are a sufficient number of production days within the 90 calendar-day period to gather appropriate data.

Response: The guidance explains that for large establishments, 90 calendar days equates to approximately 60 production days. FSIS recognizes that many small and very small establishments do not operate daily. Therefore, the guidance also states that a minimum level of records from 13 production days within those initial 90 calendar days should be used to initially validate a small or very small establishment's HACCP system. The establishment should consider focusing validation activities on the product produced most frequently within each HACCP category.

In the guidance, FSIS recognizes that there are some establishments that produce products so infrequently that they would not be able to gather records from 13 production days within those 90 initial calendar days. If the establishment infrequently produces several products that are each part of a separate HACCP category, there is

inherent risk with the processes if the establishment does not have experience in producing them. Therefore, to determine whether the system is properly designed and executed, even though the regulations provide 90 days for a conditional grant of inspection (9 CFR 304.3(b)), an establishment needing more than 90 days can ask the District Office, in writing, for additional time to collect at least 13 production days of records. The guidance explains that establishments may also consider evaluating data collected for products across multiple HACCP categories that share some common steps, ingredients, or equipment, to determine whether the data together can support its ability to meet critical operational parameters.

Scientific Support

Comment: Appendix A of the final rule, "Performance Standards for the Production of Certain Meat and Poultry Products" (64 FR 746–748) is specific to *Salmonella* but is often used to support lethality of other pathogens, such as *E. coli* O157:H7 and *Lm*. Therefore, several commenters asked whether establishments could use Appendix A as scientific support for process controls for pathogens other than *Salmonella*.

Response: FSIS has revised the validation guidance to clarify that during slaughter, in order to be most effective, it is very important that interventions have been studied for the pathogen and product pair of interest. In addition, FSIS has clarified that for thermal processing treatments, *Salmonella* can be used as an indicator for other pathogens of concern. Therefore, Appendix A can be used as scientific justification for the process without further support that the results apply to other pathogens such as *E. coli* O157:H7 or *Lm*.

Comment: Some commenters questioned whether their scientific support must be peer-reviewed. One commenter asked whether a processing authority could be an establishment owner with knowledge of the process. The commenter also asked if it could use documents that only provide a critical limit as scientific support (for example, a University publication or a textbook with growth limits of bacteria).

Response: FSIS has revised the guidance to clarify that the Agency recommends peer-reviewed scientific data to support the process used, but does not require peer-reviewed data. An establishment may use peer-reviewed scientific data or information in addition to a scientific article from a peer-reviewed journal as scientific support for its processes. Such information would include data from a

textbook on the growth limits of certain pathogens, based on a food product's water activity and pH. This information could be used as scientific support because information in scientific textbooks has generally been peer-reviewed. Peer-reviewed scientific data goes through a process of evaluation involving qualified individuals within the relevant field that ensures the integrity of the data.

Scientific data that is not peer-reviewed is less reliable than peer-reviewed data, because there could be flaws in the science that a peer review would have revealed. If an establishment uses scientific data that is not peer-reviewed, the establishment may be subject to additional scrutiny by Agency personnel performing verification activities.

An establishment may rely on a process authority to provide necessary scientific support for the establishment's process. As stated above, to meet validation requirements, the establishment is required to ensure that the scientific data and documentation provided by the processing authority supports that the process addresses the identified hazards, and meets the expectations for validation requirements.

Comment: Several commenters stated that the guidance document is still too vague in terms of how close the scientific support needs to match an actual process. For example, commenters asked whether the manufacturer of a grinder would have to be the same as the grinder used in a supporting study. Commenters also asked how significant casing size differences among the process used and support studies would need to be before the support document would no longer apply. Commenters stated that parameters are often more controlled during research than in-plant, and that it is costly for establishments to measure temperature and pounds per square inch.

Response: In the guidance, FSIS has clarified how scientific support should match an actual process. Generally, establishments should use the same critical operational parameters as those in the support documents. In some circumstances, establishments may be able to support using critical operational parameters that are different from those in the support documents (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the support documents. This

justification is needed because higher levels of a critical operational parameter may not always be equally effective. For example, antimicrobial agents may only be effective within a range of concentration after which point efficacy may decrease. Similarly, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. Establishments also need to ensure the levels are safe and suitable (<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1.pdf> and 9 CFR 424.21(c)).

Comment: Several commenters stated that FSIS Notice 36–12 (<http://www.fsis.usda.gov/oppde/rdad/FSISNotices/36-12.pdf>) suggested that the challenge study establishments used in the case of the Lebanon bologna would not be adequate support because the critical operational parameters in the study did not match those used in the establishment.

Response: The FSIS notice on Lebanon bologna explained that the actual process that the establishment used did not match the scientific support. As a result, the establishment's process did not achieve adequate lethality. Establishments producing Lebanon bologna can use the guidance as scientific support; however, they need to ensure that their process meets the critical operating parameters used in the study.

FSIS recognizes that scientific support performed in a laboratory may not always match an establishment's exact parameters. However, significant differences, such as the permeability of the casing used or the diameter of the product, are key factors that affect lethality and therefore cannot be overlooked. For instance, if an establishment wants to use a permeable casing, the establishment cannot assume that its process will achieve the same reduction in pathogens as achieved in a study using an impermeable casing.

Comment: Some comments stated that discussion of critical operational parameters in the guidance will lead some to conclude that all parameters are critical. Several commenters requested that FSIS create a third party or consortium to help establishments identify scientific support and critical operational parameters. Another commenter requested that FSIS's guidance address validation and scientific support for additional hazards, such as viruses and protozoa.

Several commenters stated that establishments do not have the expertise to scientifically support or identify critical operational parameters. One commenter stated that establishments

do not know how to test parameters of the different processes.

Response: Critical operational parameters are the specific conditions that the intervention must operate under in order for it to be effective. The guidance document explains in detail how an establishment can identify the critical operational parameters in its scientific support. Specifically, Appendix 3, provides step-by-step guidance to establishments.

FSIS will continue to post commonly cited journal articles on its Web site in which critical operational parameters have been identified and will offer support through askFSIS to establishments trying to identify critical operational parameters.

Comment: One commenter requested that reference to Purac's modeling program be made within the guidance, and that the guidance address the use of pathogen modeling programs as scientific supporting documentation. The commenter also requested an additional example in the guidance to show how an establishment could validate the effectiveness of an antimicrobial agent through pathogen modeling.

Response: FSIS has added a reference to pathogen modeling as a type of scientific support. In addition, FSIS has added an example in Appendix 3 to show how an establishment can validate its stabilization process through pathogen modeling. FSIS does not advocate certain programs and therefore did not cite Purac in the guidance.

Comment: One commenter requested a listing of surrogate or indicator organisms that can be used for validation. Another commenter requested clarification on when establishments can use scientific support based on indicator organisms.

Response: As explained in the guidance document, establishments should not rely on scientific support containing data from indicator or surrogate organisms unless available data establishes a relationship between the presence or level of a pathogen or toxin and the indicator organism. Such data can be collected from in-laboratory studies using indicator organisms that parallel the data in a challenge study performed with the inoculated pathogen. This data could be collected in the same way in which the pathogen is being tested or in another study performed under similar conditions. If similar and consistent reduction or control can be established, then control of the indicator organisms can be reliably used to indicate expected pathogen control in actual application in-plant.

2. Validation Worksheet Examples

Comment: One commenter stated that FSIS should include an explanation of how the validation worksheet examples can be used. Another commenter recommended that the guidance state that establishments have flexibility to utilize approaches other than those in the worksheet examples. Two commenters recommended that FSIS recognize in the guidance that not all critical operational parameters identified in the Appendix will apply to all processes.

Another commenter requested more detail be provided in the worksheet examples in terms of formatting and the types of data that establishments should collect.

One comment stated that establishments' environmental monitoring verifies that the Sanitation SOPs are working as intended, but does not validate them.

Response: In the guidance document, FSIS has added numerous validation worksheet examples to illustrate how an establishment may want to display its own in-plant validation data. As FSIS explains in the guidance, the validation worksheet examples are for illustration purposes only and are included to help establishments to understand the types of scientific support and in-plant documentation that are needed to comply with the validation requirements.

With regard to the comment on the Sanitation SOP monitoring, FSIS included this data in the guidance as an example of data collected during the initial 90 days of the set-up of a new program. Scientific support is needed to support the frequency of testing (which would address the factors used to determine the frequency). In-plant validation data is needed to support that the testing is adequate.

3. Microbiological Testing

Comment: One comment asked for clarification as to whether samples need to be collected for each and every process, product, or species, and whether establishments would need to collect 13 samples for every product produced, as in the regulations that require establishments to conduct testing for generic *E. coli* (9 CFR 310.25 and 381.94)

Response: If an establishment's scientific support contains microbiological data showing the efficacy of the intervention against the identified food safety hazard, then the in-plant data does not need to include sampling. In that case, the in-plant data should support that the establishment

follows the critical operational parameters from the study.

Agency Training and Implementation

Comment: Commenters stated that FSIS should ensure that inspection program personnel consistently verify and enforce validation requirements. One commenter stated that FSIS should share training for FSIS personnel with industry.

A commenter also recommended that FSIS hold regional sessions to communicate the policy to establishments, and that the Agency engage cooperative extension programs in its communication strategy. One commenter recommended that the Agency create a tutorial on understanding scientific articles and on identifying critical operational parameters. Commenters also requested that FSIS issue a notice or directive explaining how inspectors should use the validation guideline.

A few commenters requested that FSIS phase-in verification of validation requirements based on risk or product categories, rather than establishment size. One commenter requested an additional six months to gather validation documents before FSIS begins new verification activities related to validation.

Response: The guidance is meant for establishments. FSIS will ensure inspection program personnel understand validation requirements and will issue necessary instructions to field personnel so that they are aware of the final guidance and share it with establishments. FSIS will also issue necessary instructions to field personnel for them to verify that establishments meet all validation requirements.

FSIS will implement its new verification activities by phasing them in based on establishment size. For large establishments, the agency plans to wait approximately six months from the date that the final guidance is issued to start verifying and enforcing the second element of validation (initial in-plant validation). Thus, large establishments will have six months from the date that the final guidance is issued to gather all necessary in-plant demonstration documents.

FSIS intends to begin verifying that small and very small establishments meet all validation requirements nine months from the date the final guidance is issued. Therefore, these establishments will have approximately nine months from the date the final guidance is issued to gather all necessary in-plant demonstration documents before FSIS will verify and

enforce the second element of validation.

Other Changes to Validation Guidance

Examples: The guidance contains additional examples of food safety problems linked to inadequate validation and recommendations to aid establishments in meeting initial validation requirements. These examples demonstrate the need for validation and provide support for recommendations made within the guidance.

Scientific Support Documents. FSIS has added a section to the guidance that explains to establishments how to determine whether scientific support documents are sufficiently related to the process, product, and hazard identified in the hazard analysis to constitute appropriate validation. The guidance explains that the supporting documentation should identify the hazard (biological, physical, and chemical), the expected level of hazard reduction or prevention to be achieved, all critical operational parameters or conditions necessary to address the hazard, the processing steps that will achieve the specified reduction or prevention, and how these processing steps can be monitored. FSIS has also included information on how establishments can identify supporting documentation that adequately addresses the expected level of hazard or reduction or prevention to be achieved. FSIS provided examples for biological, physical, and chemical hazards that should aid establishments in ensuring that the scientific support closely matches the hazard being controlled. FSIS has also clarified when establishments may use scientific support containing data from indicator or surrogate organisms.

Critical Operational Parameters. The guidance continues to state that critical operational parameters are those necessary for interventions to be effective and explains how an establishment can identify the critical operational parameters in its scientific support. As discussed above in response to comments, establishments generally should use the same critical operational parameters as those in the support documents. However, in some circumstances, establishments may be able to support using critical operational parameters that are different from those in the support documents (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels

chosen are at least as effective as those in the support documents.

FSIS has added an additional Appendix (Appendix 2) to provide an example of a decision-making document an establishment could develop when it uses different levels of a critical operational parameter than the parameters in the support document. An establishment may use the decision-making document to explain the scientific rationale for why it is using critical operational parameters that are different from those in the support documents.

In-plant data. The guidance recommends that establishments collect in-plant validation data for a wide variety of products and worst case scenarios. Appendix 4 of the guidance contains validation worksheet examples that establishments may reference to help them understand the types of scientific support and in-plant documentation that are needed to comply with the validation requirements.

Initial validation vs. on-going verification. The guidance explains the differences between initial validation and on-going verification and the relationship between the activities performed to provide initial validation as opposed to on-going verification. The revised guidance also clarifies when changes that result from reassessment would not require validation. For example, an establishment may need to reassess its HACCP system following a change in supplier of a raw material, but the change would not require validation if the establishment determines that the composition of the raw material and microbiological profile are not significantly different from the material provided by the previous supplier. In other cases, changes that result from the reassessment would not require additional scientific support but would require additional in-plant demonstration data. For example, an establishment may find through reassessment that the design of an intervention was adequate, but that its employees are not implementing the intervention correctly. In that case, the establishment would only need to collect in-plant data to demonstrate that the intervention could be implemented appropriately. Depending on the change, the establishment would likely only need to validate that the change is functioning as intended and not the entire HACCP system. The current draft of the compliance guide is available for public viewing in the FSIS docket room and on the FSIS Web site at http://www.fsis.usda.gov/Significant_Guidance/index.asp.

Public Meeting

On June 25, 2013, the Agency will hold a public meeting to review the information presented in this document and accept comments.

Next Steps

Following the public meeting, the Agency will accept public comment for 30 days. Given the extensive opportunity for public comment on the compliance guide, it is likely that there are very few, if any, remaining issues. Therefore, FSIS does not foresee granting an extension to this final 30 day comment period. As soon as possible after the comment period ends, the Agency will issue a **Federal Register** notice announcing the final guidance and will post the final guidance to its Web page. FSIS will implement its new verification activities phased in by establishment size. As stated above, for large establishments, the Agency plans to delay verification of the second element of validation as part of its inspection activities for approximately six months from the date the final guidance is posted. For small and very small establishments, the Agency plans to delay implementation for approximately nine months from the date the final guidance is posted.

Until FSIS begins enforcing all validation requirements, FSIS inspection personnel will continue to issue noncompliance records (NRs) if an establishment lacks the required scientific or technical support for its HACCP system, or if the scientific or technical support is inadequate. FSIS will continue to issue a Notice of Intended Enforcement if, taken together with other relevant findings, an establishment's scientific or technical support is inadequate, and the Agency can support a determination that the establishment's HACCP system is inadequate for any of the reasons provided in 9 CFR 417.6.

Moreover, if, in conducting a Food Safety Assessment (FSA), an Enforcement, Investigations, and Analysis Officer (EIAO) finds that an establishment has not collected in-plant data to demonstrate that its HACCP process works as intended, the EIAO will note this finding in the FSA and inform the establishment. Until FSIS begins enforcing the in-plant data requirements, FSIS will not issue NRs or take enforcement actions based solely on a finding that an establishment lacks in-plant validation data.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at

http://www.fsis.usda.gov/regulations_policies/Federal_Register_Notices/index.asp.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_Events/Email_Subscription/. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, or audiotape.) should contact USDA's Target Center at (202) 720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Done at Washington, DC on May 23, 2013.
Alfred V. Almanza,
Administrator.

[FR Doc. 2013-12763 Filed 5-24-13; 8:45 am]

BILLING CODE 3410-DM-P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 703, 715, and 741

RIN 3133-AD90

Derivatives

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed Rule.

SUMMARY: This proposed rule permits credit unions to engage in limited derivatives activities for the purpose of mitigating interest rate risk. This proposed rule applies to federal credit unions and any federally insured, state-chartered credit unions that are permitted under applicable state law to engage in derivatives transactions. It requires any credit union seeking derivatives authority to submit an application for one of two levels of authority. Level I and Level II authority differ on the permissible levels of transactions as well as the application, expertise, and systems requirements associated with operating a derivatives program.

DATES: Comments must be received on or before July 29, 2013.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- **NCUA Web Site:** http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html. Follow the instructions for submitting comments.

- **E-Mail:** Address to regcomments@ncua.gov. Include "[Your name]—Comments on Proposed Rule—Derivatives" in the email subject line.

- **Fax:** (703) 518-6319. Use the subject line described above for email.

- **Mail:** Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314-3428.

- **Hand Delivery/Courier:** Same as mail address.

FOR FURTHER INFORMATION CONTACT:

Justin M. Anderson or Lisa Henderson, Staff Attorneys, Office of General Counsel, at the above address or telephone (703) 518-6540; J. Owen Cole, Director, Division of Capital and Credit Markets, or Rick Mayfield, Senior Capital Markets Specialist, Office of Examination and Insurance, at the above address or telephone (703) 518-6360; or Dr. John Worth, Chief Economist, Office

of the Chief Economist, at the above address or telephone (703) 518-6660.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

The NCUA Board (Board) is proposing to allow credit unions to engage in limited derivatives transactions¹ for the purpose of mitigating interest rate risk (IRR). This proposed authority does not, however, allow credit unions to offer derivatives. This proposed rule applies to all federal credit unions (FCUs) and all federally insured state-chartered credit unions (FISCU) that are expressly permitted by applicable state law to engage in derivatives transactions. The Board believes this proposed rule allows eligible credit unions to utilize an additional tool to mitigate IRR, while also reducing risk to the National Credit Union Share Insurance Fund (NCUSIF).

The rule requires eligible credit unions to apply to NCUA or, in the case of a FISCU, NCUA and the applicable state supervisory authority (SSA), for either Level I or Level II derivatives authority. As discussed in greater detail below, Level I and Level II authority differ on the permissible levels of transactions as well as the application, expertise, and systems requirements.

B. The Act and NCUA's Regulations

The Federal Credit Union Act (Act) provides FCUs with the authority to invest in certain securities, obligations, and accounts.² For safety and soundness reasons, however, NCUA has adopted regulatory restrictions on certain investments and activities permitted by the Act.³ Currently, derivatives are among the investments specifically prohibited by NCUA.⁴

¹ A derivative is an instrument whose price is dependent on or derived from one or more underlying assets. A derivatives transaction involves a contract between two parties, called counterparties, that exchange value based on the fluctuation of the underlying asset or index. A counterparty is the other party to the derivatives transaction and can include swap dealers and major swap participants, which are terms to identify entities that operate primarily in the derivatives market. These transactions may involve collateral and a collateral custodian, which is an entity that holds the collateral for the two contracting parties.

² 12 U.S.C. 1757(7) and (15).

³ 12 CFR 703.16.

⁴ *Id.* at 703.16(a). Section 703.16(a), however, provides three exceptions to the general prohibition on derivatives. First, an FCU may purchase or sell any derivatives permitted under § 703.14(g) or under § 701.21(i) of NCUA's lending regulations. Second, an FCU may purchase or sell an embedded option not required under generally accepted accounting principles (GAAP) to be accounted for separately from the host contract. Third, an FCU may enter into interest rate lock commitments or

Continued

collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent both to FSIS, at the addresses provided above, and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

USDA 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, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (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 TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_policies/Federal_Register_Notices/index.asp.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In

addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_Events/Email_Subscription/. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on: May 20, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-12661 Filed 5-28-13; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2012-0041]

Availability of Compliance Guide for Residue Prevention and Response to Comments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of the final revision of the compliance guide for the prevention of violative residues in livestock slaughter establishments. In addition, this notice summarizes and responds to comments received on the guide and residue testing issues that FSIS raised previously in the **Federal Register**.

ADDRESSES: A downloadable version of the revised compliance guide is available to view and print at http://www.fsis.usda.gov/PDF/Residue_Prevention_Comp_Guide.pdf. No hard copies of the compliance guide have been published.

FOR FURTHER INFORMATION CONTACT:

Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, at Telephone: (202) 205-0495, or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION:

I. Background

On April 25, 2012, FSIS announced the availability of a compliance guide for residue prevention (77 FR 24671) and requested comment on the guide. FSIS explained that the guide emphasizes that establishments, especially those that slaughter dairy cows and bob veal calves, should apply five basic measures to reduce or prevent

the occurrence of violative residues. The guide recommends that establishments should: (1) Confirm producer history; (2) buy animals from producers who have a history of providing residue-free animals and have effective residue prevention programs; (3) ensure that animals are adequately identified to enable traceback; (4) supply information to FSIS at ante-mortem inspection showing that animals in the lot did not come from repeat violators; and (5) notify producers in writing if their animals are found to have violative residues. Similarly, the guidance recommends that establishments notify producers in writing if their animals are found to have residues that are detectable but that do not exceed the tolerance or action levels established by the Food and Drug Administration (FDA) and the Environmental Protection Agency.

FSIS also explained that the compliance guide discusses the Agency's Residue Repeat Violator List. In addition, FSIS explained recent changes to the list, including that the list now includes only producers who have provided more than one animal with a violative residue during the past 12 months, and asked for comment on recent revisions to the list.

FSIS also announced that it recently increased testing for residues of carcasses in establishments with violations associated with the same producer or at establishments that fail to apply the residue control measures described in the compliance guide. Finally, FSIS also announced it intended to increase testing for residues in animals from producers who are under an injunction obtained by the FDA because of drug use practices that have led to residue violations.

In response to the comments it received, FSIS has updated the guidance document by substituting "residue free" and "drug free" with the phrase "free from violative residues." In addition, FSIS has included a discussion of means of livestock identification other than those discussed in the initial guidance that should be considered by livestock slaughter establishments when back tags are lost or prove ineffective in maintaining the identity of the animals.

The guide includes recommendations rather than regulatory requirements. FSIS encourages livestock slaughter establishments to follow this final guide.

As for increased testing of animals from producers under an injunction obtained by FDA, FSIS and FDA continue to discuss how this testing can best be done. FSIS did not receive any comments on this issue. FSIS advises

that it does intend to implement this increased testing.

FSIS also did not receive any comments on recent increases in testing of carcasses for residues.

II. Comments and Responses

FSIS received a total of 12 comment letters in response to the April 2012 notice from professional veterinary associations, national trade organizations, private citizens, and an animal welfare advocacy organization. Following is a summary of the comments and FSIS's responses.

Comment: Several comments stated that only a small percentage of livestock receiving a back tag at the livestock market or sale barn actually retain those tags all the way to slaughter. One comment estimated that 80 percent of back tags placed on swine fall off before the animals are presented for slaughter. Several comments conjectured that if processors refuse to purchase animals without identification as recommended by FSIS, owners of animals that unwittingly lose their back tags while in transit or holding pens will be denied market access. As an alternative to back tags, two comments requested that FSIS mandate the use of permanent ear identification tags in swine.

Response: FSIS acknowledges that incidental loss of back tags does occur while livestock are in transport and holding areas. However, FSIS believes, in some cases, back tags prove to be an acceptable form of identification. If back tags do not work in certain situations, FSIS recommends that establishments use other means of identification, like producer ear tags, feedlot identification tags, tattoos, and calf-hood tags ("bangs"). FSIS has modified the guide to address animal identification options for establishments to consider when incidental loss of back tags occurs.

FSIS has limited authority to mandate the use of specific identification devices, permanent or otherwise, on livestock presented for slaughter. Therefore, FSIS does not intend to propose changes to its regulations to require specific identification devices at this time.

Comment: Several comments opposed FSIS's recommendation that slaughter establishments notify animal producers if their animals are found to have non-violative levels of a drug residue because the information will likely confuse producers.

Response: On November 28, 2000, FSIS informed establishments that if their HACCP plans included residue controls that incorporate the best available preventive practices for slaughter establishments, if they

implement those controls effectively, and if they supply FSIS with information about violators, then the Agency will not treat violative residue findings by the establishment that are followed by appropriate corrective actions as noncompliance (65 FR 70809). The *Federal Register* notice went on to recommend that slaughter establishments notify animal producers in writing of both violative and non-violative residue findings as one of several "best preventive practices." As reaffirmed in the compliance guide, FSIS believes that such an approach will result in a decrease in violative residue findings because evidence of non-violative residues is an indication of lack of care in drug use by that producer.

Comment: Several comments requested that FSIS resume publishing the Residue Violator List in addition to the revised Residue Repeat Violator List. According to the comments, information contained within the discontinued Residue Violator List was used by certain trade organizations to target outreach on residue avoidance to reduce the probability that a repeat violation would occur.

Response: In 2011, to avoid confusion, FSIS stopped publishing the monthly Residue Violator (Alert) List that included the names of any producer, including first-time offenders, with a residue violation in the previous 12 months. FSIS replaced that list with the Residue Repeat Violator List. Published weekly, the Residue Repeat Violator List identifies producers who repeatedly (i.e., on more than one occasion) within a 12-month period have sold animals for slaughter whose carcasses were found by FSIS to contain a violative level of a chemical residue.

FSIS recognizes that posting the name of a livestock producer to a publicly-available list of residue violators may potentially result in significant economic harm to that producer. Moreover, the incentive of removal of the producer's name from the Residue Repeat Violator List, which motivates repeat violators to improve their operations to prevent violative residues, will be weakened if producers with only one violation are listed on the Web site. Finally, FSIS notes that many first-time residue violators do not go on to become repeat violators within the designated 12-month period. Therefore, FSIS does not intend to resume publishing names of producers with a single violation within a 12-month period.

Comment: Because producers or suppliers can sell livestock to multiple Federal establishments, one comment suggested that FSIS consolidate residue

test results from the supplier or producer and set an acceptance level of non-violative samples that would trigger removal of a producer from the Residue Repeat Violator List rather than use a hard 12-month timeframe.

Response: FSIS would need to evaluate existing data to set a level of acceptable non-violative residue sample results that would trigger removal of a producer from the Residue Repeat Violator List. Given the time and resources that it would take to perform this evaluation, FSIS finds that the passage of time without a violation remains the appropriate criterion for removal from the list and is not making any changes to the Residue Repeat Violator list at this time.

Comment: Two comments requested that FSIS amend the compliance guide by substituting "residue-free" and "drug residue free" with the phrase "free from violative residues".

Response: FSIS agrees with the suggested changes and has modified the compliance guide accordingly.

Comment: Two comments expressed various concerns about drug residues in horses destined to be slaughtered for human consumption.

Response: In January 2010, the USDA Office of Inspector General determined in its review of the FSIS National Residue Program for Cattle that cull dairy cows and bob veal account for 90 percent of the residues found in animals presented for slaughter. Therefore, the guide focuses primarily on establishments that slaughter these livestock. However, this guide will be useful to any establishments that slaughter horses under Federal inspection in the future. By following the recommendations in the guidance, horse slaughter establishments would employ practices that help them avoid receiving horses with residues.

USDA 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, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotope, etc.) should contact USDA's Target Center at 202-720-2600 (voice and TTY). To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and

TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_policies/Federal_Register_Notices/index.asp.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_Events/Email_Subscription/. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: May 20, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-12666 Filed 5-28-13; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF COMMERCE

Office of the Secretary

[Docket No.: 130514469-3469-01]

Draft Initial Comprehensive Plan and Draft Programmatic Environmental Assessment

AGENCY: Office of the Secretary, U.S. Department of Commerce.

ACTION: Notice of availability; request for comments.

SUMMARY: In accordance with the Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies of the Gulf States Act (RESTORE Act), the Secretary of Commerce, as Chair of the Gulf Coast Ecosystem Restoration Council (Council), announces the availability of

a Draft Initial Comprehensive Plan (Draft Plan) to restore and protect the Gulf Coast region. Council Members also have compiled preliminary lists of ecosystem restoration projects that are "authorized but not yet commenced" and the full Council is in the process of evaluating these lists; the Council announces the availability of these preliminary lists. Finally, the Council has drafted, and announces the availability of, a Draft Programmatic Environmental Assessment (Draft PEA) for the Draft Plan. These documents are available for public review and comment.

DATES: To ensure consideration, we must receive your written comments on the Draft Plan and Draft PEA by June 24, 2013.

ADDRESSES: You may submit comments on the Draft Plan, the preliminary lists of "authorized but not yet commenced" ecosystem restoration projects, and Draft PEA by either of the following methods:

- **Electronic Submission:** Submit all electronic public comments via www.restorethegulf.gov.
- **Mail/Commercial Delivery:** Please send a copy of your comments to Gulf Coast Ecosystem Restoration Council, c/o U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4077, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: The Council can be reached at restorecouncil@doc.gov.

SUPPLEMENTARY INFORMATION:

Background: In 2010, the *Deepwater Horizon* oil spill caused extensive damage to the Gulf Coast's natural resources, devastating the economies and communities that rely on it. In an effort to help the region rebuild in the wake of the spill, Congress passed and the President signed the Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies of the Gulf Coast States Act of 2012 ("RESTORE Act"). Public Law 112-141, §§ 1601-1608, 126 Stat. 588 (Jul. 6, 2012). The RESTORE Act created the Gulf Coast Ecosystem Restoration Trust Fund (Trust Fund) and dedicates eighty percent of any civil and administrative penalties paid under the Clean Water Act, after the date of enactment, by parties responsible for the *Deepwater Horizon* oil spill to the Trust Fund for ecosystem restoration, economic recovery, and tourism promotion in the Gulf Coast region. The ultimate amount of administrative and civil penalties potentially available to the Trust Fund is currently unknown because Clean Water Act claims against several responsible parties are outstanding. On

January 3, 2013, however, the United States announced that Transocean Deepwater Inc. and related entities agreed to pay \$1 billion in civil penalties for violating the Clean Water Act in relation to their conduct in the *Deepwater Horizon* oil spill. That settlement was approved by the court in February, and Transocean paid the first installment of its civil penalties to the United States at the end of March. These funds are subject to the RESTORE Act.

In addition to creating the Trust Fund, the RESTORE Act established the Gulf Coast Ecosystem Restoration Council (Council), which is chaired by the Secretary of Commerce and includes the Governors of Alabama, Florida, Louisiana, Mississippi, and Texas, and the Secretaries of the U.S. Departments of Agriculture, the Army, Homeland Security, and the Interior, and the Administrator of the U.S. Environmental Protection Agency. Among other things, the Act requires the Council to publish an Initial Comprehensive Plan to restore and protect the Gulf Coast region after notice and an opportunity for public comment.

This Draft Plan sets forth the Council's overarching goals for restoring and protecting the natural resources, ecosystems, fisheries, marine and wildlife habitats, beaches, coastal wetlands, and economy of the Gulf Coast region. Additionally, the Plan: (1) incorporates the recommendations and findings of the Gulf Coast Ecosystem Restoration Task Force (Task Force) as set forth in the *Gulf Coast Ecosystem Restoration Task Force Strategy (Strategy)*; (2) describes how Council-Selected ecosystem restoration activities will be solicited, evaluated, and funded; (3) outlines the process for the development, review, and approval of State Expenditure Plans; and, (4) provides the Council's next steps. In addition, the Council as a whole is in the process of reviewing and evaluating preliminary lists submitted by individual Council Members in order to compile, as required by the RESTORE Act, "a list of any project or program authorized prior to the date of enactment of [the Act] but not yet commenced, the completion of which would further the purposes and goals of [the Act]."

The Council has responsibility over the expenditure of sixty percent of the funds made available from the Trust Fund. The Council will administer thirty percent, plus fifty percent of the interest on Trust Fund monies, for ecosystem restoration and protection according to the Plan. The other thirty percent will be allocated to the Gulf States as described in the RESTORE Act

Rules and Regulations

Federal Register

Vol. 78, No. 167

Wednesday, August 28, 2013

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 AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 310

[Docket No. FSIS-2012-0038]

Changes to the Salmonella Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing *Escherichia coli* and *Salmonella*

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing changes to its procedures for *Salmonella* verification sampling program of raw beef products. On the date that FSIS will announce in the *Federal Register* document that responds to any comments on this document, FSIS will discontinue *Salmonella* sampling set procedures ("HC01") in ground beef products, except in establishments with results that exceeded the standard for *Salmonella* in that establishment's most recently completed sample set (i.e., in those establishments in Category 3). At the same time, FSIS will begin analyzing for *Salmonella* all raw beef samples that it collects for Shiga toxin-producing *Escherichia coli* (STEC) analysis. Therefore, FSIS will begin analyzing for *Salmonella* all samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components that it collects for STEC testing. To be consistent with the Agency's STEC analytic sample portions, FSIS laboratories will increase the raw ground beef analytic sample portion for *Salmonella* analysis from 25 grams to 325 grams. This notice describes how FSIS intends to use the results from its verification sampling program to develop new *Salmonella* performance standards for ground beef product and to estimate *Salmonella*

prevalence in raw ground beef and beef manufacturing trimmings products. Finally, this document discusses changes that the Agency is considering related to FSIS *Salmonella* sampling and testing of other products.

DATES: Submit comments on or before September 27, 2013. Interested parties need to get their comments in on time because the Agency does not intend to grant any extensions of the comment period.

ADDRESSES: FSIS invites interested persons to submit comments on this document. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW., Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0038. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW., Room 164, Washington, DC 20250-3700 between 8 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495; or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION: FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) that is intended to ensure that meat and meat food

products distributed in commerce are wholesome; not adulterated; and properly marked, labeled, and packaged. As part of its inspection program, FSIS collects samples of these products for laboratory analysis (21 U.S.C. 642(a)).

History of the Salmonella Verification Sampling Program

The *Salmonella* verification sampling program formally began with the Agency's final rule, entitled "Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems," which FSIS published on July 25, 1996 (61 FR 38805-38889; <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf>). Among other things, the PR/HACCP rule set *Salmonella* performance standards for establishments producing selected classes of raw meat products, including ground beef, steers and heifers, and cows and bulls (9 CFR 310.25(b)). In 2011, FSIS stopped sampling and testing for *Salmonella* in steers and heifers and cows and bulls because percent positive findings were very low (less than one percent), and this carcass sampling was expensive for the Agency. As stated in the PR/HACCP rule (at 61 FR 38835), FSIS selected *Salmonella* for the performance standard because it is the most common cause of foodborne illness associated with meat and poultry products; it is present to varying degrees in all major species; and the interventions targeted at reducing *Salmonella* may help reduce contamination by other enteric pathogens.

FSIS uses the *Salmonella* performance standards to verify process control in slaughter and certain processing operations. The performance standard for ground beef is based on the industry average (percent positive samples) estimated from baseline surveys conducted before PR/HACCP was implemented.

Under the existing *Salmonella* verification sampling program, the Agency assesses whether establishments meet the *Salmonella* standard by collecting randomly selected product samples using the risk-based, 3-category establishment classification system announced on February 27, 2006 (71 FR 9772). FSIS inspection program personnel collect samples and submit them to FSIS laboratories for analysis over a defined number of sequential

days of production to complete a sample set. As detailed in the February 2006 notice, the maximum number of positive samples per set for the ground beef product category is 5 of 53.

FSIS presently categorizes establishment performance as follows:

- I. Category 1. Consistent Process Control: Establishments with percent positive *Salmonella* samples at 50 percent or less of the performance standard in the two most recently completed sample sets.
- II. Category 2T. Variable Process Control but Transitioning Towards Consistent Process Control: Establishments with percent positive *Salmonella* samples at 50 percent or less of the performance standard in the most recently completed sample set, but greater than 50 percent of the performance standard in the previously completed sample set.
- III. Category 2. Variable Process Control: Establishments with percent positive *Salmonella* samples above 50 percent but not exceeding the standard in the most recently completed sample set.
- IV. Category 3. Highly Variable Process Control: Establishments with percent positive *Salmonella* samples exceeding the performance standard in the most recently completed sample set.

FSIS collects ground beef samples under project code "HC01" as part of the *Salmonella* verification sampling program and under project code "MT43" as part of the *E. coli* O157:H7 verification sampling program.

Following the implementation of PR/HACCP, FSIS analyzed only one pathogen per sample. Then, in 2008, FSIS began analyzing for *Salmonella* and *E. coli* O157:H7 ground beef samples from establishments producing less than 1,000 pounds of product per day (under the MT43S code). Using this approach, FSIS effectively gained sampling efficiencies without overly burdening the establishment with additional sample collection.

Public Health Concerns

Salmonella bacteria are among the most frequently reported causes of foodborne illness. In December 2011, a multi-state outbreak linked to a multi-drug resistant strain of *Salmonella* sickened 19 people in the Northeast United States (<http://www.cdc.gov/salmonella/typhimurium-groundbeef/010512/index.html>). In June 2012, FSIS was notified of a cluster of *Salmonella enteritidis* illnesses linked to ground beef consumption with approximately 50 case-patients across nine states (<http://www.cdc.gov/salmonella/enteritidis-07-12/index.html>). The outbreaks referenced here and others suggest that *Salmonella* in ground beef is a continuing public health concern.

The changes described below will likely improve FSIS's ability to detect

Salmonella by increasing the raw ground beef analytic sample portion for *Salmonella* analysis and increasing the number of establishments being sampled at any given time. As is also discussed below, FSIS intends to develop new performance standards that will likely lead establishments producing ground beef to strengthen their own *Salmonella* control measures. Such changes at establishments will likely have a positive impact on public health.

Changes to *Salmonella* Verification Sampling Programs for Raw Ground Beef Products

Beginning on the date FSIS will announce in the Federal Register notice that responds to any comments on this notice, FSIS will discontinue *Salmonella* sampling sets ("HC01") for ground beef product except for establishments in Category 3. At the same time, FSIS will begin analyzing for *Salmonella* all raw beef samples it collects for STEC testing. Therefore, FSIS will begin analyzing for *Salmonella* all samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components that its personnel collect for STEC testing, including raw ground beef products FSIS samples at retail stores and ground beef, trim, and other raw ground beef components FSIS samples at import establishments.

Whenever FSIS finds a product sample positive for *E. coli* O157:H7 or a non-O157 STEC, FSIS conducts follow-up sampling of product from the establishment that produced the positive product and at all suppliers that provided the source materials for the product. When FSIS begins analyzing for *Salmonella* the product collected for STEC analysis, FSIS will also begin analyzing for *Salmonella* the follow-up samples it collects in response to STEC positive results.

FSIS analyzes beef manufacturing trimmings for *E. coli* O157:H7 and the following non-O157 STECs: O26, O45, O103, O111, O121, and O145. FSIS analyzes raw ground beef and raw ground beef components other than beef manufacturing trimmings for *E. coli* O157:H7 only. FSIS is not making any changes to the STEC sampling and testing programs at this time.

The changes that FSIS is announcing to its *Salmonella* sampling procedures will permit FSIS to analyze more samples at the same time for lower Agency costs than the present method. Also, as noted above, FSIS stopped testing beef carcasses for *Salmonella* because the Agency sampling costs did not justify the results FSIS was able to

obtain. Through this new approach, FSIS will be able to analyze for *Salmonella* beef manufacturing trimmings and other raw ground beef components at slaughter establishments. FSIS believes sampling these products will provide FSIS more information about *Salmonella* at these establishments than FSIS was able to gather through carcass testing.

FSIS will increase the raw ground beef analytic portion for *Salmonella* analysis from 25 grams to 325 grams to be consistent with the STEC analytic sample portions. To support an increase in the sample size analyzed, FSIS evaluated the FSIS *Salmonella* detection method (FSIS Microbiology Laboratory Guidebook Chapter 4.06) using 325 gram samples. Based on this analysis, FSIS expects the increase in the analytical portion size to have at least the same, but likely more of a positive, impact on public health because the likelihood of detecting positive samples increases with the analytical portion size. As is explained above, FSIS will continue to schedule sets for raw ground beef in those establishments in Category 3. FSIS laboratories will continue to evaluate raw ground beef product samples collected as part of a set using a 25-gram analytic sample portion.

FSIS intends to enumerate samples that confirm *Salmonella*-positive using the Most Probable Number (MPN) quantitative procedure. FSIS will continue to evaluate *Salmonella* isolates from the screen-positive samples for multi-drug resistance, to serotype the samples, and to use pulsed-field gel electrophoresis (PFGE) to identify specific strains of *Salmonella*.

Through this analysis, FSIS will determine whether Agency-positive *Salmonella* results are associated with illnesses or serotypes of human health significance. As is currently the case, if FSIS finds that establishments have produced product associated with illness, FSIS will typically conduct an Incident Investigation Team Review or Food Safety Assessment at the establishment.

Estimating Prevalence

In developing all of its prevalence estimates, FSIS defines prevalence as the proportion of applicable product that would test positive for a given pathogen if the entire population were sampled and analyzed during a specified time period. Although it provides a useful indication of process control within that establishment, set-based verification sampling that FSIS currently uses for *Salmonella* sampling and testing in many products is not

designed to estimate national prevalence of *Salmonella* by class of products. As is discussed above, under the set-based approach, FSIS collects samples from the same establishment on a daily basis until it has collected the necessary number of samples in the applicable performance standard. In 2012, FSIS evaluated many of its sampling programs as a means to calculate prevalence estimates for pathogens in FSIS-regulated products (http://www.fsis.usda.gov/wps/wcm/connect/56b2ccbd-ad57-4311-b6df-289822d28115/Prevalence_Estimates_Report.pdf?MOD=AJPERES). The Agency concluded, given the construction of the FSIS pathogen verification sampling programs at that time, that it was only possible to utilize the *E. coli* O157:H7 pathogen verification testing program for raw ground beef ("MT43") to estimate national prevalence. Since that time, FSIS has redesigned its beef manufacturing trimmings verification sampling program such that, with a larger number of analyzed samples, it too is suitable for estimating prevalence (http://www.fsis.usda.gov/wps/wcm/connect/15e75329-978f-43f0-b8fe-101845d898f0/Redesign_Beef_Trim_Sampling_Methodology.pdf?MOD=AJPERES).

When FSIS begins analyzing all STEC samples for *Salmonella*, FSIS will be able to estimate the prevalence of *Salmonella* in raw ground beef and beef manufacturing trimmings. Therefore, FSIS will avoid the added expense of conducting separate baseline studies at periodic intervals to determine *Salmonella* prevalence in these products and will enhance the use of inspection resources. In addition, by using these continuous sampling programs rather than scheduled sets, FSIS will be able to analyze findings over time to determine trends and evaluate program effectiveness.

Because of the limited number of available samples scheduled and collected, FSIS does not believe it is possible to estimate prevalence for *Salmonella* in raw ground beef components other than beef manufacturing trimmings (such as bench trim).

New Performance Standards

After collecting at least three months of data using the new sampling and testing procedures, FSIS intends to conduct a risk assessment and develop a revised *Salmonella* performance standard for raw ground beef at a 325 gram sample size. FSIS will publish the revised *Salmonella* performance

standard in the **Federal Register** before implementing the standard.

In 2011, FSIS estimated the national prevalence of *Salmonella* in beef manufacturing trimmings (http://www.fsis.usda.gov/wps/wcm/connect/f07f5e1d-63f2-4ec8-a83a-e1661307b2c3/Baseline_Data_Domestic_Beef_Trimmings_Rev.pdf?MOD=AJPERES). After careful consideration, FSIS does not believe the low incidence of *Salmonella* on beef manufacturing trimmings supports development of a *Salmonella* performance standard for beef manufacturing trimmings. FSIS is considering using the results of this estimation to develop guidance that will assist establishments in preventing *Salmonella* contamination in beef manufacturing trimmings.

FSIS recently revised other existing *Salmonella* performance standards to achieve a public health objective. In July 2011, FSIS implemented new performance standards for both *Salmonella* and *Campylobacter* for chilled carcasses in young chicken (broilers) and turkey slaughter establishments (76 FR 15282; March 21, 2011). By December 2011, the young chicken industry was meeting the acceptable *Campylobacter* percent positive reflected in the new standard at 9.43 percent (10.4 percent acceptable). Should FSIS develop new *Salmonella* performance standards for ground beef, FSIS believes that ground beef establishments would improve process control to meet the new performance standard in a similar manner.

Except for Category 3 establishments, FSIS will discontinue set testing at least until it establishes a revised *Salmonella* performance standard for ground beef. Meanwhile, FSIS is considering alternative sampling plans. One option that FSIS is considering is a "moving window" sampling plan in which FSIS would evaluate a set number of sequential results from single establishment to assess process control. For example, if FSIS chose to evaluate 20 results under the moving window approach, FSIS would assess the most recent 20 FSIS results for a particular establishment. This new approach would allow for on-going scheduled FSIS *Salmonella* sampling, similar to the approach FSIS uses for STEC testing, as compared to a set-based approach in which FSIS schedules a large number of sequential samples at an establishment as part of a set. The "moving window" approach would provide FSIS with more flexibility for scheduling sample collection at different establishments. The Agency requests comment on the "moving window" approach.

Other Sampling Procedures

Consistent with current sampling procedures, when an establishment either processes all raw ground beef product into ready-to-eat (RTE) product or moves it to another federally-inspected establishment for further processing into RTE product, the product will be excluded from Agency verification sampling for *E. coli* O157:H7 and *Salmonella*.

Individual sample results generated from this program will be reported through the Agency's Public Health Information System. FSIS will ensure that result information is made available to establishments. Because FSIS does not recognize *Salmonella* as a pathogen that would ordinarily render the product injurious to health, and thus as an adulterant within the meaning of 21 U.S.C. 601(m)(1), individual *Salmonella* sample results will not result in regulatory control actions. Therefore, after receiving STEC (O157:H7 and non-O157) results, establishments will not need to continue to hold product that has tested negative for STEC. If raw, non-intact beef product or raw, intact beef product that is intended for use as raw, non-intact product tests positive for STEC, the product is adulterated within the meaning of 21 U.S.C. 601(m)(1) (76 FR 58157; Sep. 20, 2011) unless further processed to destroy the pathogen.

Other Changes Under Consideration

In addition to ground beef, FSIS is considering moving *Salmonella* sampling from a set-based approach to a continuous sampling and "moving window" approach for all classes of products subject to FSIS sampling and testing for *Salmonella*. As is discussed above, this approach will allow FSIS more flexibility in scheduling and collecting samples.

In addition, FSIS is considering implementing new sampling of product classes not subject to FSIS sampling and testing for *Salmonella*. For example, FSIS is contemplating initiating sampling and testing for *Salmonella* in pork trim, pork parts, ground pork, chicken parts, and lamb carcasses.

Before FSIS makes any change of this type in its testing, it will provide notice and an opportunity for comment in the **Federal Register**.

Should FSIS decide to start testing new products for *Salmonella*, it would begin by sampling to assess the prevalence of *Salmonella* in each of the new products sampled. Upon completion of the exploratory sampling period (at least three months and possibly longer), FSIS would develop

new performance standards. FSIS would announce the tentative standards in the **Federal Register** and request comment on them before finalizing.

USDA 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, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (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 TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register>.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service>. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: August 16, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-20995 Filed 8-27-13; 8:45 am]

BILLING CODE 3410-DM-P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 110

[NRC-2012-0008]

Branch Technical Position on the Import of Non-U.S. Origin Radioactive Sources

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final Branch Technical Position.

SUMMARY: In 2010, the U.S. Nuclear Regulatory Commission (NRC) staff published a final rule amending its regulations concerning export and import of nuclear equipment and material. Among other things, it added the phrase "of U.S. origin" to the first exclusion to the definition of "radioactive waste" to confirm that the return of U.S. origin radioactive sources is not classified as the import of radioactive waste. The NRC staff drafted the Branch Technical Position (BTP) on the Import of Non-U.S. Origin Sources to provide additional guidance on the application of this exclusion in the regulations.

In developing this BTP, the NRC staff has engaged with States, Low-Level Waste Compacts, industry, and the public by providing two opportunities for public comment via **Federal Register** Notice and a public meeting in 2012. The exclusion in 10 CFR part 110 reflects the United States' commitments to the policy of safe storage and disposal of disused sources in the international context, including under the Code of Practice on the International Transboundary Movement of Radioactive Waste (Code of Practice), Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management (Joint Convention), and the International Atomic Energy Agency's (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources (Code of Conduct—along with the supplementary Guidance on Import and Export). The United States' commitments include not exporting radioactive waste to other countries for disposal and, in light of the United States' strong domestic regulatory program, allowing return of disused sources manufactured or

distributed from the United States in order to prevent sources from being orphaned overseas where regulatory programs may not exist or function to an optimal level.

DATES: The BTP is effective on September 27, 2013.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

Federal e-Rulemaking Portal: Go to <http://www.regulations.gov> and search for documents filed under Docket ID [NRC-2007-0009]. Address questions about NRC dockets to Ms. Carol Gallagher at 301-492-3668 or by email Carol.Gallagher@nrc.gov.

NRC's Public Document Room (PDR): The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Jennifer C. Tobin, Office of International Programs, U.S. Nuclear Regulatory Commission, MS-O4E21, Washington, DC 20555-0001; telephone: (301) 415-2328; email: jennifer.tobin@nrc.gov.

SUPPLEMENTARY INFORMATION:

- I. History
- II. Branch Technical Position
- III. Analysis of Public Comments on Proposed Branch Technical Position

I. History

The NRC published "Notice of Public Meeting and Request for Comment on the BTP on the Import of Non-U.S. Origin Radioactive Sources," 77 FR 2924 (January 20, 2012), and received five comment letters as a result of that publication. The NRC staff made no substantive changes to the draft BTP based on these comment letters. However, minor editorial changes were made to the draft BTP to provide greater clarity.

The NRC published "Request for Comment on the BTP on the Import of Non-U.S. Origin Radioactive Sources,"

and served under such arrangement, (8) in the case of women and children temporarily residing in public or private nonprofit shelters for battered women and children, meals prepared and served, by such shelters, and (9) in the case of households that do not reside in permanent dwellings and households that have no fixed mailing addresses, meals prepared for and served by a public or private nonprofit establishment (approved by an appropriate State or local agency) that feeds such individuals and by private establishments that contract with the appropriate agency of the State to offer meals for such individuals at concessional prices.

(r)(1) Except as provided in paragraph (2), "staple foods" means foods in the following categories:

- (A) Meat, poultry, or fish.
- (B) Bread or cereals.
- (C) Vegetables or fruits.
- (D) Dairy products.

(2) "Staple foods" do not include accessory food items, such as coffee, tea, cocoa, carbonated and un-carbonated drinks, candy, condiments, and spices.

7 CFR Part 271 General Information and Definitions: Staple food means those food items intended for home preparation and consumption in each of the following food categories: Meat, poultry, or fish; bread or cereals; vegetables or fruits; and dairy products. Commercially processed foods and prepared mixtures with multiple ingredients shall only be counted in one staple food category. For example, foods such as cold pizza, macaroni and cheese, multi-ingredient soup, or frozen dinners, shall only be counted as one staple food item and will normally be included in the staple food category of the main ingredient as determined by FNS. Hot foods are not eligible for purchase with food stamps and, therefore, do not qualify as staple foods for the purpose of determining eligibility under § 278.1(b)(1) of this chapter. Accessory food items including, but not limited to, coffee, tea, cocoa, carbonated and un-carbonated drinks, candy, condiments, and spices shall not be considered staple foods for the purpose of determining eligibility of any firm. However, accessory foods that are offered for sale in authorized retail food stores are eligible food items which may be purchased with food stamp benefits.

USDA FNS Policy: "Accessory food items include coffee, tea, cocoa, carbonated and un-carbonated drinks, candy, condiments and spices. All foods not identified as accessory in the Act and regulations must be considered staple foods".

[FR Doc. 2013-25451 Filed 10-28-13; 8:45 am]

BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2013-0003]

Availability of FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of a compliance guide to assist livestock slaughter establishments in complying with the regulatory requirements for humane handling and slaughter of livestock. FSIS encourages operators of livestock slaughter establishments to follow this guidance.

DATES: The Agency must receive comments by December 30, 2013.

ADDRESSES: A downloadable version of the compliance guide is available to view and print at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance>. No hard copies of the compliance guide have been published.

FSIS invites interested persons to submit comments on this notice. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs, etc.: Send to Docket Room Manager, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW., Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2013-0003. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW., Room 8-164,

Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495, or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION: The Humane Methods of Slaughter Act (HMSA) of 1978 (7 U.S.C. 1901 et seq.) requires the use of humane methods for handling and slaughtering livestock. The HMSA states that "the use of humane methods in the slaughter of livestock prevents needless suffering; results in safer and better working conditions for persons engaged in the slaughtering industry; brings about improvement of products and economies in slaughtering operations; and produces other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce."

The HMSA is referenced in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 603) and is implemented by FSIS humane handling and slaughter regulations found at 9 CFR part 313. Establishments are required to meet the humane handling and slaughter requirements in the regulations the entire time they hold livestock in connection with slaughter.

On September 9, 2004, FSIS announced that livestock slaughter establishments should implement and maintain a systematic approach to humane handling and slaughter to best ensure compliance with the HMSA, FMIA, and the implementing regulations (69 FR 54625). A systematic approach is a comprehensive way of evaluating how livestock enter and move through an establishment. The 2004 notice outlined four steps establishments should take to develop and maintain a systematic approach. The guidance summarizes these four steps and states that under a systematic approach, establishments should:

(1) Assess the ability of their livestock handling and slaughter practices to minimize distress and injury to livestock;

(2) Design facilities and implement handling practices that minimize distress and injury to livestock;

(3) Periodically evaluate facilities and handling methods to ensure that they continue to minimize distress and injury to livestock; and

(4) When necessary, modify facilities and handling methods to ensure that they continue to minimize distress and injury to livestock.

The guidance also explains that if an establishment takes this systematic approach and incorporates three additional features, FSIS would consider it a "robust" systematic approach. These three features are:

(1) The establishment develops written procedures that it will implement to stay in compliance with the regulations or to come back into compliance should it fail to implement the program as written or fail to prevent noncompliance;

(2) The establishment maintains written records that demonstrate that the program is being implemented as written, and that the program is effectively preventing identified potential noncompliances; and

(3) These written procedures and records are made available for FSIS review upon request.

FSIS believes developing a written plan is a step toward a robust systematic approach to humane handling because a written plan can effectively address the four aspects of a systematic approach.

The Agency has developed a compliance guide to assist establishments in developing, implementing, and maintaining a systematic approach to humane handling and slaughter of livestock to comply with the regulatory requirements. Although the guide sets out recommendations rather than requirements, FSIS encourages livestock slaughter establishments to follow this guidance. This guide represents FSIS's thinking, and FSIS will update it as necessary to reflect comments received any additional information that becomes available.

USDA 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, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.)

Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotope, etc.) should contact USDA's Target Center at (202) 720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register>.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service>. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on: October 23, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-25373 Filed 10-28-13; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Forest Service

Crescent Ranger District; Oregon; Withdrawal of Notice for Preparation of an Environmental Impact Statement for the Marsh Project

AGENCY: Forest Service, USDA.

ACTION: Notice of withdrawal.

SUMMARY: The Crescent Ranger District is withdrawing their intent to prepare an Environmental Impact Statement (EIS) for the Marsh project. The original Notice of Intent (NOI) was published in the **Federal Register** on April 26, 2013 (Vol. 78, No. 81, p 24717-24718). The Forest Service has determined that an EIS is not required for this project as currently proposed and therefore, it was decided to document the project in an environmental assessment.

FOR FURTHER INFORMATION CONTACT: Tim Foley, Team Leader, Crescent Ranger District, P.O. Box 208, Crescent, Oregon, 97733, phone (541) 433-3200.

Dated: July 31, 2013.

Holly Jewkes,

Crescent District Ranger.

[FR Doc. 2013-25584 Filed 10-28-13; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Black Hills National Forest Advisory Board (Board) will meet in Rapid City, South Dakota. The Board is established consistent with the Federal Advisory Committee Act of 1972 (5 U.S.C. App. II) (FACA), and the Forest and Rangeland Renewable Resources Planning Act of 1974 (16 U.S.C. 1600 et seq.) (RPA), the National Forest Management Act of 1976 (16 U.S.C. 1612) (NFMA), and the Federal Public Lands Recreation Enhancement Act (Pub. L. 108-447) (REA).

The purpose of the Board is to provide advice and recommendations on a broad range of forest issues such as forest plan revisions or amendments and forest health, including fire and mountain pine beetle epidemics, travel management, forest monitoring and evaluation, recreation fees, and site-specific projects having forest-wide implications.

The meeting is open to the public. The purpose of the meeting is to: (1) To provide an orientation to the Board regarding Forest Funding, including appropriations and trends; (2) provide an update to the Board regarding Cave Management and White Nose Syndrome in Bats; and (3) discuss Motorized Travel Permit Fees.

DATES: The meeting will be held November 20, 2013, at 1:00 p.m.

ADDRESSES: The meeting will be held at the Forest Service Mystic Ranger District Office, 8221 South Highway 16, Rapid City SD. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Supervisor's Office, Black Hills National Forest, 1019 North Fifth Street, Custer, SD. Please call ahead to Scott Jacobson,

or any agency or instrumentality thereof; nor while using a Government-owned or lease vehicle, or while using a privately-owned vehicle in the discharge of official duties.

Moreover, candidacy for, and service in, a partisan political office shall not result in neglect of, or interference with, the performance of the duties of the employee or create a conflict, or apparent conflict, of interest.

Sections 733.103 and 733.104 of Title 5, Code of Federal Regulations, do not apply to individuals, such as career senior executives and employees of the Federal Bureau of Investigation, who are employed in the agencies and positions listed on the Web site of the United States Office of Special Counsel, at <http://www.osc.gov/haFederalFurtherRestricted.htm>, and at 5 CFR 733.105(a). These individuals are subject to the more stringent limitations described in 5 CFR 733.105 and 733.106.

Individuals who require advice concerning specific political activities, and whether an activity is permitted or prohibited under 5 CFR 733.103–733.106, should contact the United States Office of Special Counsel at (800) 854–2824 or (202) 254–3650. Requests for Hatch Act advisory opinions may be made by email to: hatchact@osc.gov.

The District of Columbia will be listed alphabetically after Crane, Indiana, and before Elmer City, Washington, at 5 CFR 733.107(c).

E.O. 12866, Regulatory Review

This regulation has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the changes will affect only employees of the Federal Government.

List of Subjects in 5 CFR Part 733

Political activities (Government employees).

U.S. Office of Personnel Management.
Elaine Kaplan,
Acting Director.

Accordingly, the Office of Personnel Management amends 5 CFR part 733 as follows:

PART 733—POLITICAL ACTIVITY— FEDERAL EMPLOYEES RESIDING IN DESIGNATED LOCALITIES

■ 1. The authority citation for part 733 is revised to read as follows:

Authority: 5 U.S.C. 7325; Pub. L. 112–230, 126 Stat. 1616 (Dec. 28, 2012); sec. 308 of

Pub. L. 104–93, 109 Stat. 961, 966 (Jan. 6, 1996).

■ 2. Section 733.107(c) is amended by adding the District of Columbia, alphabetically, to the list of other designated municipalities as set forth below.

§ 733.107 Designated localities.

* * * * *

(c) * * *

Other Municipalities

* * * * *

District of Columbia

* * * * *

[FR Doc. 2013–26741 Filed 11–6–13; 8:45 am]

BILLING CODE 6325–48–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 318, 320, 327, 331, 381, 412, and 424

[Docket No. 99–021F; FDMS Docket Number
FSIS–2005–0016]

RIN 0583–AC59

Prior Label Approval System: Generic Label Approval

AGENCY: Food Safety and Inspection
Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the meat and poultry products inspection regulations to expand the circumstances in which FSIS will generically approve the labels of meat and poultry products. The Agency also is consolidating the regulations that provide for the approval of labels for meat products and poultry products into a new Code of Federal Regulations (CFR) part.

DATES: This rule is effective January 6, 2014.

FOR FURTHER INFORMATION CONTACT: Jeff Canavan, Deputy Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Stop Code 3784, Patriots Plaza 3, 8–161A, 1400 Independence Avenue SW., Washington, DC 20250–3700; Telephone (301) 504–0879; Fax (202) 245–4792.

SUPPLEMENTARY INFORMATION:

Executive Summary

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA)

(21 U.S.C. 451 *et seq.*) direct the Secretary of Agriculture to maintain meat and poultry product inspection programs designed to assure consumers that meat and poultry products distributed to them (including imports) are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. They also prohibit the sale or offer for sale by any person, firm, or corporation of any article in commerce under any name or other marking or labeling that is false or misleading or in any container of a misleading form or size.¹ FSIS has interpreted these provisions as requiring that the Secretary of Agriculture or his or her representative approve all labels used on federally inspected and passed, and imported, meat and poultry products before the products are distributed in commerce. Without approved labels, meat and poultry products may not be sold, offered for sale, or otherwise distributed in commerce.

To ensure that meat and poultry products comply with the FMIA and PPIA and their implementing regulations, FSIS conducts a prior approval program for labels that are to be used on federally inspected meat and poultry products and imported products (see 9 CFR 317.4, 317.5, 327.14, 381.132, 381.133, 381.134, and 381.205). Under the current program, FSIS evaluates sketches of labels for approval. A “sketch label” is a printer’s proof or other version that clearly shows all required label features, size, location, and indication of final color. To obtain sketch label approval, domestic meat and poultry establishments and certified foreign establishments, or their representatives, submit sketch labels to FSIS for evaluation, except when the label is generically approved by the Agency under 9 CFR 317.5 or 381.133.

Generic label approval refers to the prior approval of labels or modifications to labels by the Agency without submitting such labels to FSIS for sketch approval. Generic label approval requires that all mandatory label features be in conformance with FSIS regulations (9 CFR 317.5(a)(1) and 381.133(a)(1)). Although such labels are not submitted to FSIS for approval, they are deemed to be approved and, therefore, may be applied to product in accordance with the Agency’s prior label approval system. Sections 317.5 and 381.133 also list the types of labels and modifications to labels that are deemed to be approved without submission to FSIS, as long as the label displays all mandatory label features in

¹ 21 U.S.C. 607(d); 21 U.S.C. 457(c).

"natural" and negative claims, may be generically approved by the Agency without being submitted for evaluation and approval. Such claims include a statement that characterizes a product's nutrient content that is consistent with the applicable Agency regulation, such as "low fat;" that has geographical significance, such as "Italian Style;" or that makes a country of origin statement on the label of any meat or poultry product "covered commodity." Consistent with the proposed rule, FSIS will not view the addition of an allergen statement (e.g., "contains soy") applied in accordance with the Food Allergen Labeling and Consumer Protection Act (FALCPA) as a special statement or claim that requires sketch approval.

Under this final rule, a label bearing a child-nutrition (CN) box will not be considered to have a special statement or claim on it that would require sketch approval by FSIS. The CN information in CN boxes is reviewed and evaluated for approval by the Agricultural Marketing Service, removing it from the realm of special statements or claims. Therefore, under this final rule a CN box on a meat or poultry product is generically approved.

When this rule becomes effective, labels that do not qualify for generic approval will receive first priority for review. Labels that do qualify for generic approval will receive a lower or second priority.

FSIS is also reorganizing the regulations in this final rule by consolidating the labeling approval rules that currently are presented separately for meat and poultry products (in 9 CFR 317.4 and 381.132, respectively) into a single, new part, 9 CFR Part 412. FSIS believes that the public will be better served by having the regulations governing label approval consolidated in one part of title 9. Rather than searching through two separate parts of title 9, 317 and 381, to find the label approval regulations, interested parties will only have to survey one, part 412, to be able to apply generically approved labels to their meat and poultry products.

Summary of and Response to Comments

FSIS received 47 separate comments to the proposed regulation from consumers (6), students (5), meat and poultry companies (9), trade associations (13), label consultants (8), health related sources (5), and an agriculture center. Just over half of the comments supported the proposal to expand generic approval. Of those, a great majority suggested expanding the generic approval system beyond that

which the Agency proposed. These commenters supported the rule on the grounds that it will streamline and modernize the prior label approval system, thereby reducing the volume of paperwork and labels that need to be filed with FSIS. They also stated that it will decrease costs and utilize FSIS and industry resources more effectively. These commenters also stated that industry members will be able to devise their own approval systems, gaining time that is lost to long Agency approval times. Commenters stated that the efficient use of industry resources will also lead to faster introduction of innovative products into the marketplace and the enhancement of food safety.

Approximately nineteen commenters opposed the rule. The major reason for their opposition was concern about allergen listings on labels. Finally, seven of the comments were outside the scope of the rule. These commenters addressed issues such as the inclusion of Country of Origin Labeling on all labels; the production and sale of labels by USDA; developing better definitions of "gluten free" and "wheat free;" defining terms like "natural;" and reconsidering the amenability of flavors. A summary of the relevant issues raised by commenters and the Agency's responses follows.

1. Allergens

Comment: Numerous commenters believe that FSIS review of labels is a critical part of ensuring the accuracy of the ingredients statement on meat and poultry products. Commenters opposed to the proposal said that it would reduce oversight in a critical food safety area and, for that reason, would increase the likelihood that meat and poultry products containing undeclared allergens would enter the marketplace, and that more recalls would occur. One commenter stated that it was important to have FSIS review food labels and take steps to be certain that labels are clear and accurate.

Response: FSIS disagrees that the expansion of generic labeling will increase the likelihood that meat and poultry products will enter the marketplace with undeclared allergens. One of the purposes of prior label review is to ensure that the up to eight labeling features required by the meat and poultry products inspection regulations are present on the label, and that any claims are appropriately supported. Another purpose is to identify undefined claims, ad copy, or other information that may be false or misleading.

Prior label review does not, however, involve comparing the information on a label directly with the ingredients actually used in the food product that is to bear the label—the only way to determine whether allergens that have not been declared on the label have actually been used in the product. It is for inspection program personnel (IPP) to conduct reviews of this kind in the establishment, after the relevant label has been approved, whether generically or on a per-case basis by label reviewers in Washington, DC. IPP review labels and compare them to actual product formulations to verify that the ingredients used in the production of the product are listed accurately on the label, that the label is not misleading, and that it is otherwise in compliance with all labeling requirements.

There were 30 allergen-related recalls of meat and poultry products during 2012. None of those recalls, however, resulted from changes that could have been identified through the Agency label review process. In some cases, labeling errors occurred because an establishment switched to a different supplier for a spice mix or blend used in product production but then did not check the new list of ingredients against its label inventory to ensure that they matched. Similarly, in other cases ingredient reformulations or product reformulations that changed the sub-listing of ingredients were not reflected on a product's label. Other labeling errors resulted from production mistakes, such as packaging the product in the wrong box.

More than 85 percent of the allergen-related recalls over the past year occurred as a result of something that happened after the label in question was approved by FSIS, a situation that prior label approval could obviously not change.

Under 9 CFR 317.2(f) and 381.118, establishments are required to list all ingredients used to formulate meat and poultry products in the ingredients statement on the product label, including potential allergens. FSIS's prior label review is not and cannot be a substitute for the careful application of labels to products by the meat and poultry industry.

Comment: Several commenters suggested that the Agency require the declaration of major allergens on the labels of FSIS-regulated foods.

Response: While a separate statement addressing specific allergens in the product is not mandatory for meat and poultry products as it is with foods regulated under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Public Law 108–282,

these statements or claims on a case-by-case basis.

Note that if a special statement or claim has been approved for an establishment under the current system, the establishment will not need to resubmit the label hearing it under this new final rule. It would only have to resubmit the label if it added a new special statement or claim to the previously approved label.

Comment: Several commenters suggested that FSIS make available a comprehensive list or guide that outlines what statements or claims need prior label approval.

Response: FSIS agrees that this is a good idea. We intend to develop a guidance document concerning claims that can and cannot be generically approved.

4. Expansion of Generic Labeling

Comment: As mentioned earlier, many of the commenters in favor of the proposed rule suggested expanding the generic approval system beyond that which was proposed.

Response: Many of the labels that commenters asked be generically approved are, under 9 CFR 412.1, which is being added to FSIS's regulations by this final rule, specifically required to be submitted for evaluation and review by FSIS. Examples of such labels and information are sketch labels for products produced under a religious exemption, sketch labels for products for foreign commerce whose labels deviate from FSIS regulations, special statements and claims, and requests for the temporary use of final labeling that is deficient in some particular. These labels are discussed later in this document.

Some of the commenters' suggested changes are not necessary because, as proposed and under this final rule, the labeling statements raised can be approved without prior submission to FSIS. An example would be foreign language labels. One commenter stated that labels containing foreign languages on products for sale in the U.S. that do not have special statements or claims should not need sketch approval from FSIS. While the current meat and poultry inspection regulations do not permit the generic approval of a label adding or deleting a direct translation of the English language into a foreign language for product sold in the U.S.,³ this final rule will do so. These types of labels do not fall into any of the categories of labels that must be submitted to FSIS for evaluation and review. Another suggested change, that

modifications to product labels reflecting changes made by suppliers should be generically approvable, is unnecessary. As in the proposal, the final rule will permit these modifications to be generically approved, and thus no expansion of the generic approval system is needed.

We were asked by a commenter if we intended to permit the generic approval of previously approved labels containing special claims when the only modification involves changes unrelated to the special claim. The answer is yes. Previously approved labels containing special claims may be generically approved if the only modification involves changes unrelated to the special claim.

Comment: Many commenters asked that FSIS allow the generic approval of final labels off of temporary labels, as well as the generic approval of temporary label extensions. Several more suggested that temporary labels that contain minor inaccuracies but present minor health risks be deemed generically approved. Others sought generic approval for different types of temporary labels on meat and poultry products. For example, commenters suggested that FSIS generically approve temporary labels when the ingredient list of a meat or poultry product changes. Another asked for generic approval of temporary labels on secondary products. Other commenters sought generic approval in other situations, such as the removal of a non-USDA-regulated ingredient from a product formula; a change of place in the order of predominance of an ingredient in a food regulated by FDA used in the formulation of a meat or poultry food product because of a change in suppliers; and a modified "blanket" approval based on a single temporary approval.

Response: After reviewing the comments, FSIS has determined that it would be inappropriate to allow the following types of labels to be deemed approved without Agency evaluation and review:

Labels bearing negative, "natural," and "organic" claims: These labels are not generically approvable because they are special claims, as defined in 9 CFR 412.1(e) of this final rule.

The meat and poultry regulations do not define "negative," "natural," or "organic." "Negative" labeling claims are defined in the Food Standards and Labeling Policy Book. Negative claims refer to statements highlighting the absence of an ingredient or another constituent of the food, an example of which, "gluten free," has been codified in 9 CFR 412.1(e). "No milk" is another

example of a negative claim that highlights the absence of an ingredient or another constituent of a food. A negative claim may also identify the absence of certain types of ingredients, e.g., "no preservatives" or "no artificial coloring" based on the product formulation. Consequently, negative claims can vary greatly, from a specific ingredient to a class of substances, making it difficult to determine whether a label bearing this type of claim is compliant.

"Natural" is also a claim that is undefined in FSIS's regulations but is defined in the Food Standards and Labeling Policy Book. However, natural is a controversial claim which has come under great scrutiny in the last several years and for which FSIS is considering rulemaking.⁴

"Organic" is not defined in FSIS's regulations. Consequently, establishments may not be familiar with the Agency's requirements for the support or application of this claim, which could result in increased labeling errors and misbranded product. While industry is familiar with the requirements for mandatory label features, as noted in the proposed rule, the Agency believes that it needs to continue to provide pre-market evaluation and approval of "organic" claims because they present significant and evolving policy issues.

For the above reasons, FSIS must see the ingredients listing on a label containing a negative, "natural," or "organic" claim to be able to verify its accuracy.

Labels marked "for export only" (previously sketch approved with minor modifications): Exports of U.S. meat and poultry products occur in the context of U.S. government-foreign government agreements. These agreements require U.S. government approval of labels on meat and poultry products to be exported. One aspect of this approval is ensuring that any changes made to labels on meat and poultry products are allowed per the importing country's laws. Therefore, labels marked "for export only" cannot be generically approved.

Labeling with special statements or claims that has been reviewed by other Government agencies: Except for meat and poultry product labels that bear child-nutrition (CN) boxes, which are reviewed and approved by the Agricultural Marketing Service (AMS),

⁴ See "Product Labeling: Definition of the Term 'Natural' and related materials (71 FR 70503, Dec. 5, 2006) and "Product Labeling: Use of the Voluntary Claim 'Natural' in the Labeling of Meat and Poultry Products" and related materials (74 FR 46951, Sep. 14, 2009).

³ 9 CFR 317.5(b)(9)(xxiv) and 381.133(b)(9)(xxv).

successfully implement these regulations.

Comment: One commenter stated that an electronic program to automatically scan and review labels would reduce the time spent by FSIS reviewing labels and would allow labeling staff to concentrate on other food safety regulations.

Response: While no system can scan and review labels, FSIS has recently released an electronic label system to allow for easier label submission. Using the Label Submission and Approval System (LSAS), establishments are able to submit label applications, supporting materials, and appeals to FSIS via the Internet. While the system will not check labels automatically for errors, it will scan them for some common errors in the label submission process, including illegibility, missing information on the transmittal form, and missing support documentation. The system also includes a feature that helps submitters determine whether a label can be generically approved, or if it must be submitted to FSIS for approval. The use of LSAS will have a positive impact on the speed and accuracy of label review.

Comment: Some commenters stated that the rule would harm industry through recalls, tagged products, loss of goodwill, and loss of valuable label inventories.

Response: FSIS disagrees with these comments. Industry is familiar with the eight mandatory labeling features that have been required for many years. Additionally, industry has had 16 years of experience applying the current generic labeling regulations.

FSIS has not observed an increase in loss of product or labels, or an increase in meat and poultry product recalls, as a result of establishments applying generically approved labels. Labels found to be deficient in some particular may be eligible for temporary approval. In addition, establishments may submit requests for temporary approval for retained product ("tagged") as an "extraordinary circumstance" as described in the following compliance policy guide on the Agency's Web site: <http://www.fsis.usda.gov/vps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/procedures-evaluating-labeling>. Labels submitted as an extraordinary circumstance are given the highest priority for label evaluation to prevent loss of product. Labels determined to be ineligible for temporary approval without modification may be brought into compliance for use through the use of pressure sensitive stickers. Pressure sensitive stickers are used to cover or

correct inaccurate or misleading information. FSIS has published a guidance document for compliance assistance on the use of pressure sensitive stickers at: <http://www.fsis.usda.gov/vps/portal/fsis/topics/regulatory-compliance/labeling/Labeling-Policies/pressure-sensitive-stickers/pressure-sensitive-stickers>. Temporary approval is not required to bring labels into compliance through the use of pressure sensitive stickers. Moreover, FSIS has regulatory authority to grant temporary approval for the use of labels that may lack some particular information if use of the labels will not misrepresent the product, present a health or safety issue, or provide an unfair economic advantage.

We recognize that this rule is more extensive than the current labeling regulations in that it increases the amount of labeling that industry can self-declare generically approved and therefore not submit to FSIS for prior approval. We therefore acknowledge the need for updated labeling information and directions to IPP in appropriately assessing the accuracy of the labeling records and whether the label has been generically approved. We intend to provide guidance and issue instructions to IPP to help them perform their in-plant labeling verification activities.

6. Implementation of the Final Rule

Comment: Many of the commenters that supported the proposed rule nonetheless had concerns about implementation of the final rule. One of these concerns was ensuring that all parties, that is, industry, the FSIS labeling staff located in Washington, DC, and IPP, understand how the generic approval program is administered, monitored, and enforced. Several commenters asked that FSIS provide an implementation plan and a consistent method and process for the clarification and redress of issues identified by IPP or establishments, along with a timetable for redress. Other implementation issues raised include:

1. FSIS issuance of a directive that details the role of IPP, including when and how to conduct a generic label verification check, how the inspector-in-charge should communicate with FSIS labeling staff, and how establishments can appeal generic labeling issues directly to the FSIS labeling staff, rather than IPP;

2. Authorizing only FSIS labeling staff, rather than IPP, to decide if a label is not eligible for generic approval, and advising IPP to contact FSIS labeling staff before taking regulatory control actions; and

3. Prohibiting the interruption of product flow unless the errors on the label constitute immediate, genuine situations of public health concern, or until it is confirmed that the errors constitute a public health concern, economic fraud, or an unfair competitive advantage.

Commenters also requested greater access to FSIS label staff and asked that the FSIS Policy and Labeling Book be updated before the final rule is published.

Response: FSIS intends to issue instructions to IPP that will address these and other issues relating to label verification activities. The instructions will include specific label tasks associated with in-plant labeling verification activities, such as verifying that all ingredients are appropriately declared on labeling. If labels are determined to be out of compliance, the instructions will provide guidance to IPP on how to document the noncompliance in the Public Health Inspection System (PHIS), and what actions are to be taken. In addition, the Agency will provide training to Agency personnel and guidance materials to industry on labeling regulations and policies, including generic labeling.

FSIS plans to provide outreach assistance to companies producing and submitting meat and poultry labels so that they may take full advantage of this time and cost saving measure. The Agency will develop compliance policy guides, webinars, and PowerPoint presentations for industry. FSIS also intends to better organize the information on its Web site to make it easier for interested parties to find labeling and standards information posted there. FSIS believes that these actions will reduce the number of label submissions to FSIS headquarters, thus increasing the availability of FSIS labeling staff.

Upon publication of this final rule, FSIS will cease adding new items to the Food Standards and Policy Labeling Book. FSIS will continue to amend or remove items in the book, as necessary, but it will no longer add new material to it beginning on the date that this final rule is published. The Agency will convey new labeling policy by other means, such as compliance policy guides.

7. Survey Data

Comment: A few commenters opposed the rule on the grounds that the Generic Label Audit System (GLAS) data supporting the proposal are not valid because of the age of the information, the manner in which labels were selected for review, and the lack of

introduction of new products into the marketplace to meet demand while not negatively affecting consumer protection from misbranded product.

The analysis of benefits and costs below is the analysis from the proposed rule. FSIS received no updates suggesting that concrete modifications to the analysis were needed, and there have been no major data changes since the proposed rule was published in December 2011. However, data were updated for the discounted cost savings to reflect the corrected discount rate calculations at 7 percent and added the discounted rate calculations at 3 percent. In addition, the total number of labels developed and applied by establishments that do not require FSIS evaluation was updated to reflect a 1 percent growth factor. After reviewing the analysis from the proposed rule,

FSIS has determined that it is still accurate.

I. Baseline

Based on the Agency's Performance Based Inspection System databases, in 2011, there were about 6,099 Federal establishments. FSIS estimates that there were approximately 266,000 approved meat and poultry product labels used by these establishments. FSIS evaluated about 66,000 of them in 2010; the remaining 200,000 were approved under the Prior Label Approval System because they met the standards for generic approval.

II. Benefits

A. Industry

This final rule will permit establishments to realize an estimated cost savings of a minimum of \$10.1 million (discounted at 7 percent over a

10-year period) for generically approving about 584,486 additional labels over a 10-year period at about \$25 per label submission,⁶ or about \$12.4 million (discounted at 3 percent over a 10-year period). FSIS considers this estimate to be an upper bound, since some establishments may continue to submit generic labels, as defined by this final rule, for review. The annualized cost savings will be \$1.9 million at 7 percent over 10 years, or \$1.7 million at 3 percent over 10 years. In the absence of this rule, establishments will not realize any cost savings because Federal regulations will continue to require establishments to submit a significant number of labels to the Labeling and Policy Development Staff (LPDS) for evaluation.⁷ Establishments will also realize an increase in the number of generically approved labels over a 10-year period under the final rule.

TABLE 2—ESTIMATED ESTABLISHMENT COST SAVINGS
(In 2010 dollars)

Year	Total number of labels developed and applied by establishments that do not require FSIS evaluation before rule	Increase in number of labels developed and applied by establishments that would not require FSIS evaluation	Total number of labels developed and applied by establishments that would not require FSIS evaluation after rule	Total cost savings Col.(C) × *\$25 from reduced need for FSIS label evaluation	To apply discount rate of 7.00%	Discounted total cost savings Col. (E) × Col. (F)
(A)	(B)	(C)	(D)	(E)	(F)	(G)
0	200,000	0	200,000	\$0	1.00	\$0
1	202,000	50,985	252,985	1,274,625	0.9346	1,191,265
2	204,020	52,515	256,535	1,312,864	0.8734	1,146,655
3	206,060	54,090	260,150	1,352,250	0.8163	1,103,841
4	208,121	55,713	263,833	1,392,817	0.7629	1,062,580
5	210,202	57,384	267,586	1,434,602	0.7130	1,022,871
6	212,304	59,106	271,410	1,477,640	0.6663	984,551
7	214,427	60,879	275,306	1,521,969	0.6227	947,730
8	216,571	62,705	279,276	1,567,628	0.5820	912,359
9	218,737	64,586	283,323	1,614,657	0.5439	878,212
10	220,924	66,524	287,448	1,663,097	0.5083	845,352
Total	2,313,367	584,486	2,897,853	14,612,147		10,095,417

Description:

Col A: Estimate is for a 10-year period. Year "0" is the year before the enactment of the rule.

Col B: Total number of labels developed and applied by official establishments that do not currently require FSIS evaluation.

Col C: Increase in the number of labels generically developed and applied by establishments as a result of the rule (i.e., would not need FSIS evaluation).

Col D: Total number of labels developed and applied by establishments after the rule was enacted.

Col E: Total cost savings realized to establishments, using an estimated \$25 as the cost per label submission to LPDS.

Col F: Discount rate of 7 percent.

Col G: Discount cost savings over 10 years.

Source: FSIS Policy Analysis Staff Calculations.

Because fewer labels will need to be submitted to the Agency for evaluation, establishments will realize a cost savings because they will no longer

need to incur costs to have certain types of labels evaluated by FSIS. Establishments have the option to continue submitting labels for review.

FSIS believes that large and some small establishments will voluntarily use generic labeling. Some small and very small establishments will continue to

⁶ The cost per label is the cost of submitting a label for review to FSIS, which averages about \$25.00 per submission. This amount will be used as a proxy to estimate the cost savings to

establishments that prepare their labels for review using FSIS Form 7234-1 "Application for approval of Labels, Markings, or Device" and preparing a

printer's proof of the label for evaluation and approval by LPDS.

⁷ See Table 2.

The final rule also does not impose any additional cost burden on establishments because first, establishments are already applying generically approved labels and maintaining all labeling records, and second, establishments are experienced in submitting labels to FSIS for evaluation. The cost of label design and products is not a part of this final rule.

IV. Overview

This final rule is beneficial because it streamlines the generic label approval process, while imposing no additional cost burden on establishments or the Agency. FSIS estimates that establishments will realize a discounted cost savings of \$10.1 million as a result of their ability to generically approve an additional 584,486 labels over a 10-year period (discounted at 7 percent) or \$12.4 million over a 10-year period (discounted at 3 percent). Furthermore, the Agency will realize a discounted cost savings of \$3.3 million for evaluating 584,486 fewer labels over a 10-year period (discounted at 7 percent) or 4.1 million over 10 years (discounted at 3 percent). This cost savings in fewer staff hours being spent evaluating labels can be redirected towards other Agency initiatives. The annualized cost savings will be \$2.58 million (\$1.9 million for establishment + \$641 thousand for the Agency) at 7 percent over 10 years or \$2.21 million (\$1.7 million + \$548 thousand) at 3 percent over 10 years. These cost savings estimates should be considered an upper bound, as described earlier. Therefore, the net benefit derived from the final rule is \$13.4 million (\$10.1 million in establishment savings plus \$3.3 million in Agency savings), discounted at 7 percent over a 10-year period or \$16.5 million (\$12.4 million in establishment savings plus \$4.1 million, in Agency savings), discounted at 3 percent, over a 10-year period.

Regulatory Flexibility Analysis

The FSIS Administrator certifies that for the purpose of the Regulatory Flexibility Act (5 U.S.C. 601–602), the final rule will not have a significant economic impact on a substantial number of small entities. The final changes will affect those entities in the United States that submit labels for review to FSIS. There are 6,099 meat and poultry establishments that could possibly be affected by this rule since all are eligible to submit labels for review and 12 small label consulting firms that are involved in various labeling activities, such as submitting labels to FSIS for evaluation on the behalf of meat and poultry establishments. Of the

6,099 establishments, there are about 2,616 small federally inspected establishments (with more than 10 but less than 500 employees) and 3,103 very small establishments (with fewer than 10 employees) based on HACCP Classification. Therefore, a total of 5,719 small and very small establishments could be affected by this rule. These small and very small establishments, like the large establishments, will be able to generically approve labels as long as there are no special claims on the labels. Small entities will not be disadvantaged because the final rule will minimize the regulatory burden on all establishments. The final rule will not have a significant impact on a substantial number of label consulting firms. Since the expanded use of generically approved labels in 1995, these firms have modified their consulting services to specialize in certain policy areas, e.g., the production and labeling of organic products and animal production raising practices. Therefore, the Agency believes that the final rule will not have a significant economic impact on a substantial number of small entities (establishments and labeling consulting firms).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule except as discussed below.

Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

USDA 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, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, or audiotope) should contact USDA's Target Center at (202)720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410 or call (202) 720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this final rule online through the FSIS Web page located at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules>.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service>. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Paperwork Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*), the information collection requirement associated with this final rule on generic label approval has been submitted for approval to OMB.

FSIS is expanding the circumstances in which FSIS will generically approve the labels of meat and poultry products. Under this final rule, more official and foreign establishments will be able to use the generic approval of product labels. As a result, fewer sketch labels will need to be submitted and evaluated by FSIS.

This information collection, after it is approved by OMB, will be merged with 0583–0092, Marking, Labeling, and Packaging. The merged information collection will result in a net reduction of 34,971 burden hours because of the

accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Front Line Supervisor must receive approval as required by §§ 316.7, 317.3, and 412.1 of this chapter, or their use must be discontinued.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 12. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

■ 13. Amend § 381.129 by revising paragraphs (b)(6)(i) and (c)(2) to read as follows:

§ 381.129 False or misleading labeling or containers.

* * * * *

(b) * * *

(6)(i) A raw poultry product whose internal temperature has ever been below 26 °F may not bear a label declaration of "fresh." A raw poultry product bearing a label declaration of "fresh" but whose internal temperature has ever been below 26 °F is mislabeled. The temperature of individual packages of raw poultry product within an official establishment may deviate below the 26 °F standard by 1 degree (i.e., have a temperature of 25 °F) and still be labeled "fresh." The temperature of individual packages of raw poultry product outside an official establishment may deviate below the 26 °F standard by 2 degrees (i.e., have a temperature of 24 °F) and still be labeled "fresh." The average temperature of poultry product lots of each specific product type must be 26 °F. Product described in this paragraph is not subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

* * * * *

(c) * * *

(2) Immediately adjacent to the calendar date will be a phrase explaining the meaning of such date in terms of "packing" date, "sell by" date, or "use before" date, with or without a further qualifying phrase, e.g., "For Maximum Freshness" or "For Best Quality."

* * * * *

§§ 381.132 and 381.133 [Removed and Reserved]

■ 14. Sections 381.132 and 381.133 are removed and reserved.

■ 15. In § 381.145, revise paragraph (f) introductory text to read as follows:

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

* * * * *

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section may only use, as a part of any label, the following logo.

* * * * *

■ 16. In § 381.175, revise paragraph (b)(6) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(6) Records of all labeling, along with the product formula, processing procedures, and any additional documentation needed to support that the labels are consistent with the Federal meat and poultry regulations and policies on labeling, as prescribed in § 412.1 of this chapter.

■ 17. In § 381.205, revise paragraph (c) to read as follows:

§ 381.205 Labeling of immediate containers of poultry products offered for entry.

* * * * *

(c) All marks and other labeling for use on or with immediate containers must be approved for use by the Food Safety and Inspection Service in accordance with part 412 of this chapter before products bearing such marks and other labeling will be permitted for entry into the United States.

■ 18. In § 381.222, revise paragraph (d) to read as follows:

§ 381.222 States designated under paragraph 5(c) of the Act; application of regulations.

* * * * *

(d) Subpart N of this part shall apply to such establishments except as provided in this paragraph (d).

(1) The operator of each such establishment shall, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use (upon the date of inauguration of inspection) to the Front Line Supervisor in which the establishment is located. Temporary approval, pending formal approval under § 412.1 of this chapter, will be granted by the Front Line Supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official

inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by section 4(h) of the Act.

(2) The Front Line Supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the FSIS Labeling and Program Delivery Staff and will retain one copy in a temporary approval file for the establishment.

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the Front Line Supervisor (showing any modifications required by the Front Line Supervisor) to the FSIS Labeling and Program Delivery Staff at headquarters, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Front Line Supervisor must receive approval as required by § 412.1 or their use must be discontinued.

(4) The Front Line Supervisor will also review all shipping containers to ensure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of pressure sensitive tape of a type that cannot be removed without visible evidence of such removal, or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of the regulations must be destroyed or removed from the official establishment.

* * * * *

■ 19. Add part 412 to subchapter E to read as follows:

PART 412—LABEL APPROVAL

Sec.

412.1 Label approval.

412.2 Approval of generic labels.

Authority: 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

(i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph. Unless the word "Irradiated" is part of the product name, labels also must bear a statement such as "Treated with radiation" or "Treated by irradiation." The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under § 317.2(c)(2) of this chapter.

* * * * *

Done in Washington, DC on: November 1, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-26639 Filed 11-6-13; 8:45 am]

BILLING CODE 3410-DM-P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2012-0035]

16 CFR Part 1500

Revocation of Certain Requirements Pertaining to Caps Intended for Use With Toy Guns and Toy Guns Not Intended for Use With Caps

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Section 106 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) deemed the provisions of ASTM International Standard F963, "Standard Consumer Safety Specifications for Toy Safety" (ASTM F963), to be consumer product safety standards issued by the U.S. Consumer Product Safety Commission (CPSC, Commission, or we). Among other things, ASTM F963 contains provisions regarding sound-producing toys. Existing CPSC regulations pertaining to caps intended for use with toy guns refer to obsolete equipment, but the ASTM F963 provisions for sound-producing toys allow the use of a broader array of more precise and more readily available test equipment for sound measurement. In addition, the ASTM standard requires fewer measurements and permits use of more automated equipment that would increase the efficiency of testing. Because the existing regulations are obsolete and have been superseded by the requirements of ASTM F963, the final rule revokes the existing

regulations pertaining to caps intended for use with toy guns and toy guns not intended for use with caps. The final rule is unchanged from the rule as proposed in the notice of proposed rulemaking (NPR).

DATES: The rule is effective December 9, 2013.

FOR FURTHER INFORMATION CONTACT:

Richard McCallion, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987-2222; email: rmccallion@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Revocation of Certain Regulations Pertaining to Toy Caps and Toy Guns Not Intended for Use With Caps

On June 25, 2012, the Commission published in the *Federal Register* an NPR to revoke certain regulations pertaining to toy caps and toy guns not intended for use with caps. 77 FR 77834. The comment period for the NPR closed on August 24, 2012. The Commission received no comments on the NPR.

The regulations pertaining to caps intended for use with toys guns in 16 CFR 1500.18(a)(5), 1500.47, and 1500.86(a)(6) were originally promulgated by the U.S. Food and Drug Administration (FDA). In September 1973, the Federal Hazardous Substances Act (FHSA) and the statute's implementing regulations were transferred from the FDA to the CPSC. See 38 FR 27012 (September 27, 1973). One of the regulations transferred to CPSC included a ban on caps intended for use with toy guns and toy guns not intended for use with caps "if such caps when so used or such toy guns produce impulse-type sound at a peak pressure level at or above 138 decibels. . . ." See 16 CFR 1500.18(a)(5). Another regulation transferred from FDA to CPSC, 16 CFR 1500.86(a)(6), exempts toy caps that produce peak sound levels of 138 to 158 decibels if: The packaging material contains a warning regarding proper use, the manufacturer notifies CPSC, and the manufacturer participates in a program to develop toy caps that produce peak pressure levels below 138 decibels. Manufacturers participating in this program are required to provide a status report to CPSC on their progress every three months. We are revoking this exemption because there are currently no manufacturers participating in this program.

Additionally, a third transferred regulation, 16 CFR 1500.47, provides the test method for determining the sound pressure level produced by toy

caps and toy guns. The method specifies the use of certain equipment, such as a microphone, preamplifier, and two types of oscilloscopes with specific response and calibration ranges. This regulation also addresses the manner in which peak sound pressure levels are measured.

Section 106 of the CPSIA mandated that the provisions of ASTM International Standard F963, "Standard Consumer Safety Specification for Toy Safety," be considered consumer product safety standards issued by the Commission under section 9 of the Consumer Product Safety Act (CPSA). References to ASTM F963 in this *Federal Register* notice are to version ASTM F963-11, which became effective on June 12, 2012. Section 4.5 of ASTM F963 establishes requirements for "sound-producing toys," and section 8.19 of ASTM F963 establishes "Tests for Toys Which Produce Noise." In general, the ASTM F963 requirements for sound-producing toys are more stringent than 16 CFR 1500.18(a)(5) and 1500.47. For example, section 4.5.1.5 of ASTM F963 states that the peak sound pressure level of impulsive sounds produced by a toy using percussion caps or other explosive action "shall not exceed 125" decibels at 50 centimeters, whereas, 16 CFR 1500.18(a)(5) imposes a ban at or above 138 decibels at 25 centimeters. As another example, section 8.19.2.4 of ASTM F963 specifies a weighted scale based on human hearing damage from the type of impulse noise being generated by the toy, whereas, 16 CFR 1500.47 specifies an unweighted scale for measuring pressure level generated by impulse-type sound. Additionally, the ASTM F963 test method specifies the use of modern equipment (microphones meeting a particular specification), whereas, 16 CFR 1500.47 specifies the use of a microphone, a preamplifier (if required), and an oscilloscope. The equipment specifications in 16 CFR 1500.47 have never been updated.

Therefore, because section 106 of the CPSIA mandates the provisions of ASTM F963 to be consumer product safety standards, and because we believe that the provisions of ASTM F963, with respect to caps intended for use with toy guns, are more stringent than 16 CFR 1500.18(a)(5), the final rule revokes 16 CFR 1500.18(a)(5). Similarly, because ASTM F963 establishes a test method for toys that produce sound, and because our existing regulation refers to obsolete or unnecessary test equipment, the final rule revokes 16 CFR 1500.47. Finally, because the final rule revokes 16 CFR 1500.18(a)(5), we are also revoking the exemptions from

Notices

Federal Register

Vol. 79, No. 3

Monday, January 6, 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

Food Safety and Inspection Service

[Docket No. FSIS-2012-0026]

Notice of Availability and Opportunity for Comments (Compliance Guideline for Controlling Salmonella in Market Hogs)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of a compliance guideline for official establishments to control and reduce the spread of *Salmonella* in hog slaughter facilities. The guidance provides information on best practices that may be applied at a hog slaughter facility to prevent, eliminate, or reduce levels of *Salmonella* on hogs at all stages of slaughter and dressing. This guideline will help hog slaughter establishments better comply with the relevant regulatory requirements. FSIS has posted this guideline on its Web page <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>.

DATES: Written comments may be submitted until March 7, 2014.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs, etc.: Send to Docket Room Manager, U.S. Department of Agriculture, Food Safety

and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0026. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Liza Murray, DVM, Risk, Innovations, and Management Staff, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW., Patriots Plaza 3, Mail Stop 3782, Room 8-126A, Washington, DC 20024; Phone: (301) 504-0845; Email: liza.murray@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

FSIS is issuing a guidance document to provide information on best practices that may be used by hog slaughter facilities in controlling and reducing the spread of *Salmonella* on market hogs.

An establishment that slaughters and processes market hogs, under HACCP, is to operate in a manner that prevents or reduces contamination at every step in the process. The establishment is to use decontamination and antimicrobial intervention treatments as necessary to remove contamination that may result from slaughtering or dressing or otherwise occurs on carcasses. The best practices outlined in this guidance are recommendations for establishments to improve their slaughter management practices to reduce levels of *Salmonella* on carcasses. The establishment that improves contamination control at appropriate processing locations will likely produce raw pork products that have fewer pathogens, including *Salmonella*.

FSIS urges the regulated industry to review the guidance and the scientific studies referenced in it. FSIS recommends that hog establishments follow this guidance to control and reduce the incidence and spread of *Salmonella*. The resulting improvements will also help establishments to better comply with the relevant regulatory requirements (9 CFR parts 310.7, 310.10, 310.11, 310.12, 310.18, 310.25, 416 and 417).

This guidance also discusses the Nationwide Microbiological Baseline Data Collection Program: Market Hog Survey that was conducted from August 2010–August 2011. The data collected and discussed in the guidance will enable the Agency to work more effectively with industry to reduce the risk of foodborne pathogens in FSIS regulated products.

FSIS welcomes comment on this compliance guidance, which will be revised as needed.

USDA 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, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (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 TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register>.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and

stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service>. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on: December 23, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-31488 Filed 1-3-14; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-967, C-570-968]

Aluminum Extrusions From the People's Republic of China: Final Results of Changed Circumstances Reviews; Partial Revocation of Antidumping and Countervailing Duty Orders

AGENCY: Enforcement and Compliance, formerly Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* November 12, 2010, for the antidumping duty order; September 7, 2010, for the countervailing duty order.

SUMMARY: On November 7, 2013, the Department of Commerce (the Department) published the notice of preliminary results of changed circumstances reviews and intent to revoke, in part, the antidumping (AD) and countervailing duty (CVD) orders on aluminum extrusions from the People's Republic of China (PRC),¹ with respect to certain rectangular wire. We invited interested parties to comment on the *Preliminary Results* and received no

comments other than support for partial revocation of the orders. Therefore, the final results do not differ from the preliminary results of reviews and we are revoking the orders with respect to certain rectangular wire. The partial revocations are effective November 12, 2010 (for AD) and September 7, 2010 (for CVD).

FOR FURTHER INFORMATION CONTACT:

James Terpstra, Office III, Antidumping and Countervailing Duty Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482-3965.

Background

On May 26, 2011, the Department published the AD and CVD orders in the *Federal Register*.² On June 20, 2013, the Department received a request on behalf of 3M Company (3M) for changed circumstances reviews to revoke, in part, the *Orders* with respect to certain rectangular wire imported by 3M. In its request, 3M attached a letter submitted on behalf of the Aluminum Extrusion Fair Trade Committee (AEFTC), the petitioners in the less-than-fair-value and CVD investigations, and the Aluminum Extrusion Council (AEC), in which representatives of the AEFTC and AEC stated that they no longer have interest in maintaining the *Orders* with respect to certain rectangular wire identified in 3M's request for the changed circumstances reviews. On July 2, 2013, 3M filed a letter containing a clarification from the AEFTC and AEC in which they stated that they no longer have interest in maintaining the *Orders* with respect to certain rectangular wire, regardless of whether 3M or another party imports it.

On August 20, 2013, we published a notice of initiation of these changed circumstances reviews.³ Because the statement provided by the AEC and offered in support of 3M's request for changed circumstances reviews did not indicate whether the AEC accounts for substantially all of domestic aluminum extrusion production, in the *Initiation Notice*, we invited interested parties to comment on the Department's initiation.

² See *Aluminum Extrusions from the People's Republic of China: Antidumping Duty Order*, 76 FR 30650 (May 26, 2011) and *Aluminum Extrusions From the People's Republic of China: Countervailing Duty Order*, 76 FR 30653 (May 26, 2011) (together, the *Orders*).

³ See *Aluminum Extrusions from the People's Republic of China: Initiation of Changed Circumstance Reviews and Consideration of Revocation of the Antidumping and Countervailing Duty Orders in Part*, 78 FR 51143 (August 20, 2013) (*Initiation Notice*).

We received no comments from interested parties.

On November 7, 2013, we published the notice of preliminary results of changed circumstances reviews, and intent to revoke the *Orders* in part.⁴ We received no comments or briefs in opposition from interested parties.⁵

Scope of the Orders

The merchandise covered by these *Orders* is aluminum extrusions which are shapes and forms, produced by an extrusion process, made from aluminum alloys having metallic elements corresponding to the alloy series designations published by The Aluminum Association commencing with the numbers 1, 3, and 6 (or proprietary equivalents or other certifying body equivalents). Specifically, the subject merchandise made from aluminum alloy with an Aluminum Association series designation commencing with the number 1 contains not less than 99 percent aluminum by weight. The subject merchandise made from aluminum alloy with an Aluminum Association series designation commencing with the number 3 contains manganese as the major alloying element, with manganese accounting for not more than 3.0 percent of total materials by weight. The subject merchandise is made from an aluminum alloy with an Aluminum Association series designation commencing with the number 6 contains magnesium and silicon as the major alloying elements, with magnesium accounting for at least 0.1 percent but not more than 2.0 percent of total materials by weight, and silicon accounting for at least 0.1 percent but not more than 3.0 percent of total materials by weight. The subject aluminum extrusions are properly identified by a four-digit alloy series without either a decimal point or leading letter. Illustrative examples from among the approximately 160 registered alloys that may characterize the subject merchandise are as follows: 1350, 3003, and 6060.

Aluminum extrusions are produced and imported in a wide variety of shapes and forms, including, but not limited to, hollow profiles, other solid profiles, pipes, tubes, bars, and rods. Aluminum extrusions that are drawn subsequent to extrusion (drawn aluminum) are also included in the scope.

⁴ See *Preliminary Results*.

⁵ On November 21, 2013, 3M submitted comments in which it stated that it supports the Department's partial revocation of the *Orders*.

¹ See *Aluminum Extrusions From the People's Republic of China: Preliminary Results of Changed Circumstances Reviews, and Intent To Revoke Antidumping and Countervailing Duty Orders in Part*, 78 FR 66895 (November 7, 2013) (*Preliminary Results*).

FDA Food Code, and lessons learned from controlling *Lm* in FSIS-inspected meat and poultry processing establishments, FSIS developed the "FSIS Best Practices Guidance for Controlling *Listeria monocytogenes* (*Lm*) in Retail Delicatessens," which provides practical recommendations that retailers can use to control *Lm* contamination and outgrowth in the deli. Retailers can use the best-practices guidance to help ensure that RTE meat and poultry products in the deli area are handled under sanitary conditions and are not adulterated under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) (see 21 U.S.C. 623(d) and 464(e)). While these practices are specifically designed to control *Lm*, they also may help control other foodborne pathogens that may be introduced into the retail deli environment and other facilities where consumers take possession of food.

The best practices are grouped in four sections: (1) Product and product handling, (2) cleaning and sanitizing, (3) facility and equipment controls, and (4) employee practices. Practices identified by the Interagency Retail *Lm* Risk Assessment that can significantly decrease the predicted risk of foodborne illness are highlighted in each section. The other practices that are based on scientific knowledge or lessons learned by FSIS are also included to help retailers increase *Listeria* control in the deli area. A self-assessment tool is provided for deli operators to help them identify the best practices they are using and to assess the need to adopt others. By following the best practices in the guidance and the 2013 FDA Food Code, retailers can help ensure that RTE products are not adulterated with *Lm*, and that the potential for listeriosis is decreased.

FSIS has posted the best-practices guidance on its Web page (<http://www.fsis.usda.gov/wps/wcm/connect/29d51258-0651-469b-99b8-e986bae8a54/Controlling-LM-Delicatessens.pdf?MOD=AJPERES>) and is requesting comments on the guidance. It is important to note that the best-practices guidance does not replace the 2013 FDA Food Code or FSIS regulations. The best-practices guidance sets out recommendations rather than requirements. The Agency will consider all comments submitted and will revise the best-practices guidance as necessary.

USDA 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, gender,

religion, age, disability, political beliefs, sexual orientation, and marital or family status. (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 TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals and other individuals who have asked to be included. The Update is available on the FSIS Web page. Through the Listserv and the Web page, FSIS is able to provide information to a much broader and more diverse audience.

In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done in Washington, DC on: April 1, 2014.
Alfred V. Almanza,
Administrator.

[FR Doc. 2014-08955 Filed 4-18-14; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2013-0029]

Availability of FSIS Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration Through Labeling

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of guidance on allergens and other ingredients of public health concern that provides recommendations for identifying hazards when conducting a hazard analysis and to prevent and control hazards through hazard analysis and critical control point (HACCP) plans or Sanitation standard operating procedures (SOPs) or other prerequisite programs with respect to these substances. The emphasis of the guidelines is on meat and poultry products. The guidelines represent the best practice recommendations of FSIS, based on scientific and practical considerations. By following these guidelines, establishments are likely to ensure that product labels declare all ingredients, as required in the regulations, and that the product does not contain undeclared allergens or other undeclared ingredients.

DATES: The Agency must receive comments by June 20, 2014.

ADDRESSES: A downloadable version of the compliance guide is available to view and print at http://www.fsis.usda.gov/Regulations_&Policies/Compliance_Guides_Index/index.asp. No hard copies of the compliance guide have been published.

FSIS invites interested persons to submit comments on this notice. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs: Send to Docket Room Manager, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2013-0029. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495, or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION: Under the Acts, meat and poultry products that contain an allergen that is not declared on the product label are adulterated because, to individuals who are allergic to the allergen, the products bear or contain a poisonous or deleterious substance (21 U.S.C. 453(g)(1) and 601(m)(1)).

Also under the Acts, meat and poultry products are misbranded if the labeling on the products is false or misleading in any particular (21 U.S.C. 601(n)(1) and 453(h)(1)). To prevent meat and poultry products from being misbranded, FSIS regulations require a listing of all ingredients on the labels of products (9 CFR 317.2(f)(1) and 381.118(a)(1)).

In recent years (2008-2012), there has been a sustained increase in the number of recalls of FSIS-regulated products that contained undeclared allergens. These recalls are preventable, as many have been due to ingredient changes, product changes, products in the wrong package, or products with misprinted labels. The Agency is issuing these guidelines to provide meat and poultry establishments with recommendations on how to identify hazards with respect to allergens and other ingredients of public health concern when conducting their hazard analysis, prevent and control these hazards through HACCP plans, Sanitation SOPs, or other prerequisite programs, and properly declare allergens in product. These guidelines also provide information on proper procedures for processing, handling, storing, and labeling a product with an allergenic ingredient or ingredient of public health concern. Although the guidelines set out

recommendations rather than requirements, FSIS encourages establishments to follow this guidance. The guidelines represent FSIS's thinking, and FSIS will update it as necessary to reflect comments received any additional information that becomes available.

USDA 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, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (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 TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/federal-register>.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service>. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: April 1, 2014.

Alfred V. Almanza,
Administrator.

[FR Doc. 2014-08956 Filed 4-18-14; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2012-0007]

HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice; response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is responding to comments on a **Federal Register** notice, "HACCP Plan Reassessment for Not-Ready-to-Eat (NRTE) Comminuted Poultry Products and Related Agency Verification Procedures," that it published on December 6, 2012. The notice provided updated information on the Agency's sampling and testing of these products, and on how it is verifying that establishments are effectively addressing the possible presence of *Salmonella* and *Campylobacter* in them.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495 or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION:

Background

In the December 6, 2012, **Federal Register** notice (77 FR 72686), FSIS informed establishments producing NRTE ground or otherwise comminuted chicken and turkey products that they must reassess their Hazard Analysis and Critical Control Point (HACCP) plans for these products. The Agency also described how it would determine whether the association of NRTE meat or poultry product with an illness outbreak would make subsequently-produced "like" product adulterated. FSIS announced that it would expand its *Salmonella* sampling beyond ground chicken and turkey to include all forms of non-breaded, non-battered comminuted NRTE chicken or turkey product not destined for further processing into ready-to-eat (RTE) products. Finally, FSIS announced that it intended to use the sampling results to determine the prevalence of *Salmonella* and *Campylobacter* in NRTE comminuted chicken and turkey and to