

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #7

Do Not Mark In This Box
Filing Date

2013 JUN -5 PM 1:20

SECRETARY OF STATE
NATALIE E. TENNANT

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: West Virginia Department of Agriculture TITLE NUMBER: 61

CITE AUTHORITY: WV Code 19-2B-3(a)

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES X NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 16

TITLE OF RULE BEING AMENDED: Inspection of Meat and Poultry

IF NO, SERIES NUMBER OF RULE BEING PROPOSED:

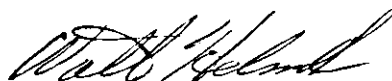
TITLE OF RULE BEING PROPOSED:

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME
EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER
FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE
AS FOLLOWS:

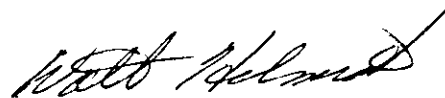
See Attached:

Use additional sheets if necessary


Authorized Signature

The Facts And Circumstances Constituting The Emergency Are As Follows:

To update our Meat and Poultry Inspection Division rules to maintain our "equal to" status with the Food Safety and Inspection Service (FSIS) and maintain our cooperative agreement that provides approximately \$800,000 per year of federal support. This allows us to adopt current Federal regulations as well as changes in the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA). FSIS has required states to adopt changes made in their regulations to facilitate enforcement. Changes required any establishment subject to inspection that believes, or has reason to believe, that an adulterated or misbranded meat or meat food product received by or originating from the establishment has entered into commerce shall promptly notify the Secretary with regard to the type, amount, origin, and destination of the meat or meat food product. Changes were made to require recall plans, documentation of process control plan reassessments, and make procedures and reassessed process control plans available to inspectors. Corresponding change were also made to the PPIA. Deleted federal regulations in Part 381 have also been removed to allow the 20,000 bird exemption to be recognized by our program at the request of constituents. This would enable individuals to legally sell up to approximately \$5,000 worth of poultry per year that is now unavailable for income. An attempt by legislature in 2013 to increase our current 1000 bird exemption was not compatible with federal regulations and would cause us to lose our "equal to" designation by FSIS. As a result we would lose the federal share (\$800,000) which is approximately one half of our annual budget.



EMERGENCY RULE QUESTIONNAIRE

DATE: May 22, 2013

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) West Virginia Department of Agriculture
Robert E. Pitts, DVM 1900 Kanawha Blvd., E, Charleston, WV 25305
304-558-2206

EMERGENCY RULE TITLE: Inspection of Meat and Poultry

1. Date of filing June 5, 2013

2. Statutory authority for promulgating emergency rule:

WV Code 19-2B-3(a)

3. Date of filing of proposed legislative rule: June 5, 2013

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? Amend current legislative rule.

5. Has the same or similar emergency rule previously been filed and expired?

No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.

This rule mandates inspected establishments to notify the WVDA if any adulterated product is received or allowed into commerce which will enable the Department to take necessary measures to minimize the potential harm to individuals and protect the health and safety of consumers of adulterated meat or poultry products. It allows small poultry farmers to sell dressed birds to maintain their livelihood and small businesses.

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

The Food Safety and Inspection Service notified our Meat and Poultry Inspection Division that we were in jeopardy of losing our "equal to" status and approximately \$800,000 of federal funding by holding up our annual self-assessment if we did not adopt this emergency rule.

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

See attached:

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

Consumption of adulterated meat or poultry products would not only be harmful to individuals that consumed the adulterated products but the resulting publicity would be highly detrimental to the small businesses involved in the production and/or distribution of the adulterated products. Market loss would likely result in the closing of these businesses, loss of jobs, and loss of services in the affected areas which could amount to millions of dollars. The 20,000 bird exemption gives us the ability to inspect the facilities used in the processing and assure sanitary standards can be met to protect the public health. If the 20,000 bird exemption is not recognized in our state, it would result in a substantial loss of income for individuals and possible loss of our federal funding if a state regulation was passed that would cause us to lose our federal funding.

Summary of Proposed Emergency Rule and Statement of Circumstances Constituting the Emergency.

This rule change adopts changes made through May 6, 2011 and March 1, 2013 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.

During this time period changes to the FMIA were included which required any establishment subject to inspection that believes, or has reason to believe, that an adulterated or misbranded meat or meat food product received by or originating from the establishment has entered into commerce shall promptly notify the Secretary with regard to the type, amount, origin, and destination of the meat or meat food product. In an additional section the Secretary shall require that each establishment subject to inspection under this chapter shall, at a minimum require each establishment to have current procedures for the recall of all meat or meat food products shipped by the establishment, document each reassessment of the process control plans of the establishment, and upon request, make the procedures and reassessed process control plans available to the inspectors.

Changes were also made to the PPIA to reflect corresponding changes relating to poultry or poultry products produced or shipped by the establishment. In all sections references made to the Secretary would be interpreted as the Director in the case of state establishments

Even though our program has been enforcing these rules, the Food Safety and Inspection Service in consultation with our counsel believed that it would be better to ask for this emergency rule to reinforce enforcement until these rules can be adopted through the regular rule making process. Our "equal to" status was withheld until we agreed to file this emergency rule and could lead to our loss of approximately \$800,000 in federal funding and our ability to maintain our state program.

Additional changes which were made in the regulations during the stated time period included allowing work time for inspectors to prepare equipment and donning and doffing of work clothing, amending the definitions and standards for the official U.S. classes of poultry, delaying the effective date of the final regulations that require nutritional labeling of the major cuts of single-ingredient, raw meat and poultry products and ground or chopped meat and poultry products, technical amendments to the labeling regulations related to reviewing and listing the food ingredients and sources of radiation listed or approved for use in the production of meat and poultry products,

adding approved uses of sodium benzoate, sodium propionate, and benzoic acid to the regulations, and establishing January 1, 2016 as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2013 and December 31, 2014.

Regulations 381.6; 381.10(a)(2), (5), (6), and (7); 381.10(b); and 381.13(b) from §61-16-3 "Deleted Regulations" of Rules on Inspection of Meat and Poultry have been removed to allow our program to adopt the 20,000 bird exemption recognized by the Food Safety and Inspection Service to assist small poultry producers. Constituents have asked for this and adopting these regulations would prevent any legislation by our legislature that would be incompatible with the federal regulations which would result in the loss of \$800,000 in matching federal funds and the loss of our state meat inspection program. This would make legal the sale of several thousand birds in the state that could be sold by individuals that would otherwise be worthless.

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.

Changes in rules are related to standards related to sanitation and food safety that are already enforced in establishments by meat inspection personnel and relate to changes in reporting that should not have any fiscal impact on plant personnel reporting or meat inspection personnel enforcement. The addition of the recognition of the 20,000 bird exemption will not require a significant amount of time for inspections and they can be done by existing personnel as part of their current responsibilities.

Date: May 16, 2013

Signature of Agency Head or Authorized Representative



**TITLE 61
LEGISLATIVE RULE
DEPARTMENT OF AGRICULTURE**

2013 JUN -5 PM 1:20

**SERIES 16
INSPECTION OF MEAT AND POULTRY**

§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 416, 417, 424, 430, 441 and 442) of the United States Department of Agriculture, promulgated in the Federal Register prior to ~~May 6, 2011~~ March 1, 2013 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; ~~381.6; 381.10 (a)(2), (5), (6), and (7); 381.10 (b); 381.13 (b); 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;

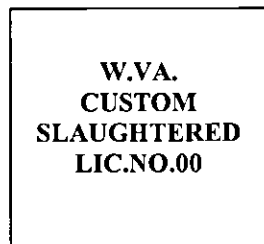
7.6.a.2. A custom stamp with the words "NOT FOR SALE" in uppercase letters at least 3/8" in height applied immediately upon receipt of a carcass or carcass parts which were slaughtered at a location other than the receiving licensed establishment;

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.

economic hardship must demonstrate to the DSO at the school where he or she is enrolled that this employment is necessary to avoid severe economic hardship. If the DSO agrees that the student should receive such employment authorization, he or she must recommend application approval to USCIS by entering information in the remarks field of the student's SEVIS record. The authority to collect this information is currently contained in the SEVIS collection of information currently approved by OMB under OMB Control Number 1653-0038.

This notice also allows F-1 students whose country of citizenship is Libya and who are experiencing severe economic hardship as a direct result of civil unrest in Libya since February 1, 2011, to obtain employment authorization, work an increased number of hours while school is in session, and reduce their course load, while continuing to maintain their F-1 student status.

To apply for work authorization an F-1 student must complete and submit currently approved Form I-765 according to the instructions on the form. The authority to collect the information contained on the current Form I-765 has previously been approved by the Office of Management and Budget under the Paperwork Reduction Act (PRA) (OMB Control No. 1615-0040). Although there will be a slight increase in the number of Form I-765 filings because of this notice, the number of filings currently contained in the OMB annual inventory for Form I-765 is sufficient to cover the additional filings. Accordingly, there is no further action required under the PRA.

Janet Napolitano,
Secretary.

[FR Doc. 2011-14482 Filed 6-9-11; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 307, 381, and 590

[Docket No. FSIS-2010-0014]

RIN [0583-AD35]

Changes to the Schedule of Operations Regulations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending

the meat, poultry products, and egg products regulations pertaining to the schedule of operations. FSIS is amending these regulations to define the 8-hour work day as including time that inspection program personnel need to spend at the workplace donning and doffing required gear, time spent walking to their workstations after donning required gear, and time spent walking from their work stations prior to doffing required gear.

DATES: Effective July 11, 2011.

FOR FURTHER INFORMATION CONTACT:

Daniel L. Engeljohn, Assistant Administrator, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250-3700, telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

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.*, provide for mandatory Federal inspection of livestock and poultry slaughtered at official establishments and of meat and poultry products processed at official establishments. The Egg Products Inspection Act (EPIA), 21 U.S.C. 1031 *et seq.*, provides for mandatory inspection of egg products processed at official plants. FSIS bears the cost of mandatory inspection provided during non-overtime and non-holiday hours of operation. Official establishments and egg products plants pay for inspection services performed on holidays or on an overtime basis.

On August 9, 2010, FSIS proposed to amend its regulations pertaining to the schedule of operations. FSIS proposed to define the 8-hour work day as including time that inspection program personnel need to spend at the workplace donning and doffing required gear, time spent walking to their workstations after donning required gear, and time spent walking from their work stations prior to doffing required gear. As explained in the preamble to the proposed rule, FSIS proposed the amendments to administer its inspection program in accord with the Supreme Court's holding in *IBP, Inc. v. Alvarez*, 546 U.S. 21 (2005), and policy guidance from the Office of Personnel Management (OPM).

Specifically, the preamble to the proposed rule explained that this regulatory change is necessary in light of the Supreme Court's ruling that the Fair Labor Standards Act (FLSA) covers (1) any activity that is integral and

indispensable to a principal activity; and (2) during a continuous workday, any walking time that occurs after the beginning of the employee's first principal activity and before the end of the employee's last principal activity. *IBP*, 546 U.S. at 37. The preamble to the proposed rule also briefly addressed OPM's treatment of the *de minimis* exception, codified at 5 CFR 551.412(a), and an OPM letter to the National Treasury Employees Union discussing that regulation. Finally, the preamble to the proposed rule described a settlement reached between FSIS and the National Joint Council of Food Inspectors regarding inspector compensation for donning and doffing activities.

Comments and FSIS Responses

FSIS received 20 comments on the proposed rule from the public, industry, and trade organizations. FSIS also received a letter concerning the proposal from the Department of Labor. Commenters generally supported that FSIS inspection program personnel should be fully compensated for work. However, commenters had varying opinions regarding the Agency's interpretation of *IBP*, the distinction between unique and non-unique gear, and application of the *de minimis* rule; and questions about how FSIS will implement the rule.

Unique Versus Non-Unique Gear and the Application of De Minimis

Several comments addressed the Agency's treatment of *IBP, Inc. v. Alvarez*, 546 U.S. 21 (2005), as it relates to the distinction between unique and non-unique gear and application of the *de minimis* rule. The two comments discussed in detail below were reflective of all comments related to this topic. "Unique" gear refers to items that are unique to the jobs at issue, such as cut-resistant gloves and chain link metal aprons in livestock slaughter establishments. "Non-unique" gear refers to generic items, such as hardhats, and hairnets, worn in all slaughter and processing establishments.

The first comment, submitted by the Department of Labor (DOL), argued that whether gear worn by employees is unique or non-unique is irrelevant to whether donning and doffing the gear is a principal, compensable activity. DOL stated that the preamble to the proposed rule incorrectly implied that *IBP* only dealt with unique protective gear. Rather, DOL stated that the two lower court cases that were consolidated by the Supreme Court in *IBP* in fact dealt with both unique and non-unique gear, and that the Supreme Court treated all items interchangeably, without regard to

weight or uniqueness, declaring that both lower court cases involved required protective gear that the lower courts found integral and indispensable to the employees' work. Next, DOL pointed out that the Supreme Court in *IBP* also cited approvingly to an older Supreme Court decision, *Steiner v. Mitchell*, 350 U.S. 247 (1956), in which the court held that changing into and out of old work clothes at a battery plant was an integral and indispensable part of the workers' principal activities, and therefore compensable. DOL argued that the old work clothes in *Steiner* clearly qualify as non-unique gear.

On the other hand, a comment submitted by an industry trade organization argued that the time associated with donning and doffing non-unique gear is noncompensable because it is *de minimis* as a matter of law. The trade organization stated that in *IBP*, the Supreme Court did not hold that the donning and doffing of non-unique gear by on-line inspectors in poultry establishments is a compensable activity. The trade organization stated that the question of what constitutes integral and indispensable activity was not addressed by the Supreme Court in that case. The trade organization stated that *IBP* only addressed whether walking time associated with donning and doffing integral and indispensable gear is compensable. The trade organization stated that the proposed rule incorrectly assumed that gear for both poultry and livestock inspection program personnel is integral and indispensable but that court precedent has not established that to be the case. The trade organization stated that, to the contrary, before *IBP* reached the Supreme Court, the 9th Circuit expressly concluded in *Alvarez v. IBP, Inc.*, 339 F.3d 894 (9th Cir. 2003), that donning and doffing time is compensable except for time associated with the donning and doffing of generic protective gear, such as the hardhats and safety goggles worn in the poultry industry, because the time it takes to don and doff such generic gear is *de minimis* as a matter of law. The trade organization stated that the Agency's proposed rule ignores the *de minimis* rule set forth by the Supreme Court in *Anderson v. Mt. Clemens Pottery Co.*, 328 U.S. 680 (1946), and OPM's rule dealing with the *de minimis* rule as applied to Federal employees, 5 CFR 551.412(a)(1).

Response:

The comments described above address two distinct concepts that must be considered in turn to determine whether inspection program personnel donning and doffing activities must be

compensated under Federal law. The first is: Are inspection program personnel donning and doffing activities integral and indispensable to their principal activity, and therefore covered under the FLSA? The second is: If the donning and doffing activities are covered under the FLSA, are they nevertheless noncompensable because they are *de minimis*? For the reasons described below, FSIS has determined that (1) inspection program personnel donning and doffing activities are covered by the FLSA; and (2) they are not *de minimis* to the extent that FSIS can reasonably account for them.

1. FSIS has determined that the FLSA covers time inspectors spend donning and doffing both unique and non-unique gear which they are directed by FSIS or an establishment to don and doff at the workplace in order to provide inspection services.

The Portal-to-Portal Act excludes from FLSA coverage time spent walking to and from the actual place of performance of the principal activity of an employee, and activities that are "preliminary or postliminary" to that principal activity. 29 U.S.C. 254(a). In *IBP*, the Supreme Court clarified the scope of what the Portal-to-Portal Act excludes from FLSA coverage, holding: (1) Any activity that is integral and indispensable to a principal activity is itself a principal activity and therefore outside the scope of the Portal-to-Portal Act, and thus covered by the FLSA; and (2) during a continuous workday, any walking time that occurs after the beginning of the employee's first principal activity and before the end of the employee's last principal activity is also outside the scope of the Portal-to-Portal Act and thus covered by the FLSA. *IBP*, 546 U.S. at 37.

Accordingly, if donning and doffing is integral and indispensable to inspectors' principal work activity, then it must also be considered a principal activity covered by the FLSA. The classification of gear as unique or non-unique has no bearing on whether the donning and doffing of such gear at the workplace is an integral and indispensable activity. For example, in *Steiner*, the Supreme Court considered whether changing into and out of old work clothes at a battery plant was an integral and indispensable part of the employees' principal activity of making batteries. 350 U.S. at 256. Although there was arguably nothing unique about the old work clothes at issue in *Steiner*, the Court held that the employees' donning and doffing activity was integral and indispensable to their principal activity. *Id.* The Court's analysis in that case hinged not upon whether the donning and doffing

involved unique or non-unique gear, but upon the relationship of the pre-shift and post-shift activity in question (i.e., donning and doffing the work clothes) to the principal productive activity performed by the employees (i.e., making batteries). Because of the toxic nature of making batteries, the plant owners provided employees with old but clean work clothes to change into and out of before and after their shift. In doing so, the plant owners were able to "make their plant as safe a place as [was] possible under the circumstances and thereby increase the efficiency of its operation." *Id.* at 249–51.

In *Alvarez*, the Ninth Circuit ruled that, in light of *Steiner*, the donning and doffing of both unique and non-unique gear by meat slaughter and processing plant employees was integral and indispensable to their principal activities of slaughtering and processing beef and therefore was not excluded from FLSA coverage by the Portal-to-Portal Act. *Alvarez*, 339 F.3d at 903. The Ninth Circuit based this conclusion on the finding that the donning and doffing activities in question were necessary to the principal work done by the employees (i.e., slaughtering and processing beef) and done for the benefit of the employer. *Id.* at 902–03. However, the Ninth Circuit ruled that since the time it takes to perform the donning and doffing of this non-unique gear is *de minimis*, therefore, it could not justify compensation for the time on these tasks. *Id.* At 904.

As the comment from the industry trade organization pointed out, the Supreme Court was not asked to review the Ninth Circuit's holding that donning and doffing were integral and indispensable to the principal activities of the meat slaughter and processing plant employees. However, the Supreme Court did consider the Ninth Circuit's related holding that during a continuous workday, time spent by employees walking to their workstation after donning their required gear was not excluded from the FLSA coverage by the Portal-to-Portal Act. *IBP*, 546 U.S. at 32. The Supreme Court's affirmation of the Ninth Circuit's holding with respect to walking to and from production areas was premised on the correctness of the Ninth Circuit's holding that the donning in question was indeed an integral and indispensable activity marking the beginning of the continuous workday. See *Perez v. Montaire Farms, Inc.*, 601 F.Supp.2d 670, 676 (D. Md. 2009).

As was the case with the gear considered in *Steiner* and *IBP*, sanitary and protective gear that FSIS inspectors are directed by FSIS or an establishment to don and doff at the workplace in

order to provide inspection services is directly related to the principal activity which they are employed to perform. The principal productive activity of FSIS inspectors is to provide inspection services at meat, poultry and egg products establishments. The purpose of food inspection is to advance FSIS's mission of protecting the health and welfare of consumers by verifying that food products are wholesome and not adulterated. Inspection program personnel don sanitary gear (e.g., hairnets, frocks, or smocks), if required by the establishment, and protective gear required by FSIS, as discussed in this Final rule under the heading "Establishment Specific Application of the Rule and What Does FSIS Mean by Required Gear" before providing inspection services, and doff it afterwards. To minimize the risk of food contamination during inspection and to ensure that inspection program personnel are protected from injury and may continue to fulfill their duties safely and without interruption. The donning and doffing of sanitary and protective gear by inspection program personnel is, therefore, necessary to the provision of proper inspection services. This is equally true of unique and non-unique gear. Accordingly, FSIS finds that all gear that inspection program personnel are directed by FSIS or an establishment to don and doff at the workplace in order to provide inspection services is integral and indispensable to the performance of their principal activities.

Because inspection program personnel's donning and doffing activities are integral and indispensable to inspection program personnel's principal activities, under the Supreme Court's ruling in *IBP*, those donning and doffing activities are themselves principal activities and are therefore covered by the FLSA. See *IBP*, 546 U.S. at 37. Additionally, during a continuous workday, if the donning and doffing are "principal activities," post-donning and pre-doffing walk time is also covered by the FLSA. *Id.*; See 29 CFR 790.6.

2. Although inspection program personnel's donning and doffing activities are covered by the FLSA, such activities might still be deemed noncompensable if they fall under the *de minimis* exception. The comment submitted by the trade organization argued that donning and doffing time at poultry slaughter establishments is never compensable because the donning and doffing of non-unique gear, such as that worn by inspectors at poultry slaughter establishments, is always *de minimis*. In light of the prevailing case law defining what constitutes *de*

minimis activities, and OPM's regulation limiting application of the *de minimis* exception in the Federal sector to periods of 10 minutes per day or less, FSIS disagrees with the trade organization comment.

Whether pre-shift and post-shift activity can be considered *de minimis* requires a fact-specific inquiry. Although, "[a]s a general rule, employees cannot recover for otherwise compensable time if it is *de minimis*," *Lindow v. United States*, 738 F.2d 1057, 1062 (9th Cir. 1984), FSIS has determined that for inspection program personnel, time spent donning and doffing is not *de minimis*.

The Supreme Court has reasoned that overtime compensation for "a few seconds or minutes" is *de minimis* "in light of the realities of the industrial world." *Anderson*, 328 U.S. at 692; see also *Lindow*, 738 F.2d at 1062. *Lindow*, one of the most frequently cited cases on the question of determining whether time spent in pre-shift and post-shift activity is *de minimis*, describes three factors to be considered: (1) The practical administrative difficulty of recording the additional time; (2) the aggregate amount of compensable time; and (3) the regularity of the additional work. *Id.* at 1063; see also *Bobo v. United States*, 136 F.3d 1465, 1468 (Fed.Cir. 1998) (citing approvingly to *Lindow*). In light of these three factors, FSIS has determined that, in most cases, the time inspection program personnel are directed to spend at the workplace donning and doffing required gear, and walking to their workstation after donning and before doffing, is not *de minimis*.

The first factor, the practical administrative difficulty of recording the additional time for payroll purposes, merits some discussion. FSIS bills federally inspected establishments for inspection services provided in excess of eight hours per shift. At slaughter establishments, carcasses are not permitted to begin passing the post-mortem inspection station on the evisceration line until an FSIS on-line inspector is at his or her post-mortem inspection station, ready to conduct carcass-by-carcass inspection. But inspectors must don and doff their required gear before they begin on-line carcass inspection. As a result, slaughter establishments must know in advance of planning their schedule of operations how much of their eight hours of free inspection services will be used for inspection program personnel donning and doffing activities. For example, if a poultry slaughter establishment does not wish to pay for overtime inspection services, and the establishment knows

that inspection program personnel must spend a total of 9 minutes per day conducting FLSA-covered donning, doffing, and walking activities, then the establishment can adjust its slaughter inspection operations accordingly. If it chooses to conduct slaughter operations for a full eight hours, it will incur overtime costs because FSIS will have provided more than 8 hours of inspection services.

In order to inform slaughter establishments how much donning and doffing time to account for as part of their regular eight hours of inspection services, FSIS will need to determine in advance of implementing this rule how much time it actually takes for inspection program personnel to conduct FLSA-covered donning, doffing, and walking activities at each individual slaughter establishment.¹ Because donning and doffing activities do not typically change from day to day at a given establishment, FSIS has determined that it is administratively practical to accurately assess the amount of time inspectors spend in those activities each day at each establishment, to inform slaughter establishments how much inspection time will be used for those activities in each respective establishment, and to ensure that inspection program personnel have the correct amount of time to conduct those activities each day.

The second *de minimis* factor, the aggregate amount of compensable time, also weighs in favor of a finding that inspection program personnel donning and doffing time is not *de minimis*. Inspection program personnel donning and doffing takes place every day, often for several minutes per day. In aggregate over time, this results in a substantial amount of compensable time.

The third *de minimis* factor, the regularity of the additional work, weighs in favor of the same conclusion because donning and doffing of generally the same gear occurs at the beginning and the end of every work day, generally for the same amount of time each day. Accordingly, FSIS finds that for inspection program personnel,

¹ However, it should be noted that FSIS does not intend to use this advance estimate of donning, doffing and walking time at each establishment for payroll purposes, but only for scheduling and billing purposes. FSIS intends to use the time studies only to provide advance notice of the duration and costs to each establishment of these principal activities. However, FSIS employees will be paid based on the time it actually takes them each day to perform these activities. FSIS anticipates that this time will be recorded on the time and attendance sheet that each inspector fills out. The actual time worked may or may not include overtime, depending on how the establishment schedules the work.

time they spend on donning and doffing activities is not *de minimis*.

The trade organization also argued that the donning and doffing of non-unique gear is always noncompensable in light of an OPM regulation addressing the *de minimis* doctrine in the context of Federal employees. See 5 CFR 551.412(a)(1). Under that regulation, "OPM limits the application of the *de minimis* doctrine to periods of 10 minutes or less per day." *Bull v. United States*, 68 Fed.Cl. 212, 226 (2005) (citing 5 CFR 551.412(a)(1); see also *Riggs v. U.S.*, 21 Cl.Ct. 664, 683 (1990) (holding that OPM's 10 minute threshold for time spent in pre-shift and post-shift activities is a proper application of the *de minimis* rule to the FLSA and the Portal-to-Portal Act).

Specifically, OPM's rule directs: "If an agency reasonably determines that a preparatory or concluding activity is closely related to an employee's principal activities, and is indispensable to the performance of the principal activities, and that the total time spent in that activity is more than 10 minutes per workday, the agency shall credit all of the time spent in that activity, including the 10 minutes, as hours of work." 5 CFR 551.412(a)(1).

The trade organization argued that under the OPM rule, preparatory and concluding activities such as inspection program personnel donning and doffing are only compensable when the total time spent in such activities is more than 10 minutes per workday. To the contrary, as the court explained in *Bull*, OPM's regulation provides an upper limit to the amount of time that a Federal agency may consider noncompensable under the *de minimis* exception, directing that if FLSA-covered activity exceeds 10 minutes per work day, the agency must compensate its employees for that activity. The rule forecloses the possibility of a Federal agency finding that an FLSA-covered preparatory or concluding activity which exceeds 10 minutes per day is *de minimis*. However, based on the three factor test discussed above, FSIS has determined that for inspection program personnel, most time spent on donning and doffing activity is not *de minimis*, so OPM's regulation limiting application of the *de minimis* doctrine is generally not applicable.

How FSIS Will Apply the Rule to Daily Operations

Several commenters sought clarification regarding how application of this rule might affect establishment operating schedules.

Response

Because inspection program personnel donning and doffing are principal activities, they will be treated in the same manner as other inspection services. Thus, the new rule specifies that the regular workweek, which consists of five 8-hour days of scheduled inspection service provided without charge, will include donning and doffing activities. Establishments must therefore understand that the 8-hours per scheduled shift of inspection service which they are provided without charge must include the time inspection program personnel need for FLSA-covered donning and doffing activities. At establishments where donning and doffing activities must occur before and after the commencement of on-line, carcass and parts inspection, FSIS will ensure that establishments know how much time inspection program personnel donning and doffing activities take so that those establishments may plan their regular operating schedules accordingly. If establishments require more than 8 hours of inspection service, they must request overtime inspection service as provided in 9 CFR 307.4(d)(3), 9 CFR 381.37(d)(3), and 9 CFR 590.126.

Establishment Specific Application of the Rule and What Does FSIS Mean by Required Gear

Some industry commenters expressed concern that FSIS would impose a "one-size-fits-all" approach to implementing this regulation by requiring each establishment to schedule the same amount of time for donning and doffing activities. The commenters contended that each establishment is different, and that the required donning, doffing and walking time should reflect the realities of each individual establishment. The commenters also requested that FSIS explain what the phrase "required gear" is intended to include.

Response

FSIS agrees that actual donning, doffing, and walking time will vary in each establishment depending on plant-specific variables. The Agency does not intend to use a one-size-fits-all approach to implement this rule. Some industry commenters misunderstood the proposed rule to state that each establishment must provide 15 minutes for donning, doffing, and walking time. This figure was only used in the context of estimating the cost to industry that may result from this rule.

FSIS agrees with the commenters that post-donning and pre-doffing walk time can vary significantly among

establishments. Also, FSIS is aware that inspectors may don and doff some equipment unique to a specific establishment. However, there is equipment that FSIS requires all of its on-line personnel to wear in meat slaughter operations and poultry slaughter operations. The following is the specific gear FSIS requires its employees to wear:

- **Hard Hats**—FSIS Directive 4791.1, Revision 2, Amendment 2 (5/15/02), the Basic Occupational Health and Safety Program, requires hard hats to be worn.

- **Hearing Protection**—FSIS Directive 4791.1, Revision 2, Amendment 2 (5/15/02), the Basic Occupational Health and Safety Program, requires hearing protection.

- **Cut Resistant and Cover Gloves**—FSIS Directive 4791.1, Revision 2, Amendment 2 (5/15/02), the Basic Occupational Health and Safety Program, requires Cut-Resistant Gloves.

- **Slaughter Equipment**—Knives, hook, steel, and scabbard. This equipment is required to perform postmortem inspection procedures as outlined in FSIS Directive 6100.2 Postmortem Livestock Inspection (9/17/07). Chapter II (pages 5–16) of this directive outlines the required inspection procedures for all species of livestock.

In response to the comment about required gear, FSIS has determined that the FLSA covers time inspectors spend donning and doffing required gear which they are directed by FSIS or an establishment (e.g., hairnets, frocks, or smocks) to don and doff at the workplace in order to provide inspection services.

Although FSIS requires inspection program personnel to wear skid-resistant footwear, FSIS allows them to don and doff this footwear at home. Accordingly, time spent donning and doffing required skid-resistant footwear is generally not compensable. However, if an individual establishment requires inspection program personnel to don and doff footwear at the establishment, then that time would be compensable.

Donning and doffing activities also include time to retrieve, clean, and store equipment to maintain sanitary conditions. Such activities were calculated and included as part of the time study mentioned in the economic analysis for the proposed rule. The letter from DOL also made specific reference to the need to compensate for the time to conduct such activities.

Also, FSIS employees are entitled to their entire lunch period. Donning and doffing activities, as well as walk time, are outside of the lunch period. The donning and doffing activity can differ

around the lunch period based on several factors including the amount of equipment (helmet, ear protection, etc.) the inspectors remove before their lunch period. Some equipment is removed based on personal comfort, and some equipment is removed because of plant requirements. For this reason, the Agency determined that the most practical and reasonable approach to assessing donning and doffing time surrounding the lunch period is to assume that the inspector will remove all personal protective equipment before taking his or her lunch period and will don all equipment after the lunch period before resuming on-line inspection duties. Therefore, donning and doffing around the lunch period will be factored into the time measurement discussed below.

After publication of this rule, FSIS will measure the amount of time it takes for on-line inspection program personnel to don and doff all required gear (including before and after the lunch period), walk to and from their workstation, and retrieve, clean, and store equipment to maintain sanitary conditions at each affected meat and poultry slaughter establishment. This cumulative total will give each plant the specific donning, doffing, walking time, retrieving, cleaning, and storage time measurement needed, so that they can account for it in their daily schedule of operations or as overtime. See footnote 1 for the explanation that this time will not be used for payroll purposes. For administrative and scheduling purposes, the time will be rounded up or down to the next whole minute. If an establishment has a concern about the outcome of the time measurements in its facility it can appeal as set out in FSIS's regulations.

Making Facilities Changes To Shorten Donning, Doffing, and Walking Time

Commenters also asked if it would be possible to make changes at their establishment to reduce donning, doffing, and walk time.

Response

Establishments may make facilities adjustments to reduce donning, doffing, and walk times, provided such changes do not affect the sanitary conditions in the establishment or impede inspection.

Overtime Charges

Several commenters stated that FSIS should not charge for overtime in 15 minute increments but only bill establishments for the actual time inspectors at the establishment take to don, doff, and walk to and from their work station.

Response

As a preliminary matter, compensable donning, doffing, and walking time will not necessarily be overtime. Consistent with current regulations, overtime will only be charged for time inspection program personnel work in excess of eight hours per workday. If an establishment's schedule of operations calls for less than eight hours of on-line inspection time, then any compensable donning, doffing, and walking time may still fit within the normal 8-hour workday. In that case, no overtime charges would result.

On the other hand, if the total workday, including on-line inspection time and compensable donning, doffing, and walking time, exceeds eight hours per workday, then all time in excess of eight hours will be charged as overtime as set forth in 9 CFR 307.6. This regulation establishes that for billing purposes, eight or more minutes shall be considered a full quarter hour. Also, the National Finance Center, which is tasked with processing our bill documents, can only bill in 15 minute increments.

FSIS Employees to Whom the Regulation Applies

FSIS received comments from Federal veterinarians stating that the proposed rule concerning donning and doffing is too limited because it does not include all personnel that must be prepared and on the line when operations start, in particular Public Health Veterinarians and Supervisory Public Health Veterinarians.

Response

The new regulations include donning, doffing, and walking time as activities that are within an FSIS inspection personnel's 8-hour work-day. This would apply to any FSIS inspection program personnel, including FSIS veterinarians, who are required to don and doff and be at an inspection station on the line at the start of a shift. In general, FSIS Veterinarians, off-line inspectors, supervisory consumer safety inspectors, and inspectors working in egg product plants are not required to be at an inspection workstation at start of or at the end of a shift. Note that for inspectors who are required to come in early, such as for pre-operational inspection, their donning, doffing, and walking time must also be accounted for.

Therefore, this regulatory change has no impact on their working conditions, unless they have to perform on-line duties in order for the establishment's line to start operating.

Change to the Regulatory Language

The letter that FSIS received from DOL stated that the proposed regulation would define the proposed 8-hour workday as including "the necessary time for FSIS inspection program personnel to put on required gear and walk to a work station and the necessary time for FSIS inspection program personnel to return from a work station and remove required gear. * * *" DOL requested that the word necessary be eliminated from the final regulation because it could be read to suggest something less than the actual time taken while performing such tasks.

Response

FSIS agrees with DOL that the actual time spent donning and doffing and the associated walk times are inspection activities that fall into the 8-hour workday. FSIS will know how much donning and doffing and walk time there is at each establishment as discussed above. FSIS believes this approach will ensure that FSIS employees are fully compensated as required by the FLSA. Therefore, to more accurately reflect that donning, doffing, and walk time are part of the inspector's 8-hour workday, FSIS has eliminated the word necessary from the final version of the regulation.

The Final Rule

Consistent with the proposed rule, FSIS is amending 9 CFR 307.4(c), 381.37(c), and 590.124 to provide that the eight hours of inspection service includes the time for inspection program personnel to put on required gear and walk to a work station and the time for inspection program personnel to return from a work station and remove required gear. Any time over those eight hours is overtime charged to an establishment. The only change, as discussed above, is to remove the word necessary from the regulatory language.

For egg product plants, FSIS's regulations at 9 CFR 590.124 define the normal operating schedule as consisting of a continuous 8-hour period per day (excluding not to exceed 1 hour for lunch) 5 consecutive days per week. FSIS does not believe additional time for donning and doffing will typically be necessary for inspection program personnel in egg product plants because inspection program personnel at those plants do not need to be at a required station for operations to begin. To ensure compliance with the applicable law and OPM guidance, however, the Agency is proposing to amend 9 CFR 590.124 to define the 8-hour work day as including the time for inspection

program personnel to put on required gear and walk to a work station and the time for inspection program personnel to return from a work station and remove required gear. The Agency anticipates that this change is likely to have little application to the work of the Agency's egg product inspection program personnel.

Executive Order 12866 and the Regulatory Flexibility Act

This rule was reviewed by the Office of Management and Budget under Executive Order 12866 and was determined to be significant.

Cost to the Industry

The FSIS cost estimate in this final rule remains similar to that of the proposed rule, but has been updated to reflect final FSIS overtime rates for FY 2011 and FY 2012.

Under this final rule, the most direct cost to the industry will be the overtime fee that the Agency will need to charge establishments for the time inspection program personnel spend donning required gear, walking to a work station, returning from a work station, and doffing required gear. If meat and poultry slaughter establishments want to maintain their normal shift length of operating for eight hours, they will incur some overtime fees. The choice is voluntary. Some meat and poultry slaughter establishments may choose not to incur the overtime charges if they expect that the decline in revenues from operating for a shorter amount of time will be smaller than the overtime fee cost. However, the Agency expects that most large meat and poultry slaughter establishments will choose to pay the overtime charge and maintain their current shift-time, as shortening the

shift time will decrease production and revenue while idling existing capacity.

The actual time FSIS inspection program personnel will take to don and doff required gear will vary in each meat and poultry slaughter establishment depending on plant-specific variables. In response to comments on the proposed rule, FSIS has decided, as discussed above, that it will measure the amount of time it takes for inspection program personnel to don and doff all required gear, walk to and from their workstation, and retrieve, clean, and store equipment to maintain sanitary conditions. See footnote 1 for the explanation that this time will not be used for payroll purposes.

For the purpose of its analysis, FSIS is using 15 minutes for donning, doffing, and walking time at all meat and poultry slaughter establishments as a reasonably conservative estimate for both poultry and livestock inspectors. The overtime fee that the Agency charges for 15 minutes is \$16.88 and \$17.16 for FY 2011 and 2012, respectively.² These costs are far less than the value of the poultry or livestock an establishment can slaughter in 15 minutes per line.

FSIS calculated these costs for the meat and poultry slaughter establishments because carcasses are not permitted to begin passing the post-mortem inspection station on the evisceration line until an FSIS on-line inspector is at his or her post-mortem inspection station, ready to conduct carcass and parts inspection.

This regulatory change should not impact the schedule of operations for meat and poultry processing establishments and egg product plants because those establishments can begin operations without FSIS inspection program personnel being at an on-line

inspection work station. Furthermore, very-small slaughter establishments typically will not be affected by this rule because of the nature of how slaughter is conducted in very-small establishments. Many of the inspectors at such establishments are on patrol assignments, inspectors typically drive up to the establishment, go into the establishment and simply put on their frock.

The most recent Agency data shows that there are 1,041 meat and poultry slaughter establishments, of which 263 are small and 566 are very small (by Small Business Administration size standards.)

FSIS started by calculating the number of inspection program personnel that this proposed rule will affect. Agency data show that there are 2,911 inspection program personnel in the poultry and meat slaughter establishments—1,954 in poultry and 957 in meat. Assuming all the establishments pay the 15-minute overtime charge per inspection program personnel, and that the establishments operate 260 days (5 days a week times 52 weeks), the annual cost for one on-line inspector will be about \$4,389 at the FY 2011 rate. The total cost to the industry will be about \$12.8 million and \$13.0 million in FY 2011 and 2012, respectively (see Table 1). Given that the annual revenue of the meat slaughtering industry alone in 2009 is about \$67.2 billion,³ the overtime cost to the industry is insignificant. If we breakdown the cost for FY 2011 by establishment size, based on the numbers of inspectors for each SBA size category, it will be \$10.6 million for the large establishments, \$2.1 million for the small and \$0.066 million for the very small establishments.⁴

TABLE 1—ESTIMATED ANNUAL COST OF THE OVERTIME CHARGE TO THE INDUSTRY

	Number of inspection program personnel	Overtime fee (15 min.)	Daily cost	Number of days	Annual cost (Daily × Number of Days)
FY 2011	2,911	\$16.88	\$49,138	260	\$12,775,797
FY 2012	2,911	17.16	49,953	260	12,987,718

Cost to the Consumer

The industry is likely to pass the increased costs on to consumers because of the inelastic nature of the consumer

demand for meat and poultry products. However, given that the total volume of meat and poultry slaughtered under Federal inspection in 2009 was about 91

billion pounds,⁵ the increased cost per pound due to the overtime fee will be only \$0.0001, on average.

² FSIS Final Rule of New Formula for Calculating the Basetime, Overtime, Holiday, and Laboratory Rates; Rate Changes Based on the Formulas; and Increased Fees for the Accredited Laboratory Program.

³ Summary of the *Animal (except Poultry) Slaughtering Industry in the U.S. and its International Trade* [2010 edition.] Supplier

Relations US, LLC. http://www.htrends.com/report-2700858-Animal_except_Poultry_Slaughtering_Industry_in_the_U.S_and_its_International_Trade_Edition.html, as of 7/16/2010.

⁴ Among the 2,911 inspectors, 2,416 are for the large establishments, 480 are for the small establishments, and 15 are for the very small establishments.

⁵ *Livestock, Dairy, & Poultry Outlook/LDP-M-188/February 24, 2010*; Economic Research Service, USDA. The Web-link to the report is <http://www.ers.usda.gov/Publications/ldp/2010/02Feb/ldpm188.pdf>.

Benefit of the Rule

This rule will ensure compliance with the law and the best use of Agency resources.

Regulatory Flexibility Analysis

The FSIS Administrator has made a determination that this final rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). There are 263 small and 566 very small meat and poultry slaughter establishments. Based on the data and information contained in the cost to industry section of this rule, the fee is, at most, \$4,389 per year for one on-line inspector for an extra 15 minutes (FY 2011 rate). The time required for donning and doffing for small and very small establishments is likely much less than 15 minutes. Furthermore, almost all the very-small establishments will not be affected by this rule because they are on a patrol assignment. Therefore, the impact will not be significant.

Paperwork Reduction Act

This final rule has been reviewed under the Paperwork Reduction Act and imposes no new paperwork or recordkeeping requirements.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at http://www.fsis.usda.gov/Regulations_Policies/2010_Final_Rules_Index/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 will 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. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-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.

List of Subjects

9 CFR Part 307

Facilities for inspection.

9 CFR Part 381

Poultry products inspection regulations.

9 CFR Part 590

Inspection of eggs and egg products (egg products inspection act).

For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

PART 307—FACILITIES FOR INSPECTION

■ 1. The authority citation for part 307 continues to read as follows:

Authority: 7 U.S.C. 394; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

■ 2. In § 307.4(c), revise the second sentence to read as follows:

§ 307.4 Schedule of operations.

* * * * *

(c) * * * The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, and shall include the time for FSIS inspection program personnel to put on required gear and to walk to a work station, and the time for FSIS inspection program personnel to return from a work station and remove required gear, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, and shall include the time for FSIS inspection program personnel to put on required gear and to walk to a work station, and the time for FSIS inspection program personnel to return from a work station and remove required gear, excluding the lunch period. * * *

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

■ 4. In § 381.37(c), revise the second sentence to read as follows:

§ 381.37 Schedule of operations.

* * * * *

(c) * * * The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, and shall include the time for FSIS inspection program personnel to put on required gear and to walk to a work station, and the time for FSIS inspection program personnel to return from a work station and remove required gear, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, and shall include the time for FSIS inspection program personnel to put on required gear and to walk to a work station, and the time for FSIS inspection program personnel to return from a work station and remove required gear, excluding the lunch period. * * *

* * * * *

PART 590—INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

■ 5. The authority citation for part 590 continues to read as follows:

Authority: 21 U.S.C. 1031–1056.

§ 590.124 [Amended]

■ 6. In § 590.124, in the second sentence, after the word “day”, add the phrase “and shall include the time for FSIS inspection program personnel to put on required gear and to walk to a work station, and the time for FSIS inspection program personnel to return from a work station and remove required gear”.

Done at Washington, DC, on: June 7, 2011.

Alfred V. Almanza,
Administrator.

[FR Doc. 2011–14442 Filed 6–9–11; 8:45 am]

BILLING CODE 3410-DM-P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 124

[Docket No. SBA–2011–0013]

8(a) Business Development Program Regulation Changes; Tribal Consultation

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice; correction.

SUMMARY: The Small Business Administration (SBA) published a

Food Safety and Inspection Service, USDA

§ 307.1

§ 306.1 Designation of circuit supervisor and assistants.

[See §§ 300.3 and 300.4 of this chapter regarding FSIS' organization and inspection program supervisors.]

[69 FR 254, Jan. 5, 2004]

§ 306.2 Program employees to have access to establishments.

[See § 300.6 of this chapter regarding access to establishments and other places of business.]

[69 FR 254, Jan. 5, 2004]

§ 306.3 Badge as identification of inspectors.

Each inspector will be furnished with a numbered official badge, which he shall not allow to leave his possession, and which he shall wear in such manner and at such times as the Administrator may prescribe.

[35 FR 15559, Oct. 3, 1970, as amended at 69 FR 254, Jan. 5, 2004]

§ 306.4 Assignment of Program employees where members of family employed; soliciting employment; procuring product from official establishments.

(a) Except as specifically authorized by the Administrator, no Program employee shall be detailed for duty at an establishment where any member of his family is employed by the operator of the establishment, or any tenant or subsidiary of such operator nor shall any circuit supervisor or other employee acting in a supervisory capacity be continued on duty at a circuit where any member of his family is so employed at any establishment under his jurisdiction. Program employees are forbidden to solicit, for any person, employment at any official establishment, or by any officer, manager, or employee thereof.

(b) Program employees shall not procure product from any official establishment or any other establishment if its operations or products are inspected or regulated under the Poultry Products Inspection Act or the Agricultural Marketing Act of 1946, as amended, or any other law administered by the Department unless the store or outlet from which the purchase is made is open to the general public and the

price paid by such employee is the same as the price paid by the general public. Program employees must pay, and obtain receipts for money paid to such establishments for all such product and keep such receipts subject to inspection by supervisory employees or other authorized Department employees.

§ 306.5 Appeals.

Any appeal from a decision of any Program employee shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, except as otherwise provided in the applicable rules of practice.

[48 FR 11418, Mar. 18, 1983, as amended at 60 FR 67454, Dec. 29, 1995]

PART 307—FACILITIES FOR INSPECTION

Sec.

307.1 Facilities for Program employees.

307.2 Other facilities and conditions to be provided by the establishment.

307.3 Inspectors to furnish and maintain implements in a sanitary condition.

307.4 Schedule of operations.

307.5 Overtime and holiday inspection service.

307.6 Basis of billing for overtime and holiday services.

307.7 Safety requirements for electrical stimulating (EST) equipment.

AUTHORITY: 7 U.S.C. 394, 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15560, Oct. 3, 1970, unless otherwise noted.

§ 307.1 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, shall be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the circuit supervisor and shall be conveniently located, properly ventilated and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to

change clothing if such clothes changing facilities are deemed necessary by the circuit supervisor. At the discretion of the Administrator, small plants requiring the services of less than one full time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing shall be provided by each establishment.

§ 307.2 Other facilities and conditions to be provided by the establishment.

When required by the circuit supervisor, the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions, shall be provided by each official establishment:

(a) Satisfactory pens, equipment, and assistants for conducting ante-mortem inspection and for separating, marking and holding apart from passed livestock those marked "U.S. suspect" and those marked "U.S. condemned" (pens, alleys, and runways shall be paved, drained, and supplied with adequate hose connections for cleanup purposes);

(b) Sufficient light to be adequate for proper conduct of inspection;

(c) Racks, receptacles, or other suitable devices for retaining such parts as the head, tongue, tail, thymus gland, and viscera, and all parts and blood to be used in the preparation of meat food products or medical products, until after the post-mortem examination is completed, in order that they may be identified in case of condemnation of the carcass; equipment, trucks, and receptacles for the handling of viscera of slaughtered animals so as to prevent contact with the floor; and trucks, racks, marked receptacles, tables, and other necessary equipment for the separate and sanitary handling of carcasses or parts passed for cooking;

(d) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;

(e) Watertight metal trucks or receptacles for holding and handling dis-

eased carcasses and parts, so constructed as to be readily cleaned; such trucks or receptacles to be marked in a conspicuous manner with the phrase "U.S. condemned" in letters not less than 2 inches high, and, when required by the circuit supervisor, to be equipped with facilities for locking or sealing;

(f) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for sterilizing all implements used in dressing diseased carcasses, floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;

(g) In establishments in which slaughtering is done, rooms, compartments, or specially prepared open places, to be known as "final inspection places," at which the final inspection of retained carcasses may be conducted (competent assistants for handling retained carcasses and parts shall be provided by the establishment; final inspection places shall be adequate in size and their rail arrangement and other equipment shall be sufficient to prevent carcasses and parts passed for food or cooking, from being contaminated by contact with condemned carcasses or parts; they shall be equipped with hot water, lavatory, sterilizer, tables, and other equipment required for ready, efficient, and sanitary conduct of the inspection; the floors shall be of such construction as to facilitate the maintenance of sanitary conditions and shall have proper drainage connections, and when the final inspection place is part of a larger floor, it shall be separated from the rest of the floor by a curb, railing, or otherwise);

(h) Retention rooms, cages, or other compartments, and receptacles in which carcasses and product may be held for further inspection (these shall be in such number and in such locations as the needs of the inspection in the establishment may require; they shall be equipped for secure locking or sealing and shall be held under locks or official seals furnished by the Department; the keys of such locks shall not leave the custody of Program employees. Every such room, compartment, or receptacle shall be marked conspicuously with the phrase "U.S. retained" in

letters not less than 2 inches high; rooms or compartments for these purposes shall be secure and susceptible of being kept clean, including a sanitary disposal of the floor liquids; establishment employees shall not enter any retention rooms or compartments or open any retention receptacles unless authorized by Program employees);

(i) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter (tanks or other rendering equipment which, under the regulations in this subchapter, must be sealed, shall be properly equipped for sealing as specified by the regulations in part 314 of this subchapter or by the circuit supervisor in specific cases);

(j) Docks and receiving rooms, to be designated by the operator of the official establishment, with the circuit supervisor, for the receipt and inspection of all products as provided in § 318.3 of this subchapter.

(k) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) and official certificates shall be kept when not in use (all such lockers shall be equipped for sealing or locking with locks or seals to be supplied by the Department; the keys of such locks shall not leave the custody of Program employees);

(l) Sanitary facilities and accommodations as prescribed by § 416.2(c), (d), (e), (f), and (h) of this chapter.

(m) In addition to any facilities required to accomplish sanitary dressing procedures, the following inspection station facilities for cattle and swine slaughter lines described in § 310.1(b) of this subchapter are required:

(1) An inspection station consisting of 5 feet of unobstructed line space for each head or carcass inspector and, for viscera table kills, 8 feet for each viscera inspector on the inspector's side of the table.

(2) A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass.

(3) A handwash lavatory (other than one which is hand operated), furnished with soap, towels, and hot and cold water, and located adjacent to the in-

spector's work area. In addition, for each head and viscera inspector on cattle slaughter lines, and each head inspector on swine slaughter lines, a sterilizer located adjacent to the inspector's work area.

(4) For mechanized operations, a line control switch located adjacent to each inspection station.

(5) Facilities to position tally sheets or other recording devices, such as digital counters, and facilities to contain condemned brands.

(6) For swine slaughter lines requiring three or more inspectors, and for those one- and two-inspector configurations where the establishment installs a mirror: At the carcass inspection station one glass or plastic, distortion-free mirror, at least 5 feet × 5 feet, mounted far enough away from the vertical axis of the moving line to allow the carcass to be turned, but not over 3 feet away, and so mounted that any inspector standing at the carcass inspection station can readily view the back of the carcass.

[35 FR 15560, Oct. 3, 1970, as amended at 47 FR 33676, Aug. 4, 1982; 50 FR 19902, May 13, 1985; 64 FR 56415, Oct. 20, 1999]

§ 307.3 Inspectors to furnish and maintain implements in a sanitary condition.

Inspectors shall furnish their own work clothing and implements, such as flashlights and triers, for conducting inspection and shall maintain their implements in sanitary condition as prescribed by § 416.3(a) of this chapter.

[64 FR 56415, Oct. 20, 1999]

§ 307.4 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of a Program employee. All slaughtering of animals and preparation of products shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established,

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the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 consecutive hours per shift during the basic workweek subject to the provisions of § 307.5: *Provided*, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, excluding lunch period. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its function. These provisions are applicable to all official establishments except in certain cases as provided in § 318.4(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take into account the efficient and effective use of inspection personnel. The work schedule must specify daily clock hours of operation and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving an addition or elimination of shifts shall be submitted

to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided*, however, minor deviations from a daily operating schedule may be approved by the inspector in charge, if such request is received on the day preceding the day of change.

(3) Request for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided*, That an inspector may be recalled to his assignment after completion of his daily tour of duty under the provisions of § 307.6(b).

[40 FR 45799, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986]

§ 307.5 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday as specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall become a holiday.

[40 FR 45800, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 724, Jan. 7, 1985; 50 FR 51513, Dec. 18, 1985; 52 FR 4, Jan. 2, 1987; 53 FR 13397, Apr. 22, 1988; 54 FR 6389, Feb. 10, 1989]

§ 307.6 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in § 307.5(a) and at the rates specified in § 391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Program employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of a Program employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

[40 FR 45800, Oct. 3, 1975, as amended at 54 FR 6389, Feb. 10, 1989]

§ 307.7 Safety requirements for electrical stimulating (EST) equipment.

(a) *General.* Electrical stimulating (EST) equipment is equipment that provides electric shock treatment to carcasses for the purpose of accelerating rigor mortis or facilitating blood removal. These provisions do not apply to electrical equipment used to stun and/or slaughter animals or to facilitate hide removal. Electrical stimulating equipment consists of two separate pieces—the control system and the applicator. The EST control system contains the circuitry to generate pulsed DC or AC voltage for stimulation and is separate from the equipment used to apply the voltage to the carcass. The voltage is applied by inserting a probe that penetrates the carcass or is inserted in the rectum, placing a clamp in the nose, a carcass rubbar, a conveyor with energized surfaces traveling with the carcass, or any other acceptable method.

(b) *Safety requirements—(1) Circuits, grounding.* Either a bonded grounding conductor shall lead from each section of the carcass rail within the stimulating enclosure to the service ground,

or the secondary voltage (stimulating circuit) shall be insulated from the service ground. If the stimulating section of the carcass rail and carcass drive mechanisms are insulated from the service ground then the stimulating rail or the return path shall be electrically bonded to the transformer secondary to isolate the stimulation voltage.

(2) *Enclosure.* Electrical stimulation shall occur in an area that will prevent persons from contacting an energized surface. If the area is surrounded by physical barriers, the enclosure shall be either electrically grounded or it shall be made of materials that do not conduct electricity. The interior of the stimulating area shall be visible from the start switch so the operator can be assured that there is no person, equipment or material present that should not be there prior to starting the stimulating sequence. If light or sound beam sensors form the enclosure, the stimulating equipment shall be automatically shut off when the sensor signals are broken.

(3) *Mandatory Warning Devices and Signals.* The following warning devices or signals shall be installed at each opening to the stimulating area through which a person would normally enter:

(i) A red light that flashes distinctly during the operating cycle of the stimulating equipment.

(ii) An ANSI Z53.1-Color Code sign reading (a) "Danger Electrical Hazard" for stimulating voltage below 50 or (b) "Danger High Voltage" for stimulating voltage above 50.

(iii) An emergency stop button.

(4) *Optional Warning Device—Horn or Bell.* If a warning horn or bell is installed, the signal shall be audible above background noises in the vicinity, and it shall sound for at least 1 second before each manual stimulation or before the carcass chain is started in an automatic system.

(c) *Operation—*

(1) *Training.* Only persons who have received safety instruction by the equipment manufacturer or designee may operate electrical stimulating equipment.

(2) *Cleaning and Maintenance.* To prevent an electrical shock to personnel,

the electricity supplied to the stimulating surfaces shall be locked-off when cleaning, mechanical inspection, maintenance or testing are performed.

(3) *Water.* To prevent an electrical shock, personnel shall not spray streams of water on energized carcasses or on energized stimulating surfaces.

(d) Special provisions for manually operated equipment.

(1) Stimulating probes or clamps shall be stored in a sanitary container which is insulated with a material approved by the Administrator.¹

(2) The electric wires attached to a clamp or probe shall not allow for contact between the probe or clamp and an electrical ground and shall not extend outside the enclosure.

[53 FR 46432, Nov. 17, 1988, as amended at 64 FR 56415, Oct. 20, 1999]

PART 308 [RESERVED]

PART 309—ANTE-MORTEM INSPECTION

Sec.

- 309.1 Ante-mortem inspection in pens of official establishments.
- 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.
- 309.3 Dead, dying, disabled, or diseased and similar livestock.
- 309.4 Livestock showing symptoms of certain metabolic, toxic, nervous, or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases.
- 309.5 Swine; disposal because of hog cholera.
- 309.6 Epithelioma of the eye.
- 309.7 Livestock affected with anthrax; cleaning and disinfection of infected livestock pens and driveways.
- 309.8 Cattle affected with anasarca and generalized edema.
- 309.9 Swine erysipelas.
- 309.10 Onset of parturition.
- 309.11 Vaccine livestock.
- 309.12 Emergency slaughter; inspection prior to.
- 309.13 Disposition of condemned livestock.
- 309.14 Brucellosis-reactor goats.

¹ A list of approved insulation materials is available upon request from the Facilities, Equipment and Sanitation Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

309.15 Vesicular diseases.

309.16 Livestock suspected of having biological residues.

309.17 Livestock used for research.

309.18 Official marks and devices for purposes of ante-mortem inspection.

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15563, Oct. 3, 1970, unless otherwise noted.

§ 309.1 Ante-mortem inspection in pens of official establishments.

(a) All livestock offered for slaughter in an official establishment shall be examined and inspected on the day of and before slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for such examination and inspection to be made on a different day before slaughter.

(b) Such ante-mortem inspection shall be made in pens on the premises of the establishment at which the livestock are offered for slaughter before the livestock shall be allowed to enter into any department of the establishment where they are to be slaughtered or dressed or in which edible products are handled. When the holding pens of an official establishment are located in a public stockyard and are reserved for the exclusive use of the establishment, such pens shall be regarded as part of the premises of that establishment and the operator of the establishment shall be responsible for compliance with all requirements of the regulations in this subchapter with respect to such pens.

§ 309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

(a) Any livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that, under part 311 of this subchapter, may cause condemnation of the carcass on post-mortem inspection, and any livestock which show, on ante-mortem inspection, any disease or condition that, under part 311 of this subchapter would cause condemnation of only part of the carcass on post-mortem inspection, shall be so handled as to retain

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§ 381.28 Report of violations.

Each inspector, agent, representative, or employee of the Inspection Service shall report, in the manner prescribed by the Administrator, all violations of the Act and noncompliance with the regulations of which he has knowledge.

Subpart F—Assignment and Authorities of Program Employees; Appeals

§§ 381.30–381.31 [Reserved]

§ 381.32 Access to establishments.

[See § 300.6 of this chapter regarding access to establishments and other places of business.]

[69 FR 255, Jan. 5, 2004]

§ 381.33 Identification.

Each inspector will be furnished with a numbered official inspection badge, which shall remain in his or her possession at all times, and which shall be worn in such manner and at such times as the Administrator may prescribe.

[59 FR 42156, Aug. 17, 1994, as amended at 69 FR 255, Jan. 5, 2004]

§ 381.34 Financial interest of inspectors.

(a) No inspector shall inspect any poultry or poultry product in which he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person with whom he is negotiating or has any arrangement concerning prospective employment, is financially interested.

(b) All inspectors are subject to statutory restrictions with respect to political activities; e.g., 5 U.S.C. 7324 and 1502.

(c) Violation of the provisions of paragraph (a) of this section or the provisions of applicable statutes referenced in paragraph (b) of this section will constitute grounds for dismissal in the case of appointees and for revocation of licenses in the case of licensees.

(d) Inspectors are subject to all applicable provisions of law and regulations and instructions of the Department and the Food Safety and Inspection Service and other authority concerning

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employee responsibilities and conduct. The setting forth of certain prohibitions in this part in no way limits the applicability of such general or other regulations or instructions.

§ 381.35 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided*, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal, and such superior shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate superior of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of \$9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

[48 FR 11419, Mar. 18, 1983, as amended at 60 FR 67456, Dec. 29, 1995]

Subpart G—Facilities for Inspection; Overtime and Holiday Service; Billing Establishments

§ 381.36 Facilities required.

(a) *Inspector's Office.* Office space, including, but not being limited to furnishings, light, heat, and janitor service, shall be provided rent free in the official establishment, for the use of Government personnel for official purposes. The room or space set apart for this purpose must meet the approval of the Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing. At

the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Each official establishment shall provide commercial laundry service for inspectors' outer work clothing, or disposable outer work garments designed for one-time use, or uniform rental service garments which are laundered by the rental service.

(b) *Facilities for ante mortem inspection.* A suspect pen is required for adequate ratite inspection.

(c) *Facilities for the Streamlined Inspection System (SIS).* The following requirements for lines operating under SIS are in addition to the normal requirements to obtain a grant of inspection. The requirements for SIS in §381.76(b) also apply.

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (c)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 4 feet along the conveyor line for the inspector, and 4 feet for the establishment helper. A total of at least 8 feet along the conveyor line shall be supplied for one inspection station and 16 feet for two-inspection stations.

(iii) Selectors or "kickouts" shall be installed in establishments with two inspection stations on a line so each inspector will receive birds on 12-inch centers with no intervening birds to impede inspection. The selector must move the bird to the edge of the trough for the inspector and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid swinging when entering the inspection station.

(iv) Each inspector's station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall be designed

so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough or other facilities shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index value of 85 where the birds are inspected to facilitate inspection.

(viii) Online handrinsing facilities with a continuous flow of water must be provided for and within easy reach of each inspector and each establishment helper. The hand-contact element must be rinsed automatically with a sufficient volume of water to remove all fat, tissue, debris, and other extraneous material from the hand contact element after each use. Both hot and cold running water shall be available at each inspection station on the eviscerating line and shall be delivered through a suitable mixing device controlled by the inspector. Alternatively, water for hand washing shall be delivered to such inspection stations at a minimum temperature of 65 degrees F.

(ix) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(x) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in §416.3(c) of this chapter.

(2) The following provisions shall apply only to prechill and postchill reinspection stations:

(i) Floor space shall consist of a minimum of 3 feet along each conveyor line and after each chiller to allow carcasses to be removed for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

(iii) A table, at least 2 feet wide, 2 feet deep, and 3 feet high designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index of 85 on the table surface shall be provided.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy access of persons working at the stations.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(d) Facilities for the New Line Speed (NELS) inspection system. The following requirements for lines operating under the NELS inspection system are in addition to the normal requirements to obtain a grant of inspection and to the requirements for NELS in §381.76 (b) and (c).

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (d)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 6 feet along the conveyor line for the estab-

lishment employee presenting the birds, 4 feet for the inspector, and 4 feet for the establishment helper. A total of at least 42 feet along the conveyor line shall be supplied for three inspection stations.

(iii) Selectors or "kickouts" shall be installed so the three inspection stations will receive birds on 18-inch centers with no intervening birds to impede inspection. The selector must move the bird to the end of the trough for the presenter, inspector, and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid splashing the mirror (paragraph (d)(1)(vii) of this section) and swinging when entering the inspection station. Guide bars shall not extend in front of the inspection station mirror to avoid obstructing the inspector's view.

(iv) Each inspector's station shall have an easily and rapidly adjustable platform, with a minimum of 14 inches of vertical adjustment, which covers the entire length of the station (4 feet) and has a minimum width of 2 feet. The platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A distortion-free mirror, at least 3 feet wide and 2 feet high, shall be mounted at each inspection station so that it can be adjusted between 5 and 15 inches behind the shackles, tilt up and down, tilt from side to side, and be raised and lowered. The mirror shall be positioned in relation to the inspection

platform so that the inspector can position himself/herself opposite it 8 to 12 inches from the downstream edge. The mirror must be maintained abrasion free.

(viii) A minimum of 200-footcandles of shadow-free lighting with minimum color rendering index value of 85¹ where the birds are inspected to facilitate inspection. A light shall also be positioned above and slightly in front of the mirror to facilitate the illumination of the bird and mirror surfaces.

(ix) "One-line" handrinsing facilities with a continuous flow of water shall be provided for and within easy reach of each inspector and each establishment presenter and helper.

(x) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(xi) Each inspection station shall be provided with receptacle for condemned carcasses and parts. Such receptacles shall comply with the performance standards in §416.3(c) of this chapter.

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of 6 feet along the conveyor line. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

(iii) A table, at least 3 feet wide and 2 feet deep, shall be provided for re-inspecting the sample birds.

(iv) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index of 85¹ on the table surface.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(e) Facilities for the New Turkey Inspection (NTI) System. The following

requirements for lines operating under the NTI System are in addition to the normal requirements to obtain a grant of inspection and to the requirements for the NTI System in §381.76 (b) and (c).

(1) The following provisions apply to every inspection station:

(i) The conveyor line must be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (e)(1)(iii) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 8 feet along the conveyor line; at least 4 feet for the inspector, and at least 4 feet for the establishment helper.

(iii) The inspector's station shall have an easily and rapidly adjustable platform with a minimum width of 2 feet which covers the entire length of the station (4 feet). The platform must adjust vertically a minimum of 14 inches, and must have a 42-inch rail on the back side and ½-inch foot bumpers on the sides and the front to allow safe working conditions.

(iv) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(v) A trough or other facilities shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be wide enough to prevent trimmings, drippage, and debris from accumulation on the floor or platforms. The clearance between suspended carcasses and the trough must be sufficient to prevent contamination of carcasses by splash.

(vi) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index value of 85¹ where the birds are inspected to facilitate inspection is required. The minimum lighting requirement for inspection stations in §381.52(b) shall not apply.

(vii) On-line handrinsing facilities with a continuous flow of water shall

¹This requirement may be met by deluxe cool white type of fluorescent lighting.

¹This requirement may be met by deluxe cool white fluorescent lighting.

be provided for and within easy reach of each inspector and each establishment helper.

(viii) Hangback racks shall be provided for and within easy reach of the establishment helper.

(ix) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in §416.3(c) of this chapter.

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of a minimum of 3 feet along the conveyor line so carcasses can be removed from each line for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor must not be less than 48 inches.

(iii) A table at least 3 feet wide and 2 feet deep designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85¹ at the table surface is required.

(v) A clipboard holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at this station.

[37 FR 9706, May 16, 1972, as amended at 38 FR 9794, Apr. 20, 1973; 47 FR 23434, May 28, 1982; 49 FR 42554, Oct. 23, 1984; 50 FR 37512, Sept. 16, 1985; 52 FR 39209, Oct. 21, 1987; 64 FR 56416, Oct. 20, 1999; 66 FR 22905, May 7, 2001]

§381.37 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of an Inspection Service employee. All eviscerating of poultry and further processing shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the in-

spector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 hours per shift during the basic workweek subject to the provisions of §381.38: *Provided*, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, excluding lunch period. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its functions. These provisions are applicable to all official establishments except in certain cases as provided in §381.145(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take in account the efficient and effective use of inspection personnel. The work schedule must specify the workweek, daily clock hours of operation, and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request

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by an establishment for a change in its work schedule involving changes in the workweek or an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided, however*, Minor deviations from a daily operating schedule may be approved by the inspector in charge if such request is received on the day preceding the day of change.

(3) Requests for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided*, That an inspector may be recalled to his assignment after the completion of his daily tour of duty under the provisions of § 381.39(b).

[40 FR 45800, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986]

§ 381.38 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest work-

day within that week shall be the holiday.

[40 FR 45801, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 51513, Dec. 18, 1985; 52 FR 5, Jan. 2, 1987; 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§ 381.39 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in § 381.38(a) and at the rate specified in § 391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Inspection Service employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of an Inspection Service employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

[40 FR 45801, Oct. 3, 1975, as amended at 54 FR 6390, Feb. 10, 1989]

Subpart H [Reserved]

Subpart I—Operating Procedures

§ 381.65 Operations and procedures, generally.

(a) Operations and procedures involving the processing, other handling, or storing of any poultry product must be strictly in accord with clean and sanitary practices and must be conducted in a manner that will result in sanitary processing, proper inspection, and the production of poultry and poultry products that are not adulterated.

(b) Poultry must be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior

estimated to be only about \$64, or about 0.7 percent of average annual sales by small entities. The dollar decrease in welfare for most small fresh bean producers would be even smaller, given that the majority planted less than an acre in green beans in 2007, while the average area planted in green beans by small-entity producers was 2.4 acres. Also, effects are likely to be smaller than indicated, to the extent that fresh French bean imports from Kenya would displace fresh bean imports from other countries.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule allows French beans and runner beans to be imported into the United States from the Republic of Kenya. State and local laws and regulations regarding French beans and runner beans imported under this rule will be preempted while the fruit is in foreign commerce. Fresh fruits and vegetables are generally imported for immediate distribution and sale to the consuming public, and remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. No retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579-0373.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

List of Subjects in 7 CFR Part 319

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

Accordingly, we are amending 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

■ 1. The authority citation for part 319 continues to read as follows:

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

■ 2. A new § 319.56-54 is added to read as follows:

§ 319.56-54 French beans and runner beans from Kenya.

French beans (*Phaseolus vulgaris* L.) and runner beans (*Phaseolus coccineus* L.) may be imported into the United States from Kenya only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pests: *Bactrocera cucurbitae*, *Chrysodeixis chalcites*, *Dacus ciliatus*, *Helicoverpa armigera*, *Lampides boeticus*, *Liriomyza huidobrensis*, *Macronellus hirsutus*, *Maruca vitrata*, *Spodoptera littoralis*, and *Thaumetobia leucotreta*.

(a) *Packinghouse requirements.* The beans must be packed in packing facilities that are approved and registered with Kenya's national plant protection organization (NPPO). Each shipping box must be marked with the identity of the packing facility.

(b) *Post-harvest processing.* The beans must be washed in potable water. Each bean pod must be either cut into chevrons or pieces that do not exceed 2 centimeters in length, or shredded or split the length of the bean pod. Split or shredded bean pod pieces may not exceed 8 centimeters in length and 8.5 millimeters in diameter.

(c) *Commercial consignments.* French beans and runner beans must be imported as commercial consignments only.

(d) *Phytosanitary certificate.* Each consignment of French beans or runner beans must be accompanied by a phytosanitary certificate issued by Kenya's NPPO attesting that the conditions of this section have been met and that the consignment has been inspected and found free of the pests listed in this section.

(Approved by the Office of Management and Budget under control number 0579-0373)

Done in Washington, DC, this 28th day of October 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011-28509 Filed 11-2-11; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS-2007-0048]

RIN 0583-AC83

Classes of Poultry

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the definitions and standards for the official U.S. classes of poultry so that they more accurately and clearly describe the characteristics of poultry in the market today. Poultry classes are defined primarily in terms of the age and sex of the bird. Genetic improvements and poultry management techniques have reduced the grow-out period for some poultry classes, while extensive cross breeding has produced poultry with higher meat yields but blurred breed distinctions. FSIS is taking this action to ensure that the labeling of poultry products is truthful and not misleading.

DATES: *Effective Date:* This rule is effective on January 1, 2014.

FOR FURTHER INFORMATION CONTACT: Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture (USDA), Washington, DC 20250-3700, Telephone (301) 504-0879, Fax (301) 504-0872.

SUPPLEMENTARY INFORMATION:

Background

On September 29, 2003, FSIS proposed to amend the definitions and standards for the official U.S. classes of poultry (68 FR 55902). Before publishing the 2003 proposed rule, the Agency had reviewed the poultry class definitions with USDA's Agricultural Marketing Service (AMS) Poultry Programs, and both agencies discussed the issue with members of the poultry industry and others knowledgeable about poultry genetics and breeding. After examining current poultry production methods and reviewing the

poultry classes defined in 9 CFR 381.170, FSIS and AMS concluded that a number of the poultry class definitions do not adequately reflect current poultry characteristics or industry practices. Therefore, FSIS, in consultation with AMS, determined that the poultry class definitions needed to be revised to more accurately and clearly describe poultry being marketed to consumers and to ensure that the labels for poultry products are truthful and not misleading. FSIS consulted with AMS during this rulemaking because AMS incorporates FSIS' regulatory poultry class standards into its U.S. Classes, Standards, and Grades for Poultry (AMS 70.200 *et seq.*).

In the 2003 proposed rule, in addition to proposing to lower the age definitions for 6 classes of poultry, FSIS requested comments on the merit of establishing ready-to-cook (RTC) carcass weights or maximums for poultry classes. The proposed classes were primarily based on the age and sex of the bird.

2009 Supplemental Proposed Rule

After FSIS published the 2003 proposed rule, AMS provided the Agency with new data that affected the proposed "roaster" class definition. These data, which were collected from the segment of the industry that routinely produces "roasters," suggested that a "roaster" class definition should include a RTC carcass weight. The data also suggested that FSIS should change the proposed weeks of age in the "roaster" class definition. Therefore, on July 13, 2009, FSIS issued a supplemental notice of proposed rulemaking to provide new information on and to re-propose the definition and standard for the "roaster" or "roasting chicken" (74 FR 33374).

In the preamble to the 2009 supplemental proposed rule, FSIS explained that, on the basis of the new AMS data, the Agency had tentatively concluded that a "roaster" or "roasting chicken" should be defined as a chicken between 8 and 12 weeks of age. The Agency noted that most of the comments submitted on the 2003 proposed "roaster" class definition

supported use of this age range for roasters (74 FR 33375).

In the 2009 supplemental proposal, the Agency also explained that it had tentatively concluded that a "roaster" or "roasting chicken" should be defined as a chicken with an RTC carcass weight of 5 pounds or more, based on survey information from AMS. The Agency stated that including the RTC carcass weight for this class of poultry would effectively differentiate "roasters" and "broilers". FSIS also explained that it had tentatively concluded that RTC carcass weight, instead of average live weight, is necessary in the class standard and definition so that FSIS can verify the appropriate use of the term "roaster" or "roasting chicken" on product labels.

FSIS reviewed the other poultry standards with AMS before issuing the 2009 rule and determined that they were still accurate, so the Agency only needed to re-propose the "roaster" definition.

Consultation With Advisory Committee

Under section 457(b)(2) of Title 21 of the United States Code, the Secretary of Agriculture is required to consult with the Secretary of Health and Human Services (HHS) and an appropriate advisory committee as provided for in 21 U.S.C. 454 before issuing standards of identity for poultry products. Pursuant to this requirement, FSIS consulted with the Food and Drug Administration (FDA), HHS, when developing the proposed rule. FDA determined that there were no existing product standards established by FDA that would be inconsistent with the revised poultry class standards as proposed. FDA has also reviewed this final rule and has determined that there are no existing FDA product standards that are inconsistent with the revised poultry class standards established in this final rule.

Also, pursuant to this requirement, in 2003, FSIS presented the proposed poultry class standards to the FSIS National Advisory Committee on Meat and Poultry Inspection (NACMPI) for consultation to ensure that there is no inconsistency between Federal and State standards. Comments submitted by NACMPI and FSIS' response are discussed below.

Response to Comments

FSIS received 9 comment letters in response to the 2003 proposed rule and 6 comment letters in response to the 2009 supplemental proposed rule on the "roaster" class definition. Comments were submitted by trade associations that represent poultry processors,

poultry processors, a non-profit organization that advocates humane treatment of farm animals, and 2 individuals.

After carefully analyzing the comments, FSIS has decided to adopt, with some changes, the poultry class definitions that it proposed in 2003 and the "roaster" class definition that it proposed in 2009.

The following is a summary of the comments submitted in response to the 2003 proposed rule and comments submitted in response to the 2009 supplemental proposed rule and FSIS' responses.

Comment: One trade association supported the 2003 proposed rule and stated that they had no objections to the proposed changes for the age definitions, proposed changes to the class definitions, deletion of the word "usually" from the age classifications, proposed changes to the game hen classes, and other proposed editorial changes.

Response: FSIS agrees with the comment.

"Roaster" Class Definition

Comment: In response to the 2003 proposed rule, FSIS received comments from the industry that suggested that FSIS adopt a "roaster" class definition that includes both an age range between 9 and 12 weeks at the time of slaughter and an average live flock weight of 7.75 to 8 pounds. The comments stated that a "roaster" class definition that includes this age range at the time of slaughter and a minimum average flock weight will provide reasonable parameters for companies that specially produce large, young "meat-type" birds.

Response: While FSIS agrees that the "roaster" class definition should include both an age range and weight requirements, the Agency does not agree that the weight should be based on the minimum average flock weight. Using RTC weight more accurately reflects the actual weight of the carcass that a consumer is purchasing. This weight is verifiable by the inspector at the processing site. The inspector cannot verify the flock weight. The flock weight is an average of a large number of birds rather than by individual bird. The variability in a flock weight may be large and not as accurate.

After consideration of the comments, and of the information that AMS obtained from "roaster" producers, FSIS has decided to adopt a "roaster" class definition that reflects AMS' recommendation to define a "roaster" as a chicken between 8 and 12 weeks of age and with a RTC carcass weight of 5 pounds or more. AMS' recommendation

¹ Ready-to-cook poultry at 9 CFR 381.1 is defined as any slaughtered poultry free from protruding pinfeathers and vestigial feathers (hair or down), from which the head, feet, crop, oil gland, trachea, esophagus, entrails, and lungs have been removed, and from which the mature reproductive organs and kidneys may have been removed, and with or without the giblets, and which is suitable for cooking without need of further processing. Ready-to-cook poultry also means any cut-up or disjointed portion of poultry or other parts of poultry, such as reproductive organs, head, or feet that are suitable for cooking without need of further processing.

is based on the results of a survey of the segment of the industry that produces "roasters," and reflects data on target weights for birds produced from 8 of the 13 "roaster" suppliers. FSIS and AMS both agree that a definition that includes RTC carcass weight rather than average live flock weight is necessary for FSIS to verify that the labeling of chickens identified as "roasters" is truthful and not misleading. This definition also more accurately reflects the characteristics of poultry labeled as "roasters."

Comment: Several comments from trade associations and poultry processors were concerned that the 2003 proposed "roaster" age definition of less than 12 weeks with no minimum RTC carcass weight would allow large "broilers" to be classified as roasters because of the overlap in the proposed age definition for the "broiler" class (less than 10 weeks of age) and the proposed age definition for "roaster" class (less than 12 weeks of age).

One comment from a poultry processor asserted that relying only on age requirements and other proposed criteria, such as characteristics of the breastbone cartilage, to define certain poultry classes, particularly the "roaster" chicken class, might cause confusion among industry and FSIS inspection program personnel. The comment stated that some establishments and FSIS inspection personnel may conclude that birds less than 12 weeks of age can be classified as either a "broiler" or a "roaster." The comment recommended that FSIS allow the "roaster" class to be a marketing term that may include young immature poultry from the "broiler" class, as long as specified weight requirements are met.

Response: As noted above, the roaster class definition in this final rule includes both an age range of 8 to 12 weeks at the time of slaughter and a RTC carcass weight of 5 pounds or more. A broiler is defined by an age of less than 10 weeks with no specified minimum RTC carcass weight. Although there is some overlap in the age definition for "broiler" and "roasters," the higher age limit for the "roaster" class combined with the minimum RTC carcass weight provides a way to clearly distinguish a "broiler" from a "roaster."

Comment: Several comments from poultry processors and an individual recommended that FSIS remove age from the definition of the "roaster" class and define "roaster" based solely on RTC carcass weight instead. According to the comments, a "roaster" class definition that includes the age of the bird is not relevant or meaningful to

consumers. The comments asserted that defining the "roaster" class by weight alone is sufficient to enable the consumer to identify the product without being misled.

Response: FSIS has determined that the definition needs to include the age range along with a minimum RTC carcass weight to ensure that only young birds are labeled as "roasters." Because production practices and housing technology have changed, the birds come to market weight much quicker than in the past. Therefore, it is important to inform consumers that "roasters" are young birds, not the more mature birds that consumers were accustomed to buying in the past. This new roaster definition was requested by the poultry industry and supported by industry comments because a definition that uses both the age and weight information is more likely to provide clarity for industry and consumers.

Most of the comments submitted on the 2003 proposal supported the use of this age range, which is consistent with the age of "roasters" in the market today.

Comment: Comments from a trade association and a poultry processor recommended that instead of a 5-pound RTC carcass weight definition for the "roaster" class, FSIS should adopt a minimum 5.5-pound RTC carcass weight as the bird exits post-chilling in the slaughter/evisceration process. According to the comment, such a definition will more accurately reflect the weight range of chickens that are marketed as "roasters" and "roasting chickens" and will maintain a distinction between "roasters" and "broilers" that are also being grown to heavier weights. Another comment suggested a "roaster" class weight definition that would include a 5.5-pound RTC carcass weight for a carcass without giblets at post chill and a 6-pound minimum RTC carcass weight for a carcass packaged with giblets.

Response: As noted above, information that AMS obtained from "roaster" producers supports a RTC carcass weight of 5 pounds or more. Birds that have the age and other characteristics of the roaster class and that have a RTC carcass weight of 5.5 pounds would be classified as "roasters." RTC weight has not been based on the weight of the carcass and the weight of the carcass plus giblets.

There was no rationale provided with the comment to support the need for 2 different weight minimums for this class of poultry. FSIS does not believe it is necessary to stipulate a minimum weight based on the carcass plus giblets.

Comment: One comment from a trade association had no opinion on whether FSIS should include a requirement for RTC carcass weights for certain poultry classes but stated that if FSIS were to adopt market-ready weights, the weight designations should not include any added solutions that are used to prepare birds for the cooking process.

Response: The minimum RTC carcass weight for the roaster class applies to carcasses that do not contain added solutions.

Comment: One comment from a poultry processor submitted in 2003 suggested that FSIS delay the issuance of any final rule to update the poultry classes to conduct the appropriate studies in consultation with consumers and the industry to craft a classification standard that accurately reflects what a "roaster" is. Another comment from a poultry processor stated that FSIS should consult with a wide cross section of buyers, consumers, and industry to determine the appropriate RTC carcass weight for the "roaster" class.

Response: As noted above, after FSIS issued the 2003 proposed rule, AMS collected new data from the segment of the industry that routinely produces "roasters." The agencies used these data to develop a roaster class definition that more accurately reflects the characteristics of chickens marketed as "roasters" and requested comments on the revised definition through a supplemental proposed rule.

Comment: Comments from a trade association and a poultry processor stated that FSIS should not require that chickens that meet the definition for the "roaster" class be labeled as "roaster" or "roasting chicken." The comments suggested that FSIS give companies the option of labeling these birds as "young chickens." According to the comment, the term "young chicken" will not mislead consumers because it does not imply the product is somehow superior to a "roaster" or "roasting chicken."

Another comment from a poultry processor asserted that designation of an RTC chicken carcass as a "broiler," "fryer," "roaster" or "roasting chicken" is not meaningful to consumers. The comment stated that consumers would likely select the RTC chicken carcass based on their needs in relation to the meal being prepared, e.g., a family of four will likely require a larger RTC chicken carcass than a single adult when preparing the same meal. The comment said that the similarities between the "broiler" or "fryer" and "roaster" or "roasting chicken" class are such that the standards are almost

interchangeable. The comment was concerned that under the proposed definitions, a "broiler" could be deemed misbranded simply because the RTC carcass weight infringes on the "roaster" class. The comment stated that FSIS should not require that chickens be labeled as a "broiler," "fryer," "roaster," or "roasting chicken," and that companies should have the option to label these poultry as "young chickens."

Response: Under the existing regulations, "broilers," and "roasters" are permitted to be labeled as "young chickens." 9 CFR 381.117(b) provides that "[t]he name of the product required to be shown on labels for fresh or frozen raw whole carcasses of poultry shall be in either of the following forms: The name of the kind (such as chicken, turkey, or duck) preceded by the qualifying term "young" or "mature" or "old," whichever is appropriate; or the appropriate class name as described in 9 CFR 381.170(a)." This final rule does not change requirements for product names in 9 CFR 381.117(b). Therefore, "broilers" and "roasters" may continue to be labeled by their class name or as "young chickens."

Young Turkeys

Comment: One comment submitted by a trade association that represents turkey processors objected to FSIS' proposal to lower the age for the young turkey class from under 8 months to less than 6 months. The comment stated that lowering the age for young turkeys by 2 months would place an undue burden on several companies that process young turkeys while providing little or no benefit to the consumer. According to the comment, if FSIS were to adopt the proposed reduction in age for the young turkey class, many establishments that process young turkeys would be dangerously close to exceeding or simply would not meet the new age requirements.

Response: After considering the comment, FSIS has decided to not lower the age definition for the young turkey class as proposed. Therefore, this final rule retains the existing "young turkey" age definition of less than 8 months.

To lower the definition to less than 6 months may adversely affect establishments that are labeling such birds as "young turkeys" under the existing regulations.

After considering the comments and recommendations from AMS, FSIS has concluded that a "young turkey" age definition of "less than 8 months" continues to accurately represent industry practices and accurately reflects the characteristics of these birds.

Broiler or Fryer Class

Comment: One commenter from a trade association noted that the terms "broiler" and "fryer" are permitted to be used interchangeably under the "broiler" or "fryer" chicken class definition. The commenter asserted that the use of both terms for one class of poultry might be confusing to consumers. The commenter suggested that FSIS either define the terms "broiler" and "fryer" in the regulations or amend the regulations to establish separate classes for "broiler" and "fryer" chickens, or for any other poultry identified by these terms.

Response: "Broiler" and "fryer" are regional terms for the same type of bird and are thus used interchangeably. The comment did not submit data to indicate that classifying chickens with certain characteristics as "broilers" or "fryers" is misleading to consumers. Therefore, FSIS is not establishing separate definitions for "broiler" and "fryer" chickens in this final rule.

Cornish Game Hens

Comment: One comment from a trade association stated that the term "hen" as used in the "Rock Cornish game hen" or "Cornish game hen" class may be misleading because the term hen implies that these birds are female while the definition states that the birds may be of either sex. The comment suggested that FSIS change the name of this poultry class to "Rock Cornish game bird" or "Cornish game bird."

Another comment from a poultry producer said that the proposed "Cornish hen" definition is inaccurate because it allows industry to call a bird that is not necessarily Cornish, and not necessarily a hen, a "Cornish hen." The comment suggested that FSIS add a definition for "poussin" to describe the next youngest bird than the "Cornish hen" if the Agency decides to keep the term Cornish hen. The comment suggested that USDA review the literature produced by the North American Meat Processors Association (NAMP) as it applies to usage of the term "poussin." According to the commenter, because USDA is attempting to have its regulations reflect usage in the poultry industry, it must consider not just the production level, but also the market.

Response: FSIS disagrees that the terms "Rock Cornish game hen" or "Cornish game hen" are misleading to consumers and that the Agency should change the name of the class to "Rock Cornish game bird" or "Cornish game bird." The existing terms for this poultry class, which provides for the

use of the term "hen" for young immature chickens of either sex, has been in place since FSIS established this poultry class definition. The term "hen" can be used for immature chickens of either sex because birds of this class are sexually immature. FSIS is not aware of any data to support that consumers are misled with the reference to "hen" in these terms. Changing the name of the class is likely to spur confusion.

FSIS also disagrees that the proposed "Cornish hen" definition is inaccurate because it allows industry to call a bird that is not necessarily Cornish, and not necessarily a hen, a "Cornish hen." The existing standards in FSIS' regulations do specify that a Cornish chicken be the progeny of a Cornish chicken crossed with another breed of chicken. However, FSIS continues to believe that it is doubtful that any purebred Cornish lines currently exist in commercial chicken production today and, therefore, the birds cannot be reliably distinguished on the basis of progeny.

FSIS also disagrees that it should add a new poultry class that would define poussin. The poultry classes in 9 CFR 381.170 represent poultry that are typically marketed to consumers and are more broadly used than the standards for poussin in NAMP's Poultry Buyers Guide.

Other Comments

Comment: A comment from an organization that advocates humane handling of farm animals and an individual stated that the lower age requirements proposed for certain poultry classes sanction and promote abnormally rapid growth in poultry, which compromises animal welfare and public health. An organization that advocates the humane treatment of farm animals recommended that FSIS adopt a "no action" alternative because the proposed amendments are largely unnecessary. According to the commenter, of the 6 definitions proposed for revision, 4 are completely accurate as currently written.

Response: FSIS disagrees that the lower age requirements proposed for the poultry classes compromise animal welfare and public health. The lower age requirements reflect the advancements in breeding and husbandry that have occurred since the poultry classes were established over 40 years ago. These advances have generally shortened the period of time required for birds to attain market-ready weights. FSIS is revising the poultry class standard to better reflect these changes.

Comment: A poultry processor requested that FSIS use this rulemaking

to replace the term "squab" in its regulations with "pigeon." The commenter stated that squab should be used to describe a young pigeon in labeling but not to define inspection amenability.

Response: This comment is outside the scope of this rule; however, the FY 2001 Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Act (the 2001 Appropriations Act), signed by the President on October 28, 2000, provided inspection amenability for ratites and squabs. The statute specifically states that "squabs" are to be inspected under the Poultry Products Inspection Act (PPIA). The 2001 Appropriations Act does not mention pigeons. Subsequently, based on that statute, FSIS conducted rulemaking to include squab in the definition of Poultry in 9 CFR 381.1.

Comment: One trade association comment stated that the proposed changes in nomenclature and weight ranges for the poultry classes may bring about price changes that may benefit the industry and retailers but may not result in benefits to consumers.

Response: FSIS does not believe the proposed changes will result in a significant change in the market price of poultry because the rule will not have much effect on consumer behavior. The rule may benefit suppliers because lowering the age limit means the suppliers will not have to keep the birds for as long as they have under current class standards for all classes of poultry whose age limits are lowered by this final rule. However, despite the potential increase in the supply of roasters, consumer demand will determine how many more roasters will be sold. The Agency does not think that the consumers will buy more roasters simply because the proposed rule lowers the age limit.

NACMPI Review

As noted above, in 2003, FSIS presented the proposed poultry class standards to the National Advisory Committee on Meat and Poultry Inspection (NACMPI). NACMPI reviewed the proposed poultry class standards and suggested that FSIS look at poultry production practices for non-traditional raising of poultry, such as organic and free-range. NACMPI recommended that FSIS not exclude any sector of the marketplace from using the standards in labeling because they use different production practices and that FSIS determine whether the non-traditional raising of poultry meets the standards in the proposed rule.

Further, the NACMPI asked if the poultry products imported have their own standard and who would know the ages on the imported poultry product.

In response to NACMPI's request, FSIS consulted with representatives from AMS's National Organic Program (NOP) to determine whether the revisions to the poultry class standards would affect the way that organic poultry are classified and labeled. NOP responded that although it does not have extensive market information on the age and size of organic poultry to fully evaluate the implications of these new classes, it does not anticipate that organic poultry growers will have difficulty raising birds with characteristics of the new class definitions. AMS/NOP contacted a poultry producer (who sells under the broiler or fryer class) to get its perspective on whether such a change would present an issue for the 25,000 organic birds they raise for the market. The producer stated that, although organic birds do take longer to get to market size because of slower weight gain (e.g., about 30% less for organic birds which take about 49 days to attain market weight), the producer does not anticipate a problem marketing "broilers" or "fryers" as defined in this rule.

In reference to NACMPI's comment on foreign trade, FSIS ensures that inspection systems in countries that export meat, poultry, and processed egg products to the United States are equivalent to those in the United States and that products from these countries are accurately labeled in accordance with domestic requirements. Also, in terms of a trade perspective, the amount of product that USDA could market under these standards of identity is very small in terms of imported product to the United States.

The Final Rule

In this final rule, FSIS is lowering the age definitions for 5 classes of poultry: "Rock Cornish game hen" or "Cornish game hen" from 5 to 6 weeks to less than 5 weeks (§ 381.170(a)(1)(i)); "broiler" or "fryer" from under 13 weeks to less than 10 weeks (381.170(a)(1)(ii)); "roaster" or "roasting chicken" from 3 to 5 months to 8 to 12 weeks of age (381.170(a)(1)(iii)); capon from under 8 months to less than 4 months (381.170(a)(1)(iv)); and fryer-roaster turkey from under 16 weeks to less than 12 weeks (381.170(a)(2)(i)). The Agency decided not to lower the age definition for a 6th class of poultry—young turkey—as proposed (see *RESPONSE TO COMMENTS*). Therefore, the age definition for a young

turkey remains at less than 8 months of age. In addition to lowering the age definition for the "roaster" class, this final rule also defines a "roaster" based on a RTC carcass weight of 5 pounds or more. Consistent with the proposal, the Agency is deleting the word "usually" from the age designation descriptions in all of the poultry class standards so that these age designations will be clear and enforceable.

Effective Date

Based on the uniform compliance date regulations, January 1, 2014 is the effective date for this final rule. January 1, 2014 is the uniform compliance date for new food labeling regulations that are issued between January 1, 2011 and December 31, 2012 (75 FR 71344, November 23, 2010.)

Other Provisions

In the 2003 proposed rule at 68 FR 55902, the Agency solicited comments on what age designations would be appropriate for poultry identified as "young geese," "mature geese," "young guineas" and "old guineas" but the Agency did not receive any comments in response.

Also, as proposed at 68 FR 55903, in addition to the changes made to the poultry class standards, this rule will delete the term "fully matured" from the yearling turkey class definition and change the name of the broiler duckling or fryer duckling class to "duckling." Birds in this class of ducks are labeled and marketed as "ducklings" without the prefixes "broiler" or "fryer." FSIS is changing the name of the roaster duckling class to "roaster duck." Roaster ducks are currently labeled and marketed as "ducks" rather than "ducklings."

In addition, the class definitions have been edited for clarity, consistency, and uniformity. For example, the class names used within the regulatory text will be placed in quotation marks to make the format of the poultry class standards regulation consistent with the other regulations that prescribe standards of identity for poultry products. References to specific numbers of weeks or months will be preceded by the words "less than" or "more than" rather than "under" or "in excess of" to improve the clarity of the regulations.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be "significant" and was reviewed by the Office of Management and Budget under Executive Order 12866.

Economic Impact of the Classes of Poultry Final Rule

This regulation may have some benefit for the industry, but it will not have a significant effect on the prices of poultry. Lowering the age limit for all the five classes of poultry will benefit the suppliers because they can sell birds at younger ages. In the case of roasters, some of the chickens that are broilers under the current standards will be qualified as roasters and can be sold at a higher per-pound price.² However, FSIS does not know how many chickens will be re-classified because there is no Agency data or market data on ages of the chickens in the market. There is also a demand constraint on how many of the re-classified chickens will be actually sold and generate the revenue. Therefore, it is very difficult to quantify the benefits to the industry.

Another possible effect on the industry is associated with possible changes to labels because of changes in classification of poultry. The "Uniform Compliance Date for Food Labeling Regulations" (75 FR 71344) allows establishments to incorporate multiple label redesigns required by multiple Federal rules into one modification during 2-year increments. If the establishments combine other labeling changes required by other Federal regulations with the labeling changes under this rule, they can spread out the cost of changing other labels.

On the demand side, this rule will not have much effect on consumers. Although some broilers will be qualified as roasters and become more expensive, consumers who want to buy broilers will still buy broilers. There is no empirical evidence of consumer preference of one class of chicken (roaster or broiler) over the other. In addition, empirical evidence shows that price elasticity for chicken in the United States is quite inelastic.³ Because the rule will not have a significant effect on the demand side and is not imposing additional cost to the suppliers, there will not be significant change in prices.

Final Regulatory Flexibility Analysis

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602,) the final rule will not have a significant impact on a substantial number of small

entities. The advancements in growing practices and technologies that have occurred since the original poultry class standards were developed are prevalent throughout the industry, regardless of the size of the entity. This rule merely updates existing regulations to reflect current poultry characteristics and production practices used throughout the entire industry. In fact, by lowering the age definition for five classes of poultry, this rule benefits the small and very small establishments as well as the large ones. It is voluntary if the establishments want to sell the large broilers as roasters; and if they decide to do so, the perceived benefits must outweigh the associated cost, such as labeling changes.

The Agency has considered two alternatives to this rulemaking. The first alternative is no rulemaking and to keep the old definitions. However, these definitions fail to take into account current poultry production practices, which have generally shortened the period of time required for poultry to gain market-ready weights. The second option is to use a weight range to define turkey and roaster classes. However, for turkeys, the Agency found such a class system would not accurately distinguish birds that differ significantly in relevant characteristics. As for roasters, information also suggests that classifying by weight alone is not an accepted practice industry-wide. In any case, both the alternatives would apply to the entire industry, and neither would have a differential effect on the small and very small establishments.

Paperwork Requirements

FSIS has reviewed this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and has determined that the information collection related to labeling has been approved by OMB under OMB Control Number 0583–0092.

FSIS does not anticipate many changes of labels due to changes in classification of poultry because many establishments are already using terms that meet the classifications established by this rule. In addition, the natural turnover of labels for poultry produced in a federally inspected facility will allow poultry establishments to incorporate label redesigns into one modification in 2-year increments based on the Uniform Compliance Date for Food Labeling Regulations (75 FR 71344). This rule established January 1, 2014, as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2011, and December 31, 2012. Hence, there will be basically

no additional paperwork burden for establishments.

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

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Additional Public Notification

FSIS will announce this final rule online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/Interim_&_Final_Rules/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

² AMS data shows the per-pound price for roasters are \$0.14 higher than broilers in 2009. *USDA Weekly Chicken Feature Activity*, July 23, 2010. <http://www.ams.usda.gov/pymarketnews>.

³ For example, a study by the Research Triangle Institute (RTI) found that U.S. demand elasticity to be –.43 for young chickens and –0.62 for other chickens. *Poultry Slaughter and Processing Sector Facility-Level Model, Final Report*. RTI. April, 2006.

delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 381

Food grades and standards, Poultry and poultry products.

For the reasons stated in the preamble, FSIS amends 9 CFR part 381 as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

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

■ 2. Section 381.170 is amended by revising paragraph (a) to read as follows:

§ 381.170 Standards for kinds and classes, and for cuts of raw poultry.

(a) The following standards specify the various classes of the specified kinds of poultry and the requirements for each class:

(1) *Chickens*—(i) *Rock Cornish game hen or Cornish game hen*. A “Rock Cornish game hen” or “Cornish game hen” is a young, immature chicken (less than 5 weeks of age), of either sex, with a ready-to-cook carcass weight of not more than 2 pounds.

(ii) *Broiler or fryer*. A “broiler” or “fryer” is a young chicken (less than 10 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and flexible breastbone cartilage.

(iii) *Roaster or roasting chicken*. A “roaster” or “roasting chicken” is a young chicken (between 8 and 12 weeks of age), of either sex, with a ready-to-cook carcass weight of 5 pounds or more, that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that is somewhat less flexible than that of a broiler or fryer.

(iv) *Capon*. A “capon” is a surgically neutered male chicken (less than 4 months of age) that is tender-meated with soft, pliable, smooth-textured skin.

(v) *Hen, fowl, baking chicken, or stewing chicken*. A “hen,” “fowl,” “baking chicken,” or “stewing chicken” is an adult female chicken (more than 10 months of age) with meat less tender than that of a roaster or roasting chicken and a nonflexible breastbone tip.

(vi) *Cock or rooster*. A “cock” or “rooster” is an adult male chicken with coarse skin, toughened and darkened meat, and a nonflexible breastbone tip.

(2) *Turkeys*—(i) *Fryer-roaster turkey*. A “fryer-roaster turkey” is an immature turkey (less than 12 weeks of age), of

either sex, that is tender-meated with soft, pliable, smooth-textured skin, and flexible breastbone cartilage.

(ii) *Young turkey*. A “young turkey” is a turkey (less than 8 months of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that is less flexible than that of a fryer-roaster turkey.

(iii) *Yearling turkey*. A “yearling turkey” is a turkey (less than 15 months of age), of either sex, that is reasonably tender-meated with reasonably smooth-textured skin.

(iv) *Mature or old (hen or tom) turkey*. A “mature turkey” or “old turkey” is an adult turkey (more than 15 months of age), of either sex, with coarse skin and toughened flesh. Sex designation is optional.

(3) *Ducks*—(i) *Duckling*. A “duckling” is a young duck (less than 8 weeks of age), of either sex, that is tender-meated and has a soft bill and soft windpipe.

(ii) *Roaster duck*. A “roaster duck” is a young duck (less than 16 weeks of age), of either sex, that is tender-meated and has a bill that is not completely hardened and a windpipe that is easily dented.

(iii) *Mature duck or old duck*. A “mature duck” or an “old duck” is an adult duck (more than 6 months of age), of either sex, with toughened flesh, a hardened bill, and a hardened windpipe.

(4) *Geese*—(i) *Young goose*. A “young goose” is an immature goose, of either sex, that is tender-meated and has a windpipe that is easily dented.

(ii) *Mature goose or old goose*. A “mature goose” or “old goose” is an adult goose, of either sex, that has toughened flesh and a hardened windpipe.

(5) *Guineas*—(i) *Young guinea*. A “young guinea” is an immature guinea, of either sex, that is tender-meated and has a flexible breastbone cartilage.

(ii) *Mature guinea or old guinea*. A “mature guinea” or “old guinea” is an adult guinea, of either sex, that has toughened flesh and a non-flexible breastbone.

* * * * *

Done at Washington, DC on October 27, 2011.

Alfred V. Almanza,
Administrator.

[FR Doc. 2011-28525 Filed 11-2-11; 8:45 am]

BILLING CODE 3410-DM-P

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Regulation D; Docket No. R-1435]

RIN No. 7100 AD 85

Reserve Requirements of Depository Institutions

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending Regulation D, Reserve Requirements of Depository Institutions, to reflect the annual indexing of the reserve requirement exemption amount and the low reserve tranche for 2012. The Regulation D amendments set the amount of total reservable liabilities of each depository institution that is subject to a zero percent reserve requirement in 2012 at \$11.5 million (up from \$10.7 million in 2011). This amount is known as the reserve requirement exemption amount. The Regulation D amendments also set the amount of net transaction accounts at each depository institution that is subject to a three percent reserve requirement in 2012 at \$71.0 million (up from \$58.8 million in 2011). This amount is known as the low reserve tranche. The adjustments to both of these amounts are derived using statutory formulas specified in the Federal Reserve Act.

The Board is also announcing changes in two other amounts, the nonexempt deposit cutoff level and the reduced reporting limit, that are used to determine the frequency at which depository institutions must submit deposit reports.

DATES: *Effective date:* December 5, 2011.

Compliance dates: For depository institutions that report deposit data weekly, the new low reserve tranche and reserve requirement exemption amount will apply to the fourteen-day reserve computation period that begins Tuesday, November 29, 2011, and the corresponding fourteen-day reserve maintenance period that begins Thursday, December 29, 2011. For depository institutions that report deposit data quarterly, the new low reserve tranche and reserve requirement exemption amount will apply to the seven-day reserve computation period that begins Tuesday, December 20, 2011, and the corresponding seven-day reserve maintenance period that begins Thursday, January 19, 2012. For all depository institutions, these new values of the nonexempt deposit cutoff level, the reserve requirement

2

§381.170

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into any separate bone-in part therefrom, for the purpose of providing a basting medium or similar function. The ingredients of the added materials and the manner of addition to the products must be found acceptable by the Administrator, in all cases. The introduction of the added materials shall increase the weight of the processed product by approximately 3 percent over the weight of the raw product after washing and chilling in compliance with §381.66. The weight of the added materials introduced into the poultry products as provided in this paragraph shall be included as part of the weight of the poultry for purposes of the net weight labeling provisions in §381.121(b).

(b) A raw poultry product, into which added materials are introduced as provided in paragraph (a) of this section must be labeled with a conspicuous, legible, and descriptive name, including terms that concisely describe the method of addition and function of the added material. All major terms in the product name must be printed with the same prominence, except that the words which describe the function of the added materials (such as "Injected for Flavored Basting") may be more prominent, provided this does not detract from the conspicuousness of the other terms in the product name (such as "Young Turkey"). The label must also bear a statement, in bold type, immediately below and adjacent to the product name, listing the common or usual names of the added materials in descending order of predominance. The first part of this statement must consist of terms adequate to inform consumers about the amount and manner of introduction of the solution (such as "Injected with approximately 3 percent of a solution of _____"), and must be printed at least one-fourth the size of the most prominent letter in the product name, with a minimum size of one-fourth inch for a ready-to-cook turkey and proportionately smaller for other poultry products. The remainder of the solution ingredients shall be declared in type at least one-eighth inch in height. The entire statement must be printed in a color that contrasts with the background and be displayed on the principal display panel.

(c) Approval for use of a label for product under this section depends upon the ability of the processor to control the finished product, within a range of three-tenths of 1 percent accuracy, so that the average percent of basting material in each outgoing lot is not greater than 3.3 percent or less than 2.7 percent of basting material when tested by an approved plant control procedure would be in compliance. As used in this section, "a lot" may be any reasonable portion of production designated by the operator of the official establishment, with a maximum of an entire shift's production from one production line. The control procedures to be eligible for approval by the Administrator must:

- (1) Assure compliance with all labeling requirements.
- (2) Control the variability of the amount of added approved solution within the limits defined above.
- (3) Provide for the disposition in accordance with the regulations of all products not in compliance with this section.
- (4) Incorporate a system of raw weight identification of a sufficient number of poultry and/or poultry parts to allow effective monitoring of the system by Federal inspectors and official establishment employees.

[37 FR 9706, May 16, 1972, as amended at 39 FR 36000, Oct. 7, 1974]

§381.170 Standards for kinds and classes, and for cuts of raw poultry.

(a) The following standards specify the various classes of the specified kinds of poultry, and the requirements for each class:

(1) *Chickens*—(i) *Rock Cornish game hen or Cornish game hen*. A Rock Cornish game hen or Cornish game hen is a young immature chicken (usually 5 to 6 weeks of age) weighing not more than 2 pounds ready-to-cook weight, which was prepared from a Cornish chicken or the progeny of a Cornish chicken crossed with another breed of chicken.

(ii) *Rock Cornish fryer, roaster, or hen*. A Rock Cornish fryer, roaster, or hen is the progeny of a cross between a purebred Cornish and a purebred Rock chicken, without regard to the weight of the carcass involved; however, the

term "fryer," "roaster," or "hen" shall apply only if the carcasses are from birds with ages and characteristics that qualify them for such designation under paragraph (a)(1) (iii) or (iv) of this section.

(iii) *Broiler or fryer*. A broiler or fryer is a young chicken (usually under 13 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and flexible breastbone cartilage.

(iv) *Roaster or roasting chicken*. A bird of this class is a young chicken (usually 3 to 5 months of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that may be somewhat less flexible than that of a broiler or fryer.

(v) *Capon*. A capon is a surgically unsexed male chicken (usually under 8 months of age) that is tender-meated with soft, pliable, smooth-textured skin.

(vi) *Hen, fowl, or baking or stewing*. A bird of this class is a mature female chicken (usually more than 10 months of age) with meat less tender than that of a roaster, or roasting chicken and nonflexible breastbone tip.

(vii) *Cock or rooster*. A cock or rooster is a mature male chicken with coarse skin, toughened and darkened meat, and hardened breastbone tip.

(2) *Turkeys*—(i) *Fryer-roaster turkey*. A fryer-roaster turkey is a young immature turkey (usually under 16 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin, and flexible breastbone cartilage.

(ii) *Young turkey*. A young turkey is a turkey (usually under 8 months of age) that is tender-meated with soft, pliable, smooth-textured skin, and breastbone cartilage that is somewhat less flexible than in a fryer-roaster turkey. Sex designation is optional.

(iii) *Yearling turkey*. A yearling turkey is a fully matured turkey (usually under 15 months of age) that is reasonably tender-meated and with reasonably smooth-textured skin. Sex designation is optional.

(iv) *Mature turkey or old turkey (hen or tom)*. A mature or old turkey is an old turkey of either sex (usually in excess

of 15 months of age) with coarse skin and toughened flesh.

(3) *Ducks*—(i) *Broiler duckling or fryer duckling*. A broiler duckling or fryer duckling is a young duck (usually under 8 weeks of age), of either sex, that is tender-meated and has a soft bill and soft windpipe.

(ii) *Roaster duckling*. A roaster duckling is a young duck (usually under 16 weeks of age), of either sex, that is tender-meated and has a bill that is not completely hardened and a windpipe that is easily dented.

(iii) *Mature duck or old duck*. A mature duck or an old duck is a duck (usually over 6 months of age), of either sex, with toughened flesh, hardened bill, and hardened windpipe.

(4) *Geese*—(i) *Young goose*. A young goose may be of either sex, is tender-meated, and has a windpipe that is easily dented.

(ii) *Mature goose or old goose*. A mature goose or old goose may be of either sex and has toughened flesh and hardened windpipe.

(5) *Guineas*—(i) *Young guinea*. A young guinea may be of either sex, is tender-meated, and has a flexible breastbone cartilage.

(ii) *Mature guinea or old guinea*. A mature guinea or an old guinea may be of either sex, has toughened flesh, and a hardened breastbone.

(b) The following standards specify the requirements for the specified cuts of poultry:

(1) "Breasts" shall be separated from the back at the shoulder joint and by a cut running backward and downward from that point along the junction of the vertebral and sternal ribs. The ribs may be removed from the breasts, and the breasts may be cut along the breastbone to make two approximately equal halves; or the wishbone portion, as described in paragraph (b)(3) of this section, may be removed before cutting the remainder along the breastbone to make three parts. Pieces cut in this manner may be substituted for lighter or heavier pieces for exact weight-making purposes and the package may contain two or more of such parts without affecting the appropriateness of the labeling as e.g., "chicken breasts." Neck skin shall not be included with the breasts, except that "turkey breasts"

may include neck skin up to the whisker.

(2) "Breasts with ribs" shall be separated from the back at the junction of the vertebral ribs and back. Breasts with ribs may be cut along the breastbone to make two approximately equal halves; or the wishbone portion, as described in paragraph (b)(3) of this section, may be removed before cutting the remainder along the breastbone to make three parts. Pieces cut in this manner may be substituted for lighter or heavier pieces for exact weight-making purposes and the package may contain two or more of such parts without affecting the appropriateness of the labeling as "breasts with ribs." Neck skin shall not be included, except that "turkey breasts with ribs" may include neck skin up to the whisker.

(3) "Wishbones" (Pulley Bones), with covering muscle and skin tissue, shall be severed from the breast approximately halfway between the end of the wishbone (hypocleidium) and front point of the breastbone (cranial process of the sternal crest) to a point where the wishbone joins the shoulder. Neck skin shall not be included with the wishbone.

(4) "Drumsticks" shall be separated from the thigh by a cut through the knee joint (femorotibial and patellar joint) and from the hock joint (tarsal joint).

(5) "Thighs" shall be disjointed at the hip joint and may include the pelvic meat, but shall not include the pelvic bones. Back skin shall not be included.

(6) "(Kind) legs" shall be the poultry product which includes the thigh and the drumstick, i.e., the whole leg, and may include the pelvic meat, but shall not include the pelvic bones. Back skin shall not be included.

(7) "Wings" shall include the entire wing with all muscle and skin tissue intact, except that the wingtip may be removed.

(8) "Backs" shall include the pelvic bones and all the vertebrae posterior to the shoulder joint. The meat shall not be peeled from the pelvic bones. The vertebral ribs and/or scapula may be removed or included without affecting the appropriateness of the name. Skin shall be substantially intact.

(9) "Stripped backs" shall include the vertebrae from the shoulder joint to the tail, and include the pelvic bones. The meat may be stripped off of the pelvic bones.

(10) "Necks", with or without neck skin, shall be separated from the carcass at the shoulder joint.

(11) "Halves" are prepared by making a full-length back and breast split of an eviscerated poultry carcass so as to produce approximately equal right and left sides.

(12) "Quarters" consist of the entire eviscerated poultry carcass, which has been cut into four equal parts, but excluding the neck.

(13) "Breast quarter" consists of half a breast with the wing and a portion of the back attached.

(14) "Breast quarter without wing" consists of a front quarter of a poultry carcass, from which the wing has been removed.

(15) "Leg quarter" consists of a poultry thigh and drumstick, with a portion of the back attached.

(16) "Thigh with back portion" consists of a poultry thigh with back portion attached.

(17) "Legs with pelvic bone" consists of a poultry leg with adhering meat and skin and pelvic bone.

(18) "Wing drummette" consists of the humerus of a poultry wing with adhering skin and meat attached.

(19) "Wing portion" consists of a poultry wing except that the drummette has been removed.

(20) "Cut-up Poultry" is any cut-up or disjointed portion of poultry or any edible part thereof, as described in this section.

(21) "Giblets" consist of approximately equal numbers of hearts, gizzards, and livers, as determined on a count basis.

(22) "Major portions" of eviscerated poultry carcasses are either carcasses from which parts may be missing, or the front or rear portions of transversely-split carcasses.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 63 FR 48960, Sept. 11, 1998]

afforded adequate time from the date of the notice of the alleged breach to rebut the allegation of a breach.

§ 201.218 Arbitration.

(a) In any livestock or poultry production contract that requires the use of arbitration the following language must appear on the signature page of the contract in bold conspicuous print:

“Right to Decline Arbitration. A poultry grower, livestock producer or swine production contract grower has the right to decline to be bound by the arbitration provisions set forth in this agreement. A poultry grower, livestock producer or swine production contract grower shall indicate whether or not it desires to be bound by the arbitration provisions by signing one of the following statements; failure to choose an option will be treated as if the poultry grower, livestock producer or swine production contract grower declined to be bound by the arbitration provisions set forth in this Agreement:

I decline to be bound by the arbitration provisions set forth in this Agreement

I accept the arbitration provisions as set forth in this Agreement”

(b) The Secretary may consider various criteria when determining whether the arbitration process provided in a production contract provides a meaningful opportunity for the poultry grower, livestock producer, or swine production contract grower to participate fully in the arbitration process. These criteria include, but are not limited to:

(1) Whether the contract discloses sufficient information in bold, conspicuous print describing all the costs of arbitration to be paid by the poultry grower, swine production contract grower, or livestock producer, and the arbitration process and any limitations on legal rights and remedies in such a manner as to allow the poultry grower, livestock producer or swine production contract grower to make an informed decision on whether to elect arbitration for dispute resolution;

(2) Whether provisions in the entire arbitration process governing the costs and time limits are reasonable;

(3) Whether the poultry grower, livestock producer, or swine production contract grower is provided access to and opportunity to engage in reasonable discovery of information held by the packer, swine contractor or live poultry dealer;

(4) Whether arbitration is required to be used to resolve only disputes relevant to the contractual obligations of the parties; and

(5) Whether a reasoned, written opinion based on applicable law, legal principles and precedent for the award is required to be provided to the parties.

J. Dudley Butler,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2011-31618 Filed 12-8-11; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. FSIS-2005-0018]

Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products; Delay of Effective Date and Correction

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule; delay of effective date and correction.

SUMMARY: The Food Safety and Inspection Service (FSIS) is delaying the effective date of the final regulations that require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products and ground or chopped meat and poultry products that were published in the **Federal Register** on December 29, 2010. The original effective date of these regulations was January 1, 2012. FSIS is taking this action in response to a request from eight trade associations. The trade associations requested that FSIS exercise enforcement discretion for a six month period following the January 1, 2012, effective date of the final rule. However, FSIS has concluded that a two month delay in the effective date will allow industry sufficient time to comply with the requirements of the final rule. The new effective date of the final rule is March 1, 2012.

FSIS is also making a correction to the final rule to clarify an amendatory instruction.

DATES: The effective date of the rule amending 9 CFR parts 317 and 381 published at 75 FR 82148, December 29, 2010, is delayed until March 1, 2012. The effective date of the correction to the rule published at 75 FR 82148, December 29, 2010, is March 1, 2012.

FOR FURTHER INFORMATION CONTACT: Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, (301) 504-0878.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 2010, FSIS published the final rule, “Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products” in the **Federal Register** (75 FR 82148) that, among other things, amended the Federal meat and poultry products inspection regulations to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products identified in §§ 317.344 and 381.444 that are not ground or chopped, except for certain exemptions. For these products, the final rule requires that nutrition information be provided on the label or at point-of-purchase (POP) (e.g., by sign or brochure), unless an exemption applies. The final rule also amended FSIS’s regulations to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. In addition, the final rule provided that when a ground or chopped product does not meet the regulatory criteria to be labeled “low fat,” a lean percentage statement may be included on the label or in labeling as long as a statement of the fat percentage that meets the specified criteria also is displayed on the label or in labeling. The required statement of fat percentage must be contiguous to, in lettering of the same color, size, and type as, and on the same color background as, the statement of lean percentage. The final rule also provided several exemptions from the nutrition labeling requirements.

Outreach: In the preamble to the final rule, FSIS stated that it would conduct meetings and webinars on the final rule and would provide additional information and guidance as needed. FSIS also stated its intention to make nutrition labeling materials that can be used at the POP of the major cuts and additional examples of acceptable labels for ground products available on the Agency’s Web site six months prior to the effective date. Since the final rule was published, FSIS has posted on its Web site the final POP materials and examples of nutrition facts panels for ground or chopped products and has conducted webinars on the final rule. In addition, the Agency has conducted many other education and outreach activities to assist retailers and Federal establishments in complying with the requirements of the final rule, such as posting a PowerPoint presentation on its Web site that gives an overview of the requirements of the final rule, presenting information and answering

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questions on the requirements of the final rule at numerous meetings, posting questions and answers on its Web site, and responding to numerous questions from stakeholders about the regulations through askFSIS at <http://askfsis.custhelp.com/>.

Request for Enforcement Discretion

FSIS received a letter dated August 12, 2011 from eight trade associations (the American Lamb Board, the American Meat Institute, the Food Marketing Institute, the National Cattlemen's Beef Association, the National Chicken Council, the National Grocer's Association, the National Pork Board, and the National Turkey Federation), which requested that FSIS exercise enforcement discretion for a six month period following the January 1, 2012, effective date of the final rule. The letter cited the Agency's 1-2 month delay in making POP and nutrition facts panel materials available on FSIS's Web site and in conducting the FSIS webinars as the basis for the enforcement discretion. As a result of FSIS's delay in providing this information to retailers, the trade associations stated that it would be difficult for retailers to have systems in place (e.g., tens of thousands of scales across the industry will have to be replaced or updated with new software) and training of tens of thousands of employees completed by the January 1, 2012, effective date. The trade associations also stated that it would be difficult for Federal establishments to redesign thousands of labels and have them approved by FSIS by the January 1, 2012, effective date.

Because of the 1-2 month delay in making the FSIS POP materials and nutrition facts panel examples available on FSIS's Web site and in beginning the FSIS webinars, FSIS has decided to delay the effective date of the final rule until March 1, 2012. The 2 month delay will ensure that industry has sufficient time to comply with the final rule and be in full compliance with the final rule on March 1, 2012.

FSIS determined that a 6 month delay in the effective date is not warranted. The request did not provide any support to justify a 6 month delay in the effective date. Even if, as the letter stated, a delay in FSIS label approval exists, a 2 month delay in the effective date would allow the Agency enough time to approve the new or redesigned nutrition labels submitted by official establishments by March 1, 2012, provided the labels are submitted by January 1, 2012. As described above under "Outreach," since the final rule was published, FSIS has conducted

many education and outreach activities to assist retailers and Federal establishments in complying with the requirements of the final rule. FSIS will continue to conduct these education and outreach activities to assist compliance by March 1, 2012.

Need for Correction

FSIS is making a correction to amendment 17f on page 82167 of the final regulations published on Wednesday, December 29, 2010, to clarify that language is being added to the end of the first sentence in § 381.500(d)(1), not at the end of the second sentence.

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. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. 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.

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Correction

In FR Doc. 2010-32485 appearing on page 82148 in the **Federal Register** of Wednesday, December 29, 2010, the following corrections are made:

§ 381.500 [Corrected]

■ 1. On page 82167, in the third column, in Part 381 Poultry Products Inspection Regulations, in amendment 17f, the instruction "Amending paragraph (d)(1) by removing the period at the end of the sentence, and by adding the following to the end of the sentence: 'except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444.'" is corrected to read "Amending paragraph (d)(1) by removing the period at the end of the first sentence, and by adding the following to the end of the first sentence: 'except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444.'"

Done in Washington, DC, on December 5, 2011.

Alfred V. Almanza,
Administrator.

[FR Doc. 2011-31625 Filed 12-8-11; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2011-0010; Airspace
Docket No. 11-AAL-1]

Amendment of Federal Airways; Alaska

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule; announcement of
effective date.

SUMMARY: This action announces the
effective date of a final rule published
in the **Federal Register** of April 28, 2011
that amends Federal airways in Alaska.

§§ 381.481-381.499

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(e)(2) and (e)(3) of this section, a product may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading, and the product is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., "for low sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) "Sugar free" and "no added sugar". Criteria for the use of the terms "sugar free" and "no added sugar" are provided for in § 381.460(c).

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 60 FR 217, Jan. 3, 1995]

§§ 381.481-381.499 [Reserved]

§ 381.500 Exemption from nutrition labeling.

(a) The following poultry products are exempt from nutrition labeling:

(1) Food products produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information.

(i) A food product, for purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product

qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claims or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g. sausage) processed at a retail store or similar retail-type establishment.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)(1) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling as provided in paragraph (c)(2) of

this section, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol.

(2) Foods represented or purported to be specifically for infants and children less than 4 years of age shall bear nutrition labeling except that:

(i) Such labeling shall not include declarations of percent of Daily Value for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber;

(ii) Nutrient names and quantitative amounts by weight shall be presented in two separate columns;

(iii) The heading "Percent Daily Value" required in § 381.409(d)(6) shall be placed immediately below the quantitative information by weight for protein;

(iv) The percent of the Daily Value for protein, vitamins, and minerals shall be listed immediately below the heading "Percent Daily Value"; and

(v) Such labeling shall not include the footnote specified in § 381.409(d)(9).

(d)(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information. The manufacturer, packer, or distributor shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., "For nutrition information call 1-800-123-4567").

(2) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in a type size no smaller than 6 point or all upper case type of 1/16-inch minimum height, except that individual serving-size packages of poultry products that have a total area available to bear labeling of 3 square inches or less may provide all required information in a

type size no smaller than 1/32-inch minimum height.

[58 FR 675, Jan. 6, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45198, Sept. 1, 1994; 60 FR 217, Jan. 3, 1995]

EFFECTIVE DATE NOTE: At 75 FR 82167, Dec. 29, 2010, § 381.500 was amended as follows, effective Jan. 1, 2012.

a. Revising paragraph (a)(1) introductory text;

b. Amending paragraph (a)(1)(ii) by adding, "including a single retail store," after the phrase "single-plant facility," and by adding "including a multi-retail store operation" after "company/firm";

c. Amending paragraph (a)(7)(i) by removing the semi-colon and "and" and adding the following at the end of the paragraph: "provided, however, that this exemption does not apply to ready-to-eat ground or chopped poultry products described in § 381.401 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under (a)(1);";

d. Amending paragraph (a)(7)(ii) by removing the period and adding the following at the end of the paragraph: "provided, however, that this exemption does not apply to multi-ingredient ground or chopped poultry products described in § 381.401 that are processed at a retail establishment, unless the establishment qualifies for an exemption under (a)(1); and";

e. Adding a new paragraph (a)(7)(iii); and

f. Amending paragraph (d)(1) by removing the period at the end of the sentence, and by adding the following to the end of the sentence: "except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444." For the convenience of the user, the added and revised text is set forth as follows:

§ 381.500 Exemption from nutrition labeling.

(a) * * *

(1) Food products produced by small businesses other than the major cuts of single-ingredient, raw poultry products identified in § 381.444 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in § 381.401 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with § 381.462(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information.

* * * * *

(7) * * *

§ 381.500

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(iii) Products that are ground or chopped
at an individual customer's request.

* * * * *

SUBCHAPTERS B-C [RESERVED]

§ 12.4 [Amended]

■ 3. Amend § 12.4, in paragraph (d)(2), by removing the words “or highly erodible land” and adding, in their place, the words “on highly erodible land.”

■ 4. Amend § 12.5 as follows:

■ a. Revise paragraph (a)(5) to read as set forth below,

■ b. Add paragraph (a)(7) to read as set forth below,

■ c. Revise paragraph (b)(5)(i) to read as set forth below.

§ 12.5 Exemption.

(a) * * *

(5) *Good faith.* (i) No person will become ineligible under § 12.4 as a result of the failure of such person to apply a conservation system on highly erodible land if all of the following apply:

(A) FSA determines such person has acted in good faith and without the intent to violate the provisions of this part;

(B) NRCS determines that the person complies with paragraph (a)(5)(ii) of this section; and

(C) The good faith determination of the FSA county or State committee has been reviewed and approved by the applicable State Executive Director, with the technical concurrence of the State Conservationist; or district director, with the technical concurrence of the area conservationist.

(ii) A person who otherwise meets the requirements of paragraphs (a)(5)(i)(A) and (a)(5)(i)(C) of this section will be allowed a reasonable period of time, as determined by NRCS, but not to exceed one year, during which to implement the measures and practices necessary to be considered actively applying the person's conservation plan, as determined by USDA. If a person does not take the required corrective actions, the person may be determined to be ineligible for the crop year during which such actions were to be taken, as well as any subsequent crop year.

(iii) Notwithstanding the good-faith requirements of paragraph (a)(5)(i) of this section, if NRCS observes a possible compliance deficiency while providing on-site technical assistance, NRCS will provide to the responsible person, not later than 45 days after observing the possible violation, information regarding actions needed to comply with the plan and this subtitle. NRCS will provide this information in lieu of reporting the observation as a violation, if the responsible person attempts to correct the deficiencies as soon as practicable, as determined by NRCS, after receiving the information, but not

later than one year after receiving the information. If a person does not take the required corrective actions, the person may be determined to be ineligible for the crop year during which the compliance deficiencies occurred, as well as any subsequent crop year.

(iv) A person who meets the requirements of paragraphs (a)(5)(i) and (a)(5)(ii) of this section will, in lieu of the loss of all benefits specified under § 12.4(d) and (e) for such crop year, be subject to a reduction in benefits by an amount commensurate with the seriousness of the violation, as determined by FSA. The dollar amount of the reduction will be determined by FSA and may be based on the number of acres and the degree of erosion hazard for the area in violation, as determined by NRCS, or upon such other factors as FSA determines appropriate.

(v) Any person whose benefits are reduced in a crop year under paragraph (a)(5) of this section may be eligible for all of the benefits specified under § 12.4(d) and (e) for any subsequent crop year if, prior to the beginning of the subsequent crop year, NRCS determines that such person is actively applying a conservation plan according to the schedule specified in the plan on all highly erodible land planted to an agricultural commodity or designated as conservation use.

* * *

(7) *Technical and minor violations.* Notwithstanding any other provisions of this part, a reduction in benefits in an amount commensurate with the seriousness of the violation, as determined by FSA, and consistent with paragraph (a)(5)(iv) of this section, will be applied if NRCS determines that a violation involving highly erodible land that would otherwise lead to a loss of benefits is both of the following:

(i) Technical and minor in nature; and

(ii) Has a minimal effect on the erosion control purposes of the conservation plan applicable to the land on which the violation occurred.

(b) * * *

(5) *Good faith violations.* (i) A person who is determined under § 12.4 of this part to be ineligible for benefits as the result of the production of an agricultural commodity on a wetland converted after December 23, 1985, or as the result of the conversion of a wetland after November 28, 1990, may regain eligibility for benefits if all of the following apply:

(A) FSA determines that such person acted in good faith and without the intent to violate the wetland provisions of this part; and

(B) NRCS determines that the person is implementing all practices in a mitigation plan within an agreed-to period, not to exceed one year; and

(C) The good faith determination of the FSA county or State committee has been reviewed and approved by the applicable State Executive Director, with the technical concurrence of the State Conservationist; or district director, with the technical concurrence of the area conservationist.

* * *

■ 5. In addition to the amendments set forth above, in the following places in part 12 remove the words “functions and values” and add in their place the words “values, acreage, and functions”:

■ a. § 12.1(b)(4),

■ b. § 12.4(c) each time it appears,

■ c. § 12.5(b)(1)(iii)(D), (b)(1)(vi)(A), (b)(1)(vi)(B), and (b)(4)(i) introductory text, (b)(4)(i)(E), (b)(4)(i)(F), (b)(4)(ii), and (b)(4)(iii).

■ d. § 12.31(d) in the final sentence only, and

■ e. § 12.33(a).

Dated: December 16, 2011.

Thomas J. Vilsack,
Secretary.

[FR Doc. 2011-33547 Filed 12-29-11; 8:45 am]

BILLING CODE 3410-05-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 303, 317, 319, and 381

[Docket No. FSIS-2011-0024]

RIN 0583-AB02

Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products; Technical Amendment

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: This document contains technical amendments to the final labeling regulations that were published in the *Federal Register* on December 23, 1999. The regulations related to harmonizing and improving the efficiency of the procedures used by the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) for reviewing and listing the food ingredients and sources of radiation listed or approved for use in the production of meat and poultry products.

DATES: December 30, 2011.

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FOR FURTHER INFORMATION CONTACT:

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690-0486.

SUPPLEMENTARY INFORMATION:**Background**

The regulations that are the subject of these technical amendments were published on December 23, 1999, in a final rule titled "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products" (64 FR 72168). Among other things, this final rule consolidated various existing regulations on food ingredients and sources of radiation into a single new part, 9 CFR part 424, applicable to both meat and poultry establishments. Specifically, it combined the separate listings of food ingredients approved for use in meat and poultry products contained in 9 CFR 318.7 and 9 CFR 381.147 into a single table (9 CFR 424.21(c)). FSIS then removed §§ 318.7 and 381.147 from the meat and poultry products inspection regulations. The Agency did not, however, replace all of the references to §§ 318.7 and 381.147 contained in the meat and poultry product inspection regulations with a reference to § 424.21(c), the correct citation.

As published, the final regulations contain this error in several locations and thus needs to be corrected. Therefore, FSIS is replacing all references to §§ 318.7 and 381.147 contained in the meat and poultry product inspection regulations with a reference to the correct section, § 424.21(c).

List of Subjects in 9 CFR Parts 303, 317, 319, and 381

Food grades and standards, Food labeling, Food packaging, Meat inspection, Poultry products.

Accordingly, 9 CFR parts 303, 317, 319, and 381 are corrected by making the following correcting amendments:

PART 303—EXEMPTIONS

- 1. The authority citation for part 303 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

- 2. In § 303.1, revise paragraph (b)(1) to read as follows:

§ 303.1 Exemptions.

* * * * *

(b)(1) The exempted custom prepared products shall be prepared and handled in accordance with the provisions of §§ 318.5, 318.6, 318.10, 381.300 through 381.311 of this subchapter and § 424.21 of subchapter E, and shall not be adulterated as defined in paragraph 1(m) of the Act. The provisions of §§ 318.5, 318.6, 318.10, and 318.300 through 381.311 related to inspection or supervision of specified activities or other action by an inspection program employee and the provisions of § 318.6(b)(9) and (10) shall not apply to the preparation and handling of such exempted products.

* * * * *

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

- 3. The authority citation for part 317 continues to read as follows:

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

- 4. In § 317.2, revise paragraph (f)(1)(vi)(B) to read as follows:

§ 317.2 Labels: definition; required features.

* * * * *

- (f) * * *
(1) * * *
(vi) * * *

(B) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with part 319 of this subchapter and with § 424.21 of subchapter E, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

* * * * *

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

- 5. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

- 6. In § 319.181, revise the second and third sentences to read as follows:

§ 319.181 Cheesefurters and similar products.

* * * They may contain binders and extenders as provided in § 424.21(c) of subchapter E. Limits on use as provided in § 424.21 are intended to be exclusive of the cheese constituent. * * *

- 7. In § 319.281, revise the first sentence of paragraph (b)(9) to read as follows:

§ 319.281 Bockwurst.

* * * * *

(b) * * *

(9) Binders and extenders may be added as provided in § 424.21(c) of subchapter E. * * *

* * * * *

- 8. R In § 319.300, revise the last sentence to read as follows:

§ 319.300 Chili con carne.

* * * The mixture may contain binders and extenders as provided in § 424.21(c) of subchapter E.

- 9. In § 319.301, revise the last sentence to read as follows:

§ 319.301 Chili con carne with beans.

* * * The mixture may contain binders and extenders as provided in § 424.21(c) of subchapter E.

- 10. In § 319.306, revise the last sentence to read as follows:

§ 319.306 Spaghetti with meatballs and sauce, spaghetti with meat and sauce, and similar products.

* * * Meatballs may be prepared with farinaceous material and with other binders and extenders as provided in § 424.21(c) of subchapter E.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

- 11. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

- 12. In § 381.118, revise the first sentence in paragraph (a)(2)(ii) to read as follows:

§ 381.118 Ingredients statement.

* * * * *

- (a) * * *
(2) * * *

(ii) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with subpart P of this part and § 424.21(c) of subchapter E, and does not exceed the amount shown in the quantifying statement. * * *

* * * * *

- 13. In § 381.129, revise paragraph (d) to read as follows:

§ 381.129 False or misleading labeling or containers.

* * * * *

(d) When sodium alginate, calcium carbonate, lactic acid, and calcium lactate are used together in a dry binding matrix in ground or formed poultry products, as permitted in

§ 424.21(c) of subchapter E, there shall appear on the label contiguous to the product name a statement to indicate the use of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.

* * * * *

■ 14. In § 381.133, revise paragraph (b)(9)(xviii) to read as follows:

§ 381.133 Generically approved labeling.

* * * * *

(b) * * *

(9) * * *

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in the quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in subpart P of this part and § 424.21(c) of subchapter E;

* * * * *

Done in Washington, DC, on December 23, 2011.

Alfred V. Almanza,
Administrator.

[FR Doc. 2011-33427 Filed 12-29-11; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 52

RIN 3150-AI81

[NRC-2010-0131]

AP1000 Design Certification Amendment

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or Commission) is amending its regulations to certify an amendment to the AP1000 standard plant design. The amendment replaces the combined license (COL) information items and design acceptance criteria (DAC) with specific design information, addresses the effects of the impact of a large commercial aircraft, incorporates design improvements, and increases standardization of the design. This action is necessary so that applicants or licensees intending to construct and operate an AP1000 design may do so by referencing this regulation (AP1000 design certification rule (DCR)), and need not demonstrate in their applications the safety of the certified design as amended. The applicant for

this amendment to the AP1000 design is Westinghouse Electric Company, LLC (Westinghouse).

DATES: The effective date of this rule is December 30, 2011. The incorporation by reference of certain material specified in this regulation is approved by the Director of the Office of the Federal Register as of December 30, 2011. The applicability date of this rule for those entities who receive actual notice of this rule is the date of receipt of this rule.

ADDRESSES: You can access publicly available documents related to this action (see Section VI. Availability of Documents) using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, 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 online in the NRC Library 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 the 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.

- *Federal Rulemaking Web site:* Public comments and supporting materials related to this final rule can be found at <http://www.regulations.gov> by searching on Docket ID NRC-2010-0131. Address questions and concerns regarding NRC dockets to Carol Gallagher; telephone at (301) 492-3668; email: Carol.Gallagher@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Ms. Serita Sanders, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone at (301) 415-2956; email: serita.sanders@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

II. Summary of Analysis of Public Comments on the AP1000 Proposed Rule

- A. Overview of Public Comments
- B. Description of Key Structures of the AP1000 Design
- C. Significant Public Comments and Overall NRC Responses

III. Discussion

- A. Technical Evaluation of Westinghouse Amendment to the AP1000 Design
- B. Changes to Appendix D

C. Immediate Effectiveness of Final Rule: Provision of Actual Notice to Southern Nuclear Operating Company

IV. Section-by-Section Analysis

- A. Scope and Contents (Section III)
- B. Additional Requirements and Restrictions (Section IV)
- C. Applicable Regulations (Section V)
- D. Issue Resolution (Section VI)
- E. Processes for Changes and Departures (Section VIII)
- F. Records and Reporting (Section X)
- V. Agreement State Compatibility
- VI. Availability of Documents
- VII. Voluntary Consensus Standards
- VIII. Finding of No Significant Environmental Impact: Availability
- IX. Paperwork Reduction Act Statement
- X. Regulatory Analysis
- XI. Regulatory Flexibility Act Certification
- XII. Backfitting and Issue Finality
- XIII. Congressional Review Act

I. Background

Title 10 of the Code of Federal Regulations (10 CFR), Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," Subpart B, presents the process for obtaining standard design certifications. Section 52.63, "Finality of standard design certifications," provides criteria for determining when the Commission may amend the certification information for a previously certified standard design in response to a request for amendment from any person.

The NRC originally approved the AP1000 design certification in a final rule in 2006 (71 FR 4464; January 27, 2006). The final AP1000 DCR incorporates by reference Revision 15 of the design control document (DCD) (ADAMS Accession No. ML053460400), which describes the AP1000 certified design. During its initial certification of the AP1000 design, the NRC issued a final safety evaluation report (FSER) for the AP1000 as NUREG-1793, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," in September 2004 (ADAMS Accession No. ML043570339) and Supplement No. 1 to NUREG-1793 (ADAMS Accession No. ML053410203).

From March 2006 through May 2007, NuStart Energy Development, LLC (NuStart)¹ and Westinghouse provided the NRC with a number of technical reports (TRs) for pre-application review of a possible amendment to the approved AP1000 certified design, in order to: (1) close specific, generically applicable COL information items (information to be supplied by COL

¹ The NuStart member companies are: Constellation Generation Group, LLC, Duke Energy Corporation, EDF-International North America, Inc., Entergy Nuclear, Inc., Exelon Generation Company, LLC, Florida Power and Light Company, Progress Energy, and Southern Company Services, Inc.

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stored, prepared, packaged, marked, and labeled as required by the regulations in this subchapter.

[35 FR 15556, Oct. 3, 1970]

PART 303—EXEMPTIONS

Sec.

303.1 Exemptions.

303.2 Experimentation: Intensity of inspection coverage.

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 303.1 Exemptions.

(a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:

(1) The slaughtering by any individual of livestock of his own raising, and the preparation by him and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock exclusively for use by him and members of his household and his nonpaying guests and employees;

(2) The custom slaughter by any person of cattle, sheep, swine, or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock, exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of his own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees: *Provided*, That the following requirements are met by such custom operator:

(1) Establishments that conduct custom operations must be maintained and operated in accordance with the provisions of §§416.1 through 416.6, except for: §416.2(g)(2) through (6) of this

chapter, regarding water reuse and any provisions of part 416 of this chapter relating to inspection or supervision of specified activities or other action by a Program employee. If custom operations are conducted in an official establishment, however, all of the provisions of Part 416 of this chapter of shall apply to those operations.

(ii) If the custom operator prepares or handles any products for sale, they are kept separate and apart from the custom prepared products at all times while the latter are in his custody;

(iii) The custom prepared products are plainly marked "Not for Sale" as provided in §316.16 of this subchapter, immediately after being prepared and are kept so identified until delivered to the owner; and

(iv) If exempted custom slaughtering or other preparation of products is conducted in an official establishment, all facilities and equipment in the official establishment used for such custom operations shall be thoroughly cleaned and sanitized before they are used for preparing any products for sale.

(b)(1) The exempted custom prepared products shall be prepared and handled in accordance with the provisions of §§318.5, 318.6, 318.7, 318.10, and 318.300 through 318.311 of this subchapter and shall not be adulterated as defined in paragraph 1(m) of the Act: *Provided*, That the provisions of §§318.5, 318.6, 318.10, and 318.300 through 318.311 relating to inspection or supervision of specified activities or other action by a Program inspector, and the provisions of §318.6(b)(9) and (10), shall not apply to the preparation and handling of such exempted products.

(2) The exempted custom prepared products shall comply with the requirements of §§316.16 and 317.16 of this subchapter.

(3) The custom operators claiming exemption under paragraph (a)(2) of this section shall keep records, in addition to records otherwise required by part 320 of this subchapter, showing the numbers and kinds of livestock slaughtered on a custom basis, the quantities and types of products prepared on a custom basis, and the names and addresses of the owners of the livestock and products.

(4) Articles capable of use as human food, resulting from the exempted custom slaughter or other preparation of products shall be promptly denatured or otherwise identified in accordance with § 325.13 of this subchapter and not removed from the establishment where the custom operations are conducted until so identified, unless they are delivered to the owner of the articles for use in accordance with paragraph (a)(2) of this section.

(c) It has been determined that it is impracticable to provide inspection of the preparation of products at establishments in any unorganized Territory at which livestock are slaughtered or their products are prepared for distribution solely within such jurisdiction and that exempting such establishments from requirements of the Act for such inspections under the conditions stated in this section will otherwise facilitate enforcement of the Act. Therefore, such inspection requirements of the Act and of the regulations in this subchapter shall not apply at such establishments if they are operated in accordance with the regulations in part 416, §§ 416.1 through 416.5 of this chapter. However, the Administrator may refuse, withdraw, or modify any exemption under this paragraph when he determines in any specific case in accordance with the applicable rules of practice that such action is necessary to effectuate the purposes of this Act.

(d)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.

(2) For purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants are the following:

(a) Cutting up, slicing, and trimming carcasses, halves, quarters, or whole-sale cuts into retail cuts such as steaks, chops, and roasts, and freezing such cuts;

(b) Grinding and freezing products made from meat;

(c) Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products;

(d) Breaking bulk shipments of products;

(e) Wrapping or rewrapping products.

(ii) Any quantity or product purchased by a consumer from a particular retail supplier shall be deemed to be a normal retail quantity if the quantity so purchased does not in the aggregate exceed one-half carcass. The following amounts of product will be accepted as representing one-half carcass of the species identified:

	One-half carcass pounds
Cattle	300
Calves	37.5
Sheep	27.5
Swine	100
Goats	25

(iii) A retail store is any place of business where:

(a) The sales of product are made to consumers only;

(b) At least 75 percent, in terms of dollar value, of total sales of product represents sales to household consumers and the total dollar value of sales of product to consumers other than household consumers does not exceed the dollar limitation per calendar year set by the Administrator. This dollar limitation is a figure which will automatically be adjusted during the first quarter of each calendar year, upward or downward, whenever the Consumer Price Index, published by the Bureau of Labor Statistics, Department of Labor, indicates a change in the price of this same volume of product which exceeds \$500. Notice of the adjusted dollar limitation will be published in the FEDERAL REGISTER.¹

¹The dollar limitation currently in effect may be obtained by contacting Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food and Safety Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447-3219.

(c) Only federally or State inspected and passed product is handled or used in the preparation of any product, except that product resulting from the custom slaughter or custom preparation of product may be handled or used in accordance with paragraph (a)(2) and (b) of this section but not for sale;

(d) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(i) of this section;

(e) The preparation of products for sale to household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section; and

(f) The preparation of products for sale to other than household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) (a), (b), (d), and (e) of this section. (A retail store at which custom slaughtering or preparation of products is conducted is not thereby disqualified from exemption as a retail store under this paragraph (d).)

(iv) *Restaurants.* (a) A restaurant is any establishment where:

(1) Product is prepared only for sale or service in meals or as entrees directly to individual consumers at such establishments;

(2) Only federally or State inspected and passed product or such product prepared at a retail store exempted under paragraph (d)(2)(iii) of this section is handled or used in the preparation of any product;

(3) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(i) of this section; and

(4) The preparation of product is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(b) The definition of a restaurant includes a caterer which delivers or serves product in meals, or as entrees, only to individual consumers and otherwise meets the requirements of this paragraph.

(c) For purposes of this paragraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food products that

are ready to eat when they leave such facility (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to a receiving restaurant by its own employees, without intervening transfer or storage, maintained in a safe, unadulterated condition during transportation, and served in meals or as entrees only to customers at restaurants, or through vending machines, owned or operated by the same person that owns or operates such facility, and which otherwise meets the requirements of this paragraph: *Provided*, That the requirements of §§ 320.1 through 320.4 of this subchapter apply to such facility. *Provided further*, That the exempted facility may be subject to inspection requirements under the Act for as long as the Administrator deems necessary, if the Administrator determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its meat or meat food products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central kitchen facility to such inspection requirements, the operator of such facility shall be afforded an opportunity to dispute the Administrator's determination in a hearing pursuant to rules of practice which will be adopted for this proceeding.

(v) *Similar retail-type establishment:* Any establishment which is a combination retail store and restaurant; any delicatessen which meets the requirements for a retail store or restaurant as prescribed in paragraphs (d)(2) (iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

(vi) *Consumer:* Any household consumer, hotel, restaurant, or similar institution as determined by the Administrator in specific cases.

(3) Whenever any complaint is received by the Administrator from any person alleging that any retail store claiming exemption under this paragraph (d), in any designated State or organized Territory that is identified under section 205 of the Act (as one

that does not have or is not exercising adequate authority with respect to recordkeeping requirements) has been operated in violation of the conditions prescribed in this section for exemption, and the Administrator, upon investigation of the complaint, has reason to believe that any such violation has occurred, he shall so notify the operator of the retail store and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator still has reason to believe that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail store would effectuate the purposes of the Act, the Administrator shall order the operator to maintain complete, accurate, and legible records of total monthly purchases and of total monthly sales of meat, meat byproducts, and meat food products, in terms of dollar values of the products involved. Such records shall separately show total sales to household consumers and total sales to other consumers and shall be maintained for the period prescribed in § 320.3 of this subchapter. If the operator maintains copies of bills of lading, receiving and shipping invoices, warehouse receipts, or similar documents which give the information required herein, additional records are not required by this subparagraph.

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to meat pizzas containing meat food product ingredients which were prepared, inspected, and passed in a cured or cooked form as ready-to-eat (i.e., no further cooking or other preparation is needed) in compliance with the requirements of the Act and these regulations; and the meat pizzas are to be served in public or private nonprofit institutions, provided that the meat pizzas are ready-to-eat (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to the receiving institution by employees of the preparing firm, receiving institution, or a food service management company contracted to

conduct food service at the public or private nonprofit institution, without intervening transfer or storage.

(2) The definitions at Chapter 1, 1-102, except 1-102(z) and the provisions of Chapters 2 through 8, except sections 2-102(a) and (b), 2-302(d), 2-403(a), 2-403(c), 2-404, 2-405, 2-407, 2-502 through 2-506, 2-508, 2-509, 4-105, 4-201(c), 4-208, 5-101(a), 5-103, 5-104, 5-202(c), 5-203, and 6-105, part IV, of the Food and Drug Administration's Food Service Sanitation Manual (1976 Recommendations), DHEW Publication No. (FDA) 78-2081, which is incorporated by reference, shall apply to the facilities and operations of businesses claiming this exemption. (These materials are incorporated as they exist on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(3) Facilities and operations of businesses claiming this exemption shall also conform to the following requirements:

(i) *Manual cleaning and sanitizing.* (A) For manual washing, rinsing and sanitizing of utensils and equipment, a sink with not fewer than three compartments shall be provided and used. Sink compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed manually or cleaned through pressure spray methods.

(B) Drain boards or easily movable dish tables of adequate size shall be provided for proper handling of soiled utensils prior to washing and for cleaned utensils following sanitizing and shall be located so as not to interfere with the proper use of the dishwashing facilities.

(C) Equipment and utensils shall be preflushed or prescraped and, when necessary, presoaked to remove gross food particles and soil.

(D) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing and sanitizing shall be conducted in the following sequence:

(1) Sinks shall be cleaned prior to use.

(2) Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.

(3) Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.

(4) Equipment and utensils shall be sanitized in the third compartment according to one of the methods prescribed in paragraph (e)(3)(i)(E) (1) through (4) of this section.

(E) The food-contact surfaces of all equipment and utensils shall be sanitized by:

(1) Immersion for at least ½ minute in clean, hot water at a temperature of at least 170 °F; or

(2) Immersion for at least 1 minute in a clean solution containing at least 50 parts per million of available chlorine as a hypochlorite and at a temperature of at least 75 °F; or

(3) Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75 °F; or

(4) Immersion in a clean solution containing any other chemical sanitizing agent allowed under 21 CFR 178.1010 that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as a hypochlorite at a temperature of at least 75 °F for 1 minute; or

(5) Treatment with steam free from materials or additives other than those specified in 21 CFR 173.310 in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or

(6) Rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under paragraph (e)(3)(i)(E)(4) of this section in the case of equipment too large to sanitize by immersion.

(F) When hot water is used for sanitizing, the following facilities shall be provided and used:

(1) An integral heating device or fixture installed in, on, or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least 170 °F; and

(2) A numerically scaled indicating thermometer, accurate to ± 3 °F, convenient to the sink for frequent checks of water temperature; and

(3) Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(G) When chemicals are used for sanitization, they shall not have concentrations higher than the maximum permitted under 21 CFR 178.1010 and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(ii) *Mechanical cleaning and sanitizing.*

(A) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils. These machines and devices shall be properly installed and maintained in good repair.

Machines and devices shall be operated in accordance with manufacturers' instructions, and utensils and equipment placed in the machine shall be exposed to all dishwashing cycles. Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer injectors, if any, shall be properly installed and maintained.

(B) The pressure of final rinse water supplied to spray-type dishwashing machines shall not be less than 15 nor

more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A 1/4-inch IPS valve shall be provided immediately up stream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(C) Machine or water line mounted numerically scaled indicating thermometers, accurate to ± 3 °F, shall be provided to indicate the temperature of the water in each tank of the machine and the temperature of the final rinse water as it enters the manifold.

(D) Rinse water tanks shall be protected by baffles, curtains, or other effective means to minimize the entry of wash water into the rinse water. Conveyors in dishwashing machines shall be accurately timed to assure proper exposure times in wash and rinse cycles in accordance with manufacturers' specifications attached to the machines.

(E) Drain boards shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and of cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities. This does not preclude the use of easily movable dish tables for the storage of soiled utensils or the use of easily movable dishtables for the storage of clean utensils following sanitization.

(F) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove gross food particles and soil prior to being washed in a dishwashing machine unless a prewashcycle is a part of the dishwashing machine operation. Equipment and utensils shall be placed in racks, trays, or baskets, or on conveyors, in a way that food-contact surfaces are exposed to the unobstructed application of detergent wash and clean rinse waters and that permits free draining.

(G) Machines (single-tank, stationary-rack, door-type machines and spray-type glass washers) using chemicals for sanitization may be used: *Provided, That,*

(1) The temperature of the wash water shall not be less than 120 °F.

(2) The wash water shall be kept clean.

(3) Chemicals added for sanitization purposes shall be automatically dispensed.

(4) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(5) The chemical sanitizing rinse water temperature shall be not less than 75 °F nor less than the temperature specified by the machine's manufacturer.

(6) Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010.

(7) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Machines using hot water for sanitizing may be used provided that wash water and pumped rinse water shall be kept clean and water shall be maintained at not less than the following temperatures:

(1) Single-tank, stationary-rack, dual-temperature machine:

Wash temperature150 °F
Final rinse temperature180 °F

(2) Single-tank, stationary-rack, single-temperature machine:

Wash temperature165 °F
Final rinse temperature165 °F

(3) Single-tank, conveyor machine:

Wash temperature160 °F
Final rinse temperature180 °F

(4) Multitank, conveyor machine:

Wash temperature150 °F
Pumped rinse temperature160 °F
Final rinse temperature180 °F

(5) Single-tank, pot, pan, and utensil washer (either stationary or moving-rack):

Wash temperature140 °F
Final rinse temperature180 °F

(I) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(iii) *Steam.* Steam used in contact with food or food-contact surfaces shall be free from any materials or additives

other than those specified in 21 CFR 173.310.

(4) For purposes of this paragraph, the term "private nonprofit institution" means "a corporation, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation, and which does not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office."

(5) The Administrator may withdraw or modify the exemption set forth in § 303.1(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department's Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such

action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect ending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(f) The adulteration and misbranding provisions of the Act and the regulations in this subchapter, other than the requirement of the official inspection legend, apply to articles which are exempted from inspection or not required to be inspected under this section. This includes the requirement that any pork and any product containing pork be prepared only in compliance with any applicable requirement for the destruction of trichina as provided in § 318.10 of this subchapter.

(g) The Administrator may extend the requirements of titles I and IV of the Act to any establishment in any State or organized Territory at which products are prepared for distribution solely within such jurisdiction, if he determines in accordance with the provisions of paragraph 301(c)(1) of the Act that it is producing adulterated products which would clearly endanger the public health.

(h) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in this subchapter in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements: *Provided*, That such waivers of the provisions of such regulations are not in

conflict with the purposes or provisions of the Act.

(Approved by the Office of Management and Budget under control number 0583-0015)

[35 FR 15558, Oct. 3, 1970, as amended at 36 FR 12002, 12004, June 24, 1971; 45 FR 27922, Apr. 25, 1980; 46 FR 46288, Sept. 18, 1981; 47 FR 746, Jan. 7, 1982; 51 FR 29909, Aug. 21, 1986; 52 FR 10032, Mar. 30, 1987; 52 FR 48091, Dec. 18, 1987; 53 FR 24679, June 30, 1988; 57 FR 34182, Aug. 3, 1992; 64 FR 56415, Oct. 20, 1999]

§ 303.2 Experimentation: Intensity of inspection coverage.

(a) Pursuant to the Processed Products Inspection Improvement Act of 1986, Title IV of the Futures Trading Act of 1986 (Pub. L. 99-641), in establishments preparing products at which inspection under the Act and regulations is required, the frequency with which and the manner in which meat food products made from livestock previously slaughtered in official establishments are examined and inspected by Program employees is to be based on considerations relevant to effective regulation of meat food products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, is so, to what extent the intensity of inspection coverage exceeds that which should be considered necessary pursuant to section 6 of the Act, as amended by section 403(a) of the Futures Trading Act of 1986, the Administrator is initiating experimentation for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Program employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(b) The determinations referred to in paragraph (a) of this section shall be made by the program and shall reflect evaluations of the performance and the characteristics and such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person conducting operations at such establishment or by anyone responsibly connected with the business conducting operations at such establishment, as "responsibly connected" is defined in section 401(g) of the Act,

(ii) The competence of the person conducting operations at such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Program employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter operations also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Poultry Products Inspection Act also are prepared at such establishment, and

(vi) The size of such establishment.

(c)(1) For the period of experimentation described in paragraph (a) of this section, the frequency of inspection by Program employees of operations other than slaughter may be reduced in an establishment in which the procedures referred to therein are

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§ 316.15 Marking outside containers of inedible grease, etc.

(a) Outside containers of inedible grease, inedible tallow, or other inedible animal fat, or mixture of any such articles, resulting from operations at any official establishment shall be marked conspicuously with the word "inedible" prior to removal from the point of filling. Containers, such as tierces, barrels, and half barrels shall have both ends painted white with durable paint, if necessary, to provide a contrasting background, and the word "inedible" shall be marked thereon in letters not less than 2 inches high, while on tank cars and tank trucks the letters shall be not less than 4 inches high.

(b) Inspected rendered animal fat which is intended not to be used for human food may also be marked "inedible" if handled as provided in paragraph (a) of this section and part 314 of this subchapter.

§ 316.16 Custom prepared products to be marked "Not for Sale."

Carcasses and parts therefrom that are prepared on a custom basis under § 303.1(a)(2) of this subchapter shall be marked at the time of preparation with the term "Not for Sale" in letters at least three-eighths inch in height, except that such products need not be so marked if in immediate containers properly labeled in accordance with the regulations in § 317.16 of this subchapter. Ink used for marking such products must comply with the requirements of § 316.5.

[35 FR 15577, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973]

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

Subpart A—General

Sec.

- 317.1 Labels required; supervision by Program employee.
- 317.2 Labels: definition; required features.
- 317.3 Approval of abbreviations of marks of inspection; preparation of marking devices bearing inspection legend without advance approval prohibited; exception.
- 317.4 Labeling approval.
- 317.5 Generically approved labeling.

- 317.6 Approved labels to be used only on products to which they are applicable.
- 317.7 Products for foreign commerce; printing labels in foreign language permissible; other deviations.
- 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.
- 317.9 Labeling of equine products.
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- 317.11 Labeling, filling of containers, handling of labeled products to be only in compliance with regulations.
- 317.12 Relabeling products; requirements.
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- 317.14-317.15 [Reserved]
- 317.16 Labeling and containers of custom prepared products.
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- 317.18-317.23 [Reserved]
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Subpart B—Nutrition Labeling

- 317.300 Nutrition labeling of meat or meat food products.
- 317.301 Required nutrition labeling of ground or chopped meat products.
- 317.302 Location of nutrition information.
- 317.303-317.307 [Reserved]
- 317.308 Labeling of meat or meat food products with number of servings.
- 317.309 Nutrition label content.
- 317.310-317.311 [Reserved]
- 317.312 Reference amounts customarily consumed per eating occasion.
- 317.313 Nutrient content claims; general principles.
- 317.314-317.342 [Reserved]
- 317.343 Significant participation for voluntary nutrition labeling.
- 317.344 Identification of major cuts of meat products.
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- 317.346-317.353 [Reserved]
- 317.354 Nutrient content claims for "good source," "high," and "more".
- 317.355 [Reserved]
- 317.356 Nutrient content claims for "light" or "lite".
- 317.357-317.359 [Reserved]
- 317.360 Nutrient content claims for calorie content.
- 317.361 Nutrient content claims for the sodium content.
- 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content.
- 317.363 Nutrient content claims for "healthy".

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317.364-317.368 [Reserved]
317.369 Labeling applications for nutrient content claims.
317.370-317.379 [Reserved]
317.380 Label statements relating to usefulness in reducing or maintaining body weight.
317.381-317.399 [Reserved]
317.400 Exemption from nutrition labeling.

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15580, Oct. 3, 1970, unless otherwise noted.

Subpart A—General

§317.1 Labels required; supervision by Program employee.

(a) When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an immediate container, there shall be affixed to such container a label as described in §317.2 except that the following do not have to bear such a label.

(1) Wrappings of dressed carcasses and primal parts in an unprocessed state, bearing the official inspection legend, if such wrappings are intended solely to protect the product against soiling or excessive drying during transportation or storage, and the wrappings bear no information except company brand names, trade marks, or code numbers which do not include any information required by §317.2;

(2) Uncolored transparent coverings, such as cellophane, which bear no written, printed, or graphic matter and which enclose any unpackaged or packaged product bearing all markings required by part 316 of this subchapter which are clearly legible through such coverings;

(3) Animal and transparent artificial casings bearing only the markings required by part 316 of this subchapter;

(4) Stockinettes used as "operative devices", such as those applied to cured meats in preparation for smoking, whether or not such stockinettes are removed following completion of the operations for which they were applied;

(5) Containers such as boil-in bags, trays of frozen dinners, and pie pans which bear no information except company brand names, trademarks, code numbers, directions for preparation and serving suggestions, and which are

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enclosed in a consumer size container that bears a label as described in §317.2;

(6) Containers of products passed for cooking or refrigeration and moved from an official establishment under §311.1 of this subchapter.

(b) Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product and which bear any written, printed, or graphic matter, shall bear all features required on a label for an immediate container.

(c) No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee.

§317.2 Labels: definition; required features.

(a) A label within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container (not including package liners) of any product.

(b) Any word, statement, or other information required by this part to appear on the label must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. In order to meet this requirement, such information must appear on the principal display panel except as otherwise permitted in this part. Except as provided in §317.7, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(c) Labels of all products shall show the following information on the principal display panel (except as otherwise permitted in this part), in accordance with the requirements of this part or, if applicable, part 319 of this subchapter:

(1) The name of the product, which in the case of a product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in part 319 of this subchapter, shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation, as prescribed in paragraph (e) of this section;

(2) If the product is fabricated from two or more ingredients, the word "ingredients" followed by a list of the ingredients as prescribed in paragraph (f) of this section;

(3) The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section;

(4) An accurate statement of the net quantity of contents, as prescribed in paragraph (h) of this section;

(5) An official inspection legend and, except as otherwise provided in paragraph (i) of this section, the number of the official establishment, in the form required by part 312 of this subchapter;

(6) Any other information required by the regulations in this part or part 319 of this subchapter.

(d) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part and part 319 of this subchapter with clarity and conspicuousness and without obscuring of such information by designs or vignettes or crowding. In determining the area of the principal display

panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. The principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is at least the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area that is 40 percent of the product of the height of the container times the circumference of the container, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: *Provided, however,* That if there is immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and which is reserved for information prescribed in paragraphs (c) (2), (3), and (5), such panel shall be known as the "20 percent panel" and such information may be shown on that panel in lieu of showing it on the principal display panel.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

(e) Any descriptive designation used as a product name for a product which has no common or usual name shall clearly and completely identify the product. Product which has been prepared by salting, smoking, drying, cooking, chopping, or otherwise shall be so described on the label unless the name of the product implies, or the manner of packaging shows that the product was subjected to such preparation. The unqualified terms "meat," "meat byproduct," "meat food product," and terms common to the meat industry but not common to consumers such as "picnic," "butt," "cala," "square," "loaf," "spread," "delight," "roll," "plate," "luncheon," and "daisy" shall not be used as names of a product unless accompanied with terms descriptive of the product or with a list of ingredients, as deemed necessary in any specific case by the Administrator in order to assure that the label will not be false or misleading.

(f)(1) The list of ingredients shall show the common or usual names of the ingredients arranged in the descending order of predominance, except as otherwise provided in this paragraph.

(i) The terms spice, natural flavor, natural flavoring, flavor and flavoring may be used in the following manner:

(A) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(B) The term "natural flavor," "natural flavoring," "flavor" or "flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powdered onion, powdered garlic, and powdered celery.

(ii) The term "corn syrup" may be used to designate either corn syrup or corn syrup solids.

(iii) The term "animal and vegetable fats" or "vegetable and animal fats" may be used to designate the ingredients of mixtures of such edible fats in product designated "compound" or "shortening." "Animal fats" as used herein means fat derived from inspected and passed cattle, sheep, swine, or goats.

(iv) When a product is coated with pork fat, gelatin, or other approved substance and a specific declaration of such coating appears contiguous to the

name of the product, the ingredient statement need not make reference to the ingredients of such coating.

(v) When two meat ingredients comprise at least 70 percent of the meat and meat byproduct ingredients of a formula and when neither of the two meat ingredients is less than 30 percent by weight of the total meat and meat byproducts used, such meat ingredients may be interchanged in the formula without a change being made in the ingredients statement on labeling materials: *Provided*, That the word "and" in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.

(vi)(A) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: *Provided*, That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as "Contains _____ percent of _____," "Less than _____ percent of _____." The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(B) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with §318.7(c)(4) and part 319 of this subchapter, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(2) On containers of frozen dinners, entrees, pizzas, and similar consumer

packaged products in cartons the ingredient statement may be placed on the front riser panel: *Provided*, That the words "see ingredients" followed immediately by an arrow is placed on the principal display panel immediately above the location of such statement without intervening print or designs.

(3) The ingredient statement may be placed on the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container.

(4) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(g)(1) The name or trade name of the person that prepared the product may appear as the name of the manufacturer or packer without qualification on the label. Otherwise the name of the distributor of the product shall be shown with a phrase such as "Prepared for * * *". The place of business of the manufacturer, packer, or distributor shall be shown on the label by city, State, and postal ZIP code when such business is listed in a telephone or city directory, and if not listed in such directory, then the place of business shall be shown by street address, city, State, and postal ZIP code.

(2) The name and place of business of the manufacturer, packer, or distributor may be shown:

(i) On the principal display panel, or

(ii) On the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container, or

(iii) On the front riser panel of frozen food cartons, or

(iv) On the information panel.

(h)(1) The statement of net quantity of contents shall appear on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph.

(2) The statement as it is shown on a label shall not be false or misleading and shall express an accurate state-

ment of the quantity of contents of the container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in §317.19. The statement shall not include any term qualifying a unit of weight, measure, or count such as "jumbo quart," "full gallon," "giant quart," "when packed," "minimum," or words of similar importance.

(3) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel in lines generally parallel to the base: *Provided*, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets the other requirements of this paragraph (h). In any case, the statement may appear in more than one line. The terms "net weight" or "net wt." shall be used when stating the net quantity of contents in terms of weight, and the term "net contents" or "content" when stating the net quantity of contents in terms of fluid measure.

(4) Except as provided in §317.7, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semisolid viscous or a mixture of solid and liquid. For example, a declaration of ¾-pound avoirdupois weight shall be expressed as "Net Wt. 12 oz." except as provided for in paragraph (h)(5) of this section for random weight packages; a declaration of 1½ pounds avoirdupois weight shall be expressed as "Net Wt. 24 oz. (1 lb. 8 oz.)," "Net Wt. 24 oz. (1½ lb.)," or "Net Wt. 24 oz. (1.5 lbs.)."

(5) On packages containing 1 pound or 1 pint and less than 4 pounds or 1 gallon, the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parentheses) in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound, or in

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Separated (Kind of Poultry) used in accordance with §381.174, individually or in combination, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and may contain Mechanically Separated (Species) used in accordance with §319.6. Such poultry products shall not contain kidneys or sex glands. The amount of poultry skin present in the sausage must not exceed the natural proportion of skin present on the whole carcass of the kind of poultry used in the sausage, as specified in §381.117(d) of this chapter. The poultry products used in the sausage shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of §381.118 of this chapter. Meat byproducts used in the sausage shall be designated individually in the ingredient statement on the label for such sausage in accordance with §317.2 of this chapter.

(c) A cooked sausage as defined in paragraph (a) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst. When such sausage products are prepared with meat from a single species of cattle, sheep, swine, or goats they shall be labeled with the term designating the particular species in conjunction with the generic name, e.g., "Beef Frankfurter," and when such sausage products are prepared in part with Mechanically Separated (Species) in accordance with §319.6, they shall be labeled in accordance with §317.2(j)(13) of this subchapter.

(d) A cooked sausage as defined in paragraph (b) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst, in conjunction with the phrase "with byproducts" or "with variety meats" with such supplemental phrase shown in a prominent manner directly contiguous to the generic name and in the same color on an identical background.

(e) Binders and extenders as provided in §319.140 of this part may be used in cooked sausage that otherwise comply with paragraph (a) or (b) of this section. When any such substance is added to these products, the substance shall

be declared in the ingredients statement by its common or usual name in order of predominance.

(f) Cooked sausages shall not be labeled with terms such as "All Meat" or "All (Species)," or otherwise to indicate they do not contain nonmeat ingredients or are prepared only from meat.

(g) For the purposes of this section: Poultry meat means deboned chicken meat or turkey meat, or both, without skin or added fat; poultry products mean chicken or turkey, or chicken meat or turkey meat as defined in §381.118 of this chapter, or poultry byproducts as defined in §381.1 of this chapter; and meat byproducts (or variety meats), mean pork stomachs or snouts; beef, veal, lamb, or goat tripe; beef, veal, lamb, goat, or pork hearts, tongues, fat, lips, weasands, and spleens; and partially defatted pork fatty tissue, or partially defatted beef fatty tissue.

[38 FR 14742, June 5, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §319.180, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§319.181 Cheesefurters and similar products.

"Cheesefurters" and similar products are products in casings which resemble frankfurters except that they contain sufficient cheese to give definite characteristics to the finished article. They may contain binders and extenders as provided in §318.7(c)(4) of this subchapter. Limits on use as provided in §318.7 are intended to be exclusive of the cheese constituent. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance. These products shall contain no more than 40 percent of a combination of fat and added water, and no more than 30 percent fat and shall comply with the other provisions for cooked sausages that are in this subchapter.

[55 FR 34683, Aug. 24, 1990, as amended at 56 FR 41448, Aug. 21, 1991]

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§319.182 Braunschweiger and liver sausage or liverwurst.

(a) "Braunschweiger" is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, and/or veal livers computed on the weight of the fresh livers. It may also contain pork and/or beef fat. Mechanically Separated (Species) may be used in accordance with §319.6. Binders and extenders may be used as permitted in §319.140. The product may have a smoked taste characteristic, which may be imparted by use of smoked meats, smoke flavoring or smoking. If prepared from components of a single species, the product name may reflect the species, e.g., "Beef Braunschweiger." Braunschweiger may also be labeled as any of the following: "Braunschweiger—A Liver Sausage," "Braunschweiger—A Liverwurst," or "Braunschweiger (Liver Sausage)" or "Braunschweiger (Liverwurst)."

(b) "Liver Sausage" or "Liverwurst" is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, veal, sheep, and/or goat livers computed on the weight of the fresh livers. It may also contain pork and/or beef byproducts. Mechanically Separated (Species) may be used in accordance with §319.6. Binders and extenders may be used as permitted in §319.140. If prepared from components of a single species, the product name may reflect that species, e.g., "Pork Liver Sausage."

[47 FR 36108, Aug. 19, 1982]

Subpart H [Reserved]

Subpart I—Semi-Dry Fermented Sausage [Reserved]

Subpart J—Dry Fermented Sausage [Reserved]

Subpart K—Luncheon Meat, Loaves and Jellied Products

§319.260 Luncheon meat.

"Luncheon Meat" is a cured, cooked meat food product made from comminuted meat. Mechanically Separated (Species) may be used in accord-

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ance with §319.6. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of luncheon meat in an amount not to exceed 3 percent of the total ingredients.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.261 Meat loaf.

"Meat Loaf" is a cooked meat food product in loaf form made from comminuted meat. Mechanically Separated (Species) may be used in accordance with §319.6. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

Subpart L—Meat Specialties, Puddings and Nonspecific Loaves

§319.280 Scrapple.

"Scrapple" shall contain not less than 40 percent meat and/or meat byproducts computed on the basis of the fresh weight, exclusive of bone. Mechanically Separated (Species) may be used in accordance with §319.6. The meal or flour used may be derived from grain and/or soybeans.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.281 Bockwurst.

(a) Bockwurst is an uncured, comminuted meat food product which may or may not be cooked. It contains meat, milk or water or a combination thereof, eggs, vegetables, and any of the optional ingredients listed in paragraph (b) of this section; and is prepared in accordance with the provisions of paragraphs (a)(1), (2), (3), and (4) of this section.

(1) Meat shall constitute not less than 70 percent of the total weight of the product and shall consist of pork or a mixture of pork and veal, pork and beef, or pork, veal, and beef. Such meat shall be fresh or fresh frozen meat. Pork may be omitted when the species or species of meat used in the product is identified in the product name (e.g., Veal Bockwurst, Beef Bockwurst, or

Beef and Veal Bockwurst). Mechanically Separated (Species) may be used in accordance with § 319.6.

(2) The "milk" may be fresh whole milk, dried milk, nonfat dry milk, calcium reduced dried skim milk, enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate, or any combination thereof.

(3) "Eggs" refer to whole eggs that are fresh, frozen, or dried.

(4) "Vegetables" refer to onions, chives, parsley, and leeks, alone or in any combination.

(b) Bockwurst may contain one or more of the following optional ingredients:

(1) Pork fat.

(2) Celery, fresh or dehydrated.

(3) Spices, flavorings.

(4) Salt.

(5) Egg whites, fresh, frozen, or dried.

(6) Corn syrup solids, corn syrup, or glucose syrup with a maximum limit of 2 percent individually or collectively, calculated on a dry basis. The maximum quantities of such ingredients shall be computed on the basis of the total weight of the ingredients.

(7) Autolyzed yeast extract, hydrolyzed plant protein, milk protein hydrolysate, and monosodium glutamate.

(8) Sugars (sucrose and dextrose).

(9) Binders and extenders may be added as provided in § 318.7(c)(4) of this subchapter. When any such substance is added to bockwurst, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance.

(c) If bockwurst is cooked or partially cooked, the composition of the raw mix from which it is prepared shall be used in determining whether it meets the requirements of this section.

[40 FR 18542, Apr. 29, 1975, as amended at 41 FR 18089, Apr. 30, 1976; 43 FR 26425, June 20, 1978; 45 FR 10318, Feb. 15, 1980; 47 FR 26374, June 18, 1982; 47 FR 28257, 28258, June 29, 1982; 55 FR 34683, Aug. 24, 1990; 56 FR 41448, Aug. 21, 1991]

Subpart M—Canned, Frozen, or Dehydrated Meat Food Products

§ 319.300 Chili con carne.

"Chili con carne" shall contain not less than 40 percent of meat computed

on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6. Head meat, cheek meat, and heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients under specific declaration on the label. The mixture may contain binders and extenders as provided in § 318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

§ 319.301 Chili con carne with beans.

Chili con carne with beans shall contain not less than 25 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6. Head meat, cheek meat, or heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients, and its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter. The mixture may contain binders and extenders as provided in § 318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

§ 319.302 Hash.

"Hash" shall contain not less than 35 percent of meat computed on the weight of the cooked and trimmed meat. The weight of the cooked meat used in this calculation shall not exceed 70 percent of the weight of the uncooked fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.303 Corned beef hash.

(a) "Corned Beef Hash" is the semi-solid food product in the form of a compact mass which is prepared with beef, potatoes, curing agents, seasonings, and any of the optional ingredients listed in paragraph (b) of this section, in accordance with the provisions of paragraphs (a) (1), (2), (3) and (4) of this section and the provisions of paragraph (c) of this section.

(1) Either fresh beef, cured beef, or canned corned beef or a mixture of two or more of these ingredients, may be used, and the finished product shall contain not less than 35 percent of beef

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computed on the weight of the cooked and trimmed beef. The weight of the cooked meat used in this calculation shall not exceed 70 percent of the weight of the uncooked fresh meat.

(2) "Potatoes" refers to fresh potatoes, dehydrated potatoes, cooked dehydrated potatoes, or a mixture of two or more of these ingredients.

(3) The curing agents that may be used are salt, sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or a combination of two or more of these ingredients. When sodium nitrate, or sodium nitrite, potassium nitrate, or potassium nitrite is used it shall be used in amounts not exceeding those specified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

(4) The seasonings that may be used, singly or in combination, are salt, sugar (sucrose or dextrose), spice, and flavoring, including essential oils, oleoresins, and other spice extractives.

(b) Corned beef hash may contain one or more of the following optional ingredients:

(1) Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap, may be used individually or collectively to the extent of 5 percent of the meat ingredients;

(2) Onions, including fresh onions, dehydrated onions, or onion powder;

(3) Garlic, including fresh garlic, dehydrated garlic, or garlic powder;

(4) Water;

(5) Beef broth or beef stock;

(6) Monosodium glutamate;

(7) Hydrolyzed plant protein;

(8) Beef fat;

(9) Mechanically Separated (Species) when derived from carcasses of cattle may be used in accordance with §319.6.

(c) The finished product shall not contain more than 15 percent fat nor more than 72 percent moisture.

(d)(1) When any ingredient specified in paragraph (b)(1) of this section is used, the label shall bear the following applicable statement: "Beef cheek meat constitutes 5 percent of the meat ingredient," or "Beef head meat constitutes 5 percent of the meat ingredient," or

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"Beef heart meat constitutes 5 percent of the meat ingredient." When two or more of the ingredients are used, the words "Constitutes 5 percent of meat ingredient" need only appear once.

(2) Whenever the words "corned beef hash" are featured on the label so conspicuously as to identify the contents, the statements prescribed in paragraph (d)(1) of this section shall immediately and conspicuously precede or follow such name without intervening written, printed, or other graphic matter.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982; 64 FR 72175, Dec. 23, 1999]

§319.304 Meat stews.

Meat stews such as "Beef Stew" or "Lamb Stew" shall contain not less than 25 percent of meat of the species named on the label, computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with §319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.305 Tamales.

"Tamales" shall be prepared with at least 25 percent meat computed on the weight of the uncooked fresh meat in relation to all ingredients of the tamales. When tamales are packed in sauce or gravy, the name of the product shall include a prominent reference to the sauce or gravy; for example, "Tamales With Sauce" or "Tamales With Gravy." Product labeled "Tamales With Sauce" or "Tamales With Gravy" shall contain not less than 20 percent meat, computed on the weight of the uncooked fresh meat in relation to the total ingredients making up the tamales and sauce or the tamales and gravy. Mechanically Separated (Species) may be used in accordance with §319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

§319.306 Spaghetti with meatballs and sauce, spaghetti with meat and sauce, and similar products.

"Spaghetti with Meatballs and Sauce" and "Spaghetti with Meat and Sauce," and similar products shall contain not

less than 12 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with §319.6. The presence of the sauce or gravy constituent shall be declared prominently on the label as part of the name of the product. Meatballs may be prepared with farinaceous material and with other binders and extenders as provided in §318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

§319.307 Spaghetti sauce with meat.

"Spaghetti Sauce with Meat" shall contain not less than 6 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with §319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.308 Tripe with milk.

"Tripe with Milk" shall be prepared so that the finished canned article, exclusive of the cooked-out juices and milk, will contain at least 65 percent tripe. The product shall be prepared with not less than 10 percent milk.

§319.309 Beans with frankfurters in sauce, sauerkraut with wieners and juice, and similar products.

"Beans with Frankfurters in Sauce," "Sauerkraut with Wieners and Juice," and similar products shall contain not less than 20 percent frankfurters or wieners computed on the weight of the smoked and cooked sausage prior to its inclusion with the beans or sauerkraut.

§319.310 Lima beans with ham in sauce, beans with ham in sauce, beans with bacon in sauce, and similar products.

"Lima Beans with Ham in Sauce," "Beans with Ham in Sauce," "Beans with Bacon in Sauce," and similar products shall contain not less than 12 percent ham or bacon computed on the

weight of the smoked ham or bacon prior to its inclusion with the beans and sauce.

§319.311 Chow mein vegetables with meat, and chop suey vegetables with meat.

"Chow Mein Vegetables with Meat" and "Chop Suey Vegetables with Meat" shall contain not less than 12 percent meat computed on the weight of the uncooked fresh meat prior to its inclusion with the other ingredients. Mechanically Separated (Species) may be used in accordance with §319.6.

[35 FR 15597, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.312 Pork with barbecue sauce and beef with barbecue sauce.

"Pork with Barbecue Sauce" and "Beef with Barbecue Sauce" shall consist of not less than 50 percent cooked meat of the species specified on the label. Mechanically Separated (Pork) may be used in accordance with §319.6.

[69 FR 34916, June 23, 2004]

§319.313 Beef with gravy and gravy with beef.

"Beef with Gravy" and "Gravy with Beef" shall not be made with beef which, in the aggregate for each lot contains more than 30 percent trimmable fat, that is, fat which can be removed by thorough, practicable trimming and sorting.

Subpart N—Meat Food Entree Products, Pies, and Turnovers

§319.500 Meat pies.

Meat pies such as "Beef Pie," "Veal Pie," and "Pork Pie" shall contain meat of the species specified on the label, in an amount not less than 25 percent of all ingredients including crust and shall be computed on the basis of the fresh uncooked meat.

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indicate if heat treatment has been used in the preparation of the product. The labeling information described in this paragraph shall be identified on the label before the product leaves the establishment at which it is manufactured.

(f) The labels of sausages encased in natural casings made from meat or poultry viscera shall identify the type of meat or poultry from which the casings were derived, if the casings are from a different type of meat or poultry than the encased meat or poultry. The identity of the casing, if required, may be placed on the principal display panel or in the ingredient statement. Establishments producing, manufacturing, or using natural sausage casings are to maintain records documenting the meat or poultry source in accordance with subpart Q of this part.

(g) The labels of sausages encased in regenerated collagen casings shall disclose this fact on the product label. The fact that the sausage is encased in collagen may be placed on the principal display panel or in the ingredient statement.

[37 FR 9706, May 16, 1972, as amended at 60 FR 55983, Nov. 3, 1995; 66 FR 40845, Aug. 6, 2001]

§ 381.118 Ingredients statement.

(a)(1) The label shall show a statement of the ingredients in the poultry product if the product is fabricated from two or more ingredients. Such ingredients shall be listed by their common or usual names in the order of their descending proportions, except as prescribed in paragraph (a)(2) of this section.

(2)(i) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: *Provided*, That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as "Contains _____ percent or less of _____," or "Less than _____ percent of _____." The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate.

No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(ii) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with § 381.147(f)(4) and subpart P of this part, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(b) For the purpose of this paragraph, the term "chicken meat," unless modified by an appropriate adjective, is construed to mean deboned white and dark meat; whereas the term "chicken" may include other edible parts such as skin and fat not in excess of their natural proportions, in addition to the chicken meat. If the term "chicken meat" is listed and the product also contains skin, giblets, or fat, it is necessary to list each such ingredient. Similar principles shall be followed in listing ingredients of poultry products processed from other kinds of poultry.

(c) The terms spice, natural flavor, natural flavoring, flavor or flavoring may be used in the following manner:

(1) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(2) The term "natural flavor," "natural flavoring," "flavor" or "flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible

yeast, herb, bark, bud, root, leaf or any other edible portions of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powdered onion, powdered garlic, and powdered celery.

(1) Natural flavor, natural flavoring, flavor or flavoring as described in paragraph (c)(1) and (2) of this section, which are also colors shall be designated as "natural flavor and coloring," "natural flavoring and coloring," "flavor and coloring" or "flavoring and coloring" unless designated by their common or usual name.

(i) Any ingredient not designated in paragraphs (c) (1) and (2) of this section whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock or poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

(d) On containers of frozen dinners, entrees, and pizzas, and similarly packaged products in cartons, the ingredient statement may be placed on the front riser panel: *Provided*, That the words "see ingredients," followed immediately by an arrow pointing to the front riser panel, are placed on the principal display panel immediately above the location of such statement, without intervening printing or designs.

(e) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(f) Establishments may interchange the identity of two kinds of poultry (e.g., chicken and turkey, chicken meat and turkey meat) used in a product formulation without changing the product's ingredient statement or product name under the following conditions:

(1)(i) The two kinds of poultry used must comprise at least 70 percent by weight of the poultry and the poultry ingredients [e.g. giblets, skin or fat in excess of natural proportions, or mechanically separated (kind)] used; and,

(ii) Neither of the two kinds of poultry used can be less than 30 percent by weight of the total poultry and poultry ingredients used;

(2) The word "and" in lieu of a comma must be shown between the declaration of the two kinds of poultry in the ingredients statement and in the product name.

[37 FR 9706, May 16, 1972, as amended at 55 FR 7294, Mar. 1, 1990; 55 FR 26422, June 28, 1990; 58 FR 38049, July 15, 1993; 59 FR 40215, Aug. 8, 1994; 63 FR 11360, Mar. 9, 1998]

§381.119 Declaration of artificial flavoring or coloring.

(a) When an artificial smoke flavoring or a smoke flavoring is added as an ingredient in the formula of any poultry product, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as "Artificial Smoke Flavoring Added" or "Smoke Flavoring Added," as applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring added as an ingredient in the formula of the poultry product.

(b) Any poultry product which bears or contains any artificial flavoring other than an artificial smoke flavoring or a smoke flavoring, or bears or contains any artificial coloring shall bear a statement stating that fact on the immediate container or, if there is none, on the product.

§381.120 Antioxidants; chemical preservatives; and other additives.

When an antioxidant is added to a poultry product, there shall appear on the label in prominent letters and contiguous to the name of the product, a statement showing the name of the antioxidant and the purpose for which it is added, such as "BHA added to help protect the flavor." Immediate containers of poultry products packed in, bearing, or containing any chemical preservative shall bear a label stating that fact and naming the additive and

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(d) If any marking is by code, the inspector in charge shall be informed as to its meaning.

[37 FR 9706, May 16, 1972, as amended at 39 FR 28516, Aug. 8, 1974; 39 FR 35784, Oct. 4, 1974]

§ 381.127 Wording on labels of shipping containers.

(a) Each label for use on a shipping container for inspected and passed poultry products shall bear, in distinctly legible form, the following information:

(1) The official inspection legend.

(2) The official establishment number of the official establishment in which the poultry product was inspected, either within the official inspection mark, or elsewhere on the container clearly visible and in proximity to the official inspection mark.

§ 381.128 Labels in foreign languages.

Any label to be affixed to a container of any dressed poultry or other poultry product for foreign commerce may be printed in a foreign language. However, the official inspection legend and establishment number shall appear on the label in English, but in addition, may be literally translated into such foreign language. Each such label shall be subject to the applicable provisions of §§ 381.115 to 381.141, inclusive. Deviations from the form of labeling required under the regulations may be approved by the Administrator in specific cases and such modified labeling may be used for poultry products to be exported: *Provided*, (a) That the proposed labeling accords to the specifications of the foreign purchaser, (b) that it is not in conflict with the Act or the laws of the country to which it is intended for export, and (c) that the outside of the shipping container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of the regulations shall apply.

§ 381.129 False or misleading labeling or containers.

(a) No poultry product subject to the Act shall have any false or misleading labeling or any container that is so made, formed, or filled as to be mis-

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leading. However, established trade names and other labeling and containers which are not false or misleading and which are approved by the Administrator in the regulations or in specific cases are permitted.

(b) No statement, word, picture, design, or device which is false or misleading in any particular or conveys any false impression or gives any false indication of origin, identity, or quality, shall appear on any label. For example:

(1) Official grade designations such as the letter grades A, B, and C may be used in labeling individual carcasses of poultry or containers of poultry products only if such articles have been graded by a licensed grader of the Federal or Federal-State poultry grading service and found to qualify for the indicated grade.

(2) Terms having geographical significance with reference to a particular locality may be used only when the product was produced in that locality.

(3) "Fresh frozen", "quick frozen", "frozen fresh", and terms of similar import apply only to ready-to-cook poultry processed in accordance with § 381.66(f)(1). Ready-to-cook poultry handled in any other manner and dressed poultry may be labeled "frozen" only if it is frozen in accordance with § 381.66(f)(2) under Department supervision and is in fact in a frozen state. "Individually quick frozen (Kind)" and terms of similar import are applicable only to poultry products that are frozen as stated on the label and whose component parts can be easily separated at time of packing.

(4) Poultry products labeled with a term quoted in any paragraph of § 381.170(b) shall comply with the specifications in the applicable paragraph. However, parts of poultry may be cut in any manner the processor desires as long as the labeling appropriately reflects the contents of the container of such poultry.

(5) The terms "All," "Pure," "100%," and terms of similar connotation shall not be used on labels for products to identify ingredient content, unless the product is prepared solely from a single ingredient.

(6)(i) Raw poultry product whose internal temperature has ever been below

26°F may not bear a label declaration of "fresh." Raw poultry product bearing a label declaration of "fresh" but whose internal temperature has ever been below 26°F is mislabeled. The "fresh" designation may be deleted from such product in accordance with § 381.133(b)(9)(xxiv). The temperature of individual packages of raw poultry product within an official establishment may deviate below the 26°F standard by 1° (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° (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.

(ii) Raw poultry product whose internal temperature has ever been at or below 0°F must be labeled with the descriptive term "frozen," except when such labeling duplicates or conflicts with the labeling requirements in § 381.125 of this subchapter. The word "previously" may be placed next to the term "frozen" on an optional basis. The descriptive term must be prominently displayed on the principal display panel of the label. If additional labeling containing the descriptive term is affixed to the label, it must be prominently affixed to the label. The additional labeling must be so conspicuous (as compared with other words, statements, designs, or devices in the labeling) that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Product described in this paragraph is subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(iii) Raw poultry product whose internal temperature has ever been below 26°F, but is above 0°F, is not required to bear any specific descriptive term. Raw poultry product whose internal temperature has ever been below 26°F, but is above 0°F, may bear labeling with an optional, descriptive term, provided the optional, descriptive term does not cause the raw poultry product

to become misbranded. If used, an optional, descriptive term must be prominently displayed on the principal display panel of the label. If additional labeling containing the optional, descriptive term is affixed to the label, it must be prominently affixed on the label. The additional labeling must be so conspicuous (as compared with other words, statements, designs, or devices in the labeling) that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(iv) Handling and relabeling of products. (A) Except as provided under paragraph (b)(6)(iii)(C) of this section, when any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, such product may be transported in commerce to an official establishment after oral permission is obtained from the Area Supervisor of the area in which that official establishment is located. The transportation of the product may be to the official establishment from which it had been transported or to another official establishment designated by the person desiring to handle the product. The transportation shall be authorized only for the purpose of the relabeling of the product. The Area Supervisor shall record the authorization and other information necessary to identify the product and shall provide a copy of the record to the inspector at the establishment receiving the product. The shipper shall be furnished a copy of the authorization record upon request.

(B) Upon the arrival of the shipment at the official establishment, a careful inspection shall be made of the product by the inspector, and if it is found that the product is not adulterated, it may be received into the establishment; but if the product is found to be adulterated, it shall at once be condemned and disposed of in accordance with § 381.95 of this subchapter. Wholesome product will be relabeled in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate.

(C) When any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment,

the owner may transport the product in commerce to a retail entity for relabeling in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate, or to other end users, such as hotels, restaurants or similar institutions; or, relabel the product in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate if the product is already at a retail entity. A hotel, restaurant or similar institution is not required to relabel product misbranded under this subpart; *Provided*, That the product is prepared in meals or as entrees only for sale or service directly to individual consumers at such institutions, and that the mark of inspection is removed or obliterated. Oral permission shall be obtained from the Area Officer-in-Charge of the Compliance Program for the area in which the product is located prior to such transportation or relabeling. The Area Officer-in-Charge shall record the authorization and other information necessary to identify the product, and shall furnish a copy of the authorization record upon request. Before being offered for sale at a retail entity, such product shall be relabeled.

(c) A calendar date may be shown on labeling when declared in accordance with the provisions of this paragraph:

(1) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(2) Immediately adjacent to the calendar date shall 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", and such phrases shall be approved by the Administrator as prescribed in §381.132.

(d) When sodium alginate, calcium carbonate, lactic acid, and calcium lactate are used together in a dry binding matrix in ground and formed poultry products, as permitted in §381.147 of

this subchapter, there shall appear on the label contiguous to the product name, a statement to indicate the use of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.

(e) When transglutaminase enzyme is used to bind pieces of poultry to form a cut of poultry, or to reform a piece of poultry from a multiple cuts of poultry, there shall appear on the label, as part of the product name, a statement that indicates that the product has been "formed" or "reformed," in addition to other preparation steps, e.g., "Formed Turkey Thigh Roast" or "Reformed and Shaped Chicken Breast."

(f) A country of origin statement on the label of any poultry product "covered commodity" as defined in 7 CFR Part 65, Subpart A, that is to be sold by a "retailer," as defined in 7 CFR 65.240, must comply with the requirements in 7 CFR 65.300 and 65.400.

[37 FR 9706, May 16, 1972, as amended at 39 FR 28516, Aug. 8, 1974; 39 FR 42339, Dec. 5, 1974; 55 FR 5977, Feb. 21, 1990; 60 FR 44412, Aug. 25, 1995; 61 FR 66200, Dec. 17, 1996; 61 FR 68821, Dec. 30, 1996; 66 FR 54916, Oct. 31, 2001; 73 FR 50703, Aug. 28, 2008]

§381.130 False or misleading labeling or containers; orders to withhold from use.

If the Administrator has reason to believe that any marking or other labeling or the size or form of any container in use or proposed for use with respect to any article subject to the Act is false or misleading in any particular, he may direct that the use of the article be withheld unless it is modified in such manner as the Administrator may prescribe so that it will not be false or misleading. If the person using or proposing to use the labeling or container does not accept the determination of the Administrator, he may request a hearing, but the use of the labeling or container shall, if the Administrator so directs, be withheld pending hearing and final determination by the Secretary in accordance with applicable rules of practice. Any such determination with respect to the matter by the Secretary shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for

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§381.132(d), for all products, except as provided in §381.133(b) (2)-(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.

(c) All labeling required to be submitted for approval as set forth in §381.132(b) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate) for a product produced in other establishments that are owned by the corporation.

(d) "Sketch" labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in subpart N of this part. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in §381.132(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in §381.133(b)(9).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days under the following conditions:

(i) The proposed labeling would not misrepresent the product;

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(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food Labeling Division, provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

[60 FR 67456, Dec. 29, 1995]

§381.133 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with subpart T of this part, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accord with this section and shows all mandatory features in a prominent manner as required in subpart N of this part, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with subpart T of this part, as required in §381.132, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in §381.233.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in subpart 381 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims (except as provided by paragraph (b)(9)(xxviii) of this section), or

guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as chicken legs or turkey breasts) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims (except as provided by paragraph (b)(9)(xxviii) of this section), or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with §381.127;

(5) Labeling for products not intended for human food, provided they comply with §§381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with §381.190(b);

(6) Poultry inspection legends, which comply with subpart M of this part;

(7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

(8) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., "lb." for "pound," or "oz." for "ounce," or of

the word "pound" for "lb." or "ounce" for "oz.";

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided that the size of the net weight statement complies with §381.121;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

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(xv) The deletion of the word "new" on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 381.125(a);

(xvii) The addition of safe handling instructions as required by § 381.125(b);

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in § 381.147 and subpart P of this part;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) The addition, deletion, or substitution of the official USDA poultry grade shield; (xxii) A change in the establishment number by a corporation or parent company for an establishment under its ownership;

(xxiii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for services sizes, provided the nutrition labeling information maintains its accuracy and consistency;

(xxiv) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information;

(xxv) The addition or deletion of a direct translation of the English language into a foreign language for products marked "for export only"; and

(xxvi) The use of the descriptive term "fresh" in accordance with § 381.129(b)(6)(i) of this subchapter.

(xxvii) The use of the descriptive term *frozen* as required by § 381.129(b)(6)(ii) of this subchapter.

(xxviii) A country of origin statement on any product label described in § 381.129(f) that complies with the requirements in that paragraph.

[60 FR 67457, Dec. 29, 1995, as amended at 61 FR 66201, Dec. 17, 1996; 73 FR 50703, Aug. 28, 2008]

§ 381.134 Requirement of formulas.

Copies of each label submitted for approval, shall when the Administrator requires in any specific case, be accompanied by a statement showing, by their common or usual names, the kinds and percentages of the ingredients comprising the poultry product and by a statement indicating the method or preparation of the product with respect to which the label is to be used. Approximate percentages may be given in cases where the percentages of ingredients may vary from time to time, if the limits of variation are stated.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 59 FR 45196, Sept. 1, 1994. Redesignated at 60 FR 67457, Dec. 29, 1995]

§ 381.136 Affixing of official identification.

(a) No official inspection legend or any abbreviation or other simulation thereof may be affixed to or placed on or caused to be affixed to or placed on any poultry product or container thereof, except by an inspector or under the supervision of an inspector or other person authorized by the Administrator, and no container bearing any such legend shall be filled except under such supervision.

(b) No official inspection legend shall be used on any poultry product or other article which does not qualify for such mark under the regulations.

§ 381.137 Evidence of labeling and devices approval.

No inspector shall authorize the use of any device bearing any official inspection legend unless he or she has on file evidence that such device has been approved in accordance with the provisions of this subpart.

[60 FR 67458, Dec. 29, 1995]

§ 381.138 Unauthorized use or disposition of approved labeling or devices.

(a) Labeling and devices approved for use pursuant to § 381.115 shall be used only for the purpose for which approved, and shall not be disposed of from the official establishment for

imposed upon the Council and upon the trustees.

(d) Any residual funds not required to defray the necessary expenses of liquidation shall be turned over to the Secretary to be disposed of, to the extent practical, to one or more domestic raspberry industry organizations in the interest of continuing processed raspberry promotion, research, and information programs.

§ 1208.74 Effect of termination or amendment.

Unless otherwise expressly provided by the Secretary, the termination of this subpart or of any regulation issued pursuant thereto, or the issuance of any amendment to either thereof, shall not:

(a) Affect or waive any right, duty, obligation or liability which shall have arisen or which may thereafter arise in connection with any provision of this subpart or any regulation issued thereunder.

(b) Release or extinguish any violation of this subpart or any regulation issued thereunder.

(c) Affect or impair any rights or remedies of the United States, or of the Secretary or of any other persons, with respect to any such violation.

§ 1208.75 Personal liability.

No member, alternate member, or employee of the Council shall be held personally responsible, either individually or jointly with others, in any way whatsoever, to any person for errors in judgment, mistakes, or other acts, either of commission or omission, as such member, alternate, or employee, except for acts of dishonesty or willful misconduct.

§ 1208.76 Separability.

If any provision of this subpart is declared invalid or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected thereby.

§ 1208.77 Amendments.

Amendments to this subpart may be proposed from time to time by the Council or by any interested person affected by the provisions of the Act, including the Secretary.

§ 1208.78 OMB control numbers.

The control number assigned to the information collection requirements by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB control number 0505-0001, OMB

control number 0581-0093, and OMB control number 0581-0257.

Dated: May 3, 2012.

David R. Shipman,
Administrator.

[FR Doc. 2012-11060 Filed 5-7-12; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 304, 381, 417 and 418

[FDMS Docket No. FSIS-2008-0025]

RIN 0583-AD34

Requirements for Official Establishments To Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is implementing provisions of the Food, Conservation, and Energy Act of 2008 by amending the Federal meat and poultry products inspection regulations to require official establishments to promptly notify the appropriate District Office that an adulterated or misbranded meat or poultry product has entered commerce; require official establishments to prepare and maintain written procedures for the recall of all meat and poultry products produced and shipped by the establishment; and require official establishments to document each reassessment of the establishment's Hazard Analysis and Critical Control Point (HACCP) plans.

DATES: Effective Date: May 8, 2012.

Applicability Dates: Amendments to §§ 304.3, 381.22, 417.4, 418.2, and 418.4 are applicable beginning June 7, 2012. For more information on applicability dates, see the section titled "Section 418.3 Effective Dates" in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, Room 349-E, Jamie L. Whitten Building, 1400 Independence Avenue SW., Washington, DC 20250; Telephone (202) 205-0495, Fax (202) 720-2025.

SUPPLEMENTARY INFORMATION:

I. Section 418.3 Effective Dates

The regulations in § 418.3 are applicable as follows:

- In large establishments, defined as all establishments with 500 or more employees, November 5, 2012.

- In small establishments, defined as all establishments with 10 or more employees but fewer than 500, May 8, 2013.

- In very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million, May 8, 2013.

II. Background

The Food Safety and Inspection Service (FSIS) administers a regulatory program under 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. The Agency is responsible for ensuring that the nation's commercial supply of meat and poultry is safe, wholesome, and correctly labeled and packaged.

On June 18, 2008, section 11017 of the Food, Conservation, and Energy Act of 2008, Public Law 110-246, 122 Stat 1651, 448-49, otherwise known as the 2008 Farm Bill, amended the FMIA and the PPIA to require establishments subject to inspection under these Acts that believe or have reason to believe that an adulterated or misbranded meat or poultry product received by or originating from the establishment has entered into commerce to promptly notify the Secretary with regard to the type, amount, origin, and destination of the meat or poultry product. The 2008 Farm Bill also requires that inspected establishments: (1) Prepare and maintain written procedures for the recall of all products produced and shipped by the establishment; (2) document each reassessment of the process control plans of the establishment (i.e., HACCP plans); and (3) upon request, make the procedures and reassessed control plans available for inspectors appointed by the Secretary to review and copy.

In the **Federal Register** of March 25, 2010 (75 FR 14361), FSIS proposed regulations to implement the new provisions of the 2008 Farm Bill. FSIS proposed to amend 9 CFR 417.4(a)(3) to require official establishments to make a written record of each reassessment of the adequacy of their HACCP plan, or to document the reasons for not making a change to their HACCP plan based on the reassessment. For annual reassessments, if an establishment determines that no changes to its

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HACCP plans are necessary, the establishment does not have to document the reasons for this determination. Furthermore, FSIS proposed to establish a new 9 CFR part 418, Recalls, under which official establishments would be required to prepare and maintain procedures for the recall of all meat and poultry products produced and shipped by the establishment, and to promptly notify FSIS within 48 hours if the establishment believes or has reason to believe that an adulterated or misbranded product received by or originating from the establishment has entered into commerce. Interested persons were invited to submit written comments by May 24, 2010.

After review and consideration of all comments, FSIS is finalizing, with three changes, the provisions in the March 2010 proposed rule. Specifically, the Agency is amending the proposal to require official establishments to promptly notify FSIS within 24 hours if the establishment believes or has reason to believe that an adulterated or misbranded product received by or originating from the establishment has entered into commerce. In addition, the Agency is amending the proposal to require new establishments to develop their written recall procedures at the same time as their HACCP plans in order to receive a Federal Grant of Inspection.

Also in response to comments, FSIS has decided to stagger the applicability date for 9 CFR part 418 based on establishment size. Existing large establishments, defined as all establishments with 500 or more employees, will have six months from the date of publication of this final rule in the *Federal Register* to prepare their written recall procedures. Existing small establishments (those with 10 or more employees but fewer than 500) and very small establishments (those with fewer than 10 employees or annual sales of less than \$2.5 million) will have one year from publication of this final rule in the *Federal Register* to prepare their written recall procedures. These changes are discussed in detail in the Agency's responses to comments.

III. Summary of and Response to Comments

FSIS received 31 comments from hospitality supply companies, supply management companies, trade groups representing meat packing and processing establishments, a trade group representing the turkey industry, a trade group representing food and beverage companies, a trade group representing organic agriculture products, a

representative from a state department of agriculture, a small processing plant, a rancher, a farmer, and 14 consumers.

A summary of issues raised by commenters and the Agency's responses follows.

A. Notification Requirement

Comment: A few comments addressed whether 48 hours is an appropriate time in which to expect official establishments that have shipped or received, or have reason to believe that they have shipped or received, adulterated or misbranded product, to notify the appropriate District Office of that situation. A consumer and a trade group representing the turkey industry stated that 48 hours is a reasonable timeframe to give establishments to notify District Offices. A trade group representing meat packing and processing establishments also stated that the proposed time period was reasonable, but was concerned that 48 hours may be an arbitrary figure. Three consumer groups and an individual consumer argued the proposed timeframe is too lax, and that establishments should notify District Offices within 24 hours if they may have shipped or received adulterated or misbranded product. One consumer group argued that allowing official establishments to wait as long as 48 hours before reporting this information to the appropriate District Office will unnecessarily delay efforts to remove adulterated or misbranded product from commerce. Another consumer group argued that 24 hours is sufficient time for establishments to notify District Offices that they may have shipped or received adulterated or misbranded product because establishments may notify the District Office by phone.

Agency's Response: FSIS agreed with commenters that 48 hours may be too long. The Agency has concluded that because notification can be made with a phone call, 24 hours is an appropriate time in which to expect official establishments that have shipped or received, or have reason to believe that they have shipped or received, adulterated or misbranded product, to notify the appropriate District Office of that situation. Therefore, the final rule requires official establishments to notify the appropriate District Office within 24 hours of learning or determining that an adulterated or misbranded product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe that this has happened.

Comment: A few comments requested that the Agency provide more guidance on when the 48-hour period would

officially begin. One comment from a consumer group argued that the proposed requirement was vague and confusing. The commenter asked that the Agency explain how much investigation an establishment owner will be required to make before the notification requirement is triggered. Another comment from a trade group representing meat packing and processing establishments recommended that the Agency work with industry on establishing the timeline. They requested that the Agency develop specific guidance that outlines a step-by-step reaction process. They also requested that FSIS consider factors such as microbial test data recovery, weekends, and Federal holidays when deciding when the 48-hour period should officially begin.

Agency's Response: The 24-hour period begins when the establishment has reason to believe that a product that is in commerce is adulterated or misbranded under the FMIA or PPIA. For example, if the results of a laboratory analysis show that raw ground beef contains *E. coli* O157:H7, or that a ready-to-eat product contains *Listeria monocytogenes* or any other pathogen, the product would be adulterated. However, there also may be situations in which laboratory results are not available, but, based on epidemiological evidence, there may be a probability of harm from consuming the product. Under these circumstances, the establishment is to consider the strength of the epidemiological evidence to determine whether there is reason to believe that the product is adulterated or misbranded.

Comment: Two comments argued that the notification requirement is "overly broad," and that minor labeling errors do not misbrand product and should be excluded from the notification requirement. They suggested that the Agency follow the standard established for the U.S. Food and Drug Administration's (FDA's) Reportable Food Registry or incorporate a *de minimis* standard. The FDA standard requires notification when there is a reasonable probability that the use of, or exposure to, the article of food will cause serious adverse health consequences or death (21 U.S.C. 350(d)).

Agency's Response: FSIS did not accept suggestions to follow the standard established for the FDA's Reportable Food Registry (RFR) or to incorporate a *de minimis* standard. FSIS assesses the public health concern or hazard presented by a product being recalled, or considered for recall, and classifies the concern as one of the

following: (1) Class I, a health-hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death; (2) Class II, a health-hazard situation where there is a remote probability of adverse health consequences from the use of the product; or (3) Class III, a situation where the use of the product will not cause adverse health consequences. If the Agency adopted the RFR standard or a similar *de minimis* standard, establishments may not be required to notify FSIS about product that could trigger a Class II or Class III recall. Furthermore, the 2008 Farm Bill provisions do not provide for a *de minimis* standard concerning the notification requirements for establishments that may have shipped or received adulterated or misbranded product. Consistent with the statute, and because the notification requirement is a preventive measure that will allow FSIS to determine more quickly whether a recall action is necessary (including detention and seizure of product by FSIS), thereby protecting public health, the final rule requires official establishments to notify the appropriate District Office of all product that is believed to be adulterated or misbranded.

FSIS is aware, however, that there can be misbranding situations because of minor labeling deficiencies, and that these deficiencies do not create health or safety issues or impart an economic advantage. If a District Office, when notified by an establishment that it has shipped or received or may have shipped or received misbranded product, identifies the violation as one that does not create a health or safety issue or economic impact, it will contact FSIS's Labeling and Program Delivery Division (LPDD) about the misbranding situation. LPDD will then contact the establishment and work with it to resolve the situation.

Comment: Two comments submitted by consumer groups requested that the final rule require official establishments to notify both the appropriate District Office and FSIS headquarters in Washington, DC. They argued that because the legislation refers to notifying the Secretary of Agriculture, and given the potential health impacts of the recall information, data should be sent to headquarters in addition to the local District Office.

Agency's Response: The Agency does not believe it is necessary for official establishments to contact both the appropriate District Office and FSIS headquarters in Washington, DC. The Secretary of Agriculture has delegated to

the Under Secretary for Food Safety the responsibility for exercising the functions of the Secretary of Agriculture under various statutes (Section 4(a) of Reorganization Plan No. 2 of 1953 (5 U.S.C. App.) and Section 212(a)(1) of the Department of Agriculture Reorganization Act of 1994, Public Law 103-354, 7 U.S.C. 6912(a)(1)), while the Under Secretary for Food Safety has delegated that authority to the Administrator of the Food Safety and Inspection Service (7 CFR 2.7, 2.18, and 2.53). In turn, each District Office, under the direction of a District Manager, has been given the authority to manage a farm-to-table food safety program of regulatory oversight and inspection in a district consisting of a State or several States and territories. Thus, the District Offices have the authority, and are fully competent, to receive and analyze information from official establishments about adulterated or misbranded product.

Comment: A trade group representing meat packing and processing establishments and a trade group that represents food and beverage companies noted that the proposed rule provides that establishments must notify FSIS of the destination of the adulterated or misbranded product. The two trade groups suggested that the Agency clearly state in the preamble to the final rule that while the statutory language specified notification of the "destination" of the adulterated or misbranded product, shipping establishments only have knowledge of, and therefore, need only provide notification about their direct consignees.

Agency's Response: Under this rule, establishments must provide all available information about the "destination" of adulterated or misbranded product. This rule does not create a duty to seek out new information; however, if establishments have information about the destination of adulterated or misbranded product beyond their direct consignees, they must provide it to the Agency.

B. Recall plans

Comment: Several comments expressed concerns about the security of plant recall information and whether recall plans would be subject to the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)).

Agency's Response: FSIS understands the nature of these comments and that many meat and poultry establishments view the data in recall procedures as confidential commercial information. Pursuant to USDA's Freedom of Information Act (FOIA) regulations (7

CFR 1.1 et seq.), FSIS is responsible for making the determination with regard to the disclosure or nondisclosure of information in records obtained from businesses. When, in the course of responding to an FOIA request, FSIS cannot readily determine whether the information obtained from a person is confidential business information, the Agency seeks to obtain and carefully consider the views of the business and provide the business an opportunity to object to any decision to disclose the information.

Under this final rule, establishments are not required to submit their recall procedures to FSIS. They must, however, make the written recall procedures available for copying. FSIS will verify that all establishments maintain the required written recall procedures. FSIS will also protect establishments' confidential business information from public disclosure to the extent authorized under FOIA and in conformity with USDA's FOIA regulations.

Comment: Two comments questioned whether the language of the proposed rule exceeded the provisions of the Farm Bill because it requires official establishments to specify in their written recall procedures how they will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

Agency's Response: FSIS has the authority to require official establishments to specify in their written recall procedures how they will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.¹ These requirements are also consistent with the legislation and with longstanding Agency guidance on recall plans.²

Comment: Several comments suggested that the Agency execute the rule in incremental stages based on business size, similar to the plan used when HACCP was implemented. Two stated that six months to one year is a reasonable time to give establishments to develop recall procedures. One comment suggested that current establishments should be given six months to develop recall procedures,

¹ See 21 U.S.C. 621, " * * and said Secretary shall, from time to time, make sure rules and regulations as are necessary for the efficient execution of the provisions of this Act, * * * and 21 U.S.C. 463(b), "The Secretary shall promulgate such other rules and regulations as are necessary to carry out the provisions of this chapter."

² See "FSIS Directive 8080.1, Rev. 6, 10/26/10, Recall of Meat and Poultry Products, Attachment 1".

but new establishments should be required to prepare their recall procedures at the same time as their HACCP plans. Another comment recommended that large establishments be required to prepare their recall procedures as soon as possible, but that small and very small establishments be given more time to comply. Yet another comment suggested that the Agency implement the rule for large establishments and review the results for one year before requiring small and very small establishments develop recall procedures.

Agency's Response: FSIS has sought to make this rule as fair and equitable as possible, regardless of an establishment's size. Therefore, the Agency asked for comments on when, after the effective date of this final rule, written recall procedures must be completed in accordance with proposed 9 CFR 418.3. Based upon the comments received, FSIS has determined that existing large establishments will have six months from the date of publication of this final rule to implement it and prepare recall plans. To minimize the burden on small businesses, small and very small establishments will have one year from the date of publication to comply.

FSIS believes that the suggestion to require new establishments to have prepared their recall procedures at the same time as their HACCP plans in order to receive a Federal Grant of Inspection has merit. Therefore, the Agency is amending 9 CFR 304.3 and 9 CFR 381.22 to require that before being granted Federal inspection, an establishment must have developed written recall procedures as required by part 418 of Title 9, Chapter III. The Office of Outreach, Employee Education and Training has model recall plans available to industry.

Reassessment of HACCP Plans

Comment: Several comments supported the documenting of HACCP reassessments, as proposed. One consumer group argued that documentation is vital because it provides a needed safeguard against evasion of reassessment requirements. The commenter stated that by making records of reassessment available for official review and copying, FSIS has the ability to preempt an outbreak by identifying overlooked hazards.

Agency's Response: The Agency agrees with comments that the documenting of HACCP reassessments is beneficial. The Agency believes that documenting HACCP reassessments will facilitate verification that establishments have appropriately

reassessed their HACCP plans. It will also help FSIS personnel to identify whether there are emerging hazards that the establishment has decided not to address.

Comment: One comment submitted by a trade group representing meat packing and processing establishments requested that the Agency clarify in the final rule that simple formatting or grammar changes of a HACCP plan do not need to be documented as reassessments.

Agency's Response: While establishments are required to document each reassessment of their HACCP plans, the Agency does not consider formatting and grammar changes to be reassessments.

Costs

Comment: The Agency received several comments addressing the cost of implementing the proposed rule. One consumer group argued that the cost of implementing the proposed rule is reasonable. The commenter argued that if the first-year industry costs will be \$5 million dollars, that cost is far less than the billions of dollars the United States incurs as a result of foodborne illnesses per year.

A few comments from very small processors or supporters of very small processors or local processors claimed that additional regulation will be an undue financial burden on small and very small establishments. One trade group representing meat packing and processing establishments believed that FSIS's estimated initial cost is already a significant cost to many small and very small establishments, and that the actual cost could potentially be much higher. The trade group suggested that the initial cost to small and very small establishments might be \$2,000; however, the trade group did not offer any data to support its claim. Another comment submitted by a consumer suggested creating waivers or exemptions for small and very small establishments.

Agency's Response: While the Agency agrees with the commenter that \$2,000 in initial cost for small and very small establishments may be a significant cost, FSIS estimates that the average initial (first-year) cost of implementing this final rule for these establishments will not be \$2,000 but would be between \$700 and \$900, with a midpoint of \$800,³ for each small or very small establishment.

³ See, Table 2 (columns 7, 8, and 9), which is the updated Table 3, Federal Register, Vol. 75, No. 57, March 25, 2010, page 14365.

IV. Executive Orders 12866 and 13563 and Regulatory Flexibility Act

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

FSIS has carefully evaluated the comments submitted in response to the proposed rule and has concluded that it is appropriate to adopt the Preliminary Regulatory Impact Analysis and the initial Regulatory Flexibility Act (RFA) assessment as final. This Final Regulatory Impact Analysis (FRIA) and final RFA assessment have changed from the Preliminary Regulatory Impact Analysis and the initial RFA assessment that were published in the proposed rule on March 25, 2010, though the methodology remains the same.

A. Baseline

FSIS expects that this final rule will affect about 6,300 official federally-inspected establishments that slaughter or process meat, meat products, poultry, and poultry products, based on FSIS's Performance Based Inspection System (PBIS) of 2011. Based on HACCP classification, about 400 are large establishments, 3,044 are small, and 2,856 are very small.⁴

B. Expected Costs

Under the current regulations, the development and maintenance of recall procedures and the written documentation of HACCP reassessments are voluntary. This final rule will make them mandatory. Costs will be incurred because about 6,300 official establishments will need to develop recall procedures and maintain written documentation of HACCP reassessments. Cost estimates are updated to reflect the most recent available data.⁵

⁴ Very small establishments have fewer than 10 employees or generate less than \$2.5 million in annual sales; and small establishments have 10 or more but fewer than 500 employees and generate more than \$2.5 million in annual sales.

⁵ This includes USDA, FSIS Performance Based Inspection System Volume Database 2011, and

The cost of notifying FSIS, with a few phone calls, facsimiles, or emails about possibly adulterated or misbranded products in commerce is negligible. FSIS has determined that there will be no impact on the Agency's operational costs resulting from this final rule, because the Agency will not need to add any staff or incur any additional non-labor expenditure when the final rule is adopted.

In addition to the extra establishment labor cost, FSIS estimates that the extra establishment material cost would be about 1 percent of the labor cost of the development of the recall procedures and the documentation of each reassessment of the HACCP plan. The first year estimated average total costs to the industry are about \$5.2 million for labor (shown in Table 1) and \$52 thousand ($0.01 \times \$5.2M = \$52,000$) for materials.

FSIS believes that the estimated cost of developing recall procedures is an overestimate because: (1) Some unknown number of establishments already have plans that could likely be adequate with little or no change, (2) establishments in the meat and poultry industries have differing levels of expertise in writing HACCP plans, (3) the Agency makes model recall plans available to the industry, and (4) establishments have a range of different

processes for producing meat and poultry products. Given the uncertainty of incurred labor cost in different regions and with various experience levels, FSIS assumes a 20% range, plus and minus 10%, of the estimated average-compliance cost. The estimated cost summary is shown in Table 1.

FSIS expects that in the first year of the final rule, one-time costs for developing recall procedures would cost the industry of approximately 6,300 establishments \$4.6 million, in an estimated range of \$4.1 and \$5.0 million, 10% lower and upper bound, respectively. Furthermore, the final rule would have first year costs of approximately \$0.5 million for documenting periodic reassessments of HACCP plans, and \$0.1 million for records backup and storage, although these costs may well be overstated. The recurring costs of developing and updating recall procedures, documenting periodic reassessments of HACCP plans, and records backup and storage for the second through the tenth year are estimated at \$610,000, \$66,000, and \$11,000, respectively (see Table 3).

The total cost for the first year is \$5.2 (\$4.6 + \$0.5 + \$0.1) million, in an estimated range of \$4.7 and \$5.7 million, 10% lower and upper bound, respectively. Considering the subsequent years cost of \$687,000, the

annualized cost over ten years using 3% and 7% discount rates is \$1.20 million (\$1.08 million and \$1.31 million, 10% lower and upper bound), and \$1.28 million (\$1.15 million and \$1.41 million, 10% lower and upper bound), respectively (Table 3).

The present value of total costs with a 3% discount rate for 10 years would be \$10.2 million, in an estimated range of \$9.2 and \$11.2 million. The present value of total costs with a 7% discount rate for 10 years would be \$9.0 million, in an estimated range of \$8.1 and \$9.9 million.

Table 2 shows the first year total costs by establishment size, of which \$0.3 million is attributed to large, \$2.5 million to small, and \$2.3 million to very small establishments. The first year cost per official establishment is between \$700 and \$900, 10% lower and upper bound, respectively.

Table 3 gives the estimated annualized cost and the present value of total cost by establishment size classes for ten years. Table 3, column 4, shows all cost categories of the first year (assumed to be 2013) and comes from Table 2, column 6, distributed by the counts of establishment size classes. The costs for years 2–10 are based on constant dollar assumption and are shown in Table 3, column 5.

TABLE 1—FIRST YEAR COST BREAKDOWN, IN DOLLARS, FOR 6,300 ESTABLISHMENTS (LABOR AND MATERIALS)

Cost component	Response rate	Required man-hours	Wage rate	Factor for paper, ink and media cost	Material (paper, ink and media) cost (x \$1,000)	Total cost (x \$1,000)	Low range (-10%) of total cost	High range (+10%) of total cost
Recall-Procedures Development (one-time)	1	20	36	1.01	46	4,582	4,124	5,040
Document Reassessment (First Year)	5	0.25	63	1.01	5	501	451	551
Records Backup and Storage (First Year)	1	0.25	36	1.50	28	85	77	94
Total					79	5,168	4,651	5,685

TABLE 2—NUMBER OF ESTABLISHMENTS, TOTAL AND AVERAGE COSTS IN SIZE (x\$1,000)

HACCP Class	Number of establishments	Recall procedures development (one-time)	Documenting HACCP reassessment	Records backup and storage	Total cost	Cost per establishment	Low estimate (-10%)	High estimate (+10%)
Very Small	2,856	2,077	227	39	2,343	0.8	0.7	0.9
Small	3,044	2,214	242	41	2,497	0.8	0.7	0.9
Subtotal	5,900	4,291	469	80	4,840	0.8	0.7	0.9
Large	400	291	32	5	328	0.8	0.7	0.9
Total	6,300	4,582	501	85	5,168	0.8	0.7	0.9

TABLE 3—ESTIMATE ANNUALIZED AND PRESENT VALUE OF THE TOTAL COST BY ESTABLISHMENT SIZE CLASS, ASSUMING CONSTANT DOLLARS

HACCP class	Number of establishment	Activities	1st year 2013	2nd-10th years 2014-22	Annualized cost at 3%	Annualized cost at 7%	Present value of total cost at 3%	Present value of total cost at 7%
Very Small	2,856	Recall-Procedures development & updating	2,077	278	483	517	4,118	3,634
		Documenting HACCP Reassessment	227	30	52	56	447	395
		Records backup and storage	39	5	9	10	76	67
		Subtotal	2,343	313	544	583	4,641	4,096
Small	3,044	Recall-Procedures development & updating	2,214	296	514	551	4,387	3,872
		Documenting HACCP Reassessment	242	32	56	60	477	421
		Records backup and storage	41	5	9	10	78	69
		Subtotal	2,497	333	579	621	4,942	4,361
Small and Very Small ...	5,900	Subtotal of Small & Very Small	4,480	646	1,123	1,204	9,582	8,457
Large	400	Recall-Procedures development & updating	291	36	65	70	555	491
		Documenting HACCP Reassessment	32	4	7	8	61	54
		Records backup and storage	5	1	1	2	12	11
		Subtotal	328	40	74	79	628	556
Total	6,300	Recall-Procedures development & updating	4,582	610	1,062	1,139	9,060	7,997
		Documenting HACCP Reassessment	501	66	116	124	985	870
		Records backup and storage	85	11	19	21	166	146
		Total	5,168	687	1,197	1,283	10,211	9,013

C. Expected Benefits

The expected benefits likely to result from this final rule are improvements in the effectiveness of the nation's food safety system for meat and poultry products and improved protection of public health. These benefits are not monetized because quantified data on benefits attributable to this final rule are not available to FSIS. The expected benefits include:

HACCP Reassessment and Documentation of Reassessments

Under this final rule, establishments must document each reassessment, the reasons for any changes to the HACCP plan, or the reasons for not changing the HACCP plan. For annual reassessments, if the establishment determines that no changes are necessary, documentation of this determination is not necessary. These provisions will allow FSIS

personnel to better verify and track that establishments are, in fact, reassessing those plans at least annually, as required by 9 CFR 417.4(a)(3), and that they are appropriately responding to their findings.

Notification Requirement

This final rule is a preventive measure that will result in FSIS being alerted to potential meat and poultry recall situations earlier than would otherwise be the case. Under this rule, establishments will be required to notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded product received by or originating from the establishment has entered commerce. This notification, in turn, will allow FSIS to initiate its preliminary inquiries more quickly and to determine more quickly whether a recall is necessary.

Improve Recall Effectiveness With Documented Procedures

FSIS expects that this final rule will assist meat and poultry establishments during recalls. By requiring these establishments to prepare and maintain recall procedures for all products they produce, FSIS expects that establishments that do not currently have such plans will be able to act more effectively to remove adulterated or misbranded products from commerce. This added efficiency and effectiveness will help establishments to move quickly to disseminate information about the need to return the product to it and thus maximize the amount of recalled product they will actually recover. Table 4 gives a summary of the benefits discussed above.

TABLE 4—SUMMARY OF BENEFITS

Benefit related to:	Required actions:	Expected benefits:
Document Reassessment	- Establishments are to document all reassessments of HACCP plans. - Establishments are to make documentation of the HACCP plans available to inspection program personnel.	Improved HACCP systems for establishments.
Notification Requirement	Establishments are to notify local FSIS District Office within 24 hours of having reason to believe that an adulterated or misbranded product received or originating from the official establishment has entered commerce.	- FSIS will be alerted to potential meat or poultry recall situations earlier than otherwise is the case today. - FSIS will be able to begin more rapidly preliminary inquiries to determine whether a recall is necessary.

TABLE 4—SUMMARY OF BENEFITS—Continued

Benefit related to:	Required actions:	Expected benefits:
Improve Recall Effectiveness	Establishments are to prepare and maintain recall procedures for all products they produce.	- Establishments will be able to act more effectively to remove adulterated or misbranded products from consumers. - Establishments will be able to move quickly to disseminate information about the need to return product to it. - Establishments will be able to maximize the amount of product they will be able to receive.

D. Regulatory Flexibility Act Analysis

The FSIS Administrator has certified that this final rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601).

These small entities number about 5,900 federally-inspected establishments. The average cost to small and very small businesses will be in the range of \$700 to \$900 (Table 2).

Based on data recorded in the PBIS (2011)⁶ volume database, and slaughter volume recorded in the FSIS Animal Disposition Reporting System (ADRS, 2008)⁷ database, and volume estimates of the USDA Economic Research Service (ERS, 2009)⁸, these 5,900 small entities process about 12 percent or about 8 billion pounds of the U.S. meat and poultry food supply per annum. Further, FSIS estimated that the average processing volume per establishment of 5,900 small entities was about 1.4 million pounds (8,000,000,000/5,900) per annum. Thus, the average cost for the first year of this final rule to small entities will be less than one tenth of one cent (e.g., \$0.0006 = \$800/1,400,000) of meat and poultry food products per pound. This is a relatively insignificant cost to the small entities because most of their meat and poultry food products are valued at more than \$1.50 per pound. The average cost for the following years, based on annual recurring costs, decreases to less than one hundredth of one cent per pound.

E. Alternatives

The option of no rulemaking is unavailable. FSIS was directed to

conduct this rulemaking by Congress. As discussed above, FSIS considered a longer time period (48 hours) for establishments to notify FSIS when they have reason to believe that adulterated or misbranded products of theirs may have entered commerce. This option was rejected in response to comments received. Also in response to comments, FSIS is providing a phased-in implementation period, with more time allowed for small and very small establishments than for larger establishments, rather than a uniform implementation period. This latter amendment should lessen the burden on smaller entities.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. When this final rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Requirements

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection and recordkeeping requirements included in this rule have been submitted for approval to OMB.

Title: Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments.

Type of Collection: New.

Abstract: Under this final rule, FSIS is requiring three information collection activities. First, FSIS requires that official establishments notify the appropriate District Office that an adulterated or misbranded product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe that this has happened. FSIS is requiring that this notification occur

as quickly as possible, but within 24 hours of the establishment learning or determining that an adulterated or misbranded product received by or originating from it has entered commerce. Second, FSIS is requiring that establishments prepare and maintain written procedures for the recall of meat and poultry products produced and shipped by the establishment for use should it become necessary for the establishment to remove product from commerce. These written recall procedures have to specify how the establishment will decide whether to conduct a product recall and how the establishment will effect the recall, should it decide that one is necessary. Finally, FSIS is requiring that establishments document each reassessment of the establishment's HACCP plans. FSIS requires establishments to reassess their HACCP plans annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Under this rule, establishments must document each reassessment, the reasons for any changes to the HACCP plan, or the reasons for not changing the HACCP plan. For annual reassessments, if the establishment determines that no changes are necessary, documentation of this determination is not necessary. The recall procedures and reassessment documentation will have to be made available for official review and copying.

Estimate of Burden of Average Hours per Response: 1.159.

Respondents: Official meat and poultry products establishments.

Estimated Number of Respondents: 6,300.

Estimated Number of Responses: 40,960.

Estimated Number of Responses per Respondent: 6.5.

Estimated Total Annual Burden on Respondents: 47,475.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection

⁶ USDA, FSIS Performance Based Inspection System Volume Database 2011. The number of establishments is the number of Federally-inspected processing and slaughter establishments.

⁷ USDA, FSIS Animal Disposition Reporting System Database 2008.

⁸ USDA, Economic Research Service, Food Availability (Per Capita) Data System—Per capita food availability data compiled reflect the amount of food available for human consumption in the United States. March 2009, <http://www.ers.usda.gov/Data/FoodConsumption>.

Service, USDA, Room 6081, South Agriculture Building, 1400 Independence Avenue SW., Washington, DC 20250.

E-Government Act Compliance

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to government information and services, and for other purposes.

Executive Order 13175

This final rule has been carefully evaluated for potential tribal implications in accordance with Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. FSIS has concluded based on its evaluation that this final rule will not have any direct or substantial effects on Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power or responsibilities between the Federal Government and Indian Tribes because there are currently no federally-inspected meat or poultry establishments owned or operated by Indian Tribes in tribal areas or on tribal reservations.

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 rule online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_policies/interim_final_rules/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.

List of Subjects in 9 CFR Parts 304, 381, 417 and 418

Hazard Analysis and Critical Control Point (HACCP) Systems, Meat inspection, Poultry and poultry products inspection, Reporting and recordkeeping requirements, Recalls.

For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III, as follows:

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

■ 1. The authority citation for part 304 continues to read as follows:

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

■ 2. In § 304.3, paragraph (a) is revised to read as follows:

§ 304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment must have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 of this chapter.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53

■ 4. In § 381.22, paragraph (a) is revised to read as follows:

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment must have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter, and written recall procedures as required by part 418 of this chapter.

* * * * *

PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

■ 5. The authority citation for part 417 continues to read as follows:

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 U.S.C. 1901–1906; 7 CFR 2.18, 2.53.

■ 6. In § 417.4, paragraph (a)(3) is redesignated as paragraph (a)(3)(i) and a new paragraph (a)(3)(ii) is added to read as follows:

§ 417.4 Validation, Verification, Reassessment.

* * * * *

(a) * * *

(3) *Reassessment of the HACCP plan.*

(i) * * *

(ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.

* * * * *

■ 7. A new part 418 is added to read as follows:

PART 418—RECALLS

Sec.

418.1 [Reserved]

418.2 Notification.

418.3 Preparation and maintenance of written recall procedures.

418.4 Records.

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 418.1 [Reserved]

§ 418.2 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or

originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

§ 418.3 Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

§ 418.4 Records.

All records, including records documenting procedures required by this part, must be available for official review and copying.

Done in Washington, DC, on May 1, 2012.

Alfred V. Almanza,
Administrator.

[FR Doc. 2012-10917 Filed 5-7-12; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2011-1066; Directorate Identifier 2011-NM-050-AD; Amendment 39-16917; AD 2012-01-05]

RIN 2120-AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD) for certain Airbus Model A300 B2-1C, B2K-3C, B2-203, B4-2C, B4-103, and B4-203 airplanes; and Model A300 B4-601, B4-603, B4-620, B4-622, B4-605R, B4-622R, and F4-605R airplanes. That AD currently requires repetitive inspections for cracking in Gear Rib 5 of the main landing gear (MLG) attachment fittings at the lower flange, and repair if necessary; and provides an optional spot-facing modification around certain fastener holes, which would terminate certain repetitive inspections. This new

AD mandates the optional spot-facing modification. This AD was prompted by new cases of cracks discovered during scheduled maintenance checks. We are issuing this AD to prevent cracking of the Gear Rib 5 right-hand and left-hand attachment fitting at the lower flanges of the MLG, which could result in failed bolts penetrating through the rear spar and into a fuel tank, consequent fuel loss, and reduced structural integrity of the airplane.

DATES: This AD becomes effective June 12, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 12, 2012.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of January 5, 2011 (75 FR 74610, December 1, 2010).

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of July 18, 2006 (71 FR 33994, June 13, 2006).

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of April 12, 2000 (65 FR 12077, March 8, 2000).

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of October 20, 1999 (64 FR 49966, September 15, 1999).

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov> or in person at the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057-3356; telephone (425) 227-2125; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the *Federal Register* on October 11, 2011 (76 FR 62673), and proposed to supersede AD 2010-23-26, Amendment 39-16516 (75 FR 74610, December 1, 2010). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

Following the occurrence of cracks on the MLG [main landing gear] Rib 5 RH [right-hand] and LH [left-hand] attachment fitting lower flanges, DGAC [Direction Générale de l'Aviation Civile] France AD 2003-318(B) was issued to require repetitive inspections and, as terminating action, the embodiment of Airbus Service Bulletins (SB) A300-57-0235 and A300-57-6088 * * *.

Subsequently, new cases of cracks were discovered during scheduled maintenance checks by operators of A300B4 and A300-600 type aeroplanes on which the terminating action SB's were embodied. This condition, if not corrected, could affect the structural integrity of those aeroplanes.

To address and correct this condition, Airbus developed an inspection programme for aeroplanes modified in accordance with SB A300-57-0235 or A300-57-6088. This inspection programme was required to be implemented by DGAC France AD F-2005-113, original issue and later revision 1 [parallel to part of FAA AD 2006-12-13, Amendment 39-14639 (71 FR 33994, June 13, 2006)].

A new EASA [European Aviation Safety Agency] AD 2008-0111, superseding DGAC France AD F-2005-113R1, was issued to reduce the applicability. For aeroplanes already compliant with DGAC France AD F-2005-113R1, no further action was required.

Since EASA AD 2008-0111 issuance, Airbus reviewed the inspection programmes of SB A300-57A0246 and SB A300-57A6101 to introduce repetitive inspections including a new inspection technique for holes 47 and 54 and to reduce inspections threshold and intervals from 700 Flight Cycles (FC) to 400 FC until a revised terminating action is made available.

For the reasons stated above, EASA AD 2009-0081 superseded EASA AD 2008-0111 and required operators to comply with the new inspection programme introduced in Revisions 3 of Airbus SB A300-57A0246 and Airbus SB A300-57A6101.

EASA AD 2009-0081 R1 [which corresponds to FAA AD 2010-23-26, Amendment 39-16516 (75 FR 74610, December 1, 2010)] has been published to introduce an optional terminating action which consisted of spot-facing the sensitive holes of the MLG Rib 5 (LH and RH) bottom flanges.

Later discussions with Airbus have demonstrated the necessity to require the spot-facing modification as a final solution (no longer optional). This new [EASA] AD retains the inspection requirements of EASA AD 2009-0081 R1, which is superseded, and requires the spot-facing of sensitive holes of the MLG Rib 5 (LH and RH) bottom flanges as terminating action.

Required actions include repairing discrepancies (e.g., cracking or a second oversize or greater fastener hole). You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received. The

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inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

(c)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency or the Secretary of the Interior to act on a request for certification within a reasonable period (which shall not exceed 1 year after receipt of such request).

(2) However, certification is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification and meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

[35 FR 15558, Oct. 3, 1970, as amended at 41 FR 4889, Feb. 3, 1976; 44 FR 68813, Nov. 30, 1979; 62 FR 45024, Aug. 25, 1997; 64 FR 56415, Oct. 20, 1999; 64 FR 66545, Nov. 29, 1999; 65 FR 2284, Jan. 14, 2000]

§ 304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, as required by §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with § 417.4 of this chapter.

[61 FR 38864, July 25, 1996]

PART 305—OFFICIAL NUMBERS; INAUGURATION OF INSPECTION; WITHDRAWAL OF INSPECTION; REPORTS OF VIOLATION

Sec.

- 305.1 Official numbers; subsidiaries and tenants.
- 305.2 Separation of official establishments.
- 305.3 Sanitation and adequate facilities.
- 305.4 Inauguration of inspection.
- 305.6 Reports of violations.

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15559, Oct. 3, 1970, unless otherwise noted.

§ 305.1 Official numbers; subsidiaries and tenants.

(a) An official number shall be assigned to each establishment granted inspection. Such number shall be used to identify all inspected and passed products prepared in the establishment. More than one number shall not be assigned to an establishment.

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certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification or to meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

(3) Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

(4) In the case of any activity which will affect water quality but for which there are no applicable water quality standards, no certification is required prior to the grant of inspection but such grant will be conditioned upon a requirement of compliance with the purpose of the Federal Water Pollution Control Act as provided in paragraph 21(b)(9) of said Act.

[37 FR 9706, May 16, 1972, as amended at 64 FR 66545, Nov. 29, 1999]

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, in accordance with part 416 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, in accordance with §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP

plan, in accordance with § 417.4 of this chapter.

[61 FR 38866, July 25, 1996]

Subpart E—Inauguration of Inspection; Official Establishment Numbers; Separation of Establishments and Other Requirements; Withdrawal of Inspection

§ 381.25 Official establishment numbers.

An official establishment number shall be assigned to each establishment granted inspection service. Such number shall be used to identify all containers of inspected poultry products prepared in the establishment. An establishment shall not have more than one establishment number.

§ 381.26 Separation of establishments.

Each official establishment shall be separate and distinct from any other official establishment and from any unofficial establishment except an establishment preparing meat products under the Federal Meat Inspection Act or under State meat inspection. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe.

§ 381.27 Inauguration of service; notification concerning regulations; status of uninspected poultry products.

The inspector in charge or his supervisor shall, upon or prior to the inauguration of service, inform the operator of the establishment of the requirements of the regulations. If the establishment at the time service is inaugurated contains any poultry product which has not been inspected and marked in compliance with the regulations, its identity shall be maintained, and it shall not be represented or dealt with as a product which has been inspected. Such products may not be shipped in commerce unless such products are eligible for such shipment under an exemption from inspection under subpart C and comply with all requirements of said subpart.

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shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

[61 FR 38868, July 25, 1996, as amended at 62 FR 61009, Nov. 14, 1997]

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation

or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) *Initial validation.* Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) *Ongoing verification activities.* Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3) *Reassessment of the HACCP plan.* Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained

in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

(b) *Reassessment of the hazard analysis.* Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.

(d) *Records maintained on computers.* The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) *Record retention.* (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by §417.3 of this part;

(d) HACCP records are not being maintained as required in §417.5 of this part; or

(e) Adulterated product is produced or shipped.

and direct effects on Tribal governments and will not have significant Tribal implications.

F. Effective Date

This interim rule reflects a recommendation submitted to the Secretary by the NOSB for the purpose of fulfilling the requirements of 7 U.S.C. 6517(e) of the OFPA. Section 7 U.S.C. 6517(e) requires the NOSB to review each substance on the National List within 5 years of its publication. Pursuant to 5 U.S.C. 553, it is found and determined upon good cause that it is impracticable and contrary to the public interest to give preliminary notice prior to putting this rule into effect in order to ensure the continued use of nutrients vitamins and minerals in organic products after October 21, 2012, and avoid widespread disruption to the organic market. Accordingly, this rule shall be effective on October 21, 2012.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

Dated: September 21, 2012.

David R. Shipman,
 Administrator, Agricultural Marketing
 Service.

[FR Doc. 2012–23748 Filed 9–26–12; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 307 and 381

[Docket No. FSIS–2011–0032]

RIN 0583–AD48

Additional Changes to the Schedule of Operations Regulations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the meat and poultry product regulations pertaining to the schedule of operations. FSIS is amending these regulations to define the 8-hour workday as including time that inspection program personnel need to

prepare the inspection station, if necessary, or retrieve and return lot tally sheets; the time necessary for FSIS inspection program personnel to sharpen knives, if necessary; and the time necessary to conduct duties scheduled by FSIS, including administrative activities. The activities are integral and indispensable to inspectors' work and are part of the continuous workday as defined by the Fair Labor Standards Act. Therefore, they are activities that need to be part of the Agency's regulatory definition for the 8-hour workday.

DATES: Effective November 26, 2012.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Acting Assistant Administrator, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250–3700, telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

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.*, provide for mandatory Federal inspection of livestock and poultry slaughtered at official establishments and of meat and poultry products processed at official establishments. FSIS bears the cost of mandatory inspection provided during non-overtime and non-holiday hours of operation. Official establishments pay for inspection services performed on holidays or on overtime.

On March 19, 2012, FSIS proposed to amend its regulations pertaining to the schedule of operations (77 FR 15976). FSIS proposed to amend these regulations to define the 8-hour workday as including time that inspection program personnel need to prepare the inspection station at meat slaughter establishments, if necessary, or to retrieve and return lot tally sheets at poultry slaughter establishments; the time necessary for FSIS inspection program personnel to sharpen knives, if necessary, at meat slaughter establishments; and the time necessary to conduct duties scheduled by FSIS, including administrative activities at meat and poultry slaughter establishments. The activities are integral and indispensable to the principal work of inspection program personnel as defined in 29 CFR 790.8, "Principal" activities. Therefore, these activities need to be part of the Agency's regulatory definition for the 8-hour workday.

Response to Comments

FSIS received one comment within the scope of the rulemaking regarding the proposed rule change from an association representing the meat industry. The comment raised the following issues:

De Minimis

The commenter stated that FSIS has ignored the Office of Personnel Management (OPM) regulation 5 CFR 551.412(a) that governs the exclusion of *de minimis* actions from compensable activities. The commenter stated that the OPM rule excludes preparatory activities that last less than 10 minutes and also stated that the proposed rule identified two of three activities specified in the proposal—administrative activities and preparation for inspection—as each taking less than 10 minutes per day. Therefore, the commenter asserted that the OPM regulation precludes the need for the proposed rule.

Response

As stated in the proposed rule, FSIS considers these activities as integral and indispensable to the principal work of inspection program personnel as defined in 29 CFR 790.8, "Principal" activities. As integral and indispensable work activities under the Fair Labor Standards Act, FSIS finds that these activities should be included as part of the continuous workday when reading both 5 CFR 551.412(a) and the OPM definition of "workday" at 5 CFR 551.411(a), together. 5 CFR 551.412(a) cannot be properly read alone to exclude time spent on indispensable work activities during the continuous workday from compensable hours of work. Any duties scheduled by FSIS, including administrative duties, are integral and indispensable to the essential work of inspection program personnel because they enable inspection program personnel to carry out their work effectively. The preparation of the workstation is an integral and indispensable activity ensuring that inspectors have the necessary stamps used to identify condemned parts while conducting their inspection duties. Therefore, administrative duties and the preparation of the work station in cattle slaughter establishments are integral and indispensable to the principal work of inspection program personnel as defined in 29 CFR 790.8, "Principal" activities, and thus, these activities need to be part of the Agency's regulatory definition for the 8-hour workday.

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Knife Sharpening

The commenter did not dispute that knife sharpening is a compensable activity but did oppose the standardized approach in the proposed rule that would give inspectors one 15-minute period for knife sharpening if they perform on-line duties in a cattle slaughter establishment 3 days or less per week or if they perform on-line duties in a swine slaughter establishment, and two 15-minute periods for knife sharpening if they perform on-line duties in a cattle slaughter establishment 4 or more days per week. The commenter stated that plants should be permitted to conduct individualized assessments of the time it takes inspectors to sharpen their knives.

Response

The time estimates FSIS developed in the proposed rule for knife sharpening were based on an Agency CD-ROM training video, "Knife-Safety and Sharpening Skills," and the numbers of times per week for knife sharpening were based on a variety of factors, including the species being inspected (i.e., cattle or swine) and the number of carcasses inspected. The time allocations that FSIS is finalizing are necessary to ensure the safe and proper use of knives during inspection. The Agency cannot ensure the safety of its inspectors and that proper knife sharpening occurs if each establishment determines for itself how long it should take inspectors to sharpen a knife because each establishment will have a financial incentive to reduce this amount of time. Therefore, when FSIS implements this rule, it will ensure inspection program personnel have an appropriate amount of time to sharpen their knives.

Inaccurate Inspector Time Records

The commenter stated that because inspectors bill in 15-minute increments, all slaughter facilities already pay inspectors for time during which inspection work is not being done. The commenter stated that a facility should be permitted to review inspectors' time records and offer corrections supported by reports and stamped surveillance footage, if necessary, before inspectors submit their time records. The commenter also stated that during interruptions for line stoppages or equipment failures, inspectors should make use of the time that they are not on the line for activities such as knife sharpening. The commenter also stated that if inspectors choose not to use such

time, establishments should not have to pay overtime for the activity.

Response

FSIS supervisors assign work to inspection program personnel. FSIS will ensure that its supervisory personnel instruct inspection program personnel to complete the activities addressed in this final rule during any time remaining in a 15-minute increment of overtime or during work times when they are not on the line. However, FSIS does not agree that establishments should implement a formal monitoring program, such as video surveillance of FSIS employees or checking inspector time sheets. FSIS supervisors ensure that employees accurately record the time that they work. Establishment management should discuss any concerns about the time worked by FSIS inspectors with FSIS supervisors.

Line Time

Lastly, the commenter stated that any additional time inspectors need to be compensated for under the proposed rule should not count against the 10-hour-per-day limit of actual inspector time permitted by FSIS.

Response

FSIS ensures that the maximum time an employee may work on the slaughter line is ten (10) hours per work day. While knife sharpening, station preparation, and administrative duties are integral to the work and conducted during the continuous workday, they are activities not done on the slaughter line itself. Therefore, these activities are not subject to the 10 hour per day limit of slaughter line activity.

Amendment to 9 CFR 307.4(c) and 381.37(c)

After consideration of the comments received and for the reasons discussed above, FSIS is adopting the proposed rule as a final without revision and is amending the meat regulations to provide that the 8 hours of inspection service provided to establishments free of charge will include activities necessary to fully carry out an inspection program, including time for inspection program personnel to prepare the work station; the time necessary for FSIS inspection program personnel to sharpen knives, if necessary; and the time necessary to conduct duties scheduled by FSIS, including administrative duties. When the rule goes into effect, FSIS will direct its supervisory personnel at livestock slaughter establishments to conduct a new time measurement that measures the amount of time it takes to don

required gear, walk to a work station, prepare the work station, and doff required gear. If establishments do not provide a knife sharpening service, the establishment will also need to incorporate the times and frequencies discussed above in response to comments on knife sharpening into the 8 hours of inspection or request that knife sharpening be done in an overtime period.

FSIS is amending the poultry products regulations to provide that the 8 hours of inspection service provided to establishments free of charge will include activities necessary to fully carry out an inspection program, including time for inspection program personnel to retrieve and return lot tally sheets and the time necessary to conduct duties scheduled by FSIS, including administrative duties. Inspection program personnel in poultry products establishments do not use knives when conducting inspection activities and do not need to prepare the work station. When this rule goes into effect, FSIS will direct its supervisory personnel in poultry slaughter establishments to conduct a new time measurement that measures the amount of time it takes inspection program personnel to don required gear, pick up a lot tally sheet, and doff required gear.

In addition, when this rule goes into effect, slaughter establishments will need to provide inspection program personnel 1 minute every day to complete time and attendance activities.

As with the provisions for donning, doffing, and the associated walk time, establishments will need to either incorporate the time for inspection program personnel performing on-line inspection duties to conduct knife sharpening, to complete the time and attendance reporting, and to prepare for inspection into their hours of operation or request overtime charges. The regulations provide that FSIS will bill overtime in 15-minute increments (9 CFR 307.6 and 381.39). Therefore, in situations where establishments have requested overtime, FSIS, when possible, will instruct inspection program personnel performing on-line inspection duties to do the activities addressed in this rule during any time that remains within 15-minutes of requested overtime.

Executive Order 12866 and the Regulatory Flexibility Act

This rule has been designated non-significant under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

Cost to the Industry

Under this final rule, the most direct cost to the industry will be the overtime fee that the Agency will need to charge slaughter establishments for the time inspection program personnel spend in three groups of activities: (1) Sharpening knives, (2) completing administrative activities, and (3) preparing for inspection. As we explained in the cost analysis of the Final Rule on Changes to the Schedule of Operations Regulations (76 FR page 33979), if meat and poultry slaughter establishments want to maintain their normal shift length of operating for 8 hours, they would incur some overtime fees.¹ Although the choice is voluntary, the Agency expects that most meat and poultry slaughter establishments will choose to maintain their current shift-time, as shortening the shift-time will decrease production and revenue while idling existing capacity. However, FSIS does not expect the overtime fee from these three groups of activities to be significant because (1) the establishments have options, as we will discuss later, besides paying overtime for some of these activities, and (2) the time for carrying out administrative activities and preparing for inspection (including preparing an inspection station and picking up and dropping off lot tally sheets) is small—one minute or two per day—and will probably not push the overtime over the 15-minute threshold to incur more overtime charge than are currently assessed for donning and doffing activities.

Similar to donning and doffing, the actual time FSIS inspection program personnel will take to perform these activities will vary in each meat and poultry slaughter establishment depending on plant-specific variables. FSIS developed estimates on the amount of time it takes for inspection program personnel to perform these activities and requested public comments. FSIS did not receive any comments on the estimates, so FSIS's estimates remain the same in this final rule.

Knife-sharpening:

a. Two 15-minute periods per week for inspection program personnel who perform on-line inspection duties in beef slaughter operations for 4 or more days per week.

b. One 15-minute period per week for inspection program personnel on the beef slaughter line for 3 days or less per

week or in a swine slaughter establishment.

- One minute per day to complete administrative activities.
- Two minutes or less for preparing for inspection.

Agency personnel data² show that there are 3,053 inspection program personnel performing on-line inspection duties in poultry and meat slaughter establishments—2,037 in poultry, 1,000 in meat, and 16 in establishments that slaughter both meat and poultry. Data from an Agency survey³ indicates that among the meat slaughtering inspectors, 56 percent work in beef establishments that operate 4 or 5 days per week, 4 percent work in beef establishments that operate less than 4 days per week, 36 percent work in swine establishments, and 4 percent work in lamb, sheep, and goat establishments. Because lamb, sheep, and goat establishments are small or very small establishments, inspection program personnel would be able to complete the activities addressed in this final rule within the 8-hour day, and, therefore, there are no related cost calculations for these establishments in this final rule. Applying the percentages to the total of 1,016 meat slaughter inspectors,⁴ we have 573 inspection program personnel working in beef establishments that operate 4 or 5 days per week, and 409 working in either beef establishments that operate less than 4 days per week or swine establishments. The overtime fee that the Agency charges for each 15-minute interval is \$17.08 for FY 2012.

Multiplying this number by the Agency-estimated knife-sharpening time, we estimated the annual cost for knife sharpening time to be about \$1,776.3 (\$17.08 per quarter-hour × 2 knife-sharpening periods per week × 52 weeks per year) per inspection program personnel in beef slaughter establishments that operate 4 days or more a week, and \$888.2 (\$17.08 per quarter-hour × 52 weeks per year) per inspection program personnel in beef slaughter establishments that operate 3 days or less or in swine establishments. If the industry had to pay all the meat slaughter inspectors to sharpen their knives, the total cost to the industry would be about \$1.38 million (\$1,776.3 × 573) + (\$888.2 × 409). However, the actual impact would be much less because the industry can offer knife-sharpening services to Agency

inspection program personnel instead of paying overtime for it.

If an establishment provides a knife-sharpening service, FSIS will instruct inspection program personnel to use that service. An Agency query⁵ found that the majority of the meat-slaughter establishments are offering knife sharpening to their employees, and about 91% of those also offer the service to Agency inspection program personnel. We expect that many other establishments will start offering the service to avoid paying overtime charges when this rule becomes effective.

As for the other two groups of activities, the time they take is minimal. According to the Agency's estimates mentioned above, these activities combined will be at most 3 minutes per day. In addition, FSIS will permit the establishment to take on the responsibility of preparing the inspection station for inspection program personnel in livestock slaughter establishments. Given that the Agency charges overtime in 15-minute increments, and that it believes the donning, doffing, and walking time to be usually less than 15-minutes, time for these additional activities can be absorbed in the overtime period for donning, doffing, and walking time in most cases, thus not causing any additional overtime. In the unlikely, worst-case scenario where these activities push the daily overtime beyond the first 15-minute interval, the establishments would pay each inspection program personnel another \$4,441 (\$17.08 per inspector × 5 days per week × 52 weeks per year) annually. However, the Agency believes this scenario would apply to only a very small percentage of the inspection program personnel.

Comparing the cost to the annual revenue of the meat slaughtering industry alone, which is about \$67.2 billion,⁶ the costs of this rule to the industry will not be significant.

Cost to the Consumer

The industry is likely to pass the increased costs on to consumers because of the inelastic nature of the consumer demand for meat and poultry products. However, given that the total volume of meat and poultry slaughtered under Federal inspection in 2010 was about 92

¹ This regulatory change should not impact the schedule of operations for meat and poultry processing establishments and egg product plants because those establishments can begin operations without FSIS inspection program personnel being at an on-line inspection work station.

² As of November 2011.

³ Survey date is March 2011.

⁴ We count the inspection program personnel in combined meat and poultry as meat inspectors so not to underestimate the cost, as poultry slaughter inspectors do not currently have to sharpen knives.

⁵ OFO conducted the query in November 2011.

⁶ Summary of the Animal (except Poultry) Slaughtering Industry in the U.S. and its International Trade [2010 edition.] Supplier Relations US, LLC. http://www.htrends.com/report-2700858-Animal_except_Poultry_Slaughtering_Industry_in_the_U_S_and_its_International_Trade_Edition.html, as of 11/16/2011.

billion pounds,⁷ the increased cost per pound due to the overtime fee will be less than \$0.0001 on average.

Benefits of the Rule

This final rule will include integral and indispensable work activities (as defined by the Fair Labor Standards Act) into the defined inspector "workday." Therefore, this rule will help ensure compliance with the law and the improved use of Agency resources.

Regulatory Flexibility Analysis

The FSIS Administrator has made a determination that this final rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). There are 263 small and 566 very small meat and poultry slaughter establishments (by Small Business Administration standard). In small and very small establishments, inspection program personnel typically have adequate time during their tour of duty to sharpen their knives as well as conduct the other activities under this final rule, because they do not have to be on-line for 8 hours. Therefore, the impact will not be significant.

Paperwork Reduction Act

This final rule has been reviewed under the Paperwork Reduction Act and imposes no new paperwork or recordkeeping requirements.

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/>

⁷ *Livestock, Dairy, & Poultry Outlook/LDP-M-209/November 16, 2011; Economic Research Service, USDA.*

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. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. 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.

List of Subjects

9 CFR Part 307

Government employees, Meat inspection.

9 CFR Part 381

Government employees, Poultry products inspection.

For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III as follows:

PART 307—FACILITIES FOR INSPECTION

■ 1. The authority citation for part 307 continues to read as follows:

Authority: 7 U.S.C. 394; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

■ 2. In § 307.4(c), remove the second sentence and add two sentences in its place to read as follows:

§ 307.4 Schedule of operations.

(c) * * * The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, except that, when possible, the Department shall schedule the basic workweek so as to

consist of 5 consecutive 8-hour days Monday through Friday. The 8-hour day excludes the lunch period but shall include activities deemed necessary by the Agency to fully carry out an inspection program, including the time for FSIS inspection program personnel to put on required gear and to walk to a work station; to prepare the work station; to return from a work station and remove required gear; to sharpen knives, if necessary; and to conduct duties scheduled by FSIS, including administrative duties. * * *

* * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

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

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

■ 4. In § 381.37(c), remove the second sentence and add two sentences in its place to read as follows:

§ 381.37 Schedule of operations.

* * *

(c) * * * The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday. The 8-hour day excludes the lunch period but shall include activities deemed necessary by the Agency to fully carry out an inspection program, including the time for FSIS inspection program personnel to put on required gear, pick up required forms and walk to a work station; and the time for FSIS inspection program personnel to return from a work station, drop off required forms, and remove required gear; and to conduct duties scheduled by FSIS, including administrative duties. * * *

* * *

Done at Washington, DC, on: September 21, 2012.

Alfred V. Almanza,
Administrator.

[FR Doc. 2012-23682 Filed 9-26-12; 8:45 am]

BILLING CODE 3410-DM-P

FEDERAL TRADE COMMISSION

16 CFR Parts 2 and 4

Rules of Practice

AGENCY: Federal Trade Commission ("Commission" or "FTC").

ACTION: Final rule.

Food Safety and Inspection Service, USDA

§ 307.4

letters not less than 2 inches high; rooms or compartments for these purposes shall be secure and susceptible of being kept clean, including a sanitary disposal of the floor liquids; establishment employees shall not enter any retention rooms or compartments or open any retention receptacles unless authorized by Program employees);

(i) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter (tanks or other rendering equipment which, under the regulations in this subchapter, must be sealed, shall be properly equipped for sealing as specified by the regulations in part 314 of this subchapter or by the circuit supervisor in specific cases);

(j) Docks and receiving rooms, to be designated by the operator of the official establishment, with the circuit supervisor, for the receipt and inspection of all products as provided in § 318.3 of this subchapter.

(k) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) and official certificates shall be kept when not in use (all such lockers shall be equipped for sealing or locking with locks or seals to be supplied by the Department; the keys of such locks shall not leave the custody of Program employees);

(l) Sanitary facilities and accommodations as prescribed by § 416.2(c), (d), (e), (f), and (h) of this chapter.

(m) In addition to any facilities required to accomplish sanitary dressing procedures, the following inspection station facilities for cattle and swine slaughter lines described in § 310.1(b) of this subchapter are required:

(1) An inspection station consisting of 5 feet of unobstructed line space for each head or carcass inspector and, for viscera table kills, 8 feet for each viscera inspector on the inspector's side of the table.

(2) A minimum of 50 foot candles of shadow-free lighting at the inspection surfaces of the head, viscera, and carcass.

(3) A handwash lavatory (other than one which is hand operated), furnished with soap, towels, and hot and cold water, and located adjacent to the in-

spector's work area. In addition, for each head and viscera inspector on cattle slaughter lines, and each head inspector on swine slaughter lines, a sterilizer located adjacent to the inspector's work area.

(4) For mechanized operations, a line control switch located adjacent to each inspection station.

(5) Facilities to position tally sheets or other recording devices, such as digital counters, and facilities to contain condemned brands.

(6) For swine slaughter lines requiring three or more inspectors, and for those one- and two-inspector configurations where the establishment installs a mirror: At the carcass inspection station one glass or plastic, distortion-free mirror, at least 5 feet x 5 feet, mounted far enough away from the vertical axis of the moving line to allow the carcass to be turned, but not over 3 feet away, and so mounted that any inspector standing at the carcass inspection station can readily view the back of the carcass.

[35 FR 15560, Oct. 3, 1970, as amended at 47 FR 33676, Aug. 4, 1982; 50 FR 19902, May 13, 1985; 64 FR 56415, Oct. 20, 1999]

§ 307.3 Inspectors to furnish and maintain implements in a sanitary condition.

Inspectors shall furnish their own work clothing and implements, such as flashlights and triers, for conducting inspection and shall maintain their implements in sanitary condition as prescribed by § 416.3(a) of this chapter.

[64 FR 56415, Oct. 20, 1999]

§ 307.4 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of a Program employee. All slaughtering of animals and preparation of products shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established,

the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 consecutive hours per shift during the basic workweek subject to the provisions of § 307.5: *Provided*, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, excluding lunch period. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its function. These provisions are applicable to all official establishments except in certain cases as provided in § 318.4(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take into account the efficient and effective use of inspection personnel. The work schedule must specify daily clock hours of operation and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving an addition or elimination of shifts shall be submitted

to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided*, however, minor deviations from a daily operating schedule may be approved by the inspector in charge, if such request is received on the day preceding the day of change.

(3) Request for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided*, That an inspector may be recalled to his assignment after completion of his daily tour of duty under the provisions of § 307.6(b).

[40 FR 45799, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986]

§ 307.5 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday as specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall become a holiday.

[40 FR 45800, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 724, Jan. 7, 1985; 50 FR 51513, Dec. 18, 1985; 52 FR 4, Jan. 2, 1987; 53 FR 13397, Apr. 22, 1988; 54 FR 6389, Feb. 10, 1989]

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be provided for and within easy reach of each inspector and each establishment helper.

(viii) Hangback racks shall be provided for and within easy reach of the establishment helper.

(ix) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in §416.3(c) of this chapter.

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of a minimum of 3 feet along the conveyor line so carcasses can be removed from each line for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor must not be less than 48 inches.

(iii) A table at least 3 feet wide and 2 feet deep designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85¹ at the table surface is required.

(v) A clipboard holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at this station.

[37 FR 9706, May 16, 1972, as amended at 38 FR 9794, Apr. 20, 1973; 47 FR 23434, May 28, 1982; 49 FR 42554, Oct. 23, 1984; 50 FR 37512, Sept. 16, 1985; 52 FR 39209, Oct. 21, 1987; 64 FR 56416, Oct. 20, 1999; 66 FR 22905, May 7, 2001]

§381.37 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of an Inspection Service employee. All eviscerating of poultry and further processing shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the in-

spector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 hours per shift during the basic workweek subject to the provisions of §381.38: *Provided*, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, excluding lunch period. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its functions. These provisions are applicable to all official establishments except in certain cases as provided in §381.145(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take in account the efficient and effective use of inspection personnel. The work schedule must specify the workweek, daily clock hours of operation, and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request

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by an establishment for a change in its work schedule involving changes in the workweek or an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided, however*, Minor deviations from a daily operating schedule may be approved by the inspector in charge if such request is received on the day preceding the day of change.

(3) Requests for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided*, That an inspector may be recalled to his assignment after the completion of his daily tour of duty under the provisions of § 381.39(b).

[40 FR 45800, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986]

§ 381.38 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest work-

day within that week shall be the holiday.

[40 FR 45801, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 51513, Dec. 18, 1985; 52 FR 5, Jan. 2, 1987; 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§ 381.39 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in § 381.38(a) and at the rate specified in § 391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Inspection Service employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of an Inspection Service employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

[40 FR 45801, Oct. 3, 1975, as amended at 54 FR 6390, Feb. 10, 1989]

Subpart H [Reserved]

Subpart I—Operating Procedures

§ 381.65 Operations and procedures, generally.

(a) Operations and procedures involving the processing, other handling, or storing of any poultry product must be strictly in accord with clean and sanitary practices and must be conducted in a manner that will result in sanitary processing, proper inspection, and the production of poultry and poultry products that are not adulterated.

(b) Poultry must be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior

products. However, FSIS will not make any changes to the performance standards for these products until FSIS has evaluated all comments received and has analyzed the results of the new testing.

USDA Nondiscrimination Statement

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Additional Public Notification

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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: February 11, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-05342 Filed 3-6-13; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 424

[Docket No. FSIS-2011-0018]

RIN 0583-AD47

Food Ingredients and Sources of Radiation Listed and Approved for Use in the Production of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to remove sodium benzoate, sodium propionate, and benzoic acid from the list of substances that the regulations prohibit for use in meat or poultry products. New uses of these substances in meat or poultry products will continue to be approved by the Food and Drug Administration (FDA) for safety and by FSIS for suitability. FSIS will add approved uses of these substances to the list of approved substances contained in the Agency's directive system.

DATES: Effective May 6, 2013.

FOR FURTHER INFORMATION CONTACT:

Charles Williams, Director, Policy Issuances Division, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250-3700, (202) 720-5627.

SUPPLEMENTARY INFORMATION:

Background

On May 7, 2012, FSIS issued a proposed rule entitled "Food Ingredients and Sources of Radiation Listed and Approved for Use in the Production of Meat and Poultry Products" and requested comments on the document (77 FR 26706). FSIS proposed to remove sodium benzoate, sodium propionate, and benzoic acid from the list of substances that the regulations prohibit for use in meat or poultry products.

As explained in the proposal, under the Federal Food Drug and Cosmetics Act (FFDCA) (21 U.S.C. 301 *et seq.*), FDA

is responsible for determining the safety of ingredients and sources of irradiation used in the production of meat and poultry products, as well as prescribing safe conditions of use. Under 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.*), FSIS is responsible for determining the suitability of FDA-approved substances in meat and poultry products. Pursuant to a Memorandum of Understanding (MOU) that was implemented in January 2000, FDA and FSIS work together to evaluate petitions requesting the approval of new substances, or new uses of previously approved substances, for use in or on meat and poultry products. The MOU is available for viewing by the public in the FSIS docket room and on the FSIS Web site at: http://www.fsis.usda.gov/Regulations_Policies/Labeling_FDA_MOU/index.asp. Under this MOU, if FDA and FSIS approve an ingredient for use in meat or poultry products, FDA establishes the parameters of the approved use under its regulatory system. FSIS also lists the substance in FSIS Directive 7120.1, "Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products," as part of a comprehensive listing of the substances that have been reviewed and that have been accepted as safe and suitable. (The Directive is available at: <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1.pdf>.)

The proposed rule also explained that, under FSIS's regulations, certain antimicrobial substances are prohibited for use in meat or poultry products because these substances have the potential to conceal damage or inferiority when used at certain levels (9 CFR 424.23(a)(3)). Among these substances are potassium sorbate, propylparaben (propyl phenoxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate.

In 2006, Kraft Foods Global, Inc. petitioned FSIS to amend the Federal meat and poultry products inspection regulations to permit the use of sodium benzoate and sodium propionate as acceptable antimicrobial agents that may be used in combination with other approved ingredients to inhibit the growth of *Listeria monocytogenes* (Lm) in ready-to-eat (RTE) meat and poultry products. On July 26, 2010, Kemin Food Technologies petitioned FSIS to amend the regulations to permit the use of liquid sodium propionate and liquid sodium benzoate as acceptable antimicrobial agents in meat and poultry products.

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After receiving each petition, FSIS conducted an initial evaluation of the requested action to confirm that FDA had no objections to the safety of sodium benzoate, sodium propionate, or benzoic acid at the proposed levels of use. FSIS also considered each petitioner's supporting data on the suitability of these substances for use in meat and poultry products. FSIS concluded that the petitioners had established the safety of sodium benzoate, sodium propionate, and benzoic acid at the proposed levels of use but that the Agency needed additional data to make a final suitability determination. Therefore, in July 2007, FSIS issued a waiver of provisions under 9 CFR 303.1(h) and 381.3(b) to enable Kraft to conduct various experimental trials involving the use of sodium benzoate and sodium propionate, in combination with other ingredients, to control the growth of *Lm* in RTE meat and poultry products. Additionally, from September 2010 through March 2011, FSIS issued waivers to Kemin and to various meat and poultry product processing establishments to conduct trials on the use of antimicrobial agents containing liquid sodium propionate and propionic acid supplied by Kemin for *Lm* control in RTE meat and poultry products.

While operating under the waivers, the Kemin and Kraft companies gathered sufficient data to support the use of sodium propionate, sodium benzoate, and benzoic acid as antimicrobial agents in RTE meat and poultry products. Kraft submitted data collected from its in-plant trials and from scientific studies that show that these substances do not conceal damage or inferiority or make products appear better or of greater value than they are under the proposed conditions of use. Kraft submitted research findings to demonstrate that its proposed use of sodium benzoate and sodium propionate is effective in controlling the growth of *Lm* in RTE meat and poultry products. Kemin also submitted findings supporting the use of its sodium propionate and propionic acid formulations.

The Kemin petition and supporting materials are available for viewing by the public on the FSIS Web site at http://www.fsis.usda.gov/PDF/Petition_Kemin.pdf. The Kraft petition is available at: http://www.fsis.usda.gov/PDF/Petition_Kraft.pdf.

Final Rule

After considering the comments received and discussed below, FSIS has determined that sodium benzoate, sodium propionate, and benzoic acid,

under the conditions proposed in the petitions, are both safe and suitable for use as antimicrobial agents in certain RTE meat and poultry products. Therefore, FSIS is amending 9 CFR 424.23(a)(3) to remove these substances from the list of prohibited substances that may be used " * * * in or on any product, only as provided in 9 CFR Chapter III."

Under this final rule, use of these substances in or on meat or poultry products will continue to be approved by FDA for safety and by FSIS for suitability. FDA will continue to establish the parameters of the approved use under its regulatory system, and FSIS will list approved uses of these substances in the table of approved substances in Directive 7120.1. In that directive, FSIS will specify that sodium propionate (generally recognized as safe under 21 CFR 184.1784) can be used as an antimicrobial in various meat and poultry products in an amount not to exceed 0.5 percent (by weight of total formulation) when used alone. Sodium propionate is a direct food ingredient that must be labeled by its common or usual name in the ingredients statement of a product (21 CFR 101.4, 9 CFR 317.2(f), 381.118(a)).

The directive also will state that, when used as an antimicrobial, sodium benzoate can be used in various meat and poultry products at up to 0.1 percent when used alone (21 CFR 184.1733). Sodium benzoate is a direct food additive that must be labeled by its common or usual name in the ingredients statement of a product. Similarly, benzoic acid is a generally recognized as safe (GRAS) direct food ingredient that can be used in various meat and poultry products at up to 0.1 percent (21 CFR 184.1021 and similarly must be labeled (21 CFR 101.4, 9 CFR 317.2(f) and 381.118(a)).

The uses of these substances are consistent with FDA regulations and reflect the levels that the petitioners requested to use in meat and poultry products and that they provided supporting data. Also, the use of these substances enhances food safety by controlling *Lm* in RTE products.

The Kraft petition also addressed sodium diacetate (GRAS under 21 CFR 184.1754 when used as an antimicrobial agent under cGMP). The company intends to use this substance in combination with sodium benzoate and sodium propionate. Sodium diacetate is not one of the substances considered in this rulemaking because is not prohibited by FSIS regulations. When sodium benzoate, sodium propionate, or sodium diacetate are used in combination with each other, the overall

maximum level for the combination cannot exceed 0.1 percent (in accordance with 21 CFR 184.1(d)). FSIS will include this information in the directive.

As a result of amending 9 CFR 424.23(a)(3), the procedures for listing approved uses of sodium propionate, benzoic acid, and sodium benzoate in the FSIS directive will be consistent with the procedures for listing approved uses in meat and poultry products of other safe and suitable substances. Approved new uses of potassium sorbate, propylparaben (propyl p-hydroxybenzoate), and calcium propionate will continue to be listed through rulemaking because the regulations (9 CFR 424.23(a)(3)) prohibit their use in meat and poultry products.

FSIS carefully considered all the comments received and developed the following responses.

Discussion of Comments

FSIS received 20 comments in response to the proposed rule. Members of the public submitted twelve, organizations related to the food industry five, and a food safety consulting firm, a non-profit association, and a trade association each submitted one. Several commenters supported the proposal to remove sodium benzoate, sodium propionate, and benzoic acid from the list of substances that the regulations prohibit for use in meat or poultry products. They stated that the additives are effective as anti-*Listeria* agents and are suitable for specified uses in meat and poultry products.

FSIS agrees that adding sodium propionate to the list of approved ingredients also provides meat and poultry processors greater flexibility in formulating new products while protecting the food supply against *Listeria*. Moreover, sodium propionate and propionic acid, which are GRAS (21 CFR 170.30, 21 CFR 184.1784) for use as antimicrobials under current good manufacturing practices, have been confirmed as safe and effective at inhibiting *Lm*. Sodium propionate does not mask spoilage or negatively affect sensory attributes. This ingredient provides the benefit of lowering sodium contribution in meat and poultry products, while extending shelf-life.

The following is a discussion of the relevant issues raised in the comments.

Comment: A commenter asked why there were no tests involving the human body after eating the substances. Another commenter expressed concern about the cumulative effects of combined dosages of sodium benzoate,

sodium propionate, and benzoic acid on children.

Response: FSIS and FDA do not conduct tests of the effects of food ingredients directly on humans. For a GRAS substance, such as the substances discussed in this rule, generally available data and information about the use of the substance are known and widely accepted and FDA has a basis for concluding that there is consensus among qualified experts that the data and information establish that the substance is safe under the conditions of its intended use (21 CFR 170.36(c)(4)(i)(C)). For a food additive, privately held data and information about the use of the substance are sent by the sponsor to FDA. FDA then evaluates the data and information to determine whether they establish that the substance is safe under the conditions of its intended use (21 CFR 171.1).

FSIS and FDA have evaluated all the data and determined that the uses of these substances considered in this rule are safe for individual consumers, including children.

Comment: A few commenters disapproved removing sodium benzoate, sodium propionate, and benzoic acid from the list of substances prohibited from use in meat and poultry products because they stated that these ingredients would have harmful effects on human health. One commenter explained that, as a potential consumer of harmful additives, she found the evidence submitted by Kraft Foods and Kemin Food Technologies insufficient to prove that all three agents are safe for use in meat and poultry products. Specifically, the commenter stated that Kemin had relied on old research (a 1973 study conducted by the Select Committee on Generally Recognized as Safe Substances) to prove the safe use of sodium benzoate and benzoic acid and that new research must be performed to ensure the safety of benzoic acid for public use.

Another commenter expressed concern because Kraft stated that it used Lem-O-Fos in its meat and poultry products to "enhance antimicrobial activity." The commenter stated that studies have shown that when benzoic acid is mixed with citric acid it forms benzene, which is a carcinogen. In the commenter's opinion, the substances should be kept separate from one another or concrete evidence must prove that the mixture does not constitute a hazard to consumers.

Another commenter stated that, in the early 1990s, the FDA urged companies not to use benzoate in products that also contain ascorbic acid. The commenter

noted that a lawsuit filed in 2006 by private attorneys ultimately forced Coca-Cola, PepsiCo, and other soft-drink makers in the United States to reformulate affected beverages—typically fruit-flavored products. According to this commenter, soft-drink makers are now eliminating the use of benzoate in combination with vitamin C worldwide. This commenter stated that these developments should cause FDA and FSIS to reconsider whether benzoate should continue to be classified as GRAS. Another stated that the GRAS status of the sodium benzoate should be reviewed to take into account changes in consumer diets and advances in science and technology. The commenter also stated that FSIS should not expand its use until a safety assessment is done and noted that the European Union is in the process of reviewing its safety now.

Response: FDA and FSIS have considered the points made by the commenters and have determined that there are no human health hazards arising from the approved uses that will be listed in FSIS Directive 7120.1.

The conditions under which benzene is produced in soft drinks are different from the conditions under which benzene could be produced in ready-to-eat (RTE) meats. RTE meats have a pH close to neutral, are continuously refrigerated or stored at room temperature (canned RTE meats), and are protected from excessive exposure to light. Therefore, the use of sodium benzoate in RTE meats does not present a safety concern even if combined with Vitamin C or similar compounds.

Regarding the concern that the GRAS status of sodium benzoate should be reviewed, FDA has confirmed that the petitioner's intended use of sodium benzoate is covered under the GRAS regulations (at 21 CFR 184.1733) and that there are no safety issues with the intended use. FSIS accepts the conclusion of FDA. Further, FSIS is aware that the Codex Committee on Food Additives (1995)¹ has also approved the use of benzoates in cured (including salted) and dried non-heat treated processed (including comminuted) meat and poultry products, at a maximum level of 0.1 percent.

Regarding the European Union's evaluation, the European Food Safety Authority (EFSA) issued a data call June 1, 2012, on the occurrence in foods and

beverages of certain food additives (sorbates, benzoates, and gallates) that were already permitted in the EU before January 20, 2009. Benzoic acid and sodium benzoate are among the ingredients on the list. The data are to be used to re-evaluate the ingredients. We understand from EFSA that the report on this re-evaluation will be available in late Spring 2013. When the re-evaluation is completed, experts in this Agency, and particularly in FDA, will consider the results and their possible implications. At this time, however, the available evidence supports the safety of the use of these ingredients.

Comment: One commenter supported the proposed rule but suggested that more studies be conducted on the effects of these three preservatives in higher dosages (higher than the use levels currently permitted under the FDA GRAS regulations), possible allergic reactions through contact or ingestion and the extent of those reactions, and potential alternatives to these preservatives that produce the same outcome without the use of preservatives.

Response: The levels that FSIS would allow to be used under this rule have not been shown to cause allergic reactions. Data on uses at higher levels would be evaluated under the joint FDA and FSIS ingredient approval system.

Data in the scientific literature on the amounts of these substances that are necessary to trigger or give rise to allergic reactions are not available. Food additives, such as benzoic acid and benzoates, have been known to cause hypersensitivity reactions. Such reactions are known to be very unusual in healthy individuals. However, in some cases, doses as low as 50 mg of benzoates have been shown to cause allergic reactions in individuals already suffering from allergic reactions. Information on the effects of these doses on healthy individuals is not currently available. Therefore, it is important that food additives or ingredients that may cause severe allergic or hypersensitivity reactions be appropriately declared in the ingredient statement on the product label.

Industry is likely to pursue research on the preservatives that are the subject of this rulemaking and on others. FSIS and FDA will continue to review new substances for safety and suitability under the MOU.

Comment: A commenter recommended not specifying a pH range of 4.8 to 5.2 percent for the use of sodium propionate as indicated in the Kemin petition, increasing the permissible use level of propionate

¹ Codex Alimentarius Committee on Food Additives. 1995. Codex General Standard for Food Additive, Codex Stan 192, pg 80. Available at: <http://www.codexalimentarius.org/committees-and-task-forces/en/?provide=committeeDetail&idList=9>. Accessed November 9, 2012.

when used in combination with other antimicrobial ingredients, and specifying that the substances are to be used in meat and poultry, including RTE products. The commenter explained that a higher pH provides several benefits including greater stability of the antimicrobial solution, better handling and shipping classifications, and improved sensory characteristics in finished meat products.

The commenter further stated that not including a pH specification in the approved ingredient listing in the FSIS Directive will provide room for innovation and fair competition in the market. Moreover, a permitted use level of sodium propionate in RTE meat and poultry products is necessary because the firm's testing results indicate that propionate, when combined with commonly used existing antimicrobials for meat and poultry (e.g., lactate, acetate, and diacetate), is required at higher levels to ensure safety of uncured high-moisture items.

Response: As noted above, sodium propionate that meets food grade standards as outlined in the Food Chemicals Codex, when used in accordance with 21 CFR 184.1784, is GRAS for use as an antimicrobial agent in meat products with no other limitations than cGMP. Therefore, FSIS will not specify a pH level in its Directive 7120.1. Also, since 21 CFR 184.1784 does not prescribe a maximum use level for sodium propionate, when the substance is used in combination with another antimicrobial agent, the maximum level for the combination is governed by the maximum use level of the other antimicrobial. For example, when sodium propionate is used in combination with sodium benzoate, the maximum level for the mixture is not to exceed 0.1 percent. When sodium propionate is used in combination with sodium diacetate, the maximum use level for the mixture is not to exceed 0.25 percent.

The directive will specify the uses of benzoic acid, sodium benzoate, and sodium propionate in meat and poultry products, including RTE meat and poultry products.

Executive Order 12866, Executive Order 13563, and Regulatory Flexibility Act

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been determined not to be significant and therefore has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

The rule will benefit companies that want to use these substances in the production of meat and poultry products by expediting the approval process. It will also benefit consumers by expediting the approved use of substances that enhance food safety by controlling the growth of *Lm* in RTE meat and poultry products. The rule also will make the approval process for new uses of sodium propionate, sodium benzoate, and benzoic acid in meat and poultry products consistent with the process for obtaining approval for other safe and suitable substances.

There are no expected costs associated with this final rule. All substances intended for use in the production of meat and poultry products will continue to be subject to FDA evaluation for safety and FSIS evaluation for suitability. Company costs and the agencies' costs associated with these evaluations will not be affected by this final rule.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the FSIS Administrator has determined that this final rule will not have a significant impact on a substantial number of small entities. This determination is based primarily on the fact that the final rule will not affect the process for approving new uses of sodium benzoate, sodium propionate, and benzoic acid in meat or poultry products. This final rule will make the process of listing approved uses of these substances more efficient by eliminating the need for FSIS to conduct rulemaking each time a new use is approved.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) has no retroactive effect; and (2) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5, 381.35, and 590.300 through 590.370, respectively, must be exhausted before any judicial challenge may be made of the application of the provisions of the final rule, if the

challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA, PPIA, or EPIA.

Paperwork Reduction Act

This rule does not contain any new information collection or record keeping requirements that are subject to the Office of Management and Budget (OMB) approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

FSIS will announce the availability of this final rule on-line through the FSIS Web page located at http://www.fsis.usda.gov/regulations_policies/Interim_Final_Rules/index.asp.

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 our constituents and stakeholders. The *Update* is communicated via Listserv, a free email subscription service for industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The *Update* also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

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/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.

List of Subjects in 9 CFR Part 424

Food additives, Food packaging, Meat inspection, Poultry and poultry products.

For the reasons set forth in the preamble, FSIS is amending 9 CFR part 424 as follows:

PART 424—PREPARATION AND PROCESSING OPERATIONS

■ 1. The authority citation for part 424 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

■ 2. In § 424.23, revise paragraph (a)(3) to read as follows:

§ 424.23 Prohibited uses.

(a) * * *

(3) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid shall not be used in cooked sausages or any other meat; sulfurous acid and salts of sulfurous acid shall not be used in or on any meat; and niacin or nicotinamide shall not be used in or on fresh meat product; except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), and calcium propionate, may be used in or on any product, only as provided in 9 CFR Chapter III.

* * * * *

Done at Washington, DC on: February 28, 2013.

Alfred V. Almanza,
Administrator.

[FR Doc. 2013-05341 Filed 3-6-13; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2012-0720; Directorate Identifier 2012-NM-059-AD; Amendment 39-17360; AD 2013-04-03]

RIN 2120-AA64

Airworthiness Directives; Cessna Aircraft Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Cessna Aircraft Company Model 750 airplanes. This AD was prompted by reports of loss of displayed airspeed. This AD requires inspecting certain logic modules to determine if certain cabin altitude/pitot static heater module

assemblies are installed and replacing those assemblies with a new assembly; and revising the Non-Normal Procedures Section of the airplane flight manual (AFM) to include procedures for resetting the pitot switch in the event of pitot heater failure and for total loss of airspeed indication. We are issuing this AD to prevent the loss of all displayed airspeed, which could result in reduced ability to control the airplane.

DATES: This AD is effective April 11, 2013.

The Director of the Federal Register approved the incorporation by reference of certain publication listed in the AD as of April 11, 2013.

ADDRESSES: For service information identified in this AD, contact Cessna Aircraft Co., P.O. Box 7706, Wichita, Kansas 67277; telephone 316-517-6215; fax 316-517-5802; email citationpubs@cessna.textron.com; Internet <https://www.cessnasupport.com/newlogin.html>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Christine Abraham, Aerospace Engineer, Electrical Systems and Avionics Branch, ACE-119W, FAA, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209; phone: 316-946-4165; fax: 316-946-4107; email: Christine.Abraham@faa.gov.

SUPPLEMENTARY INFORMATION:**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM published in the *Federal Register* on July 17, 2012 (77 FR 41937).

That NPRM proposed to require inspecting certain logic modules to determine if certain cabin altitude/pitot static heater module assemblies are installed and replacing those assemblies with a new assembly; and revising the Non-Normal Procedures Section of the AFM to include procedures for resetting the pitot switch in the event of pitot heater failure and for total loss of airspeed indication.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal (77 FR 41937, July 17, 2012) and the FAA's response to each comment.

Request To Change Compliance Time

Cessna Aircraft Company (Cessna) requested that the NPRM (77 FR 41937, July 17, 2012) use the compliance time described in Cessna Service Letter SL750-30-08, Revision 1, dated July 11, 2011, of within two years or 1,200 flight hours after July 11, 2011 (The issue date of Cessna Service Letter SL750-30-08, Revision 1), whichever occurs first. Cessna noted that the proposed NPRM compliance time is within 600 flight hours or one year after the effective date of the AD, whichever occurs first. Cessna stated that the NPRM compliance time will extend the compliance time beyond what is suggested by Cessna Service Letter SL750-30-08, Revision 1, dated July 11, 2011.

We disagree with the request to change the compliance time. We coordinated with Cessna regarding the compliance time difference prior to issuing the NPRM (77 FR 41937, July 17, 2012). We have determined that a compliance time of within 600 flight hours or one year after the effective date of the AD (whichever occurs first) is an appropriate compliance time to adequately address the identified unsafe condition. If additional data are presented to justify a shorter compliance time, we might consider further rulemaking. We have not changed the AD in this regard.

Request To Change Logic Module Designators

Cessna requested that we change the reference designators to the logic modules in paragraph (g) of the NPRM (77 FR 41937, July 17, 2012). Cessna stated that NC006 and NC007 are the correct reference designators for the logic modules.

We agree to change the references because we have determined that the commenter's stated references are

§ 424.23

government acting under authority granted by the NRC.

(ii) Documentation that the machine radiation source irradiation facility is registered with the appropriate State government, if applicable.

(iii) Documentation that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(iv) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.

(v) A certification by the operator that the irradiation facility personnel will only operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(vi) A certification by the operator that the key irradiation personnel, who monitor or control daily operations, have been trained in food technology, irradiation processing, and radiation health and safety.

(vii) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(4) *Labeling.* (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 (c)(4)(i). 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). Any label bearing the logo or any wording of explanation with respect to this logo must be approved as required by Section 317.4. of this chapter or subparts M and N of part 381.

9 CFR Ch. III (1-1-11 Edition)



(ii) For meat food or poultry products that have been irradiated in their entirety, but that are not sold in packages, the required logo must be displayed to the purchaser with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. Unless the word "Irradiated" is part of the product name, the labeling counter sign, card, or other device 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.

(iii) The inclusion of an irradiated meat food or poultry product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling.

(iv) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section, provided that such statements are not false or misleading. Statements that there has been a specific reduction in microbial pathogens must be substantiated by processing documentation.

[64 FR 72175, Dec. 23, 1999, as amended at 64 FR 72165, Dec. 23, 1999; 65 FR 34391, May 30, 2000]

§ 424.23 Prohibited uses.

(a) *Substances that conceal damage or inferiority or make products appear better or of greater value.* No substance may be used in or on any meat if it conceals damage or inferiority or makes the

product appear to be better or of greater value than it is. Therefore:

(1) Paprika or oleoresin paprika may not be used in or on fresh meat, such as steaks, or comminuted fresh meat, such as chopped and formed steaks or patties; or in any other meat consisting of fresh meat (with or without seasoning).

(2) Paprika or oleoresin paprika may be used in or on chorizo sausage and other meat in which paprika or oleoresin paprika is permitted as an ingredient in a standard of identity or composition in part 319 of this subchapter.

(3) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid shall not be used in cooked sausages or any other meat; sulfurous acid and salts of sulfurous acid shall not be used in or on any meat; and niacin or nicotinamide shall not be used in or on fresh meat product; except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate may be used in or on any product, only as provided in 9 CFR Chapter III.

(b) *Nitrates*. Nitrates shall not be used in curing bacon.

PART 430—REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

Sec.

430.1 Definitions.

430.4 Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products.

AUTHORITY: 7 U.S.C. 450; 7 U.S.C. 1901-1906; 21 U.S.C. 451-470, 601-695; 7 CFR 2.18, 2.53.

SOURCE: 68 FR 34224, June 6, 2003, unless otherwise noted.

§430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE

product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that

captivity must also comply with the requirements of § 3.101(b) of this subchapter.

(c) Dealers, exhibitors, intermediate handlers, and carriers must provide and document participation in and successful completion of training for personnel regarding their roles and responsibilities as outlined in the plan. For current licensees and registrants, training of dealer, exhibitor, intermediate handler, and carrier personnel must be completed by September 27, 2013. For new dealers, exhibitors, intermediate handlers, or carriers licensed or registered after July 29, 2013, training of personnel must be completed within 60 days of the dealer, exhibitor, intermediate handler, or carrier putting their contingency plan in place. Employees hired 30 days or more before their contingency plan is put in place must also be trained by that date. For employees hired less than 30 days before that date or after that date, training must be conducted within 30 days of their start date. Any changes to the plan as a result of the annual review must be communicated to employees through training which must be conducted within 30 days of making the changes.

PART 3—STANDARDS

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

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

■ 6. In § 3.101, paragraph (b) is amended by adding a new sentence at the end of the paragraph to read as follows:

§ 3.101 Facilities, general.

* * *

(b) * * * Facilities handling marine mammals must also comply with the requirements of § 2.134 of this subchapter.

* * *

Done in Washington, DC, this 20th day of December 2012.

Rebecca Blue,

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2012–31422 Filed 12–28–12; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. FSIS–2012–0039]

RIN 0583–AD05

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is establishing January 1, 2016, as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2013, and December 31, 2014. FSIS periodically announces uniform compliance dates for new meat and poultry product labeling regulations to minimize the economic impact of label changes.

DATES: This rule is effective December 31, 2012. Comments on this final rule must be received on or before January 30, 2013.

ADDRESSES: FSIS invites interested persons to submit relevant comments on this proposed rule. 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 online instructions at that site for submitting comments.

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

- *Hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, Patriots Plaza 3, 355 E. Street SW., 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2012–0039. 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 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Telephone: 301–504–0879.

SUPPLEMENTARY INFORMATION:

Background

FSIS periodically issues regulations that require changes in the labeling of meat and poultry food products. Many meat and poultry establishments also produce non-meat and non-poultry food products that are subject to the jurisdiction of the Food and Drug Administration (FDA). FDA also periodically issues regulations that require changes in the labeling of products under its jurisdiction.

On December 14, 2004, FSIS issued a final rule that established January 1, 2008, as the uniform compliance date for new meat and poultry labeling regulations issued between January 1, 2005, and December 31, 2006. The 2004 final rule also provided that the Agency would set uniform compliance dates for new labeling regulations in 2-year increments and periodically issue final rules announcing those dates. Consistent with that final rule, the Agency has published three final rules establishing the uniform compliance dates of January 1, 2010, January 1, 2012, and January 1, 2014 (72 FR 9651, 73 FR 75564, and 75 FR 71344).

The Final Rule

This final rule establishes January 1, 2016, as the uniform compliance date for new meat and poultry product labeling regulations that are issued between January 1, 2013 and December 31, 2014, and is consistent with the previous final rules that established uniform compliance dates. In addition, FSIS' approach for establishing uniform compliance dates for new food labeling regulations is consistent with FDA's approach. FDA is also planning to publish a final rule establishing a new compliance date.

Two-year increments enhance the industry's ability to make orderly adjustments to new labeling requirements without unduly exposing consumers to outdated labels. With this approach, the meat and poultry industry is able to plan for use of label inventories and to develop new labeling materials that meet the requirements of all labeling regulations made within the two year period, thereby minimizing the economic impact of labeling changes.

This compliance approach also serves consumers' interests because the cost of multiple short-term label revisions that

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would otherwise occur would likely be passed on to consumers in the form of higher prices.

FSIS encourages meat and poultry companies to comply with new labeling regulations as soon as it is feasible. If companies initiate voluntary label changes, they should consider incorporating any new requirements that have been published as final regulations.

The new uniform compliance date will apply only to final FSIS regulations that require changes in the labeling of meat and poultry products and that are published after January 1, 2013, and before December 31, 2014. For each final rule that requires changes in labeling, FSIS will specifically identify January 1, 2016, as the compliance date. All meat and poultry food products that are subject to labeling regulations promulgated between January 1, 2013 and December 31, 2014, will be required to comply with these regulations when introduced into commerce on or after January 1, 2016. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2016, the Agency will determine an appropriate compliance date and will publish that compliance date in the rulemaking.

In rulemaking that began with the May 4, 2004, proposed rule, FSIS provided notice and solicited comment on the concept of establishing uniform compliance dates for labeling requirements (69 FR 24539). In the March 5, 2007, final rule, FSIS noted that the Agency received only four comments in response to the proposal, all fully supportive of the policy to set uniform compliance dates. Therefore, in the March 5, 2007, final rule, FSIS determined that further rulemaking for the establishment of uniform compliance dates for labeling requirements is unnecessary (72 FR 9651). The Agency did not receive comments on the final rule. Consistent with its statement in 2007, FSIS finds at this time that further rulemaking on this matter is unnecessary. However, FSIS is providing an opportunity for comment on the uniform compliance date established in this final rule.

Executive Order 12988

This final rule has been reviewed under the Executive Order 12988, Civil Justice Reform. Under this final rule: (1) All state and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no retroactive proceedings will be required before parties may file suit in court challenging this rule.

Executive Orders 12866 and 13563 and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order (E.O.) 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been reviewed under E.O. 12866. The Office of Management and Budget (OMB) has determined that it is not a significant regulatory action under section 3(f) of E.O. 12866 and, therefore, it has not been reviewed by OMB.

This rule does not have a significant economic impact on a substantial number of small entities; consequently, a regulatory flexibility analysis is not required (5 U.S.C. 601–612).

Paperwork Requirements

There are no paperwork or recordkeeping requirements associated with this policy under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

E-Government Act Compliance

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

USDA Nondiscrimination Statement

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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).

Additional Public Notification

FSIS will announce this rule online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_policies/Interim_Final_Rules/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: December 21, 2012.

Alfred V. Almanza,
Administrator.

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DEPARTMENT OF ENERGY

10 CFR Parts 429 and 431

[Docket Number EERE–2012–BT–CE–0048]

RIN 1904–AC90

Energy Conservation Program: Certification of Commercial and Industrial HVAC, Refrigeration and Water Heating Equipment

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

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (DOE or the “Department”) is adopting amendments to the compliance dates for manufacturers to submit certification reports for certain commercial and industrial equipment covered under the Energy Policy and