

Rules and Regulations

Federal Register

Vol. 82, No. 169

Friday, September 1, 2017

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

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 300, 441, 530, 531, 532, 533, 534, 537, 539, 540, 541, 544, 548, 550, 552, 555, 557, 559, 560, and 561

[Docket No. FSIS–2017–0003]

Changes to the Inspection Coverage in Official Establishments That Slaughter Fish of the Order Siluriformes

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Response to comments; confirmation of implementation date.

SUMMARY: The Food Safety and Inspection Service (FSIS) is confirming that on September 1, 2017, it will adjust inspection coverage at official establishments that slaughter fish of the order Siluriformes from all hours of operation to once per production shift. FSIS also is responding to comments received on the May 17, 2017 **Federal Register** document that announced these changes.

DATES: FSIS will adjust inspection coverage at official establishments that slaughter Siluriformes fish from all hours of operation to once per production shift, beginning September 1, 2017.

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

Background

On December 2, 2015, FSIS amended its regulations by publishing the final rule, “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish” (80 FR 75590). Fish of the order Siluriformes include, but are not limited to, “catfish” (fish of the family Ictaluridae) and “basa” and “swai” (fish of the family Pangasiidae). For convenience, this notice will use

“fish” to mean all fish of the order Siluriformes.

Specifically, the final rule established regulations to implement the provisions of the 2008 and 2014 Farm Bills, which amended the Federal Meat Inspection Act (FMIA) to include fish as amenable and to provide for their inspection by FSIS. In the preamble to the final rule, FSIS stated that during an 18-month transitional period, it would assign inspection program personnel to be present during all hours of operation at domestic establishments that slaughter fish and, at the start of the period, assign inspection program personnel to conduct inspection at processing-only facilities at least quarterly. FSIS also stated that it might adjust inspection frequency in fish slaughter establishments in the future and, that at the end of the 18-month transitional period, inspection program personnel would be assigned at least once per day per shift at processing-only establishments (80 FR 75606).

On May 17, 2017, FSIS announced and requested comment on its decision to adjust inspection coverage at fish slaughter establishments, starting September 1, 2017, from all hours of operation to once per production shift (82 FR 22609). This decision was based on the Agency’s experience inspecting official fish slaughter establishments since implementing the mandatory inspection program on March 1, 2016. FSIS found that the typical fish slaughter operation is a streamlined, automated process that combines slaughter with processing in the same continuous operation, more like meat processing-only operations than like slaughter operations for other species amenable to the FMIA.

A consumer advocacy organization requested that FSIS extend the comment period by 30 days, so as to make informed comments. FSIS agreed and on June 16, 2017, extended the comment period until July 17, 2017 (82 FR 27680). At the conclusion of the comment period, FSIS had received eight comments. After reviewing these comments, FSIS is affirming its plan to adjust inspection coverage at official fish slaughter establishments from all hours of operation to once per production shift, beginning September 1, 2017. Issues raised by the comments received and FSIS’s responses follow.

Comments and FSIS Responses

FSIS received eight comments in response to its announced plans to adjust inspection coverage at official fish slaughter establishments. The comments were from two trade associations, one fish establishment, two FSIS inspectors, two consumer advocacy organizations and a foreign government. Four of the comments supported the change, agreeing that establishments that slaughter fish are most similar in operation and design to meat processing-only establishments and, therefore, should be inspected like a meat processing-only establishment, as opposed to meat slaughter establishments, *i.e.*, once per production shift.

The comment from the foreign government agreed with the rationale for the proposed change, but advocated for even less frequent inspection of fish, owing to its position that fish products pose little risk to the public health. As stated above, amendments to the FMIA in 2008 and 2014 directed FSIS to inspect the preparation of fish and fish products. USDA has historically interpreted the requirements in the FMIA for inspection of meat processing to mandate inspection at least once per production shift. Because FSIS has determined that operations in fish slaughter establishments are more like those in meat processing-only establishments, it is requiring inspection at a frequency of once per production shift there, as well.

Several of the supportive comments expressed concern that the adjustment in inspection frequency would affect an establishment’s approved hours of operation (typically 8-hour shifts) and charges for inspection services outside these hours. It will not. The regulations at 9 CFR 307.4 through 307.6, and associated FSIS policies, regarding the provision of inspection services, would continue to apply to fish establishments. Official fish establishments should coordinate with their District Office to determine hours of operation and for clarification on what activities require inspection.

Comments from the two consumer advocacy organizations and from an FSIS inspector opposed the change. One of the consumer advocacy organizations questioned the Agency’s implementation of inspection under 21 U.S.C. 606, for both fish and other meat

products, as allowing for inspection once per shift. This commenter further opined that Congress, in fact, intended for FSIS to “apply a greater care in inspecting catfish than with other meat food products,” because of the addition of paragraph (b) under this section, which directs USDA to consider the conditions under which fish is raised and transported.

FSIS disagrees. A narrow interpretation of the language in 21 U.S.C. 606, requiring that each unit of meat product be individually inspected by FSIS before movement in commerce, would create enormous costs without significantly increasing the effectiveness of inspection. USDA has never interpreted this language so narrowly in administration of the FMIA at meat processing-only establishments. In regard to the new section 21 U.S.C. 606(b), FSIS has determined that this section grants the Agency authority to conduct verification activities regarding the raising or transport of fish, but does not address the frequency of inspection or verification activities regarding the preparation of fish. Again, FSIS believes that the risks associated with fish slaughter are more closely aligned with meat processing, as further confirmed by explicit Congressional exemption of fish from the ante-mortem and post-mortem inspection provisions of the FMIA.

When FSIS inspection program personnel visit meat processing-only establishments, they systematically verify compliance with the regulatory requirements. Inspectors routinely check the cleanliness of equipment and facilities, wholesomeness of incoming source materials, processing procedures, Hazard Analysis and Critical Control Point (HACCP) records, product labels, as well as other things. In addition, they submit samples for analysis, as directed in FSIS’s Public Health Information System. FSIS inspection program personnel assigned to official fish establishments will be instructed to follow the same procedures. Therefore, we believe this approach will provide a high level of assurance that the fish products are safe, wholesome, and properly packaged and labeled, and that the public health will continue to be effectively protected by the change in inspection coverage.

Both comments from consumer advocacy organizations raise concerns about the effect of the adjustment in inspection frequency on the Agency’s programs to ensure the safety of imported fish and fish products. One comment contends that FSIS has not considered the conditions under which imported fish have been raised or

transported. The other comment cites the number of shipments of foreign fish and fish products rejected by FSIS for import or recalled from commerce, because of violative residues found through FSIS testing, as evidence that foreign fish production, processing and inspection systems are inadequate. The commenter suggests that inspection during all hours of operation should be required for foreign slaughter and processing of fish intended for import to the United States.

FSIS does consider the conditions under which imported fish are raised and transported through both the equivalence process and its testing of imported fish and fish products. When applying to export fish and fish products to the United States, a foreign country’s Central Competent Authority (CCA) must demonstrate to FSIS that it ensures fish for export are raised and transported under conditions that prevent product adulteration. For example, the CCA must provide information regarding how it ensures that fish are not grown or farmed under conditions that would cause them to be adulterated; details of its sampling of feed, fish or the body of water from which the fish are harvested; and information on its program for ensuring that fish are transported under sanitary conditions from harvest to processing establishments. A foreign country’s inspection program cannot be deemed equivalent unless the CCA demonstrates that it prevents the adulteration of fish during raising and transport.

Additionally, FSIS tests fish and fish products collected during reinspection for chemical residues, *Salmonella*, and speciation. In regard to chemical residues, FSIS tests imported fish for veterinary drug residues, including nitrofurans and some fluoroquinolones; malachite green; gentian violet; metals and pesticides. This testing serves to verify that imported fish were raised under conditions to prevent product adulteration and keeps adulterated fish and fish products out of United States commerce.

In regard to inspection frequency for imported fish and fish products, the FMIA and the regulations specifically require that imported products be held to the same standards as domestic products. The FMIA at 21 U.S.C. 620 requires that no product may be imported into the United States unless it complies with all applicable provisions of the FMIA and the regulations issued thereunder. The fish import regulations at 9 CFR 557.3 specifically require that no fish or fish product offered for importation from any foreign country shall be admitted

into the United States if it is adulterated or misbranded or does not comply with all the requirements that would apply to it if it were a domestic product.

Therefore, because FSIS will require government inspection of fish preparation at least once per production shift, to be determined equivalent, a foreign country’s fish inspection system must also provide government inspection at least once per production shift. FSIS sees no basis to impose inspection requirements for imported fish that are in addition to those applied to domestic fish. Food safety issues with imported fish can be addressed through import reinspection, enforcement and the equivalence process.

Finally, one inspector opposed the change in inspection frequency at fish slaughter establishments, expressing concern that the change would result in increased workloads for inspectors that are currently assigned to these establishments. FSIS disagrees. The change in inspection frequency will simply place establishments that slaughter fish into “patrol assignments” including other meat and poultry processing establishments. The inspection workload for affected inspectors will be no different than the workload associated with current patrol assignments of processing establishments.

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Fax: (202) 690–7442.

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Additional Public Notification

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Done at Washington, DC on: August 29, 2017.

Paul Kiecker,
Acting Administrator.

[FR Doc. 2017-18591 Filed 8-31-17; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF ENERGY

10 CFR Part 1016

[Docket No. DOE-HQ-2015-0029-0001]

RIN 1992-AA46

Safeguarding of Restricted Data by Access Permittees

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE or Department) has revised its regulations governing the standards for safeguarding Restricted Data by access permittees. The previous version of this regulation was promulgated in 1983. Since 1983, changes in organizations, terminology, and DOE and national policies rendered portions of the previous regulation outdated. This version updates existing requirements.

DATES: This rule is effective October 2, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Linda Ruhnow, Office of Security Policy at (301) 903-2661; *Security.Directives@hq.doe.gov*.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Section by Section Analysis
- III. Regulatory Review and Procedural Requirements
 - A. Review Under Executive Order 12866
 - B. Review Under the Regulatory Flexibility Act
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 - G. Review Under the Unfunded Mandates Reform Act of 1995
 - H. Review Under Executive Order 13211
 - I. Review Under the Treasury and General Government Appropriations Act of 1999
 - J. Congressional Notification
 - K. Approval by the Office of the Secretary

I. Background

The U.S. Department of Energy may issue an access permit to any person, as set forth in 10 CFR part 725, who requires access to Restricted Data applicable to civil uses of atomic energy for use in his/her business, trade or profession. 10 CFR part 725 specifies the terms and conditions under which the Department will issue an access permit and provides for the amendment, renewal, suspension, termination and revocation of an access permit.

The regulations in 10 CFR part 1016 establish requirements for the safeguarding of Secret and Confidential Restricted Data received or developed under an access permit. This part does not apply to Top Secret information because no such information may be provided to an access permittee within the scope of this regulation. The regulations in this part apply to all persons who may require access to Restricted Data used, processed, stored, reproduced, transmitted, or handled in connection with an access permit.

The original regulations for the safeguarding of Restricted Data were Atomic Energy Commission regulations that were transferred to the Energy Research and Development Administration (ERDA) upon its formation in 1974 (Energy Reorganization Act of 1974; Pub. L. 93-438). The regulations were subsequently revised to conform to ERDA's organization (41 FR 56775, 41 FR 56785-56788, Dec. 30, 1976). The regulations were updated and transferred from 10 CFR part 795 to 10 CFR part 1016 in Aug. 10, 1983 (48 FR 36432). DOE has developed this version

of 10 CFR part 1016 to reflect organizational, terminology and policy changes that have occurred since the regulations were last revised.

DOE proposed changes to the regulations at 10 CFR part 1016 on November 16, 2016 (81 FR 80612). No comments were received. No changes were made to the proposed regulations except to modify the definition of an "L" access authorization in § 1016.3, Definitions.

II. Section by Section Analysis

With the exception of the definition of an "L" access authorization in § 1016.3, Definitions, the modifications to 10 CFR part 1016 adopted in this final rule are described in the Section by Section Analysis in section II of DOE's notice of proposed rulemaking published on November 16, 2016 (81 FR 80612). In § 1016.3, Definitions, the definition of "L" access authorization was modified from DOE's proposed changes to update the type of background investigation required by DOE and national level directives. The reference to National Agency Checks with Local Agency Checks and Credit Check background investigation has been replaced with a Tier III background investigation.

III. Rulemaking Requirements

A. Review Under Executive Order 12866

This action does not constitute a "significant regulatory action" as defined in section 3(f) of Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of a regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking" (67 FR 53461, Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. DOE has made its procedures and policies available on the Office of the General Counsel's Web site (www.gc.doe.gov).

DOE has reviewed this rule under the Regulatory Flexibility Act and certifies that, as adopted, the rule would not have a significant impact on a substantial number of small entities.