



**Billing Code 3410-DM-P**

**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

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### **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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themselves, and have the option to password protect their accounts.

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

Paul Kiecker,

Acting Administrator

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