



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: Notification and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing and requesting comment on its plan to adjust inspection coverage at official establishments that slaughter fish of the order Siluriformes, which include catfish, from all hours of operation to once per production shift.

DATES: Submit comments on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments relevant to adjusting inspection coverage as discussed and outlined in this notification. Only comments addressing the scope of this notification will be

considered.

Comments may be submitted by one of the following methods:

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

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

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

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2017-0003. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to [http://www.regulations.gov](http://www.regulations.gov/).

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots

Plaza 3, 355 E. Street SW, Room 164-A, Washington, DC  
20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through  
Friday.

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.

SUPPLEMENTARY INFORMATION:

Background

On December 2, 2015, FSIS published the final rule,  
"Mandatory Inspection of Fish of the Order Siluriformes and  
Products Derived from Such Fish," which amended its  
regulations to establish a mandatory inspection program for  
fish of the order Siluriformes (80 FR 75590). 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 all fish of the order  
Siluriformes as an amenable species (21 U.S.C. 601(w)(2))  
and provided for their inspection under Section 606,  
"Inspection and labeling of meat food products" (21 U.S.C  
606(b)). 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 notification will use "fish" to mean all fish of the order Siluriformes.

The 2008 and 2014 Farm Bills placed the authority for FSIS's inspection of fish under Section 606 of the FMIA (21 U.S.C. 606(b)), "Inspecting and labeling of meat food products." FSIS's longstanding and well-known interpretation of Section 606 is that it only requires inspection once per production shift. Further, the Farm Bills amended the FMIA to add a new Section 625 (21 U.S.C. 625), which explicitly excludes fish from the statutory provisions requiring ante-mortem and post-mortem inspection and humane methods of slaughter (21 U.S.C. 603, 604, 605 and 610(b)). These requirements, again, not applicable to inspection of fish, can only be implemented through inspection at all times when an establishment is conducting slaughter operations. Accordingly, FSIS does not believe that Congress intended for FSIS to inspect the slaughter or slaughter and processing of fish during all hours of an establishment's operations, but instead intended that FSIS inspect fish establishments consistent with how FSIS inspects meat and poultry processing establishments, at

least once per production shift.

In the final rule discussion of inspection coverage at official fish establishments, the Agency stated that upon initial implementation of fish inspection on March 1, 2016, although not required by the FMIA, it would assign inspection personnel during all hours of operation at official establishments that kill live fish and at least quarterly at processing-only establishments (80 FR 75606). This level of inspection coverage was intended to provide an orderly transition from the FDA regulatory model to the FSIS inspection model and to assist official fish establishments in bringing their operations into full compliance with the new regulations. Providing inspection coverage during all hours of operation at official fish slaughter establishments also assisted the Agency in gaining experience and insight into commercial fish production in the United States, from the receiving of live fish to the fabrication of fish products.

The Agency provided for an 18-month transitional period, from March 1, 2016, until September 1, 2017, during which it is exercising broad enforcement discretion and taking enforcement actions when establishments produce

adulterated or misbranded product, or when there is intimidation of or interference with FSIS personnel. In the final rule, FSIS stated that, based on its findings during and after the 18-month transitional period, it may adjust inspection frequency in official fish slaughter establishments in the future, meaning that although inspection would be provided when an establishment is operational, it may not be during all hours of operation (80 FR 75606). The Agency also stated that it would establish the criteria it would follow in determining how inspection would be adjusted and make these criteria available to the public. In addition, the Agency stated 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.

FSIS is announcing that it has decided to adjust its inspection coverage at official fish slaughter establishments, starting September 1, 2017, the date of full enforcement of the regulatory requirements for fish, from all hours of operation to once per production shift. As discussed below, this decision is based on the Agency's experience inspecting fish slaughter establishments since

implementing the mandatory inspection program on March 1, 2016. As discussed in the final rule, on September 1, 2017, inspection program personnel will be assigned at least once per day per shift at processing-only establishments (80 FR 75607).

#### Fish Slaughter Establishment Operations

At this time, there are 16 official fish slaughter establishments that receive inspection during all hours of operation. All of these establishments receive live fish that are subsequently slaughtered and further processed. The FSIS definition of "slaughter," with respect to fish, is the "intentional killing under controlled conditions" (9 CFR 531.1)). "Further processing" is defined as "smoking, cooking, canning, curing, refining, or rendering," (9 CFR 531.1) and includes processes such as cutting and packaging. FSIS defined the terms "slaughter" and "further processing," for fish based on the inspection operations of other FMIA amenable species, e.g., cattle and swine, and its adaptation of the meat regulations.

From FSIS's inspection experience in these fish slaughter establishments, the fish are raised either contiguous to the establishment, or in close proximity, and

are transported to the facility in aerated live haul trucks. The live fish are unloaded, drained, and weighed before being moved to holding vats or carried by conveyor to an electrical stunner. The fish are sorted by size or weight, with the fish that are processed typically weighing less than two pounds each. Dead and diseased fish and undesirable species are sorted manually prior to processing. The deheading, eviscerating, filleting, and skinning operations are typically automated, and the process flows quickly and seamlessly on conveyor belts. When the operations are manual, the size and immobility of the fish allow the process to move quickly. Thus, the typical farm-raised fish slaughter operation is a streamlined, automated process that combines slaughter with processing in the same continuous operation. As such, fish slaughter operations are more closely aligned with meat processing-only operations, as opposed to meat slaughter operations.

FDA's definition of fish processing combines the slaughter and processing steps, "Processing means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing,

changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding” (21 CFR 123.3(k)(1)). This definition accurately describes FSIS’s observations and experience in fish slaughter establishments, i.e., a continuous slaughter and processing system. In addition, the fish industry’s longstanding practice is to use the term “processor” to refer to any type of fish manufacturing operation, including those that receive and kill live fish. FSIS intends to amend the regulatory definition of “processing” with respect to fish to be more consistent with FDA’s definition.

Starting on September 1, 2017, FSIS is making an adjustment in its inspection coverage at official fish slaughter establishments based on the following criteria:

- FSIS’s longstanding interpretation of Section 606 of the FMIA (21 U.S.C. 606(b)) requiring inspection once per production shift.

- FSIS’s in-plant experience thus far confirming that fish slaughter establishments are most similar in operation and design to meat processing-only establishments. Thus, once per production shift inspection coverage will ensure

FSIS verifies whether establishments are in compliance with all regulatory requirements.

- FSIS's more efficient use of inspection resources by including fish slaughter establishments in once-per-production shift inspection assignments for meat and poultry establishments that only process product.

Thus, based on the above criteria, the Agency has determined that adjusting the inspection coverage at fish slaughter establishments on September 1, 2017, from all hours of operation to once per production shift will enable it to provide adequate inspection coverage to fulfill the FMIA mandate and allow it to most efficiently equip its workforce with the resources and tools they need to protect public health.

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Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

### Additional Public Notification

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

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

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

Done at Washington, DC on: May 12, 2017.

Alfred V. Almanza,

Administrator.

[FR Doc. 2017-09993 Filed: 5/16/2017 8:45 am; Publication Date: 5/17/2017]