

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	14,000.1	8/17/17
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**CONSUMER SAFETY INSPECTOR RESPONSIBILITIES AT FISH
ESTABLISHMENTS**

NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL SEPTEMBER 1, 2017. CONSUMER SAFETY INSPECTORS ARE ALLOTTED 1 HOUR OFFICIAL TIME TO REVIEW THIS DIRECTIVE.

I. PURPOSE

A. This directive instructs Consumer Safety Inspectors (CSIs) on how to verify regulatory compliance at official establishments that prepare (slaughter or process) fish of the order Siluriformes. This includes all establishments that prepare farm-raised or wild-caught fish. This directive instructs CSIs on how to perform inspection in such establishments, beginning on September 1, 2017, after the 18-Month transitional period.

B. In this directive, the term “fish” refers to fish of the order Siluriformes and products derived from these fish. For guidance on acceptable common or usual names, see [Siluriformes Fish Species List](#).

KEY POINTS:

- *Fish are considered meat and are amenable to the Federal Meat Inspection Act*
- *Beginning September 1, 2017, CSIs assigned to establishments that prepare fish are to verify that establishments comply with all applicable regulatory requirements*
- *CSIs will perform inspection verifications on every shift at fish establishments; CSIs are not required to be present in establishments at all times.*
- *CSIs are to document regulatory noncompliance on noncompliance records, whenever they observe that fish establishments do not comply with applicable regulatory requirements*

*Specific instructions for sampling are described in [FSIS Directive 14,010.1](#), *Speciation, Residue and Salmonella Testing of Fish of the order Siluriformes from Domestic Establishments**

II. CANCELLATION

*FSIS Notice 24-17, *Consumer Safety Inspectors Responsibilities at Fish (of the Order Siluriformes) Establishments during the 18-Month Transitional Period*, 4/28/17*

DISTRIBUTION: Electronic

OPI: OPPD

III. BACKGROUND

FSIS jurisdiction over fish started on March 1, 2016. (See Attachment 1 for final rule requirements.) FSIS provided an 18-month transitional period to give affected establishments the opportunity to bring their operations into full compliance with FSIS regulatory requirements. At the completion of the transitional period, September 1, 2017, establishments are required to fully comply with FSIS regulatory requirements. For example, fish establishments must have Hazard Analysis and Critical Control Point (HACCP) plans, Sanitation Standard Operating Procedures (SOPs), and Recall Plans by September 1, 2017, although establishments have 90 days after September 1, 2017, to validate their HACCP systems. All noncompliance is to be documented on noncompliance records.

IV. INSPECTION IN OFFICIAL ESTABLISHMENTS THAT SLAUGHTER OR PROCESS FISH

A. The CSI is to perform inspection verification tasks during each operational shift and any inspection activities requiring overtime inspection are to be conducted as set out in [FSIS Directive 12,600.2](#), *Reimbursable Overtime Inspection Services at Meat and Poultry Establishments*.

B. The CSI is to follow the instructions in pertinent directives to perform inspection verification tasks. In general, the CSI is to perform, in the same manner for fish, the same inspection verification tasks that apply to meat (e.g., HACCP, Sanitation SOP, Sanitation Performance Standards, Hazard Analysis Verification, Economic/Wholesomeness). For example, the CSI is to follow the instructions in [FSIS Directive 5000.1](#), *Verifying an Establishment's Food Safety System*, to verify HACCP, Sanitation SOPs, and Sanitation Performance Standards and [FSIS Directive 7000.1](#), *Verification of Non-Food Safety Consumer Protection Regulatory Requirements*, to verify non-food safety consumer protection regulatory requirements.

NOTE: Attachment 2 is a list of Public Health Inspection System (PHIS) verification tasks and the associated fish regulations. Attachment 3 is a list of directives that apply to CSIs in fish establishments.

C. The CSI is to review the establishment profile to ensure the correct inspection tasks are listed in the establishment task list. This may include selecting tasks that were previously de-selected during the transitional period. FSIS Directives [5300.1](#), *Managing the Establishment Profile in the Public Health Information System* and [13,000.1](#), *Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)*, provide instructions on how to view or edit the establishment task list in the PHIS profile.

D. When performing the Sanitation and HACCP verification tasks, the CSI is to document the specific regulations in 9 CFR Parts 416 and 417 and, as applicable, the regulations specific to fish (9 CFR Parts 530 through 555).

E. Not all meat regulations apply to fish. The CSI is to verify ONLY whether the establishment meets those meat inspection regulations cross-referenced in 9 CFR Parts 530 through 555. The CSI is not to verify whether the establishment meets regulations that are not referenced in the fish regulations. The CSI is not to verify whether the establishment meets any poultry regulations.

F. When performing the Pre-Op Sanitation SOP Review and Observations task in fish processing operations, the CSI is to follow instructions for raw processing operations in [FSIS Directive 5000.4](#), *Performing the Review Component of PBIS 01B02 Procedure and PHIS Pre-op Sanitation SOP Review and Observation Task in Federally Inspected Processing, Slaughter and Import Establishments*.

G. When performing the Review of Establishment Data task, the CSI is also to review any establishment records that pertain to pre-harvest standards and transportation to processing establishments (9 CFR Part 534), in addition to the HACCP records described in [FSIS Directive 5000.2](#), *Review of Establishment Testing Data by Inspection Program Personnel*. These may include water quality records for ponds and other waters where fish are harvested, and pond treatment records (e.g., chemicals or drugs). CSIs that

have concerns that these records demonstrate that fish were raised under conditions that may result in adulterated or unwholesome product (e.g., evidence of heavy metals, pesticides, fertilizers, industrial chemicals or drugs) should verify that the establishment took appropriate action in accordance with their HACCP system. The CSI is to consider how the establishment controls chemical hazards at fish receiving (e.g., HACCP critical control point or pre-requisite program) and whether the establishment implemented those controls. If the CSI has questions about the records or whether a situation demonstrates noncompliance, he or she should seek guidance on the matter from their FLS

H. The CSI is to follow the instructions in [FSIS Directive 5420.1](#), *Food Defense Tasks and Threat Notification Response Procedures for the Office of Field Operations*, to perform one comprehensive food defense task per quarter. The CSI is to observe as many food-defense practices as possible, but is not expected to walk or drive around the waters where fish are raised (e.g., ponds, raceways, or other bodies of water), even if such bodies of water are on the establishment premises. When completing task question 1, in the Food Defense task, the CSI is to consider whether the establishment has procedures in place to prevent unauthorized access to the ponds or raceways that are located on the establishment premises. If the CSI does not know the answer to a question, he or she is to discuss the question with establishment management at a weekly meeting. Additional information on food defense practices that are specific to fish establishments can be found in FSIS' [Food Defense Guidelines for Siluriformes Fish Production and Processing](#).

I. The CSI is to perform Other Inspection Requirements verification tasks to determine whether the establishment adequately disposes diseased or otherwise adulterated fish carcasses and parts (9 CFR 539.1), as well as dead fish that exhibit signs of disease, spoilage, or decomposition (9 CFR 540.1).

1. The task location depends on the points in the process where the establishment examines whole fish and fish products for quality or acceptability. This may include various points in the process, such as initial sorting of live fish, or after evisceration of whole fish, or after the fillet, trim, and cut-up processes.
2. The CSI is to verify establishment control for the following conditions:
 - a. Abscesses, sores, ulcers, cysts, nodules, or encapsulated worms;
 - b. Red spots (petechial hemorrhages) covering more than 50 percent of the tissue;
 - c. Evidence of spoilage or decomposition in whole fish or processed product (e.g., off odor, slimy tissue, brown to yellowish-gray color);
 - d. Unusual gross deformities caused by disease or chemical contamination; and
 - e. Disease, spoilage, or decomposition of dead fish arriving at the establishment.

NOTE: IPP are to be aware that fish that die on the way to the establishment and are received with live fish are not subject to condemnation, unless they are in a diseased or spoiled state. For example, dead fish that arrive on ice in a fishing vessel or other means of conveyance are not subject to condemnation unless they are decomposed or exhibit signs of disease or spoilage.

3. The CSI is to document noncompliance when he or she observes loss of process control. Conditions, as identified in 2 above, that are severe or numerous enough to affect the usability of the product, or the CSI identifies multiple, recurring instances it demonstrates loss of process control and the establishment's quality procedures failure to discard fish or fish products that exhibit these conditions. The CSI is to cite:

- a. 9 CFR 539.1 for conditions described in 2. a. through d. above; or

- b. 9 CFR 540.1 for dead fish that exhibit areas of disease, spoilage, or decomposition. Infrequent incidences of disease, spoilage or decomposition on individual fish or fish products would not demonstrate noncompliance; and
- c. 9 CFR 301.2(3) the product is unfit for human food.

J. The rules of practice apply to fish inspection actions (9 CFR Part 561).

K. The CSI is to follow the sampling instructions in [FSIS Directive 14,010.1](#).

V. SUPERVISORY RESPONSIBILITIES

A. Supervisory personnel are to assist CSIs in matters involving the verification of regulatory compliance in establishments that process fish.

B. Supervisory personnel are to ensure that CSIs make informed regulatory decisions consistent with statutory authority, properly document inspection findings, and take appropriate actions to prevent adulterated or misbranded fish product from entering commerce.

VI. QUESTIONS

Refer questions regarding this directive to your district's Siluriformes Point of Contact (POC) (see attachment 4). If further guidance is required then the POC can contact the Headquarters subject matter experts with specific questions or submit her or his questions to askFISH.



Assistant Administrator
Office of Policy and Program Development

FINAL RULE REQUIREMENTS

On December 2, 2015, FSIS published the final rule “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish” (80 FR 75590). The final rule amends the Agency’s regulations to establish a mandatory inspection program for fish of the order Siluriformes, whether farm-raised or wild-caught, and for products derived from these fish. The final rule explains that, because these fish are amenable to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(w)(2)), this new fish inspection program is part of FSIS’s meat inspection program.

The following sections of the FMIA do not apply to fish:

1. Ante-mortem and post-mortem inspection (21 U.S.C. 603 and 604);
2. Humane slaughter (21 U.S.C. 603 and 610(b));
3. Inspection of carcasses and parts before their entry into establishments or further-processing departments (21 U.S.C. 605); and
4. The exemptions from inspection for personal use, custom, and on-farm slaughter and processing (21 U.S.C. 623).

Operations of types traditionally or usually conducted at retail stores, restaurants, or similar facilities, for the preparation of fish or fish products for sale in normal retail quantities, are exempt from regular FSIS inspection (21 U.S.C. 661(c)(2)). These exempt operations include the slaughtering by a retail operator of live fish bought by a consumer at the facility in accordance with the consumer’s instructions. A normal retail quantity of fish or fish product sold to a household consumer is less than or equal to 75 pounds. A normal retail quantity sold to a non-household consumer is less than or equal to 150 pounds in the aggregate.

In addition to other requirements, the final rule requires official establishments that prepare or process fish for human food to:

1. Provide FSIS personnel with access to the establishment for the examination of facilities, records, and inventory and the sampling of inventory (9 CFR 530.3 and 550.4);
2. Not assault, threaten to assault, intimidate, or interfere with FSIS personnel (9 CFR 561.1);
3. Comply with the requirements contained in 9 CFR Parts 416, Sanitation, and 417, Hazard Analysis and Critical Control Point (HACCP) Systems (9 CFR 537.1);
4. Maintain written recall plans (9 CFR 532.2) and notify the FSIS District Office of any adulterated or misbranded product that the establishment has received or shipped in commerce (9 CFR 537.3);
5. Label packages of fish that are not ready-to-eat with safe-handling instructions that include “fish” in the rationale statement (e.g., “This product was prepared from inspected and passed fish.”) (9 CFR 541.7)); and
6. Label packages of fish with the appropriate common or usual name of the fish (9 CFR 541.7).

The fish labeling regulations permit the use of the term “catfish” only on labels of fish classified within the family Ictaluridae (9 CFR 541.7(d)(2)). For reference, Attachment 2 provides a list of fish requirements.

Attachment 2

Fish Regulations

Verification Tasks	Fish Regulations	Other Regulations	FSIS Directives
Pre-OP SSOP Record Review	537.1	Part 416	5000.1
Pre-OP SSOP Review and Observations	548.1(a)	Part 430	5000.4
Operational SSOP Record Review	548.5	301.2	10,240.4
Operational SSOP Verification	531.1		
Sanitation Performance Standards	531.1 537.1 540.3 548.1(a)	416.1 through 416.6	5000.1
Hazard Analysis Verification	537.1 537.2	417.2 417.3(b)(4) 417.4 417.5(a)(1)&(2) 430.4(b)(1)(2)&(3) 430.4(c)(7)	5000.1 5000.6
Review of Establishment Data	537.1 550.1 550.6	416.16(a)&(c) 417.5(a)(1) 417.5(f) 320.1 320.6	5000.2
Big 8 Formulation Verification	537.1 541.7 550.6 537.3	Parts 416 & 417 Part 317, subpart A 320.6 418.2	7230.1
Raw Intact HACCP	537.1 531.1 540.3 541.7 544.1 548.1 548.2 548.8 555.1(b) 531.1	Part 417 Part 317 Part 424 318.14 441 442 301.2	5000.1

Verification Tasks	Fish Regulations	Other Regulations	FSIS Directives
Raw Non-Intact HACCP	537.1 531.1 540.3 541.7 544.1 548.1 548.2 548.8 555.1(b) 531.1 550.1 550.2 550.3	Part 417 Part 317 Part 424 318.14 441 442 301.2 320.1 320.2 320.3	5000.1
Thermally Processed – Commercially Sterile HACCP	537.1 531.1 540.3 541.7 544.1 548.1 548.2 548.6 548.8 555.1(b) 531.1	Part 417 Part 317 Part 424 318.14 318.300 through 318.311 301.2	5000.1 7530.1 7530.2
Not Heat Treated Shelf Stable HACCP	537.1 531.1 540.3 541.7 544.1 548.1 548.2 548.5 548.8 555.1(b) 531.1	Part 417 Part 317 Part 424 Part 430 318.14 301.2	5000.1
Heat Treated – Shelf Stable HACCP	537.1 531.1 540.3 541.7 544.1 548.1 548.2 548.5 548.8 555.1(b) 531.1	Part 417 Part 317 Part 424 Part 430 318.14 301.2	5000.1 10,240.4

Verification Tasks	Fish Regulations	Other Regulations	FSIS Directives
Fully Cooked – Not Shelf Stable HACCP	537.1 531.1 540.3 541.7 544.1 548.1 548.2 548.5 548.8 555.1(b) 531.1	Part 417 Part 317 Part 424 Part 430 318.14 301.2	5000.1 10,240.4
Heat Treated – Not Fully Cooked – Not Shelf Stable HACCP	537.1 531.1 540.3 541.7 544.1 548.1 548.2 548.8 550.1 550.2 550.3 555.1(b) 531.1	Part 417 Part 317 Part 424 318.14 320.1 320.2 320.3 320.6 301.2	5000.1
Secondary Inhibitors – Not Shelf Stable HACCP	537.1 531.1 540.3 541.7 544.1 548.1 548.2 548.5 548.8 555.1(b)	Part 417 Part 317 Part 424 Part 430 318.14	5000.1 10,240.4
Economic X Percent (%) Solution	541.7	317.2(e)(2) 317.8	7000.1 7620.3
Economic Batter/Breading	531.1 541.7	317.8 319.880	7000.1 7620.3
Labeling Product Standards	541.7	317.8 Part 319	7000.1 7620.3
Labeling Child Nutrition/Grade Labeling/Declared Count/Vignette	541.7	317.2(b)(c)(h)(i)(j)&(k) 317.8	7000.1
Labeling Net Weights	531.1 541.7(a) 541.7(e)	317.2(c)&(h) 442.1 442.2 442.3 442.4	7000.1 NIST Handbook 133; 4 th Ed. NIST Handbook 44,

		442.5	1999 Ed.
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Verification Tasks	Fish Regulations	Other Regulations	FSIS Directives
General Labeling	531.1 541.1 541.2 541.3 541.4 541.5 541.7(a)(c)(d)(e)(f)&(g) 544.1 548.2 548.6 548.8 550.1	Part 317 Part 424 318.14 412 441.10 320.1	6700.1 7000.1 7120.1 7221.1 7620.3
Exemptions	533.1		
Other Inspection Requirements	532.1 533.3 533.4 533.5 534.1 534.2 534.3 534.4 539.1(a)(1) 539.1(a)(2) 539.1(b) 539.1(c) 539.1(d) 540.1 540.2 540.3 537.3 550.1 550.2 550.3	320.1 320.2 320.3 320.6 Part 418	

List of Directives Applicable to CSIs, Who Perform Inspection Verification in Establishments that Prepare or Process Fish

Directive	Title
5000.1	Verifying an Establishment's Food Safety System
5000.2	Review of Establishment Testing Data by Inspection Program Personnel
5000.3	Identification and Segregation of Product
5000.4	Performing the Review Component of PBIS 01B02 Procedure and PHIS Pre-op Sanitation SOP Review and Observation Task in Federally Inspected Processing, Slaughter and Import Establishments
5000.5	Verification of Less than Daily (Ltd) Sanitation Procedures in Processing Operations
5000.6	Performance of the Hazard Analysis Verification (HAV) Task
5000.8	Verifying Compliance with Requirements for Written Recall Procedures
5000.9	Verifying Video or Other Electronic Monitoring Devices
5010.1	Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management
5060.1	Hygiene and Biosecurity Practices
5300.1	Managing the Establishment Profile in the Public Health Information System
5420.1	Food Defense Verification Tasks and Threat Notification Response Procedures for the Office of Field Operations
5500.2	Significant Incident Response
5500.4	Products Intentionally Adulterated with Threat Agents
5620.1	Using askFSIS
5730.1	Responsibilities in Dual Jurisdiction Establishments
6700.1	Retained Water in Raw Meat and Poultry
7000.1	Verification of Non-Food Safety Consumer Protection Regulatory Requirements
7000.2	Experimental and Sample Products Policy
7000.4	Verifying Certain Transferred Labeling
7020.1	Verifying Donation of Misbranded and Economically Adulterated Meat and Poultry Products to Non-Profit Organizations
7120.1	Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products
7221.1	Prior Labeling Approval
7230.1	Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common (Big 8) Food Allergens
7235.1	Mandatory Safe Handling Statements on Labeling of Raw and Partially Cooked Meat and Poultry Products
7237.1	Labeling of Ingredients
7310.5	Presence of Foreign Material in Meat or Poultry Products
7520.2	Procedures for Condition of Canned Product Container Examination
7530.1	Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile, Canned Product
7530.2	Verification Activities in Canning Operations that Choose to Follow the Canning Regulations
7620.3	Processing Inspectors' Calculations Handbook

Directive	Title
<u>10,210.5</u>	FSIS Sampling Data Reporting through Laboratory Information Management System-Direct
<u>10,240.4</u>	Verification Activities for the <i>Listeria monocytogenes (Lm)</i> Regulation and the Ready-to-Eat (RTE) Sampling Program
<u>10,800.1</u>	Residue Sampling, Testing and Other Verification Procedures Under the National Residue Program for Meat and Poultry Products
<u>12,600.1</u>	Voluntary Reimbursable Inspection Services
<u>12,600.2</u>	Reimbursable Overtime Inspection Services and Meat and Poultry Establishments
<u>12,700.1</u>	Operations Occurring Outside Approved Hours
<u>13,000.1</u>	Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)
<u>13,000.2</u>	Performing Sampling Tasks in Official Establishments Using the Public Health Information System
<u>13,000.3</u>	Responding in PHIS to Industry Appeal of a Noncompliance Record
<u>13,000.4</u>	PHIS Disconnected State and Offline Synchronization Application

District	Primary Siluriformes Contact	
	Email	Phone
Alameda	Amin, Abdalla - FSIS <Abdalla.Amin@fsis.usda.gov>	(510) 769-5712
Atlanta	Halteman, Debra - FSIS <Debra.Halteman@fsis.usda.gov>	(404) 562-5907
Chicago	Aguado, Beatrice - FSIS <Beatrice.Aguado@fsis.usda.gov>	(630) 639-6147
Dallas	Claudet, Amanda - FSIS <Amanda.Claudet@fsis.usda.gov>	(469) 657-8731
Denver	Sherman, Paul - FSIS <Paul.Sherman@fsis.usda.gov>	(503) 399-5841
Des Moines	Black, John - FSIS <John.Black@fsis.usda.gov>	(515) 727 8982
Jackson	Coley, Donald - FSIS <Donald.Coley@fsis.usda.gov>	(601) 965-4312
Philadelphia	Clifford, Jay - FSIS <Jay.Clifford@fsis.usda.gov>	(857) 366-1764
Raleigh	Johnson, Susan - FSIS <Susan.Johnson@fsis.usda.gov>	(304) 266-4225
Springdale	Brown, Deanna A. - FSIS <Deanna.Brown@fsis.usda.gov>	(479) 387-5264