

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

FSIS NOTICE

09-16

2/3/16

**OFFICE OF INVESTIGATION, ENFORCEMENT AND AUDIT (OIEA) RESPONSIBILITIES
RELATED TO SILURIFORMES FISH AND FISH PRODUCTS**

DO NOT IMPLEMENT THIS NOTICE UNTIL MARCH 1, 2016

I. PURPOSE

A. This notice informs personnel of the Office of Investigation, Enforcement, and Audit's (OIEA) Enforcement and Litigation Division (ELD) and Compliance and Investigations Division (CID) of new requirements in the recently published final rule, "Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish" ([80 FR 75589](#)). The notice instructs ELD personnel how to conduct a compliance background inquiry on applicants for Grants of Inspection for Siluriformes fish and fish products. It also instructs CID personnel how to conduct surveillances and investigations at warehouses, distributors, transporters, retailers, ports of entry, and other in-commerce businesses that involve Siluriformes fish and fish products during the 18-month transitional period. This notice does not instruct CID personnel on how to collect samples of feed and pond water for cause (e.g., in response to a violative test result for a sample collected within an official establishment). FSIS will issue those instructions to CID personnel at a later date.

B. In this notice, the term "fish" refers to fish of the order Siluriformes and products derived from these fish. Below are acceptable common or usual names that would need to be on the label of fish subject to FSIS inspection.

DISTRIBUTION: Electronic

NOTICE EXPIRES: 3/1/17

OPI: OPPD

ORDER	FAMILY	ACCEPTABLE COMMON OR USUAL NAMES	GENUS SPECIES
SILURIFORMES*	Ictaluridae	Blue Catfish or Catfish	<i>Ictalurus furcatus</i>
		Channel Catfish or Catfish	<i>Ictalurus punctatus</i>
		White Catfish or Catfish	<i>Ameiurus catus</i>
		Black Bullhead or Bullhead or Catfish	<i>Ameiurus melas</i>
		Yellow Bullhead or Bullhead or Catfish	<i>Ameiurus natalis</i>
		Brown Bullhead or Bullhead or Catfish	<i>Ameiurus nebulosus</i>
		Flat Bullhead or Bullhead or Catfish	<i>Ameiurus platycephalus</i>
	Clariidae	Whitespotted fish or Chinese fish	<i>Clarias fuscus</i>
		Sharptooth Clarias Fish	<i>Clarias gariepinus</i>
		Broadhead Clarias Fish	<i>Clarias macrocephalus</i>
		Walking Clarias Fish	<i>Clarias batrachus</i>
	Pangasius	Swai or Sutchi or Striped Pangasius or Tra	<i>Pangasianodon hypophthalmus</i>
		Basa	<i>Pangasius bocourti</i>
		Mekong Giant Pangasius	<i>Pangasius gigas</i>
		Giant Pangasius	<i>Pangasius sanitwongsei</i>

* This list is not all-inclusive. A complete list is available in the Integrated Taxonomic Information System (ITIS) at <http://www.itis.gov>.

II. GENERAL REQUIREMENTS OF THE REGULATIONS FOR FISH OF THE ORDER SILURIFORMES AND PRODUCTS DERIVED FROM SUCH FISH

A. 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 75589). FSIS published the final rule in response to provisions of the 2008 and 2014 Farm Bills. The rule establishes a mandatory inspection program for fish of the order Siluriformes and products derived from these fish.

B. The 2008 and 2014 Farm Bills amended the Federal Meat Inspection Act (FMIA) such that 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. Exemptions from inspection for personal use, as well as for custom and on-farm slaughter and processing (21 U.S.C. 623).

NOTE: Fish products, like other meat products, that are prepared at retail stores and restaurants using operations of the type traditionally and usually conducted at those venues are exempt from mandatory FSIS inspection under 21 U.S.C. 661(c)(2))(9 CFR 532.3). In addition, the retail store exemption for fish includes the slaughter of live fish at retail stores or restaurants

for consumers who purchase the fish at those facilities, and in accordance with the consumers' request. A retail quantity of fish or fish products sold to a household consumer is a normal retail quantity if it does not exceed 75 pounds, and the quantity of fish or fish product sold by a retail supplier to a non-household consumer is a normal retail quantity if it does not exceed 150 pounds in the aggregate.

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

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 (9 CFR 541.7).

NOTE: 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 1 provides a complete list of fish requirements with hyperlinks.

D. Farms and transporters that supply fish to official establishments must register with the FSIS Administrator using FSIS Form 5021-1, *Registration of Meat and Poultry Handlers* (9 CFR 550.5) by September 1, 2017.

E. All official fish establishments will operate under FSIS jurisdiction starting on March 1, 2016. However, to provide for an orderly changeover from Food and Drug Administration oversight to FSIS oversight, FSIS is providing an 18-month transitional period to give affected establishments with opportunity to train personnel and to bring their operations into full compliance with the new regulations. This period also provides official fish establishments with additional time to prepare labels, HACCP plans, Sanitation Standard Operating Procedures, and written recall plans. Moreover, throughout the transitional period, FSIS personnel will use broad discretion in enforcing the regulatory requirements, except when the establishment has produced adulterated or misbranded fish product, or when there is intimidation of or interference with FSIS personnel.

F. FSIS will not reinspect or enforce FSIS requirements on imported fish and fish products until April 15, 2016. FSIS is delaying reinspection and enforcement of FSIS requirements for imported products to provide for product in transit on the effective date of the rule.

III. BACKGROUND INQUIRIES

A. Before an establishment may receive a Grant of Inspection, ELD personnel are to conduct a

compliance background inquiry of the applicant's business and responsibly connected persons identified on the application.

B. The District Office may not proceed with processing the application for inspection until the completion of the ELD evaluation and notification of the findings. ELD personnel are to follow [FSIS PHIS Directive 5220.1](#), *Granting, Refusing, Voluntary Suspension or Voluntary Withdrawal of Federal Inspection Service*.

IV. IN-COMMERCE SURVEILLANCE AND INVESTIGATIONS

A. When conducting in-commerce surveillance, CID Investigators are to follow [FSIS Directive 8010.1](#), *Methodology for Conducting In-Commerce Surveillance Activities*.

B. CID Investigators are to conduct investigations according to [FSIS Directive 8010.2](#), *Investigative Methodology*.

C. CID Investigators are to follow [FSIS Directive 8410.1](#), *Detention and Seizure*, if they find fish product that:

1. Contains a poisonous or deleterious substance that may render it injurious to health (e.g., a violative residue, an undeclared ingredient of public health concern, or another adulterant);
2. Contains any pesticide, food additive, or color additive that is unsafe under the Federal Food, Drug, and Cosmetic Act;
3. Is unsound, unhealthful, unwholesome, or otherwise unfit for human food;
4. Is prepared, packed, or held under insanitary conditions that render it injurious to health;
5. Is offered for sale under the name "Catfish" but does not contain fish of the family Ictaluridae;
6. Is offered for sale without a label on immediate container; or
7. Is offered for sale without the name of packer/distributor and address is missing.

D. If Investigators find any other noncompliance with the FMIA, they are to contact their supervisor to determine the appropriate enforcement action.

E. CID investigators are to follow [FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products*, if FSIS requests a voluntary recall of fish and fish products.

V. SAMPLING

CID Investigators are to follow [FSIS Directive 8010.3](#), *Procedures for Evidence Collection, Safeguarding and Disposal*. The methodology for collecting samples from feed and ponds will be issued at a later date.

VI. OUTREACH

During the 18-month transitional period, CID Investigators are to conduct educational outreach at firms and facilities that supply or transport live fish to official establishments or store fish products as part of their in-commerce surveillance activities. As part of their outreach, CID Investigators are to encourage these entities to register with FSIS as required in 9 CFR 550.5

and to inform them that they are required to register by September 1, 2017.

VII. QUESTIONS

Refer questions through supervisory channels.

A handwritten signature in black ink, appearing to read "David Joseph". The signature is written in a cursive style with a large initial "D" and a prominent "J".

Assistant Administrator
Office of Policy and Program Development

(Attachment 1)

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
GENERAL REQUIREMENTS; DEFINITIONS	PART 530	Part 300
General	§530.1	§300.1, §300.2
FSIS organization for inspection of fish and fish products	§530.2	§300.3
Access to establishments	§530.3	§300.6
DEFINITIONS	PART 531	Part 301
Definitions	§531.1	§301.2
REQUIREMENTS FOR INSPECTION	PART 532	Part 302, Part 304, Part 305
Establishments requiring inspection; other inspection	§532.1	§302.1
Application for inspection, etc.	§532.2	§304.1, §304.2, §304.3
Exemption of retail operations	§532.3	§303.1
Inspection at official establishments; relation to other authorities	§532.4	§302.2
Exemption from definition of fish product of certain human food products containing fish	§532.5	
SEPARATION OF ESTABLISHMENT; FACILITIES FOR INSPECTION, ETC.	PART 533	Part 305, Part 306, Part 307
Separation of establishments	§533.1	§305.2
Facilities for Program employees	§533.3	§307.1
Other facilities and conditions to be provided	§533.4	§307.2
Schedule of operations	§533.5	§307.4
Overtime and holiday inspection service	§533.6	§307.5
Basis of billing for overtime and holiday services	§533.7	§307.6
PRE-HARVEST STANDARDS AND TRANSPORTATION TO PROCESSING ESTABLISHMENT	PART 534	
General	§534.1	
Water quality for food fish	§534.2	
Standards for use of drugs and other chemicals in feed and in fish growing ponds	§534.3	
Transportation to processing plant	§534.4	
SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEMS	PART 537	Part 416, Part 417
Basic requirements	§537.1	Part 416, Part 417
Hazard Analysis and HACCP plan	§537.2	Part 417, §417.2
MANDATORY DISPOSITIONS; PERFORMANCE STANDARDS, ETC.	PART 539	Part 311
Disposal of diseased or otherwise adulterated fish carcasses or parts	§539.1	
Physical, chemical or biological contaminants	§539.2	
HANDLING AND DISPOSAL OF CONDEMNED AND OTHER INEDIBLE	PART 540	Part 314

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
MATERIALS		
Dead fish	§540.1	§314.8
Specimens for educational, research, and other nonfood purposes; permits	§540.2	§314.9
Handling and disposal of condemned or other inedible materials	§540.3	Part 314
MARKS, MARKING AND LABELING OF PRODUCTS AND CONTAINERS	PART 541	Part 312, Part 316
General	§541.1	
Official marks and devices to identify inspected and passed fish and fish products	§541.2	§312.2
Official seals for transportation of products	§541.3	§312.5
Official export inspection marks, devices, and certificates	§541.4	§312.8
Official detention marks and devices	§541.5	§329.2
Labels required; supervision of a Program employee	§541.7	Part 317, Part 441, Part 442
FOOD INGREDIENTS PERMITTED	PART 544	Part 424
Use of food ingredients	§544.1	Part 424
PREPARATION OF PRODUCTS	PART 548	Part 318
Preparation of fish products	§548.1	
Requirements concerning ingredients and other articles used in the preparation of fish products	§548.2	§318.6
Samples of products, water, dyes, chemicals, etc., to be taken for examination	§548.3	§318.9
Mixtures containing product but not amenable to the Act	§548.4	§318.13
Ready-to-eat fish products	§548.5	Part 430
Canning and canned products	§548.6	Part 318, subpart G (§§318.300-318.311)
Use of animal drugs	§548.7	
Polluted water contamination at establishment	§548.8	§318.14
Accreditation of non-Federal chemistry laboratories	§548.9	Part 439
STANDARDS OF IDENTITY AND COMPOSITION	PART 549 (RESERVED)	Part 319
RECORDS REQUIRED TO BE KEPT	PART 550	Part 320
Records required to be kept	§550.1	§320.1
Place of maintenance of records	§550.2	§320.2
Record retention period	§550.3	§320.3
Access to and inspection of records, facilities, and inventory; copying and sampling	§550.4	§320.4
Registration	§550.5	§320.5
Information and reports required from official	§550.6	§320.6

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
establishment operators		
Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations	§550.7	§320.7
EXPORTS	PART 552	Part 322
Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation	§552.1	§322.1, §322.2, §322.4
TRANSPORTATION OF FISH PRODUCTS IN COMMERCE	PART 555	Part 325
Transportation of fish products	§555.1	§325.1
fish product transported within the United States as part of export movement	§555.2	§325.3
Unmarked, inspected fish product transported under official seal between official establishments for further processing	§555.3	§325.5
Handling of fish products that may have become adulterated	§555.4	§325.10
Transportation of inedible fish product in commerce	§555.5	§325.11
Certificates	§555.6	§325.14
Official seals; forms, use, and breaking	§555.7	§325.16
Loading or unloading of fish products in sealed transport conveyances	§555.8	§325.17
Diverting of shipments	§555.9	§325.18
Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles	§555.10	§325.19
Transportation and other transactions concerning dead, dying, or diseased fish, and fish or parts of fish that died otherwise than by slaughter	§555.11	§325.20
Means of conveyance in which dead, dying, or diseased fish or parts of fish must be transported	§555.12	§325.21
IMPORTATION	PART 557	Part 327
Definitions; application of provisions	§557.1	§327.1
Eligibility of foreign countries for importation of fish products into the United States	§557.2	§327.2
No fish product to be imported without compliance with applicable regulations	§557.3	§327.3
Imported fish products; foreign certificates required	§557.4	§327.4
Importer to make application for inspection of fish products for entry	§557.5	§327.5
Fish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment	§557.6	§327.6

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
Products for importation; movement prior to inspection; handling; bond; assistance	§557.7	§327.7
Import fish products; equipment and means of conveyance used in handling to be maintained in sanitary condition	§557.8	§327.8
[Reserved]	§557.9	§327.9
Samples; inspection of consignments; refusal of entry; marking	§557.10	§327.10
Receipts to importers for imported fish product samples	§557.11	§327.11
Foreign canned or packaged fish products bearing trade labels; sampling and inspection	§557.12	§327.12
Foreign fish products offered for importation; reporting of findings to Customs	§557.13	§327.13
Marking of fish products and labeling of immediate containers thereof for importation	§557.14	§327.14
Outside containers of foreign fish products; marking and labeling; application of official inspection legend	§557.15	§327.15
Small importations for importer's own consumption; requirements	§557.16	§327.16
Returned U.S. inspected and marked fish products	§557.17	§327.17
Fish products offered for entry and entered	§557.18	§327.18
Specimens for laboratory examination and similar purposes	§557.19	§327.19
[Reserved]	§557.20 [Reserved]	
[Reserved]	§557.21 [Reserved]	
[Reserved]	§557.22 [Reserved]	
[Reserved]	§557.23 [Reserved]	
Appeals; how made	§557.24	§327.24
Disposition procedures for fish product condemned or ordered destroyed under import inspection	§557.25	§327.25
Official import inspection marks and devices	§557.26	§327.26
DETENTION, SEIZURE, CONDEMNATION	PART 559	Part 329
Fish and other articles subject to administrative detention	§559.1	§§ 329.1, 329.2, 329.3, 329.4, 329.5
Articles or fish subject to judicial seizure and condemnation	§559.2	§§ 329.6, 329.7, 329.8
Criminal offenses	§559.3	§329.9

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
STATE-FEDERAL, FEDERAL-STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS	PART 560	Part 321, Part 331
Cooperation with States and Territories	§560.1	§321.1
Cooperation of States in Federal programs	§560.2	§321.2
Cooperation of States in the interstate shipment of fish and fish products	§560.3	§321.3
Designation of States under the FMIA	§560.4	Part 331, §331.3, §331.5, §331.6
RULES OF PRACTICE	PART 561	Part 500
Rules of practice governing proceedings under the FMIA for criminal violations	§561.2	Part 335