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

FSIS NOTICE	23-16	4/14/16

CONSUMER SAFETY INSPECTORS RESPONSIBILITIES AT FISH (OF THE ORDER SILURIFORMES) ESTABLISHMENTS DURING THE 18-MONTH TRANSITIONAL PERIOD

I. PURPOSE

A. This notice provides instructions to Consumer Safety Inspectors (CSIs) on how to verify regulatory compliance at official establishments that slaughter, slaughter and process, or process fish of the order Siluriformes during the 18-month transitional period, March 1, 2016 to September 1, 2017. This notice also provides documentation procedures under the Public Health Information System (PHIS) during the 18-month transitional period. This notice reissues instructions issued in FSIS Notice 08-16 and includes revisions to that notice which:

1. Extend the instructions to CSIs assigned to official establishments that only process fish;
2. Provide updated sampling project codes;
3. Clarify that, for now, only raw, single ingredient Siluriformes fish products are eligible for sampling;
4. Clarify that the CSI is to collect a frozen sample only if a fresh sample is not available;
5. Clarify how the CSI is to complete the paired sampling tasks in PHIS; and
6. Provide the PHIS questionnaire associated with the sampling task.

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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 such fish.

ORDER	FAMILY	ACCEPTABLE COMMON OR USUAL NAMES	GENUS AND SPECIES
SILURIFORMES*	Ictaluridae	Blue Catfish or Catfish	*Ictalurus furcatus*
		Channel Catfish or Catfish	*Ictalurus punctatus*
		White Catfish or Catfish	*Ameiurus catus*
		Black Bullhead or Bullhead or Catfish	*Ameiurus melas*
		Yellow Bullhead or Bullhead or Catfish	*Ameiurus natalis*
		Brown Bullhead or Bullhead or Catfish	*Ameiurus nebulosus*
		Flat Bullhead or Bullhead or Catfish	*Ameiurus platycephalus*
	Clariidae	Whitespotted fish or Chinese fish	*Clarias fuscus*
		Sharptooth Clarias Fish	*Clarias gariepinus*
		Broadhead Clarias Fish	*Clarias macrocephalus*
		Walking Clarias Fish	*Clarias batrachus*
	Pangasiidae	Swai or Sutchi or Striped Pangasius or Tra	*Pangasianodon (or Pangasius) hypophthalmus*
		Basa	*Pangasius bocourti*
		Mekong Giant Pangasius	*Pangasius gigas*
		Giant Pangasius	*Pangasius sanitwongsei*
* This list is not all-inclusive. A complete list is available in the Integrated Taxonomic Information System (ITIS) at http://www.itis.gov.			

II. BACKGROUND

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 75590). The final rule amends the Agency's regulations to establish a mandatory inspection program for fish of the order Siluriformes and for products derived from these fish. The final rule explains that, because these fish are amenable under 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.

B. 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).

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. 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 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 only "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).

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 list of fish requirements.

D. FSIS jurisdiction over all official fish establishments started 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 the 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.

NOTE: During the transitional period, fish establishments will be permitted to use up their existing label inventories. However, as is outlined in Attachment 2 of this notice, FSIS is encouraging establishments to purchase, print, or modify (with pressure-sensitive stickers) labels after March 1, 2016, that would comply with all of the FSIS labeling requirements.

E. 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. Attachment 2 provides specific examples of adulteration (violative residues, product contamination) and of misbranding (incorrect common or usual name based on species testing, over-declared net weight) for which FSIS would take enforcement actions, and of situations in which discretion is appropriate throughout the 18-month transitional period. As is outlined in Attachment 2, for noncompliance for which FSIS does not issue a noncompliance record (NR), the CSI will issue a Memorandum of Interview (MOI) and will continue to work with the establishment to bring it into full compliance with the regulatory requirements by September 1, 2017.

III. INSPECTION DURING TRANSITIONAL PERIOD (MARCH 1, 2016 – SEPTEMBER 1, 2017)

A. A CSI will be present during all hours of each production day in all official fish slaughter and slaughter-processing establishments, and at least once per quarter in official fish processing-only establishments.

B. The CSI is to follow the instructions provided in FSIS PHIS Directive 13,000.1, *Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS),* for scheduling and recording inspection tasks.

C. When a CSI rotates into an assignment or conducts an inspection at an official fish establishment for the first time, he or she is to:

1. Review the establishment's profile in PHIS to become familiar with the information in the profile;

2. Update the PHIS profile as instructed in FSIS Directive 5300.1, as necessary (e.g., as the CSI becomes familiar with the establishment's operations, and information about the establishment is made available to him or her); and

3. Have an entrance meeting with establishment management to familiarize himself or herself with the establishment and inquire about the specific operations of that establishment.

D. At least once a week in official fish establishments that slaughter and as part of each visit in official fish processing-only establishments, the CSI assigned to the establishment is to:

1. Meet with establishment management to discuss issues of concern; and

2. Take notes at the meetings and document the notes in a MOI according to the instructions in Section IV of FSIS Directive 5010.1, *Food Safety Related Topics for Discussion During Weekly Meetings with Establishment Management*.

E. While performing his or her inspection activities, the CSI is to take actions as outlined in Attachment 2, depending on the noncompliance found. The CSI is to take immediate regulatory control action (as per 9 CFR Part 561) when the establishment has produced adulterated or misbranded fish product. In addition, the CSI is to document his or her findings on FSIS Form 5400-4*, Noncompliance Record* (NR), according to the instructions in Chapter V of FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, and provide a copy of the NR to establishment management. If the CSI is uncertain whether conditions support a particular determination, he or she is to discuss the issue with his or her immediate supervisor before taking action.

F. The CSI is not to release product or equipment affected by the control action until he or she has verified that the establishment has restored sanitary conditions or has completed the proper product disposition.

G. If there is reason to believe that adulterated or misbranded product (as outlined in Attachment 2) is in commerce, or the CSI identifies other significant problems, the CSI is to contact his or her supervisor immediately.

H. The CSI is to document findings that do not result in direct product adulteration or misbranding (as outlined in Attachment 2) on a MOI. The CSI is to include a detailed description of the findings, a list of the relevant regulations, and information about when and how the establishment plans to correct the issue. The CSI is to discuss the findings with the establishment while emphasizing the importance of correcting the problem in a timely manner and provide a copy of the MOI to establishment management.

I. If the CSI observes recurring minor deficiencies (i.e., those captured in a MOI) from the same cause or observes a lack of progress by the establishment to remedy already documented minor deficiencies, the CSI is to notify his or her supervisor as soon as possible to prevent the production of adulterated product or significant misbranding of product. The supervisor is to discuss these concerns with the District Manager (DM), and, if warranted, the DM is to issue a Notice of Warning (NOW) to the establishment.

IV. ON-SITE SAMPLING PROCEDURES FOR OFFICIAL ESTABLISHMENTS THAT SLAUGHTER FISH

A. FSIS will conduct periodic sampling and testing for chemical residues and speciation at official fish slaughter establishments to ensure that the product is not adulterated, and, based on species testing, the product is not misbranded. In addition, FSIS will begin collecting data to determine the prevalence of *Salmonella* in raw fish. The CSI is to collect samples when directed to do so in the PHIS.

NOTE: During the transitional period while FSIS is learning about Siluriformes fish production practices and about the parameters affecting biological, chemical, and physical relatedness of fish, in domestic operations, FSIS will apply the mark of inspection prior to determining whether applicable FSIS test results for adulterants or species are acceptable. At this time, FSIS believes that fish are reared more similarly to poultry flocks than other livestock species in that exposure to possible contaminants, including medical treatment with drugs, is likely to impact all fish rather than individual fish. However, for imported product, because discrete units of product are presented for reinspection at the Point of Entry (POE) and such product generally is frozen, FSIS will not apply the mark of inspection until acceptable FSIS results for adulterants and species become available. If, during the transitional period, FSIS finds widespread non-compliance for adulterants or speciation, the Agency will issue instructions to inspection program personnel to withhold the mark until acceptable test results become available. After the transitional period and upon careful review of compliance performance during this period, FSIS expects to withhold the mark when testing for adulterants until acceptable results become available.

B. If a sample tests violative for a residue, or is misbranded based on species testing results, the CSI is to record his or her findings in an NR as instructed in Attachment 2 and immediately contact his or her supervisor. FSIS will evaluate the need to gain regulatory control, including effectuating a recall on a case-by-case basis during the transitional period.

NOTE: For lotting purposes, lots should be defined so that if a violative result is found for one lot, the product from an other lot would not be implicated. In the United States, fish are routinely grown in the same pond and later harvested as a single population for slaughter. Most residues of public health concern are absorbed or ingested by the fish directly from the water. In addition, data supports that if one fish sampled from a pond contains a violative residue, most of the fish collected at the same time from the same pond would likely contain the same violative residue. Thus, CSIs are to be aware that it would be nearly impossible to justify a lotting system in which fish collected at the same time from the same pond are identified as separate lots.

C. Paired sample requests (one for microbiological analysis and one for chemical analysis) will appear as directed tasks on the establishment task list in PHIS. The CSI is to follow the instructions provided in FSIS PHIS Directive 13,000.2, *Performing Sampling Tasks in Official Establishments Using the Public Health Information System*, for accepting, scheduling, and completing a directed sampling task using the PHIS.

Sampling project codes will appear as follows:

RES_FI – Residue and Species testing (chemical analysis)
EXP_FI_MIC01 – *Salmonella* testing (microbiological analysis)

NOTE: FSIS will analyze samples for *Salmonella,* chemical residues, and species testing.To accomplish this analysis, the CSI is to complete, print, and submit two separate lab submission forms with the collected samples.

D. The CSI is to request sampling supplies at least 72 hours before the day of scheduled sample collection. The CSI is to follow the instructions provided in FSIS PHIS Directive 13,000.2 for ordering sampling supplies through the PHIS. As an alternative, the CSI may submit requests for sampling supplies to FSIS Laboratories via Outlook, by rotating use of the following e-mail addresses:

1. Eastern Laboratory (SamplingSupplies-EasternLab@fsis.usda.gov); or

2. Western Laboratory (SamplingSupplies-WesternLab@fsis.usda.gov).

DI. The CSI is to include the following information in the e-mail request for supplies:

1. The sampling project code;

2. The establishment number and establishment name;

3. The CSI's name and contact phone number; and

4. The specific supplies needed.

Supplies needed for each fish sampling event include (see Attachment 3):

1 – Shipping Box (M-USDA20) with packing materials
2 – Pairs Sterile Gloves
2 – Sterile Fill-Line Closure Bags
2 – One gallon Zip Lock Bags, non-sterile
2 – 6"x12" Plastic Bags
2 – FedEx Billable Stamps
1 – FSIS Form 7355-2A/2B

F. The CSI is to randomly select a day, shift, and time within the sampling window after the sample collection date indicated. The CSI is to collect samples from all shifts the establishment operates. There needs to be an equal chance that sampling will occur during any particular shift. At this time, the CSI is not to collect samples of whole fish (head-on or headless).

G. The CSI is to sample raw, single ingredient fish products in their final package, whenever possible. The CSI is to put the product (in its final packaging) in the one gallon non-sterile bag that is provided to him or her with the microbiology sampling supplies and the chemistry sampling supplies. The CSI is to collect the appropriate number of packaged products, so that two one-pound samples are submitted (one pound for microbiological testing and one pound for residue and species testing). The paired samples must come from the same lot of fish and be collected at the same point in the process.

H. If product is not available in the final package, or if the final package is greater than one pound, the CSI is to use aseptic technique to collect enough product to fill to the line of each fill-line closure bag for submitting these samples. To ensure a successful sample collection process and decrease the number of sample discards, the CSI is to:

1. Wash and scrub his or her hands to the mid-forearm before starting the sample collection procedure, and dry his or her hands using disposable paper towels;

2. Wear sterile gloves and follow the aseptic technique while collecting samples. The sampled product is the only item that should contact the external surface of the sterile glove on the sampling hand. The outside surfaces of the sample container are not sterile;

3. Collect the sample after the establishment has applied all interventions and as close to finished as possible. The CSI is to collect a sufficient amount of product to fill the two fill-line closure bags up to the fill-line indicated on the bag. The CSI is not to underfill or overfill the bags;

4. Carefully squeeze out the air remaining in each fill-line closure bag and tightly fold over the top at least four times, as trapped air and loose seals may lead to leakage. The CSI is to fold over the side tabs to secure the folds in place and not tie the ends. These steps will ensure a successful sample collection process and decrease the number of sample discards;

5. The CSI is to only collect a frozen sample if a fresh sample is not available. However, if frozen finished product packages weigh more than 2 pounds, the CSI is to ask the establishment to slack fill two one-pound finished product packages for sampling purposes. The CSI is to submit the two slack-filled bags in the two non-sterile one gallon bags (or larger secondary bags as needed); and

6. Place the completed sample forms and any unused sample seals inside the 6”x12” plastic bags provided and then place the bags inside the shipping container.

I. The CSI is to complete the paired sampling tasks in PHIS. The CSI is to:

1. Follow the instructions provided in FSIS Directive 13,000.2 for completing the sampling tasks using PHIS. To assist in the completion of the sampling tasks, the CSI may choose to print a draft copy of the sampling forms from PHIS for use during sample collection;

2. Enter all requested sample information in PHIS and complete the sample questionnaire, when applicable. The list of questions is included in Attachment 4, “Sampling Questionnaire:” and

3. When the sample data collection entry is completed; click the “Submit to Lab” button for both sampling tasks, print the finalized forms, and sign both forms. PHIS will display a message stating that the sample collection information has been successfully submitted.

J. To package and ship the sample, the CSI is to follow instructions provided in FSIS Directive 7355.1*, Use of Sample Seals for Program Samples and Other Applications*, and in FSIS Directive 10,800.1.

K. The CSI is to periodically check PHIS or LIMS-Direct for the status of the test results. LIMS-Direct reports test results upon completion of the sample analysis. The CSI can also access test results in PHIS through the Laboratory Sample data field on the Inspector Home page. If the FSIS Laboratory discards a sample submitted, the CSI is to take appropriate action based on the reason for sample discard. The CSI is to refer to FSIS Directive 10,800.1, Chapter Five, Section IX., and Attachment 2 of this notice for actions to take if a noncompliant result is reported. Positive *Salmonella* sample results will not result in regulatory control actions. The CSI is to provide a printed copy of the test results to the establishment management.

V. CERTIFYING FISH PRODUCTS FOR EXPORT

A. In official fish slaughter and slaughter and processing establishments, the CSI is to issue official export certificates for the shipment of inspected and passed fish products to any foreign country as instructed in FSIS Directive 9000.1*, Export Certification*.

B. When the CSI receives a completed and signed FSIS Form 9060-6: *Application for Export*, from an official fish slaughter or slaughter and processing establishment, he or she is to review the FSIS Export Library to determine export requirements by country. If the product is eligible, the CSI is to issue a FSIS

Form 9060-5-S, *Siluriformes Fish and Fish Product Export Certificate*, and provide an export stamp to the applicant.

C. When the exporting establishment stages the product, the CSI is to perform a reinspection to determine whether the product is wholesome and properly labeled, and that the export stamp is properly applied. The CSI should be particularly alert for signs that product is or may become adulterated or unwholesome (e.g., off-condition odor, torn, damp cartons, or other evidence of insanitary handling or storage).

D. After the CSI deems the shipment acceptable, he or she is to sign and date the completed FSIS Form 9060-5-S and any other required supplemental letterhead certificates from the export library and return the export certification documents to the export applicant.

E. For non-inspection services not provided by FSIS (e.g., grading) and export certification at official fish processing-only establishments, the CSIs are to be aware that those services will continue to be provided by other agencies.

VI. SUPERVISORY RESPONSIBILITIES

A. Supervisory personnel are to assist CSIs with concerns raised about fish establishment issues and documentation.

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

VII. QUESTIONS

Submit questions to AskFish@fsis.usda.gov .

Assistant Administrator
Office of Policy and Program Development

ATTACHMENT 1

Fish requirements

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 MATERIALS	PART 540	Part 314

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
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 establishment operators	§550.6	§320.6
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	§552.1	§322.1, §322.2, §322.4

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
transportation		
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
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
RULES OF PRACTICE	PART 561	Part 500
Rules of practice governing proceedings under the FMIA for criminal violations	§561.2	Part 335

ATTACHMENT 2

EXAMPLES OF ADULTERATION/MISBRANDING/WHERE CONSEQUENCES (NR OR MOI)

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
The product for any reason is unsound, unhealthful, unwholesome, or otherwise unfit for human food (e.g., produced without benefit of inspection)	9 CFR 531.1	Yes	No	Yes	Immediately
The product contains a deleterious substance that may render it injurious to health (e.g., a violative residue, an adulterant, or an undeclared allergen)	9 CFR 531.1	Yes	No	Yes	Immediately
The product bears or contains any pesticide, food additive, or color additive which is unsafe under the FFDCA	9 CFR 531.1	Yes	No	Yes	Immediately
The product has been prepared, packed, or held under insanitary conditions that render it injurious to health	9 CFR 531.1	Yes	No	Yes	Immediately

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
The product is offered for sale under the name “Catfish” but does not contain fish of the family Ictaluridae	9 CFR 531.1	Yes	No	Yes	Immediately
Conditions throughout plant are insanitary and result in direct product adulteration	9 CFR 537.1, 416.1 and 531.1	Yes	No	Yes	Immediately
Conditions outside plant are insanitary and result in direct product adulteration	9 CFR 537.1, 416.2(a) and 531.1	Yes	No	Yes	Immediately
Use/storage of pest control products results in direct product adulteration	9 CFR 537.1, 416.2(a) and 531.1	Yes	No	Yes	Immediately
Existing buildings, rooms, or compartments are not of sound construction/kept in good repair and such conditions result in direct product adulteration	9 CFR 537.1, 416.2(b)(1) and 531.1	Yes	No	Yes	Immediately
Edible product is handled, processed, or stored in a room with inedible product resulting in direct product adulteration	9 CFR 416.2(b)(4) and 531.1	Yes	No	Yes	Immediately

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Existing ventilation system is inadequate to control odors or condensation resulting in direct product adulteration	9 CFR 537.1, 416.2(d) and 531.1	Yes	No	Yes	Immediately
Water is used/reused in a manner that directly adulterates product	9 CFR 537.1, 416.2(g) and 531.1	Yes	No	Yes	Immediately
Equipment, utensils, and refuse receptacles are used or maintained in a manner that directly adulterates product	9 CFR 537.1, 416.3 and 531.1	Yes	No	Yes	Immediately
Food contact surfaces, including utensils and equipment, are not properly cleaned or sanitized resulting in direct product adulteration	9 CFR 537.1, 416.4(a) and 531.1	Yes	No	Yes	Immediately
Non-food contact surfaces, including utensils and equipment, are not properly cleaned or sanitized resulting in direct product adulteration	9 CFR 537.1, 416.4(b) and 531.1	Yes	No	Yes	Immediately

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Product is directly adulterated during processing, handling, storage, loading, and unloading at and during transportation from the establishment	9 CFR 537.1, 416.4(d) and 531.1	Yes	No	Yes	Immediately
Establishment personnel do not adhere to hygienic practices and by not doing so directly adulterate product	9 CFR 537.1, 416.5(a)or(c) and 531.1	Yes	No	Yes	Immediately
Employee clothing is not maintained or readily cleaned and such conditions directly adulterate product	9 CFR 537.1, 416.5(b) and 531.1	Yes	No	Yes	Immediately
Ingredient of public health concern (e.g., a “Big 8” allergen) is not declared on product label resulting in direct product adulteration	9 CFR 541.7(a), 317.2(c)(2) and 531.1	Yes	No	Yes	Immediately
Net weight is over-declared resulting in economic adulteration of product	9 CFR 541.7(e), 317.2(c)(4), 442.2(a) and 531.1	Yes	No	Yes	Immediately

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
No label on immediate container	9 CFR 541.7(a) and 317.1	Yes (because such a label was required while under FDA jurisdiction)	No	Yes	Immediately
Name of packer/distributor and address is missing	9 CFR 541.7(a) and 317.2(c)(3)	Yes (because this information was required while under FDA jurisdiction)	No	Yes	Immediately
Isolated conditions in the plant are insanitary but such conditions DO NOT result in direct product adulteration	9 CFR 537.1 and 416.1	No	Yes	N/A	By end of 18-month transitional period (However, if conditions worsen and direct product adulteration is imminent, the establishment would be in violation of 9 CFR 531.1 - addressed above.)

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Isolated conditions outside the plant are insanitary but such conditions DO NOT result in direct product adulteration	9 CFR 537.1 and 416.2(a)	No	Yes	N/A	By end of 18-month transitional period (However, if conditions worsen and direct product adulteration is imminent, the establishment would be in violation of 9 CFR 531.1 - addressed above.)
Pest control products are not stored correctly but such conditions DO NOT result in direct product adulteration	9 CFR 537.1 and 416.2(a)	No	Yes	N/A	By end of 18-month transitional period (However, if conditions worsen and direct product adulteration is imminent, the establishment would be in violation of 9 CFR 531.1 - addressed above.)

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Existing buildings, rooms, or compartments are not of sound construction/kept in good repair but such conditions DO NOT result in direct product adulteration	9 CFR 537.1 and 416.2(b)(1)	No	Yes	N/A	By end of 18-month transitional period (However, if conditions worsen and direct product adulteration is imminent, the establishment would be in violation of 9 CFR 531.1 - addressed above.)
Lighting is of insufficient quality but such conditions DO NOT result in direct product adulteration	9 CFR 537.1 and 416.2 (c)	No	Yes	N/A	By end of 18-month transitional period

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Existing ventilation system is inadequate to control odors or condensation but such conditions DO NOT result in direct product adulteration	9 CFR 537.1 and 416.2(d)	No	Yes	N/A	By end of 18-month transitional period (However, if conditions worsen and direct product adulteration is imminent, the establishment would be in violation of 9 CFR 531.1 - addressed above.)
Existing establishment does not have sewage system approval letter on file as required (If something else about the existing sewage system could/does adulterate product, e.g., the existing system does not prevent back-flow conditions, the establishment would be in violation of 9 CFR 531.1 - addressed above.)	9 CFR 537.1 and 416.2(f)	No	Yes	N/A	By end of 18-month transitional period

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Existing establishment does not have a water potability report on file as required (If the establishment cannot provide proof that potable water is being used to process fish, the establishment would be in violation of 9 CFR 531.1 – addressed above.)	9 CFR 537.1 and 416.2(g)	No	Yes	N/A	By end of 18-month transitional period
Problems with existing dressing rooms, lavatories, and toilets but such conditions DO NOT result in direct adulteration of product	9 CFR 537.1 and 416.2(h)	No	Yes	N/A	By end of 18-month transitional period (However, if conditions worsen and direct product adulteration is imminent, the establishment would be in violation of 9 CFR 531.1 - addressed above.)

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Equipment, utensils, and refuse receptacles are maintained in an insanitary manner but such conditions DO NOT result in direct adulteration of product	9 CFR 537.1 and 416.3	No	Yes	N/A	By end of 18-month transitional period (However, if conditions worsen and direct product adulteration is imminent, the establishment would be in violation of 9 CFR 531.1 - addressed above.)
Incorrectly formatted/ otherwise non-compliant product name (other than use of the name “Catfish” on products that do not contain fish of the family Ictaluridae)	9 CFR 541.7(a) and 317.2(c)(1)	No	Yes	N/A	By end of 18-month transitional period
Incorrect/missing ingredients (other than ingredients of public health concern)	9 CFR 541.7(a) and 317.2(c)(2)	No	Yes	N/A	By end of 18-month transitional period

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Incorrectly formatted net weight	9 CFR 541.7(a) and 317.2(c)(4)	No	Yes	N/A	By end of 18-month transitional period
USDA inspection legend/EST number does not appear on label	9 CFR 541.2 and 317.2(c)(5)	No (because FSIS will require name of establishment on label, which should be sufficient for traceback)	Yes	N/A	By end of 18-month transitional period
Incorrect inspection legend appears on label (e.g., poultry legend)	9 CFR 541.2 and 317.2(c)(5)	No	Yes	N/A	By end of 18-month transitional period
Incorrect or missing handling statement	9 CFR 541.7(a) and 317.2(k)	No (because this is a new labeling requirement)	Yes	N/A	By end of 18-month transitional period
Incorrect or missing safe handling instructions (when required)	9 CFR 541.7(c) and 317.2(l)	No (because this is a new labeling requirement)	Yes	N/A	By end of 18-month transitional period

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Incorrect or missing nutrition facts panel (when required)	9 CFR 541.7(f) and 317.300	No	Yes	N/A	By end of 18-month transitional period
Label contains unapproved special statement or claim	9 CFR 541.7(g) and 412.1	No	Yes	N/A	By end of 18-month transitional period
Product contains food ingredients not specified in 9 CFR 424.21(c) or FSIS Directive 7120.1	9 CFR 544.1(a) and 424.21	No (because FSIS is in the process of updating its list of safe and suitable ingredients used in the production of fish. However, if the product contains unhealthful or unwholesome ingredients, e.g., those not approved for use in fish by the FDA, the establishment would be in violation of 9 CFR 531.1 - addressed above.)	Yes	N/A	By end of 18-month transitional period

Findings Observed	Citation	Issue NR	Issue MOI	Take Appropriate Reg Control Action	Time to correct
Retained water in product is not declared or supported	9 CFR 541.7(e) and 441.10	No	Yes	N/A	By end of 18-month transitional period
No/incomplete labeling record on file	9 CFR 550.1, 320.1(b)(11) and 412.1(a)	No	Yes	N/A	By end of 18-month transitional period

ATTACHMENT 3

Sampling Supplies

1 – Shipping Box (M-USDA20) with packing materials (ice pack, cardboard separator, foam plug)
2 – Pairs of sterile gloves
2 – Sterile fill-line closure bags
2 – One-gallon zipper-lock bags
2 – 6”x12” plastic bags
2 – FedEx billable stamp
1 – FSIS Form 7355-2A/2B

ATTACHMENT 4

Sampling Questionnaire: Raw Fish Exploratory Microbiological Sampling and Residue Sampling

In PHIS, these questions will appear in the residue (RES_FI) sampling task.

1. Was the sample collected frozen or fresh?
    a. Fresh, not frozen
    b. Frozen
2. Was the sample collected:
    a. Boneless
    b. Bone-in
    c. Partially deboned
    d. Unknown
3. Does the establishment use any antimicrobial intervention(s) during the processing of the sampled lot?
    a. Yes (complete 3a)
    b. No

3a. If you selected "Yes," please specify the name of the antimicrobial intervention(s) used: [free text]

If more than one intervention was used during the processing of the sampled lot, please separate the different interventions used with a comma. Example: hot water, chlorine

4. Which family within the order of Siluriformes do the fish subject to the sampled lot claim to belong according to the label?
    a. Ictaluridae
    b. Clariidae
    c. Pangasiidae
    d. Other
5. Is the sampled lot labeled as "Catfish" in its finished product form?
    a. Yes
    b. No

6. How will fish subject to the sampled lot be used or further processed? (Please check all that apply.)

   a. Raw, single ingredient, not-frozen

   b. Raw, single ingredient, frozen

   c. Raw, multiple ingredient, not-frozen

   d. Raw, multiple ingredient, frozen

   e. For further processing into comminuted or otherwise non-intact product

   f. For further processing into RTE product

   g. For further processing into heat-treated, but not fully cooked, not shelf-stable product

   h. For further processing into heat-treated, but not fully-coked, shelf-stable product

   i. Other (complete 6a)

6a. If you selected “Other,” please specify: [free text]