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

# **FSIS DIRECTIVE**

14,950.1 Revision 1 3/16/23

INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES AT OFFICIAL IMPORTINSPECTION ESTABLISHMENTS THAT RECEIVE SHIPMENTS OF SILURIFORMES FISH AND FISH PRODUCTS

#### **CHAPTER I - GENERAL**

#### I. PURPOSE

- A. This directive instructs inspection program personnel (IPP) on how to perform import reinspection at official import inspection establishments that receive shipments of Siluriformes fish. This directive has been updated to remove language related to the initial transition of Siluriformes fish to FSIS jurisdiction and to remove the requirement that each shipment of fish that is offered for import into the United States must be accompanied by a paper import inspection application.
- B. In this directive, the term "fish" refers to fish of the order Siluriformes and products derived from these fish.

#### KEY POINTS

Fish are amenable to the Federal Meat Inspection Act (FMIA)

- As such, the import directives that apply to meat also apply to fish
- IPP are to conduct the product examination (PE) type of inspection (TOI) and other TOIs applicable to fish according to instructions provided in this directive
- Specific instruction for residue and speciation sampling is described in <u>FSIS Directive 14,100.1</u>, Siluriformes Sampling at Import Establishments.

#### II. CANCELLATION

FSIS Directive 14,950.1, Inspection Program Personnel Responsibilities at Official Import Inspection Establishments that Receive Shipments of Siluriformes Fish and Fish Products, 8/24/17.

#### III. BACKGROUND

- A. Refer to <u>FSIS Directive 14,000.1</u>, Consumer Safety Inspector Responsibilities at Fish Establishments for general background information.
- B. FSIS began reinspecting all fish products exported to the United States on August 2, 2017.

DISTRIBUTION: Electronic OPI: OPPD

# CHAPTER II – APPLICATION, PRESENTATION, PRESTAMPING AND LABEL VERIFICATION OF IMPORTED FISH

#### I. IMPORT APPLICATION

IPP are to follow the instructions in <u>FSIS Directive 9900.4</u>, *Import Applications*, for the review, completion, or rejection of import applications, as appropriate, in the Public Health Information System (PHIS). FSIS Directive 9900.4 also provides instructions on how to proceed when errors or missing information are identified on a paper application or on an electronic application.

#### II. SHIPMENT PRESENTATION

IPP are to follow the instructions in <u>FSIS Directive 9900.1</u> *Imported Product Shipment Presentation* when performing a document review, monitoring a Failure to Present, and verifying the proper presentation of shipments of fish and fish products.

#### III. PRESTAMPING

IPP are to follow the instructions in <u>FSIS Directive 9900.3</u>, *Prestamping Imported Product*, on how to verify that the requirements and associated procedures for the prestamping of imported fish and fish products are met.

# IV. LABEL VERIFICATION

IPP are to follow the instructions in <u>FSIS Directive 9900.5</u>, *Label Verification of Imported Meat, Poultry, and Egg Products*, when conducting label verification procedures on imported fish and fish products.

**NOTE:** The term "catfish" applies exclusively to fish of the family Ictaluridae under the order of Siluriformes. All other fish species are restricted from being labeled as "catfish." Please refer to <u>FSIS</u> <u>Directive 14000.1</u> for guidance on speciation and acceptable common or usual names for fish of the order Siluriformes.

#### **CHAPTER III - PE TOI**

#### I. GENERAL

- A. PE TOIs are conducted to identify defects such as filth, mold, extraneous materials (e.g., wood, glass, chemicals, or insects), stains, and off-condition that assist with determining the wholesomeness of a product. The defects are classified either as a public health (PH) concern or as an other consumer protection (OCP) concern (e.g., certain labeling, presence of fins).
- B. IPP are to follow the instructions in <u>FSIS Directive 9900.2</u>, *Import Reinspection of Meat, Poultry, and Egg Products*, Part IV when prioritizing reinspection.
- C. Once a shipment is presented, and a PE TOI is assigned by PHIS, IPP are to have the establishment remove the sample units from the container; and, if frozen, temper the product until just thawed. IPP are then to examine the products.

**NOTE:** When PHIS is not available, IPP are to refer to <u>FSIS Directive 9500.1</u>, Contingency Plan for Import Reinspections When the Public Health Information System (PHIS) is Not Available.

#### II. SAMPLE UNITS FOR PE TOI

A. IPP are to use Table 1: Sampling Plans, when determining the sample unit weight and sample unit size. The sample unit weight and sample unit size are not contingent on lot size (count), or weight. (e.g., if the shipment is 1 carton or 10,000 cartons [any weight], the sample unit weight, and number of samples, identified in Table 1, remains the same).

- B. Sample units will fall into one of two categories:
  - 1. Category 1: Single-ingredient fresh/frozen raw fish, and further processed fish; or
  - 2. Category 2: Multi-ingredient fresh/frozen raw fish (including raw intact fish with added solutions), and further processed fish

**TABLE 1: SAMPLING PLANS** 

		Category 1		Category 2	
		Number of S	Samples	Number of	Samples
Lot Size (pounds)	Sample Unit Weight	Any shipping container that does not contain fully labeled immediate containers (e.g., bulk packed filets)	Product packaged in fully labeled immediate containers > 3 lbs.	Any shipping container that does not contain fully labeled immediate containers (e.g., bulk packed fish sticks)	Product packaged in fully labeled immediate containers > 3 lbs.
No Limit	Minimum 1 pound	12	9	18	12

**EXAMPLE:** If frozen fish filets (Category 1) are staged in bulk 20-pound shatterpack boxes (box of frozen fish or fish filets separated by interleaved polyethylene sheets), the official number of selected units is 12 boxes. The import establishment is then to collect a 1-pound random sample from each of the 12 boxes in a sanitary manner suitable to FSIS.

**EXAMPLE:** If boxes with two 5-pound bags of fully labeled frozen heat treated fish sticks with multiple ingredients (Category 2) are staged, the official number of selected units is 12 boxes. The import establishment would remove one 5-pound bag from each box, and then collect a 1-pound random sample from each bag in a sanitary manner suitable to FSIS.

#### III. SELECTION AND SECURING OF SAMPLES FOR PE TOI

- A. Selecting samples IPP are to follow the procedures below when selecting samples from a staged lot:
  - 1. Generate random numbers based on the number of samples that are needed;
  - 2. Select the containers that match each random number; and
  - 3. Ensure selected units are numbered, and that each corresponding sample is identified with the same number as the unit the sample was taken from.

- B. Securing samples for PE TOI IPP are to follow the procedures below when securing samples:
  - 1. Ensure that sample security for FSIS samples is maintained from the time they are identified for removal from the lot until the reinspection is completed;
  - 2. Identify each sample container with "USDA Official Import Sample";



- 3. Ensure sample units can be associated with their original container, when applicable;
- 4. Ensure samples are handled in a manner that will not result in cross-contamination with meat, poultry, egg products, or other lots of exposed fish; and
- 5. Handle exposed sample units in a sanitary manner.

#### IV. REMOVAL OF SAMPLES FOR PE TOI

A. IPP are to ask official import inspection establishment personnel to remove the product samples (Table 1) from the container. This should be achieved in a sanitary and timely manner. It may be necessary to cut with a saw, partially temper, or completely defrost the samples to examine internal and cut surfaces during the examination.

- B. The product sample is to be taken using a random, non-biased selection as follows:
  - 1. When product falls into Category 1, select the appropriate number of samples according to Table 1 (e.g., if the 12 selected units are 20-pound solid blocks of frozen fish, the import establishment is to remove 1 pound of product from each 20-pound block. The 1-pound sample should be taken from random locations within each of the 12 blocks that were selected. If the selected units are 4-pound fully labeled bags of individually quick frozen (IQF) filets, remove 1 pound from each of the nine units that are selected); or
  - 2. When product falls into Category 2, select the appropriate number of samples according to Table 1 (e.g., If the product is in 12 oz. cans, take sufficient number of cans as the selected units to equal or exceed 1-pound for each of the 18 samples. If the product is in 4-pound fully labeled boxes of fish sticks, remove 1 pound of the fish sticks from each of the twelve 4-pound units that were selected so that you have twelve 1-pound samples).

# V. DEFROSTING SAMPLES FOR PE TOI

- A. Samples are to be tempered in a rapid and efficient manner only to a point that allows for examination of outside surface of the product.
- B. Temper frozen intact fish (e.g., whole fish, filets, loins, chunks, and blocks), and breaded fish products by:
  - 1. Placing the product in bags, sealing the bags, running tap water over the bags until just thawed; or

- 2. Placing the product in bags, and then placing into tubs of water at room temperature until just thawed. Unlike meat, warm water immersion may cook fish products, so room temperature or cooler water is recommended.
- C. IPP are to examine the samples as soon as the outside surface is exposed through tempering, or the outside glaze is removed.
- D. Raw fish products have a high risk of spoilage, so applicable samples need to be immediately examined for off-condition before any other TOI is performed.
- E. Fish samples used for the actual examination are to be discarded after the product exam is complete, unless the sample is being saved for training purposes.
- F. Do not use samples from the product exam to submit for laboratory analysis. Laboratory samples must be collected aseptically.

# VI. PRESENTING SAMPLES FOR PE TOI

IPP are to ask official import inspection establishment personnel to:

- 1. Remove the sample from the container and place it on a dry sanitary surface with adequate space for the product to be spread out so a thorough examination can be conducted; or
- 2. Remove the sample from the packaging if the product is packaged (e.g., individually vacuum packaged portions, boxes of fish sticks), and then present the packaging with the sample on a sanitary surface for examination.

# VII. INSPECTING SAMPLES, IDENTIFYING DEFECTS, AND RECORDING RESULTS

- A. When inspecting samples, IPP are to:
  - Spread the sample out on a sanitary surface and examine the product for color, foreign material, off condition, and other defects. Inspect each sample for external defects before inspecting it for off condition.
  - 2. Once samples have been examined for external defects and any findings documented, break the flesh of the product and smell close to the nose to detect any putrid or foul odors indicating off condition. This may require breaking the unit in more than one location to make a final decision. IPP are to wash hands, or change gloves, between samples when off-condition odors are detected. This will prevent cross contamination from sample to sample.
  - 3. Samples used for the examination from passed lots are to be discarded in an inedible container unless defects are identified. The remainder of the fish from the sample container not selected for the examination is to be returned to the lot.
  - 4. For whole fish (e.g., fresh or frozen, individually wrapped, shatterpack boxes or vacuum packed, without any coating):
    - a. Examine all the inside and outside portions and surfaces of the product samples;
    - b. Examine the body cavity of the fish; and

c. Smell for possible off-condition odor.

**NOTE**: If the product is whole, ungutted fish, IPP are only to inspect the external surfaces of the fish.

- 5. For fish filets, steaks, loins, strips, chunks (e.g., fresh or frozen, individually wrapped vacuum packed or in shatterpack boxes, without any coating):
  - a. Examine all external, internal, and cut surfaces of the product samples; and
  - b. Smell for possible off-condition odor.
- 6. For fish blocks (e.g., fresh or frozen blocks that are uniformly shaped masses of cohering fish filets or a mixture of filets, pieces, and minced fish flesh, or entirely minced fish flesh intended for further processing):
  - a. Examine all external, internal, and cut surfaces of the product samples; and
  - b. Smell for possible off-condition odor.

**NOTE:** Frozen fish are much less likely to have an off-condition odor even if the product is off-condition. Consequently, frozen product may need to be gently thawed for any off-condition to be evident.

- 7. For breaded fish products, (e.g., fish sticks, patties or any irregular-shaped pieces of fish, similar to a long, thin filet, breaded or battered, raw or heat treated, or pre-cooked, usually machine cut from fish block, then coated and fried):
  - a. Examine all external, internal, and cut surfaces of the product samples;
  - b. Make at least one lengthwise cut to look for possible defects; and
  - c. Smell for possible off-condition odor.
- 8. For canned fish products (e.g., catfish, catfish with added ingredients), request that import establishment personnel remove the sample from the container and place it on a sanitary surface adequate to spread the product out for thorough examination:
  - a. Spread out the product to observe for defects;
  - b. Observe the inside of the can or package for possible defects; and
  - c. Smell for possible off-condition odor.
- B. When identifying defects IPP are to:
  - Remove sample defects from the applicable sample unit; and select defect classification Physical Examination 3 (PE3) in PHIS when conducting reinspection of imported fish. Only classify the "TYPE" of defect using the criteria in <u>Attachment 1</u>: Product Examination 3 (PE3) (Modified For Siluriformes Fish);
  - 2. Only classify a defect in PHIS under the appropriate "Type" if it meets the criteria established in the modified table;

- 3. Discard defects from passed lots in an inedible container; and
- 4. Keep defects from a TOI entered as "Fail" under FSIS control and keep refrigerated or frozen until the final disposition of the lot.

**NOTE:** The district office may request defects be held for training or correlation purposes. Off-condition fish should be frozen in order to be effectively used (after thawing) for training or correlation purposes. Frozen off-condition product should be used fairly soon after freezing for such purposes.

- C. When Recording Results ("Pass" or "Fail" Criteria), IPP are to:
  - 1. Use Attachment 1: Product Examination 3 (PE3) (Modified For Siluriformes Fish) to classify defects.
  - 2. Record all PH defects in PHIS and ensure that the TOI result selected is "Fail." IPP are to describe the defect details clearly and accurately size, color, texture, dimension, smell (if applicable), and any other details necessary to clearly describe their observation. IPP are to refuse entry on the lot.

**NOTE:** These descriptions are the official record of the defect and, in the case of a failed TOI; they are used as the official description of the issue conveyed to the foreign government. Therefore, it is essential that these descriptions are as detailed as possible.

- 3. Record all OCP defects in PHIS. The OCP defects may or may not result in a failed TOI. These defects should be described in detail as referenced above in the free text section of the TOI defect table in PHIS.
- D. Once IPP reinspect all samples, they are to consider additional criteria when determining if an OCP defect should result in a "Pass" or "Fail" TOI. Additional criteria may include, but are not limited to:
  - 1. Does the number, type, and/or size of defects affect the safety of the product?
  - 2. Are defects severe or numerous enough to affect the usability of the product?
  - 3. If limited to one sample unit, after that carton and/or the defect itself is condemned, is there any additional evidence that the remainder of the lot is adulterated or misbranded? If not, safety and usability would not be affected once the defect and/or its carton are condemned.
- E. IPP are to record all OCP defects in PHIS. An OCP defect may result in a failed TOI. IPP are to consult with their frontline supervisor (FLS) prior to recording a failed TOI for an OCP in PHIS. The rate of non-compliance and the effect on the usability of the product is to be considered when making decisions to fail a TOI based on the observation of an OCP defect. Additionally, IPP are to determine, based on product examination, whether the defect is an isolated occurrence (e.g., a one-time occurrence in the samples examined or one that is widespread), and whether the defect results in misbranded product or product that cannot be further processed or consumed.
- F. IPP are to follow instructions in <u>FSIS Directive 9900.8</u>, *Meat, Poultry, and Egg Products Refused Entry into the United States* for controlling, monitoring, and disposing of any refused entry product.

# CHAPTER IV - CONDITION OF CONTAINER, NET WEIGHT, AND LABORATORY TOI

# I. CONDITION OF CONTAINER TO

- A. IPP should only conduct a condition of container TOI for shipments of imported fish and fish products in rigid metal or glass containers, semi-rigid containers that have double seams, and retorted pouches and trays.
- B. When PHIS assigns a condition of container TOI, IPP are to follow the instructions provided in <u>FSIS</u> <u>Directive 9900.2</u>.
- C. If a shipment fails the condition of container TOI, IPP are to follow the instructions in <u>FSIS Directive</u> <u>9900.8</u> for refused entry instructions.

# **II. NET WEIGHT TOI**

When PHIS assigns a Net Weight TOI, IPP are to follow the instructions provided in <u>FSIS</u> <u>Directive 9900.2</u>, Part XVIII when conducting a net weight reinspection.

# III. LABORATORY SAMPLING TOI

IPP are to follow the instructions in <u>FSIS Directive 14,100.1</u>, *Siluriformes Sampling at Import Establishments*, to sample fish at official import inspection establishments for residue, speciation, and IMVRTE when sampling TOIs are assigned through PHIS.

# CHAPTER V - COMPLETING DATA ENTRY, HANDLING REFUSED ENTRY, SUPERVISORY RESPONSIBILITIES

#### I. DATA ENTRY

A. After all pending TOIs are completed and found to be acceptable, IPP are to document the disposition in PHIS and release acceptable units to close out the lot.

#### B. IPP are to:

- 1. Enter all findings and results into PHIS;
- 2. Ensure that all of the information necessary to complete the assignment is entered into PHIS;
- 3. Ensure that the assignment is properly completed and closed in the system;
- 4. Follow the instructions in FSIS Directive 9900.8 for all refused entry instructions; and
- 5. Consult their FLS regarding any problems with data entry or questions related to completing data entry and closing the case file.
- C. Case File: IPP are to retain all documents related to a specific inspection event in a case file. This would include any documentation provided by the establishment to initiate the inspection, any documents or notes generated by IPP during performance of the inspection, any documentation provided by the establishment or applicant regarding appeals, any documentation regarding refused entry extensions and dispositions, and any additional documentation or correspondence requested by their immediate supervisor. Case files should be filed by country and certificate number and retained under FSIS control in accordance with FSIS Directive 2620.1, FSIS Records Management Program.

#### II. REFUSED ENTRY

- A. IPP are to follow the refused entry instructions in <u>FSIS Directive 9900.8</u> and seek assistance from their respective FLS for disposition of the lot.
- B. IPP are to ensure that the product containers for refused product are identified with the "United States Refused Entry" stamp, and are to monitor the disposition of the refused product as set out in <u>FSIS Directive</u> 9900.8.

# III. SUPERVISORY RESPONSIBILITIES

- A. Supervisory personnel are to assist IPP with any issues raised regarding documentation, e.g., foreign inspection certificates, and reinspection of imported fish.
- B. Supervisory personnel are to ensure that IPP make informed decisions consistent with statutory authority, properly document their findings, and take the appropriate actions to prevent adulterated and misbranded fish product from entering commerce.

# **CHAPTER VI - APPEALS**

- A. FSIS regulations in <u>9 CFR 557.24</u> provide that the importer of record, owner or their representative of imported product may appeal any inspection decision or action, including a failed TOI. Appeals are to be made to the program employee's immediate supervisor having responsibility over the subject matter of the appeal. Initial appeals of an applicable decision or action, as well as subsequent appeals of denied appeals through final Agency action, must be made within 30 calendar days after receipt of written notification of the contested decision or action.
- B. Supervisors may receive appeals orally or in writing.
- C. The following outlines the chain-of-command for appeal decisions:
  - 1. Immediate Supervisor;
  - 2. District Manager/Deputy District Manager;
  - 3. Executive Associate for Regulatory Operations;
  - 4. Deputy Assistant Administrator for Office of Field Operations/Assistant Administrator for Office of Field Operations; and
  - Administrator for FSIS.

# **CHAPTER VII - QUESTIONS**

Refer questions regarding this directive to your supervisor or the Office of Policy and Program Development through <u>askFSIS</u> or by telephone at 1-800-233-3935. When submitting a question, complete the <u>web form</u> and select Import for the Inquiry Type.

**NOTE:** Refer to FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

Assistant Administrator

Office of Policy and Program Development

# **DEFECT CLASSIFICATION - INSPECTION**

IPP are to select defect classification PE3 in PHIS when conducting reinspection of imported Siluriformes fish. However, when recording defects, IPP should only classify the "TYPE" of defect using the criteria below.

# PRODUCT EXAMINATION 3 (PE3) (MODIFIED FOR SILURIFORMES)

# DEFECT CRITERIA FOR GROUND, COMMINUTED, PROCESSED, IQF, CANNED OR PACKAGED FISH OF THE ORDER SILURIFORMES

3A. Food Safety or Public Health (PH) Defects					
TYPE	DESCRIPTION	CODE			
OFF CONDITION	Zero Tolerance				
	Spoiled - Fish that has an offensive or objectionable odor, color, texture.				
	<b>Fecal</b> - Aroma associated with feces. Sometimes found in very advanced spoilage of seafood.				
	<b>Moldy/Musty</b> - Aroma associated with moldy cheese or bread, or a wet moldy basement, dank cellar				
	Off odor - Atypical (usually unpleasant) characteristics often associated with				
	deterioration or transformation of a product. Off odors, most often linger in the nose				
	<b>Putrid/Sour</b> - Aroma associated with decayed, rotting meat. Aroma is lingering and often gives a heavy, cloying nose and throat feel.				
	Rancid - Odor or flavor associated with rancid oil.				
	Slimy - A fluid substance, which is viscous, slick, elastic, gummy, or jelly-like.				
OTHER CHEMICAL OR PHYSICAL HAZARDS	An amount of any substance or material capable of causing injury or illness (e.g., poisonous ortoxic chemicals, pieces of metal, glass, hard plastic, wood); or unidentifiable foreign material of size rendering the product unwholesome.	PH			
OTHER HARMFUL	An amount of the following that renders the product unwholesome:	PH			
MATERIAL OR CONDITIONS	Large insects, insects associated with insanitary conditions, or evidence of rodent activity; and				
	Defects of a number or size seriously affecting product usability (e.g., large numbers of bones in a boneless fish stick).				
BB. Other Consumer	Protection (OCP) Defects				
TYPE	DESCRIPTION	CODE			
OTHER	Defects of a number or size affecting product usability.	OCP			
	Skin - Attached skin on a product that is labeled as skinless.  Viscera - improper removal of viscera, kidney, reproductive organs.  Fins - presence of fins, pieces of fins or dorsal spines except in headed and gutted, or headed and dressed, or Siluriformes fish steaks.				