

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

FSIS DIRECTIVE

14,000.2

4/2/19

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

I. PURPOSE

A. This directive provides instructions to the Office of Investigation, Enforcement, and Audit's (OIEA) Enforcement and Litigation Division (ELD) on how to conduct a compliance background inquiry on applicants for Grants of Inspection (GOIs) for Siluriformes fish and fish products. It also provides instructions to OIEA Compliance and Investigations Division (CID) personnel on how to conduct surveillance and investigations at warehouses, distributors, transporters, retailers, ports of entry, and other in-commerce businesses that handle Siluriformes fish and fish products. The instructions in this directive were previously issued in FSIS Notice 11-18.

B. In this directive, the term "fish" refers to fish of the order Siluriformes and products derived from these fish. Examples of acceptable common or usual names that would need to be on the label of fish subject to FSIS inspection can be found in [FSIS Directive 14,000.1, Consumer Safety Inspectors Responsibilities at Fish \(of the Order Siluriformes\) Establishments](#). More examples of acceptable common or usual names can be found in the U.S. Food and Drug Administration's (FDA) "Guidance for Industry: The Seafood List--FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce," <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm113260.htm> and 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](#)). 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 an amenable species 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. For fish products, as with other meat products, the requirements for mandatory FSIS inspection do not apply to operations of the type traditionally and usually conducted at retail stores and restaurants when those operations are conducted at any retail store or restaurant for sale in normal retail quantities (21 U.S.C. 661(c)(2)). Significantly, the retail store exemption for fish includes the slaughter of wholesome fish at retail stores or restaurants for consumers who purchase the fish at those facilities and in accordance with the consumers' request (9 CFR 532.3). 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.

DISTRIBUTION: Electronic

OPI: OPPD

C. 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)).

D. Persons, firms, or corporations engaged in business, in or for commerce, as a farmer; wholesaler; broker; transporter; renderer; animal food manufacturer; or public warehouse operator must register with FSIS using FSIS Form 5020-1, *Registration of Meat and Poultry Handlers* (9 CFR 550.5).

III. BACKGROUND INQUIRIES

A. Before an establishment may receive a GOI, ELD personnel are to conduct a compliance background inquiry of the applicant’s business and responsibly connected persons identified on the application. ELD personnel are to follow [FSIS PHIS Directive 5220.1](#), *Granting, Refusing, Voluntary Suspension or Voluntary Withdrawal of Federal Inspection Service*.

B. The Office of Field Operations (OFO) District Office may not proceed with processing the application for a GOI until the completion of the ELD evaluation and notification of the findings.

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*. However, CID investigators are only to visit fish transporters and farms for cause (e.g., in response to a violative test result for a sample collected within an official establishment).

B. When conducting investigations, CID investigators are to follow [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 chemical residue, an undeclared ingredient of public health concern, or other 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 may render it injurious to health;
5. Is offered for sale under the name “catfish” but does not contain fish of the family Ictaluridae; or
6. Is not eligible to be imported into the United States.

D. If CID 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

A. Environmental Samples

1. CID investigators may be directed by the Emergency Management Committee or OIEA Assistant Administrator to collect pond water samples or feed samples for cause (e.g., in response to a violative test result for a fish sample collected within an official establishment). CID investigators are to collect pond water samples from the pond where the positive violative residue product originated from, or if not available, a pond under the control of the same owner. CID investigators may also collect feed samples from the same lot that was fed to the fish, or if not available or unknown, feed from the same supplier.
2. CID investigators are to contact the Eastern Laboratory at least 72 hours prior to the day of sample collection to coordinate receipt of supplies. CID investigators can contact the Food Emergency Response Network (FERN) Coordinator at the Eastern Laboratory at 706-713-5898. Once samples are collected, CID investigators will submit the samples to the FERN laboratory designated on the shipping form.
3. CID investigators are to:
 - i. Wash and sanitize their hands to the mid forearm. Some lotions and soaps will contain dyes that could potentially interfere with sample analyses. Wear sterile gloves on both hands when collecting a sample (refer to [FSIS Directive 10,250.1, Attachment 1](#) for instruction on the proper use of sterile disposable gloves);
 - ii. For Feed Collection:
 1. Open the sterile container and set aside. Use a sterile scoop;
 2. Aseptically collect 200 grams of feed using a sterile scoop. Place the feed in the sterile Whirl-Pak® bag;
 3. Shake the sample to the bottom and expel excess air from the sample collection bag. Fold over the top edge and secure it with the attached wire. Seal the Whirl-Pak® bag; and
 4. Place a small bar-code sticker over the junction between the bottle and cap, according to [FSIS Directive 7355.1, Use of Sample Seals for Laboratory Program Samples and Other Applications](#). Place the Whirl-Pak® bag into a non-sterile secondary zipper-lock bag and seal the bag.
 - iii. For Pond Water Collection:
 1. Aseptically collect 1 liter of pond water in a wide-mouth collection bottle. This may be achieved by using a sterile pitcher (beaker with a handle) to collect the water and aseptically transferring the water over to a wide-mouth collection bottle;
 2. Tightly cap the collection bottle and gently mix by rotating back and forth; and
 3. Place a small bar-code sticker over the junction between the bottle and cap, according to [FSIS Directive 7355.1](#). Place the collection bottle into a secondary zipper-lock bag and seal the bag.

VI. CID SAMPLE SUBMISSION RESPONSIBILITIES

A. To package and ship the sample, the CID investigator is to complete the following:

1. Place the absorbent pad on the bottom of the shipping container, then place the corrugated cardboard pad on top of the absorbent pad;
2. Follow the instructions in [FSIS Directive 7355.1](#) on using the FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A/2B) to ensure that sample integrity and identity are maintained;
3. Place all Whirl-Pak®-bagged samples and the wide-mouth collection in the shipping container on top of the corrugated cardboard;
4. Review the information on the pre-printed carrier billable stamp (i.e., FedEx billable stamp) provided with the sampling supplies and select the billable stamp with the laboratory name and address that corresponds to the FERN laboratory name and address printed on the FSIS sample form to ensure delivery of the sample to the correct FERN laboratory. Enter the return address information on the airbill;
5. Place the completed sample form and any unused sample seals in the shipping container;
6. Insert the foam plug and press down to minimize the space between the sample and foam plug. If the shipping container does not have a foam plug, place the insulated lid on the container. Do not overfill the shipping container;
7. Complete the information on the large bar-coded seal from the same FSIS Form 7355-2A/2B sample seal set, sign the seal, and affix the signed, large bar code seal across the seam of the closed sample box flap. For shipping containers with self-sticking closures, apply the large bar-coded seal to the closed inner flap of the box parallel to the edge of the closed flap. Then, close the outer flap over the seal and engage the self-sticking closures to secure the top;
8. Ensure that the carrier (i.e., FedEx) billable stamp placed on the shipping container matches the requesting laboratory listed as item 5 in the Collection Information block on the submission form. Affix the billable stamp to the shipping container and remove any old stamp receipts and shipping bar codes from the container; and
9. Ensure that the samples collected remain under FSIS control prior to pick up by the contract carrier.

B. The CID investigator is to check periodically LIMS-Direct for the status of the test results. LIMS-Direct reports test results upon completion of the sample analysis. The CID investigator can also access test results in the Public Health Information System through the Laboratory Sample data field on the Inspector Home page. If the FERN Laboratory discards a sample submitted, the CID investigator is to take appropriate action based on the reason for sample discard.

VI. QUESTIONS

Refer questions through supervisory channels.

A handwritten signature in black ink, reading "Salvatore J. Wagner". The signature is fluid and cursive, with the first name "Salvatore" written in a larger, more prominent script than the last name "J. Wagner".

Assistant Administrator
Office of Policy and Program Development