

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

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**FSIS DIRECTIVE**

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14,010.1

8/17/17

**SPECIATION, RESIDUE, AND *SALMONELLA* TESTING OF FISH OF THE ORDER SILURIFORMES FROM DOMESTIC ESTABLISHMENTS**

**NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL SEPTEMBER 1, 2017. INSPECTION PROGRAM PERSONNEL WHO COLLECT THESE SAMPLES ARE ALLOTTED 1 HOUR OFFICIAL TIME TO REVIEW THIS DIRECTIVE.**

**I. PURPOSE**

This directive provides instructions to inspection program personnel (IPP) for collecting and submitting samples of raw fish of the order Siluriformes (referred from here on as “fish”) for speciation, residue, and *Salmonella* testing. This directive also instructs IPP to refer to [FSIS Directive 10240.4](#), *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program* for sampling procedures of ready-to-eat (RTE) fish products under the RTEPROD\_RAND program.

**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 these fish 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. The final rule defines the term “catfish” to apply exclusively to fish of the family Ictaluridae under the order of Siluriformes. All other species of fish are restricted from being labeled as “catfish.” FSIS will conduct periodic sampling and testing for speciation of raw fish at official fish establishments to ensure the product is not misbranded.

C. FSIS will conduct periodic sampling and testing for chemical residues of raw fish at official fish establishments to ensure that the product is not adulterated. In addition, FSIS will conduct exploratory sampling and testing for *Salmonella* in raw fish.

D. RTE fish will be sampled for *Salmonella* and *Listeria monocytogenes* under the RTEPROD\_RAND program.

**III. GENERAL SAMPLING PROCEDURES**

A. IPP are to routinely update product volumes in the Public Health Information System (PHIS) to ensure that all information is accurate (see [FSIS Directive 5300.1](#), *Managing the Establishment Profile in the Public Health Information System*).

B. IPP are to not withhold the mark of inspection for raw fish pending acceptable FSIS test results for adulterants, including chemical residues, or species (See Part F below for RTE products). If, in the future, FSIS finds widespread non-compliance for adulterants or speciation, the Agency will issue instructions to IPP to withhold the mark until acceptable test results become available.

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**DISTRIBUTION:** Electronic

**OPI:** OPPD

C. Regarding lotting, establishments should define lots so that if a violative result is found for one lot, the product from another lot would not be implicated (multiple lots processed at the same time and in the same space).

**NOTE:** In the United States, farm raised fish are routinely grown in the same pond and later harvested as a single population for slaughter. Most residues are absorbed or ingested by these fish directly from the water or feed. 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, IPP 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. In addition, establishments may comingle fish from several ponds during production. If that is the case, then the fish from all ponds processed on that particular day could be implicated in the event of a violative residue.

D. Sampling project codes for raw fish are:

1. RES\_FI – Residue and Species testing (chemical analyses); and
2. EXP\_FI\_MIC01 – *Salmonella* testing (microbiological analysis).

E. For RTE fish, IPP are to follow the instructions in [FSIS Directive 10,240.4](#), Chapter I and IV for selecting, collecting, and submitting the samples. As with other RTE products, IPP are to withhold the mark of inspection until acceptable results are received. (See Part B above for raw products) If an establishment produces RTE meat, poultry, and fish products, IPP are to randomly select amongst the products, alternating between products with each sampling event in keeping with the definition of the RTEPROD\_RAND project.

#### **IV. ORDERING RAW FISH SAMPLING SUPPLIES**

A. IPP are to request sampling supplies for fish at least three business days before sampling is to begin. IPP are to follow the instructions provided in [FSIS Directive 13,000.2](#), *Performing Sampling Tasks in Official Establishments Using the Public Health Information System* for ordering sampling supplies through the PHIS.

B. IPP may also submit requests for sampling supplies via Outlook:

1. [SamplingSupplies-EasternLab@fsis.usda.gov](mailto:SamplingSupplies-EasternLab@fsis.usda.gov); or
2. [SamplingSupplies-WesternLab@fsis.usda.gov](mailto:SamplingSupplies-WesternLab@fsis.usda.gov).

C. IPP are to use the subject heading “Fish Sampling Supplies” in the email and include the establishment name and number, the project code (“RES\_FI” or “EXP\_FI\_MIC01”), the IPP’s contact name, establishment name, telephone number, and a list of the supplies needed.

#### **V. SELECTING RAW FISH SAMPLES**

A. Before collecting samples, IPP are to be familiar with random sampling, which may include the use of random number tables or using computer generated random numbers. There is a random-number generator available on FSIS computers (Start Menu → FSIS Applications → Tools → Random Number Generator). IPP are to randomly select a day, shift, and time within the sampling window after the sample collection date indicated. There needs to be an equal chance that sampling will occur during any particular shift.

B. IPP are to randomly select a product type to sample. If the establishment produces more than one fish product type (steaks, fillets, nuggets, etc.), then IPP are to alternate sampling of the product types during each paired sampling task to ensure that all products are collected throughout the sampling project.

C. IPP are to only sample raw single ingredient products. Non-intact (i.e., injected) and breaded products are excluded from sampling.

D. If the establishment is processing whole fish at the designated sampling time, IPP are to contact the laboratory (using the email addresses noted in Section IV. B. at least three business days before sampling) for additional guidance and sampling supplies.

E. Paired sample requests (one for microbiological analysis and one for chemical analyses) will appear as directed tasks on the establishment task list in PHIS. IPP are to follow the instructions provided in [FSIS Directive 13,000.2](#) for accepting, scheduling, and completing a directed sampling task using the PHIS.

1. IPP are to schedule both the microbiological sampling task and the chemical sampling task for the same day and for the same laboratory. IPP are to collect both samples on the same day, from the same product type, and are to submit them to the same laboratory in the same shipping container with their respective forms.
2. IPP are to follow the instructions provided in [FSIS Directive 13,000.2](#) to cancel the microbiological sampling task when the product is intended for use in RTE product or will receive another full lethality treatment at a federally inspected establishment only. The chemical sampling task must still be completed.
3. IPP are to also cancel both sampling tasks when the product does not bear a mark of inspection because it is processed under a retail exemption. Such product cannot be further processed within an official establishment.
4. In the event IPP receive a sampling task for a sampling program for which the establishment is not eligible, IPP are to indicate "Requested sample/product never slaughtered/produced" as the reason for canceling the task. IPP are to note that canceling a task and providing this justification does not ensure that IPP will not receive additional sampling tasks. If IPP receive a sampling task, and the establishment is not eligible for sampling, they are to review the establishment profile to make sure it is accurate and make necessary changes to correct the information in the profile.

## **VI. COLLECTING RAW FISH SAMPLES**

A. IPP are to notify official establishment management before collecting samples.

B. IPP are to sample raw, single ingredient fish products in their final package, whenever possible. IPP are 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. IPP are 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.

C. If the final package is greater than one pound, IPP are to request the establishment slack fill the two packages, each weighing one pound. IPP are to submit the two slack-filled bags in the two non-sterile one gallon bags (or larger secondary bags as needed).

D. If product is not available in the final package, IPP are to use aseptic technique to collect enough product to fill to the line of each fill-line closure bag for submitting these samples. Extraneous organisms from the environment, hands, clothing, sample containers, and sampling devices may lead to erroneous analytical results. Stringent requirements for microbiological analysis are necessary; therefore, use of aseptic sampling techniques and clean, sanitized equipment are of utmost importance. Stringent requirements are also imperative for chemical analysis as many dyes used in soaps and lotions contain residues, such as crystal violet, that could be inadvertently transferred to the sample. To ensure a successful sample collection and decrease the number of sample discards, IPP are 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 (refer to [FSIS Directive 10250.1](#), *Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products*, Appendix 1 for instructions on how to put on 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 the finished product stage as possible. IPP are to collect a sufficient amount of product to fill the two Whirl-Pak® bags up to the fill-line indicated on the bags. IPP are not to under fill or overfill the bags; and
4. Carefully squeeze out the air remaining in each Whirl-Pak® bag and tightly fold over the top of the bag at least four times, as trapped air and loose seals may lead to leakage. IPP are to fold over the side tabs to secure the folds in place and not tie the ends.

E. IPP are to sample a frozen product only if a non-frozen product is not available for sampling.

F. IPP are to complete the paired sampling tasks in PHIS. Specifically, IPP are to:

1. Follow the instructions provided in [FSIS Directive 13,000.2](#) for completing the sampling tasks using PHIS. Print a copy of the completed microbiological sampling form and the chemical sampling form from PHIS;
2. Enter all requested sample information in PHIS and complete the sample questionnaire;
3. When the sample data collection entry is completed; click the “Submit to Lab” button for both the microbiological sampling task and the chemical sampling task. Print both of the finalized forms, and sign both forms. PHIS will display a message stating that the sample collection information has been successfully submitted; and
4. Place both of 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.

G. It is highly recommended to ship the sample the same day it is collected. If the sample cannot be shipped the same day it is collected then the plant must provide a secure place with an acceptable locking device (USDA lock) for holding the samples in the refrigerator (fresh samples) or freezer (frozen samples) where the integrity of the sample can be maintained during storage.

## VII. SUBMITTING THE RAW FISH SAMPLES COLLECTED

A. IPP will receive a shipping container with sorting labels affixed to the exterior (“RES\_FI” and “EXP\_FI\_MIC01”) and one set of supplies as annotated below:

1. Two pairs of sterile gloves
2. Two, 24-ounce lined Whirl-Pak® bags
3. One, 2-gallon zipper lock bag, non-sterile
4. Sample seals
5. Absorbent pad
6. Cardboard separator
7. Gel coolant pack
8. 6” x 12” plastic sleeve for the printed/signed sample forms
9. Shipping container
10. FedEx preprinted air bills



B. IPP are to use only the shipping materials provided by the laboratory and refer to [FSIS Directive 7355.1](#), *Use of Sample Seals for Program Samples and Other Applications*, for complete instructions on the proper use of sample seals.

C. At least one (1) day prior to packing and shipping the sample, IPP are to pre-chill the shipping container in a refrigerator or freezer and place the gel coolant packs in the freezer.

D. On the day of sample shipping, IPP are to:

1. Retrieve the frozen gel coolant packs from the freezer and the pre-chilled shipping container;
2. Place the absorbent pad on the bottom of the shipping container;
3. Place all sample bags for a sample into a 2-gallon zipper lock bag, expel the excess air from the bag, and close the bag using the zipper lock closure. Apply the medium sized bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to the zipper lock bag. Place the sealed sample bag in the shipping container. Place the cardboard separator on top of the sample and then the frozen gel pack. When needed, place a second frozen gel coolant pack on top to ensure that the sample arrives at the laboratory at an acceptable temperature and will not be too warm;
4. Review the information on the pre-printed carrier shipping air bill (i.e., FedEx air bill) provided with the sampling supplies and select the air bill with the laboratory name and address that corresponds to the FSIS laboratory name and address printed on the FSIS sample form to ensure delivery of the sample to the correct FSIS laboratory. Enter the return address information on the air bill;

5. Ensure both the microbiological and chemical forms are in the plastic sleeve and placed inside the shipping container;
6. Insert the foam plug and press down to minimize the space between the foam plug and the gel pack and sample. If the shipping container does not have a foam plug, place the insulated lid on the container. Do not overfill the shipping container;

**NOTE:** Do not tape or wrap the samples or use any newspaper or similar material as packing material. Use of such materials may result in a sample discard by the laboratory.

7. Apply the FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A) to the inner flap of the shipping container as described in [FSIS Directive 7355.1](#). IPP are to close the box flaps so that the container closure system is secure. IPP are not to tape the box if there are tapeless closures;
8. Affix the carrier shipping air bill on the shipping container and remove any old stamp receipts and carrier 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.

### **VIII. REPORTING OF DATA**

IPP are 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. IPP 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, IPP are to take appropriate action based on the reason for sample discard. IPP are to provide a printed copy of the test results to the establishment management.

### **IX. FSIS ACTIONS AFTER A POSITIVE FSIS SAMPLING RESULT**

- A. Positive *Salmonella* sample results will not result in regulatory control actions for raw fish.
- B. If a product sample collected by IPP tests violative for chemical residues, all product in the sampled lot is considered adulterated.
- C. IPP are to refer to [FSIS Directive 10,800.1](#), *Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products*, Chapter 5, Section I, Part E, subsections a, b, and c, when citing Noncompliance Reports (NRs) for violative residues. IPP may also issue a NR under 9 CFR 539.2.
- D. If a product sample collected by IPP is determined not to be of the family Ictaluridae and is labeled as catfish, then IPP are to consider the fish misbranded and are to issue a NR under 9 CFR 531.1.
- E. If a RTE product tests positive for *Salmonella* or *Listeria monocytogenes*, the product will be considered adulterated. IPP are to refer to [FSIS Directive 10,240.4](#), Chapters V and VI for FSIS actions to take after receipt of a positive sample result and to verify product disposition.

## X. QUESTIONS

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

A handwritten signature in black ink that reads "Sabrina J. Wagner". The signature is written in a cursive style with a large, stylized initial 'S'.

Assistant Administrator  
Office of Policy and Program Development

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