

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

FSIS DIRECTIVE

14,010.1
Revision 2

1/17/25

SILURIFORMES SAMPLING IN DOMESTIC ESTABLISHMENTS

I. PURPOSE

This directive provides inspection program personnel (IPP) instructions at domestic establishments for collecting raw fish samples of the order Siluriformes (referred from here on as “fish”) for speciation and residue sampling. FSIS is reissuing this directive to account for recent changes to the ready-to-eat (RTE) sampling program (RTEPROD) that is used for RTE fish products.

II. CANCELLATION

FSIS Directive 14,010.1, Rev. 1, *Siluriformes Sampling in Domestic Establishments*, 10/3/22

III. BACKGROUND

- A. FSIS will conduct periodic sampling for chemical residues in raw fish at official fish establishments to ensure that the product is not adulterated.
- B. The final rule “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish” ([80 FR 75590](#); December 2, 2015) defines the term “catfish” to apply exclusively to fish of the family Ictaluridae under the order Siluriformes. All other fish species are restricted from being labeled as “catfish.” FSIS will conduct speciation verification of raw fish at official fish establishments to ensure the product is not misbranded. This sampling will be performed when IPP are not able to confirm the species based on visual inspection.
- C. FSIS will analyze RTE fish products for *Salmonella* and *Listeria monocytogenes* (Lm). IPP are to refer to [FSIS Directive 10,240.3, FSIS Ready-to-Eat Sampling Programs](#) for sampling procedures of RTE fish products under the RTEPROD program.

IV. SIGNIFICANT CHANGES

Changed RTEPROD_RAND to RTEPROD as the sampling program for RTE fish products.

V. 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:

1. Withhold the mark of inspection on raw, **wild-caught** fish pending acceptable FSIS residue results. FSIS data indicate that violative residues, in particular environmental contaminants, are more likely in wild-caught fish versus farm raised fish. IPP are not to withhold the mark of inspection pending FSIS speciation results.
2. Not withhold the mark of inspection for raw, **farm-raised** fish pending acceptable FSIS residue or speciation results. If, in the future, FSIS finds widespread noncompliance for residues or speciation in farm-raised fish, the Agency will issue additional instructions.

C. Regarding lotting, FSIS recommends establishments 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).

1. IPP are to be aware that it would be nearly impossible to support a lotting system in which **farm-raised** fish collected at the same time from the same pond are identified as separate lots. 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. In addition, if establishments comingle fish from several ponds, then the fish from all ponds processed on that day could be implicated in the event of a violative residue.
2. IPP are to be aware that an establishment may identify a single **wild-caught** fish as a lot. Wild fish are migratory. Fish may encounter residues in a river or stream other than where it was caught. Thus, fish collected from the same river at the same location may not necessarily have been exposed to the same residues.

D. Sampling project codes for raw fish are:

1. RES_FI – Siluriformes residue testing; and
2. CG_FISH – Collector-generated speciation testing.

D. Residue sampling tasks (RES_FI) will appear as directed tasks on the establishment's task list in PHIS. 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*, to schedule and complete a directed sampling task.

E. IPP are to be aware that FSIS assigns RES_FI sampling tasks randomly and not all establishments will receive a sampling task each month.

F. If 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. Sampling tasks are assigned according to the information IPP place in the establishment profile. IPP are to follow instructions in [FSIS Directive 5300.1](#) to maintain the establishment profile information.

G. As described in [FSIS Directive 14,000.1](#), *Consumer Safety Inspector Responsibilities at Fish Establishments*, IPP are to perform the PHIS Labeling – Product Standards task to determine whether the establishment accurately labels fish of the order Siluriformes at least once per quarter. IPP are to refer to [IPP Help](#) → [Catfish Basics](#) for visually identifying catfish as one of three species. If IPP are unable to

confirm the identity of the fish (i.e., not a whole fish, not one of the three species identified on IPP Help) at the time IPP perform the PHIS Labeling – Product Standards task, IPP are to assign a collector-generated sampling task (CG_FISH) and complete the sampling task for species verification. To schedule a collector-generated speciation sampling task, IPP are to:

The screenshot shows the PHIS Sample Management - Sample Collection interface. On the left, a sidebar menu lists various tasks: Establishment Profile, Coverage Assignments, Task Calendar, Inspection Verification, Sample Management (selected), Create Sampling Task (highlighted with a red circle), Check Lab Availability, Animal Disposition, Export, View Report, and APM. The main content area has a title bar 'Sample Management - Sample Collection' and a 'Generate a Sample' section. This section contains two dropdown menus: 'Establishment*' and 'Project Code*', both with 'Select One' options. A 'Save' button is located at the bottom right. A legend indicates '*' = Required.

1. Click on the Schedule Sampling Task link under the Sample Management tab;
2. Select the establishment; and
3. Select CG_FISH as the project code.
4. Select “Speciation” for the analysis name.

VI. ORDERING RAW FISH SAMPLING SUPPLIES

A. IPP are to request sampling supplies for fish at least 3 business days before sampling is to begin if they have not received sampling supplies. IPP are to follow the instructions provided in [FSIS Directive 13,000.2](#) for ordering sampling supplies through PHIS.

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

1. [FSIS - Sampling Supplies - Eastern Lab](#); or
2. [FSIS - Sampling Supplies - Western Lab](#).

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 “CG_FISH”), the IPP’s contact name, establishment name, and telephone number.

VII. 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. There needs to be an equal chance that sampling will occur during any shift.

- B. IPP are to randomly select a product type to sample. If the establishment produces more than one product type (steaks, fillets, nuggets, etc.), then IPP are to alternate product types during each sampling task to ensure that they collect all products throughout the sampling project.
- C. IPP are to only sample single-ingredient products for RES_FI and CG_FISH. IPP are not to sample multi-ingredient fish products, such as breaded or battered fish products.
- D. If the establishment only repackages or repackages the fish products and does not process fish, the product is not eligible for sampling.
- E. Secondary processors are not eligible for residue sampling. IPP are to only collect residues from primary processors that receive the live fish for processing.
- F. 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 VI. B.](#) at least 3 business days before sampling) for additional guidance and sampling supplies.

VIII. COLLECTING RAW FISH SAMPLES

- A. IPP are to notify official establishment management no more than 1 day 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 non-sterile bag provided in the sampling supplies. IPP are to collect the appropriate number of packaged products, so that a 1-pound sample is submitted.
- C. If the final package is greater than one pound, IPP are to request the establishment slack fill a package weighing one pound.
- D. If product is not available in the final package, IPP are to:
1. Fill a sterile Whirl-Pak® bag in a sanitary manner;
 2. Collect the sample after the establishment has applied all interventions and as close to the finished product stage as possible;
 3. Collect enough product to fill the Whirl-Pak® bag up to the fill-line indicated on the bag. IPP are not to underfill or overfill the bag; and
 4. Carefully squeeze out the air in the 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.

IX. SUBMITTING THE RAW FISH SAMPLES COLLECTED

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

1. Two pairs of gloves;
2. Two, 24-ounce lined Whirl-Pak® bags;
3. Two, 1-gallon zipper lock bag, non-sterile;
4. Sample seals;
5. Absorbent pad;
6. Cardboard separator;
7. Gel coolant pack(s);
8. Foam plug;
9. Two 6” x 12” plastic sleeve for the printed/signed sample forms;
10. Two FedEx preprinted air bills; and
11. Shipping container (M-20).



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. IPP are to ship the sample the same day as collection, if possible. If the sample cannot be shipped the same day of collection, the establishment must provide a secure place with an acceptable locking device (USDA lock) for holding the samples in the freezer where the integrity of the sample can be maintained during storage.

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

1. Retrieve the frozen gel coolant packs from the freezer and the shipping container;
2. Place the absorbent pad on the bottom of the shipping container;
3. Place the sample bag into a non-sterile zipper lock bag, expel the excess air from the bag, and close the bag using the zipper lock closure. Apply the small-sized, bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to the zipper lock bag in accordance with [FSIS Directive 7355.1](#);
4. Place the sealed sample bag in the shipping container on top of the absorbent pad;

5. Place the cardboard separator on top of the sample and then the frozen gel pack. When needed, place the sample between two cardboard pads and two frozen coolants to ensure that the sample arrives at the laboratory at an acceptable temperature;
6. Review the information on the pre-printed carrier shipping air bill (i.e., FedEx air bill) provided with the sampling supplies. Select the air bill with the laboratory name and address that corresponds to the laboratory name and address on the FSIS sample form to ensure delivery of the sample to the correct laboratory. Enter the return address information on the air bill;
7. Place the completed sample form and any unused sample seals inside the 6"x12" plastic bags provided and then place the bags inside the shipping container;
8. 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.

9. 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;
10. 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
11. Ensure that the samples collected remain under FSIS control prior to pick-up by the contract carrier.

X. REPORTING OF DATA

IPP are to periodically check PHIS for the status of the test results 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.

XI. FSIS ACTIONS AFTER AN UNACCEPTABLE FSIS SAMPLING RESULT

A. If a product sample collected by IPP tests violative for chemical residues, all product in the sampled lot is considered adulterated. If the product is no longer within the establishment's control, IPP are to notify the District Office through their supervisory channels.

B. 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 4, Section I when citing Noncompliance Reports (NRs) for violative residues. IPP may also issue an NR under [9 CFR 539.2](#).

C. If a product speciation sample is not of the family Ictaluridae and is labeled as catfish, then IPP are to consider the fish misbranded and are to issue an NR under [9 CFR 531.1](#). If the product is no longer within the establishment's control, IPP are to notify the District Office through their supervisory channels.

XII. QUESTIONS

Refer questions regarding this directive to your supervisor and if needed to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, complete the [web form](#) and select General Inspection Policy for the inquiry type.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink, appearing to read "Rachel A. Edelstein". The signature is fluid and cursive, with the first name "Rachel" being the most prominent part.

Assistant Administrator
Office of Policy and Program Development