FSIS DIRECTIVE 14,100.1 8/24/17

SPECIATION, RESIDUE, AND SALMONELLA TESTING OF FISH OF THE ORDER SILURIFORMES AT OFFICIAL IMPORT INSPECTION ESTABLISHMENTS

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

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) at Official Import Inspection Establishments (OIIE) on the sampling procedures of fish of the order Siluriformes (referred to here on as “fish”) for chemical residue, speciation, and Salmonella testing. This directive also instructs IPP to refer to FSIS Directive 9900.6, Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products for sampling procedures of ready-to-eat (RTE) fish products under the IMVRTE program, and provides instruction on the Third Party Hold/Test Type of Inspection (TOI).

II. CANCELLATION

FSIS Notice 40-17, Revised – Inspection Program Personnel Responsibilities at Official Import Inspection Establishments with a Siluriformes Grant of Inspection, 7/28/17

III. 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) that establishes a mandatory inspection program for these fish and for products derived from these fish, including imported fish products. The final rule explains that because these fish are amenable species under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(w)(2)), the new inspection program for these fish 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 Siluriformes. All other species of fish are restricted from being labeled as “catfish.”

C. FSIS will conduct sampling on raw fish products for chemical residues, speciation, and Salmonella at OIIEs that have a Grant of Inspection (GOI) for Siluriformes fish. This sampling and testing will be conducted to ensure that the product is not adulterated with violative chemical residues. It will also ensure the product is not misbranded based on species testing. In addition, FSIS will continue collecting data to monitor the presence of Salmonella in raw fish.

D. FSIS will conduct sampling on RTE fish products for Salmonella and Listeria monocytogenes (Lm) at OIIEs that have a GOI for Siluriformes fish. This sampling and testing will be conducted to ensure that the product is not adulterated.

E. As of August 2, 2017, all imported Siluriformes fish and fish products are subject to FSIS reinspection.

F. FSIS will sample harvested whole fish.

DISTRIBUTION: Electronic

OPI: OPPD
G. For additional guidance not provided in this directive (e.g., TOIs not performed, sample receipts, discards, positive and failed results), IPP are to refer to FSIS Directive 9900.6.

H. In the event of violative chemical residue findings in raw product, FSIS will require submission of third party analytical results and chemical independence rationale for all subsequent lots from the same foreign establishment as detailed in the Criteria for Chemical Independence of Siluriformes Production Lots. This requirement will replace the intensified level of reinspection until the foreign country is found equivalent.

IV. GENERAL SAMPLING POLICIES

A. FSIS will sample and analyze imported raw fish for chemical residues, species, and Salmonella when assigned by the Public Health Information System (PHIS). PHIS may assign one, two, or three laboratory sampling TOIs for raw products, with each chemical TOI being assigned to a specific laboratory. Shipping containers will contain two sets of supplies in the event PHIS assigns two or more TOIs at one time (e.g. PHIS assigns Fish, CHEM-EL and Fish, Micro, both of which can go to Eastern Laboratory in the same shipping container). IPP are to ensure that each sample is shipped to the corresponding laboratory, as annotated in the chart in Section C. below.

B. FSIS will analyze RTE products for Salmonella and Lm when assigned by PHIS. At this time, FSIS does not have a validated method for speciation or chemical residues in RTE fish products and, therefore, will not analyze RTE fish products for speciation or chemical residues.

C. PHIS will assign TOIs as listed below:

<table>
<thead>
<tr>
<th>TOI Name (Event)</th>
<th>Sampling Project Code</th>
<th>Product Type</th>
<th>Analysis</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish, CHEM-EL</td>
<td>IMPFISH_CH_E</td>
<td>Raw</td>
<td>MRM, Metals, Antifungal Dyes, and Speciation</td>
<td>Eastern Laboratory</td>
</tr>
<tr>
<td>Fish, CHEM-WL</td>
<td>IMPFISH_CH_W</td>
<td>Raw</td>
<td>Pesticides and Nitrofurans</td>
<td>Western Laboratory</td>
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<tr>
<td>Fish, Micro</td>
<td>IMPFISH_MI</td>
<td>Raw</td>
<td>Salmonella</td>
<td>Either Eastern or Western Laboratory (stated on sample form)</td>
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<tr>
<td>IMVRTE</td>
<td>IMVRTE</td>
<td>RTE</td>
<td>Salmonella, Lm</td>
<td>Either Eastern, Midwestern, or Western Laboratory (stated on sample form)</td>
</tr>
<tr>
<td>3rd Party Hold/Test</td>
<td>Not Applicable</td>
<td>All</td>
<td>Chemical residues</td>
<td>Not Applicable – Importer’s Responsibility</td>
</tr>
</tbody>
</table>

NOTE: The Third Party Hold/Test TOI is a pass/fail TOI that will be completed by Recall Management and Technical Analysis Division (RMTAD).

D. Raw fish samples submitted for Salmonella (TOI Fish, Micro) are not required to be held pending results, as this information is only being collected to inform future sampling plans for Salmonella in fish. Raw fish samples submitted for speciation and chemical residue analyses (TOI Fish, CHEM-EL and TOI Fish, CHEM-WL) are required to be held under the importer’s control until these laboratory results are received confirming the wholesomeness and labeling of the product. RTE samples submitted for Salmonella and Lm analyses (TOI IMVRTE) are required to be held under the importer’s control until laboratory results are received. Any lots assigned a laboratory TOI at the Intensified level should be held at the OIIE until the results are reported in accordance with FSIS Directive 9900.6, Chapter I, Section IV.
E. Each time IPP have a laboratory sample TOI assigned to a lot, they are to notify OIIE management, and ask whether the importer will be holding the lot on-site at the OIIE or off-site under the importer’s control. When product is held off-site, the importer is to provide the name and address of the off-site location in writing to IPP, and IPP are to add this information to the questionnaire when applicable and attach this information to the case file. IPP are to follow the guidance in **FSIS Directive 9900.6**.

V. ORDERING SAMPLING SUPPLIES

A. IPP at an OIIE with a GOI for Siluriformes fish are to request sample collection supplies in advance, so they will be readily available when needed.

B. 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 PHIS.

C. For raw fish samples, IPP are to request enough sampling supplies in the event that TOIs for both the Eastern Laboratory and Western Laboratory are assigned to the same lot.

D. For RTE fish samples, IPP are to request one set of sampling supplies from the laboratory designated in PHIS.

E. If the establishment receives whole fish between 8 and 13 inches long, include in the comment section that larger bags and shipping containers are needed for the collection of whole fish.

F. IPP may also submit requests for sampling supplies via Outlook:
   - **FSIS - Sampling Supplies - Midwestern Lab** (only available for RTE, not raw fish);
   - **FSIS - Sampling Supplies - Eastern Lab;** or
   - **FSIS - Sampling Supplies - Western Lab**.

G. IPP are to use the subject heading “Fish Sampling Supplies” in the email and include the establishment name and number, the project code (“IMPFISH_CH_E,” “IMPFISH_CH_W,” “IMPFISH_MI,” and “IMVRTE”), the IPP’s contact name, establishment name, telephone number, and a list of the supplies needed, and whether or not the establishment receives whole fish between 8 and 13 inches long.

H. If the establishment receives whole fish larger than 13 inches, IPP are to contact the labs to discuss which supplies are needed.

VI. SELECTING THE SAMPLE

A. For RTE fish products, IPP are to refer to **FSIS Directive 9900.6, Chapter III** for instructions on the selection, sampling, and submission of eligible products.

B. For raw fish products, IPP are to only sample intact products. For clarification, fish products that are still marinated (marinated by soaking) or tumbled without a vacuum are considered intact. IPP are not to sample non-intact fish products including those that have been injected or vacuum tumbled. In addition, IPP are not to collect breaded or battered fish products.

C. When PHIS assigns a laboratory TOI, IPP are to:

   1. Identify each shipping container selected as a sample with "USDA OFFICIAL IMPORT SAMPLE." When PHIS assigns a product exam in addition to laboratory TOIs, identify the carton or cartons
from which the laboratory sample was obtained by double stamping the carton or cartons with the sample stamp;

2. Collect samples from one single production code or date; and

3. Schedule the assigned laboratory sampling TOIs in PHIS:
   a. Click on the “Find Import Shipments” on the left navigation menu.

![Image of navigation menu]

b. Enter the application number into the “Application Number” field and click Search.

![Image of import reinspection form]

c. Click on the triangle to the left side of the data; then click on the arrow icon to the left of the Lot ID in the expanded field.

![Image of import reinspection form with data]

d. The list of assigned TOIs will appear. Click on the applicable TOI.
e. Click on “Sample Form” at the bottom of the page.

f. The screen will automatically display the “Generate a Sample” tab. Fill out all fields.

g. Select “Sample Collection Data.”
h. Fill out all aspects of the form including questionnaires on the “Additional Info” tab. Ensure the product code or production date is annotated on each sample form so in the case of a violative residue, the product can be properly dispositioned and identified to the foreign government for follow-up investigation. When completed, click on the print form at the top right of the page for each laboratory TOI assigned to the lot. Then click the submit button at the bottom of the page for each laboratory TOI assigned. IPP must sign all laboratory sampling forms.

i. IPP at OIEEs are to cancel the laboratory sample TOIs through PHIS when they determine that the product is ineligible (Section V. B. above). They are to select the most appropriate reason in PHIS for not performing the TOI.

D. If the product is a whole raw fish, (e.g. fish with organs still present), IPP are to collect fish that are between 8 and 13 inches, if available. If multiple sizes are present, IPP are to select the larger sizes as long as the fish is still less than 13 inches. If the fish is less than 8 inches or greater than 13 inches, IPP are to contact the laboratories to assess feasibility of sampling. Fish greater than 13 inches will require a
larger shipping container. It may be prohibitive for the laboratories to test fish smaller than 8 inches, depending on what supplies they have available.

VII. COLLECTING RAW SAMPLES

A. IPP are to sample fish products in their final package, whenever possible. IPP are to put the product (in its final packaging) in the non-sterile bag (one sample per bag) that is provided with the microbiology sampling supplies and the chemistry sampling supplies. IPP are to collect the appropriate number of final packaged products, so that one-pound samples are submitted for each TOI assigned by PHIS (one pound for microbiological testing; one pound for pesticides and nitrofurans; and one pound for Multi-Residue Method (MRM), metals, antifungal dyes and species testing). All samples must come from the same production code or date.

B. If product is not available in the final package, IPP are to use aseptic technique to collect enough product to fill to the line on each sterile Whirl-Pak® bag provided for submitting these samples. In general, extraneous organisms from the environment, hands, clothing, sample containers, and sampling devices may lead to erroneous analytical results. Stringent requirements for microbiological and chemical residue analyses (some inks and dyes contain residues and could interfere with the analysis) are necessary; therefore, use of aseptic sampling techniques and clean, sanitized equipment are of utmost importance. Do not collect a laboratory sample from the Product Exam 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, 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. IPP are to collect a sufficient amount of product to fill the sterile Whirl-Pak® bags up to the fill-line indicated on the bag. IPP are not to under fill or overfill the bags. It is not necessary to weigh the bags as filling the bags to the fill-line will approximate one pound; and

4. Carefully squeeze out the air remaining in each fill-line closure 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.

C. IPP are to ensure all TOIs in PHIS are complete by following the instructions in VI.C. above.

D. Place the corresponding sample form in the 6" x 12" plastic bag provided, ensuring that:

1. Samples destined for the Eastern Laboratory have the “IMPFISH_CH_E” sample form and the Eastern Laboratory FedEx preprinted air bill; and

2. Samples destined for the Western Laboratory have the “IMPFISH_CH_W” sample form and Western Laboratory FedEx preprinted air bill.

E. The Salmonella samples collected will rotate between the Eastern and Western Laboratories for testing. IPP are to submit the Salmonella samples to the laboratory indicated on the “IMPFISH_MI” sample form. There will be two separate shipping containers for IPP to submit the samples to the corresponding laboratory.
VIII. SUBMITTING THE SAMPLES COLLECTED

A. IPP will receive two shipping containers with sorting labels affixed to the exterior ("IMPFISH_CH_E" or "IMPFISH_CH_W" and with "IMPFISH_MI") and two sets of supplies (sufficient to cover three sampling events, in the event PHIS assigns all three TOIs at the same time) as annotated below:

1. Two pairs of sterile gloves;
2. Two sterile Whirl-Pak® bag;
3. Two non-sterile zipper lock bags;
4. Sample seals;
5. Absorbent pad;
6. Cardboard separator;
7. Gel coolant pack;
8. Foam plug;
9. Two, 6" x 12" plastic sleeve for the printed/signed sample forms;
10. FSIS Form 7355-2A/B;
11. Two FedEx preprinted air bills; and
12. Shipping container

B. For fillets, IPP are to use the M-20 shipping containers (medium size) and one-gallon zipper lock bags. For whole fish between 8 and 13 inches long, IPP are to use the M-54 shipping containers (large size) and larger zipper lock bags.

C. 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.
D. IPP are to store the sample shipping containers in the cooler or freezer area of the establishment and place the gel coolant packs in the freezer.

E. Samples should be shipped on the same day as collection, if possible. However, if the samples cannot be shipped on the same day as the collection, place the bagged samples in a secure refrigerator (if sample is fresh) or freezer, (if sample is frozen), until the samples can be shipped overnight on the next available shipping day.

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

1. Retrieve the frozen gel coolant packs from the freezer and the pre-chilled shipping containers;

2. Place one absorbent pad on the bottom of each shipping container;

3. Place each of the bagged samples into its own zipper lock bag, expel the excess air from each zipper lock bag, and close the bags using the zipper lock closure. Apply the medium sized bar-coded FSIS Laboratory Sample Identification Label (FSIS Form 7355-2B) to each zipper lock bag;

4. Place the sealed sample bags containing the sample in the corresponding shipping container on top of the absorbent pad. Ensure each shipping container has the correct number of samples destined for the corresponding laboratory as annotated on the sample form and on the FedEx air bill;

5. Place the corrugated cardboard pad on top of the sample(s) and then place the frozen gel coolant on top of the cardboard pad. When needed, place the sample(s) 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 FedEx air bills 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(s) to ensure delivery of the sample to the correct FSIS laboratory. Enter the return address information on the air bill;

7. Insert the foam plug and press down to minimize the space between the sample and foam plug. If the shipping containers do not have a foam plug, place the insulated lid on the containers. Do not overfill a 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.

8. 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;

9. Affix the carrier shipping air bill on the appropriate shipping container. Remove any old stamp receipts and carrier shipping bar codes from the container; and

10. Ensure that the samples collected remain under FSIS control prior to pick-up by the contract carrier.
 IX. THIRD PARTY HOLD/TEST LABORATORY SAMPLING

A. When laboratory violations significant to public health have been found, subsequent lots may be subjected to a Third Party Hold/Test in which the product is held until the importer or their representative has it tested through a third-party laboratory and provides the results and chemical independence rationale to FSIS and FSIS has reviewed the submission and made a decision on product disposition. The laboratory’s scope of accreditation must include methods that detect and confirm the compounds identified by FSIS in the Chemical Laboratory Guidebook, and results must be presented to the Agency’s headquarters component through an analytical package submission that shows the product is “not adulterated.” Importers are also required to submit a rationale sufficient to establish chemical independence of each subsequent lot from any previous violative lots as part of their analytical package. These packages will be reviewed by FSIS headquarters staff. IPP will not conduct sampling or complete this TOI.

B. When PHIS assigns the Third Party Hold/Test, IPP are to:

1. Notify OIIE management that the shipment is subject to Third Party Hold/Test requirements;

2. Perform all other assigned TOIs (e.g. LVP or product exam) and collect FSIS samples for any laboratory TOIs assigned by PHIS. After all TOIs are performed, IPP are to notify OIIE that Third Party Hold/Test process may begin;

NOTE: If PHIS assigns laboratory TOIs, third party sampling may commence immediately after FSIS selects and submits laboratory samples provided all other TOIs are completed.

3. Permit the OIIE to apply the mark of inspection to lots that will be moved off-site pending third party results provided the lots are held intact under the importer’s control as specified in FSIS Directive 9900.6, Chapter V, Section G; and

4. For product held off-site, include documentation (letter, email, etc.) in the case file noting the intended storage location prior to allowing the OIIE to apply the mark of inspection.

C. RMTAD will coordinate review of analytical packages with the Office Public Health Science (OPHS).

1. Upon completion of the review, RMTAD-Imports will complete the Third Party Hold/Test TOI in PHIS and notify the appropriate Frontline Supervisor (FLS) and the District Office (District Manager and Deputy District Managers) of the result and subsequent actions required, i.e., release or refuse entry. RMTAD will complete the refused entry notification, if applicable, and notify the applicant.

2. IPP will notify OIIE management of disposition: passed and released or refused entry.

3. If the shipment was also assigned other TOIs which have not been completed yet (e.g., FSIS laboratory results), IPP will not release the lot until all FSIS requirements have been met.

4. In the event product fails the Third Party Hold/Test, RMTAD will fail the TOI, issue a refused entry, and notify the FLS and the District Office (District Manager and Deputy District Managers). IPP will follow the procedures outlined in FSIS Directive 9900.6, Chapter I, Section V and Section VI.I.5 and Chapter VI, Section IV.A that covers lots that are held off-site.

X. REPORTING OF DATA

A. IPP are to report results in accordance with FSIS Directive 9900.6, Chapter 1, Section VI.I.
B. Speciation: The laboratories will only report speciation as violative in LIMS when product is labeled as “Catfish” and it is not from the family Ictaluridae. All other speciation results that indicate the fish tested are not the species reflected on the label (but not labeled as catfish) will be reported as “Indeterminate.”

C. Samples refused entry for speciation may be considered misbranded and can be brought into compliance in accordance with 9 CFR §557.13 and 9 CFR §327.13(a)(4). IPP are to follow FSIS Directive 9900.5, Label Verification of Imported Meat, Poultry, and Egg Products, Section V.C. when handling a refused entry for a Species TOI failure.

D. For reference, a list of requirements for imported Siluriformes fish can be found in 9 CFR §327 and 9 CFR §557.

E. Chemical Residue Analysis: For chemical residue test results reported as “Residue Detected – violative,” IPP are to refer to FSIS Directive 9900.6, Chapter 1, Section VI.I for instructions on reporting results and refer to FSIS Directive 9900.8, Meat, Poultry, and Egg Products Refused Entry into the United States (U.S.) for refused entry procedures.

F. Microbiological Analysis of Raw Fish: Positive Salmonella results in raw product will not result in a regulatory control action, or Failure in PHIS.

G. RTE Fish Products: IPP are to refer to FSIS Directive 9900.6, Chapter 1, Section VI.I for instructions on reporting results and refer to FSIS Directive 9900.8 for refused entry procedures.

H. For Passed (e.g., Negative, Not Detected) Laboratory Results, IPP are to release the lot.

XI. COMPLETING 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 PHIS; and

4. Consult their FLS regarding any problems with data entry or questions related to completing data entry and closing the case file.

XII. QUESTIONS

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

Assistant Administrator
Office of Policy and Program Development
<table>
<thead>
<tr>
<th>District</th>
<th>Primary Siluriformes Contact</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alameda</td>
<td>Amin, Abdalla - FSIS <a href="mailto:Abdalla.Amin@fsis.usda.gov">Abdalla.Amin@fsis.usda.gov</a></td>
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