Hold-and-Test Sampling Protocol for Shipments of Siluriformes Fish/Fish Products from Foreign Establishments that Export Product that Contains a Violative Chemical Residue(s) as Identified by FSIS Border Sampling and Testing

Under the Federal Meat Inspection Act and implementing regulations, the Food Safety and Inspection Service (FSIS) ensures that Siluriformes fish and fish products in foreign and domestic commerce are safe, wholesome, and not adulterated or misbranded. FSIS samples imported product, in part, for drug, pesticide, and other chemical residues to ensure that the products are safe, wholesome, and not adulterated. Drug, pesticide, or other chemical residues present at levels in excess of tolerances or action levels set by the Food and Drug Administration (FDA) or Environmental Protection Agency, or dyes or other residues not approved for use in amenable species including Siluriformes fish and fish products adulterate these products. During the transitional period, until full implementation of the Siluriformes fish and fish product inspection regulations which begins on September 1, 2017, FSIS is conducting random and targeted sampling and testing of both domestic and imported Siluriformes products, in part, for violative chemical residues.

In order to make the best use of available resources for sampling and testing during the transitional period and to ensure that the transitional process is as smooth and effective as possible for all parties, while still fulfilling our mission to protect public health, FSIS is following an interim policy (outlined below) specifically for imported products. During the transitional period, if imported Siluriformes fish and fish products are determined to be violative through testing for drugs, pesticides, dyes, metals, nitrofurans or other chemical residues that are not permitted for use or are found in excess of acceptable tolerance or action levels, FSIS will:

- Immediately notify the Central Competent Authority (CCA) – the agency or agencies responsible for food inspection – for the country in which the shipping establishment is located of the findings.
    - FSIS will expect a timely response from the CCA that ensures appropriate corrective actions are implemented.
- Immediately notify the United States importer of record responsible for the shipment, as well as all other known importers of Siluriformes fish products from the same foreign establishment. All subsequent entries from the shipping establishment will have to be held intact and not released into commerce until the importer of record has arranged to have the shipment sampled and tested through a third-party laboratory. 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 through an analytical package submission that shows the product is "not adulterated."
    - The importer of record will have to notify FSIS of the location of the shipments that are on hold. The location of the shipments may or may not be an official import inspection establishment ("I-house").
    - FSIS may elect to collect a sample from such shipments.
    - The importer of record should obtain and submit information about each shipment that provides the rationale as to why the shipment is chemically independent of the shipment found by FSIS to be positive for a chemical residue.
- Decide whether to permit entry of the subsequent shipments on the basis of the third-party private laboratory analytical results for the group or class of chemical residue found

by FSIS in other product from the same establishment. NOTE: Chemical residues can be segregated into five groups: pesticides, veterinary drugs, nitrofurans, dyes, and metals. FSIS further divides the pesticides and veterinary drugs by class.

- Have the importer of record submit the private laboratory analytical information packages along with the rationale for why the shipment is chemically independent of the shipment found by FSIS to be violative for a chemical residue to the Agency at importinspection@fsis.usda.gov for review. The Agency will review the packages and analytical results and decide whether the shipment should be released into commerce or refused entry, and whether FSIS will collect a sample from this shipment. At a minimum, laboratory packages should include:
    - Description of the product including identification and size of lot;
    - Rationale from the establishment to support why fish in this shipment are chemically independent from the violative lot from the same establishment (e.g., fish were sourced from a different supplier or pond);
    - Production dates for fish in the shipment;
    - Name and accreditation number of the private laboratory;
    - Type of analysis conducted;
    - Analytical method and results;
    - Details about how the sample was collected and integrity was maintained;
    - Details about sample preparation;
    - Standard data; and
    - Details about instrumentation used.

NOTE: The FDA's *Submission of Laboratory Packages by Accredited Laboratories* is the best available guidance on the quality and type of test data and information from accredited laboratories FSIS would expect to see in a laboratory package submission. Importers of record that follow the guidance in this document can be fairly certain that they would meet FSIS expectations when the package also includes the few FSIS-specific items bulleted above.

FSIS may pursue a recall action for any product with violative residues that is not destroyed or that is not returned to the exporting country intact. FSIS will also pursue a recall action for any product that enters commerce without submission of a laboratory package that contains test results and chemical independence rationale after the time in which the importer of record, and all other importers, has been notified of a FSIS-positive test result from the same establishment.

Once the CCA proffers adequate corrective measures that have been effectuated and a production date is assigned to fish from the establishment that is determined to be chemically independent of the fish in the shipment found by FSIS to be violative for a chemical residue, FSIS will notify the CCA and importers that shipments of fish produced on or after the implementation date for corrective actions are no longer subject to the hold-and-test sampling protocol defined in this communication for Siluriformes fish products.

Questions about this process should be submitted to importinspection@fsis.usda.gov.