

March 2, 2017

**To: USDA FSIS Docket Clerk, Washington, DC**  
Department of Agriculture  
Food Safety and Inspection Service Room  
2534 South Building  
1400 Independence Ave., SW  
Washington, DC 20250-3700

**Subject: PETITION REGARDING OVER SAMPLING OF IMPORTED CATFISH FOR RESIDUE TESTING**

**Request:** Bien Dong Seafood Company Limited, Lot II - 18B1, 18B2, Tranoc II Industrial Zone, Phuocthoi Ward, Omon District, Cantho City, Vietnam, is petitioning the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) to establish consistent regulatory Agency policy for residue sampling of all meat produced under the Federal Meat Inspection Act (FMIA), which includes catfish. This includes history based sample selection. The over-regulating of residue testing for imported catfish is being instituted above and beyond what is being conducted for domestic catfish and other meat products imported into the United States. Accordingly, Bien Dong Seafood is requesting immediate changes to FSIS' current policy of over sampling of imported catfish for residue testing. This petition is being submitted in accordance with FSIS regulations and the attached supporting documentation.

We appreciate your immediate attention to this matter.

Sincerely



Leonard Lang

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The sampling policies put in place for catfish go above and beyond what is done for imported meat?

9 CFR 557.6 - The electronic inspection system will be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

FSIS Directives referenced under the letter to foreign countries identifies that residue sampling will follow FSIS Directive 97. 17 6

None of the above are followed in the current Catfish residue-sampling program for imported products. Bien Dong Seafood is being over sampled. The number of samples selected by FSIS is more than any other foreign producer.

***Bien Dong Seafood has no prior violations related to chemical residues based on FSIS sampling. The sampling has been above and beyond what other companies with the same history have exhibited.***

***The sample regiment for normal sampling is based on a statistical random sample selection. Increased or intensified testing goes above and beyond the normal level of sampling. Bien Dong is being subjected to more samples for no public health reason.***

***Bien Dong Seafood is requesting that the policy for residue sampling be put forth as the regulation states; equivalent to imported meat. Random selection unless a public health issue is identified through the sampling.***

***We are petitioning the agency to allow for the equivalent regulation and policy to be put in place involving the treatment of imported catfish residue sampling.***

***Based on 9 CFR 392.5 c- Once a petition is submitted in accordance with this part, it will be filed by the FSIS Docket Clerk, stamped with the date of filing, and assigned a petition number. Once a petition has been filed, FSIS will notify the petitioner in writing and provide the petitioner with the number assigned to the petition and the Agency contact for the petition. The petition number should be referenced by the petitioner in all contacts with the Agency regarding the petition.***

Chemical compounds analyzed in the national residue program include approved and unapproved veterinary drugs, pesticides, and environmental compounds. The NRP is designed to: (1) provide a structured process for identifying and evaluating chemical compounds used in food animals; (2) analyze chemical compounds of concern; (3) collect, analyze, and report results; and, (4) identify the need for regulatory follow-up subsequent to the identification of violative levels of chemical residues. Bien Dong is requesting a response or update to the attached petition.

On December 2, 2015, FSIS published the final rule, "Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish." The 2008 Farm Bill amended the Federal Meat Inspection Act (FMIA), to make Siluriformes a species amendable to the FMIA and therefore, subject to FSIS inspection. FSIS is providing an 18-month transitional period for the inspection of Siluriformes and

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the residue testing will be done based on parameters set forth in the final rule. During the first 18 months FSIS, will schedule routine testing of Siluriformes for malachite green, nitrofurans, veterinary drugs, gentian violet, metals, and pesticides residues. FSIS plans to take at least one sample per month per domestic slaughter establishment. FSIS plans to sample every import shipment that is scheduled for re-inspection.

**21 U.S.C.**

**United States Code, 2014 Edition**

**Title 21 - FOOD AND DRUGS**

**CHAPTER 12 - MEAT INSPECTION**

**SUBCHAPTER I - INSPECTION REQUIREMENTS; ADULTERATION AND MISBRANDING**

**Sec. 620 - Imports**

*(g) Administration of animal drugs or antibiotics; terms and conditions; entry order violations  
The Secretary may prescribe terms and conditions under which amenable species that have been administered an animal drug or antibiotic banned for use in the United States may be imported for slaughter and human consumption. No person shall enter amenable species into the United States in violation of any order issued under this subsection by the Secretary.*

**FROM FINAL RULE- VII. Public Health Considerations:**

*FSIS proposed to conduct regular residue sampling, as it does for imported meat products, to ensure the safety of imported catfish products (9 CFR 557.6(a)(3)). 557.6 Fish and fish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.*

*(a) (1) Except as provided in §§ 557.16 and 557.17, all fish and fish products offered for entry from any foreign country shall be reinspected by a Program inspector before they shall be allowed entry into the United States.*

*(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance.*

*(3) The electronic inspection system will be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.*

*(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic system.*

**FSIS Directive 9900.6**

**<https://www.fsis.usda.gov/wps/wcm/connect/a7a9ec1b-5c67-46f3-932d-ce781bcbc494/9900.6.pdf?MOD=AJPERES>**

**IV. REINSPECTION CATEGORIES**

A. Assignment is the reinspection TOI for a specific lot of imported meat, poultry or egg products.

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B. Level of Reinspection (LOR) is the intensity of reinspection assigned for an imported lot based on the compliance history of the foreign establishment and the country for a specific TOI and product. TOIs are assigned at one of three levels:

1. Normal is a LOR where randomly selected lots are assigned TOIs based on the FSIS annual sampling plan. Under normal level of sampling, the importer of record (IOR) is required to maintain control of product tested for adulterants by FSIS and is not to allow such product to enter commerce unless and until negative results are received;

2. Increased is a LOR above the normal level that is directed by a FSIS management decision. Under increased reinspection, FSIS may hold, on a case-by-case basis, lots of imported meat, poultry, or egg products pending receipt of a laboratory analysis. If FSIS does not place the product on hold, the importer of record is still required to hold product tested for adulterants by FSIS and is not to allow such product to enter commerce unless and until negative results are received; or

3. Intensified is a LOR that is implemented automatically by PHIS when a TOI is reported as "Fail." Under intensified reinspection, FSIS holds the sampled lot at the official import inspection establishment pending receipt of laboratory analysis. The sampled lot is not allowed to move offsite to be held.

#### **Letter to Siluriforme Importers**

<https://www.fsis.usda.gov/wps/wcm/connect/23e4b97e-ac59-4728-b1ab-b994ea23cf3b/Letter-Siluriformes-Importer-Broker.pdf?MOD=AJPERES>

Shipments of Siluriformes fish and fish products selected for reinspection will be subject to sampling and analysis by FSIS. Sample analyses will include tests for species, chemical residues, and Salmonella. With the exception of imported Siluriformes fish or fish products that FSIS tests for Salmonella, FSIS will withhold the mark of inspection for product that FSIS reinspects, samples, and tests until acceptable results are received by the importer from FSIS, as per the procedures in FSIS Directive 9900.6 Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products.

In performing import sampling and analysis, if FSIS finds adulterated Siluriformes fish and fish products (e.g., fish that contains a violative residue or that have been held under insanitary conditions that result in direct product contamination), or if it finds misbranded products (e.g., products labeled "Catfish" which do not contain fish of the family Ictaluridae), the products will be refused entry. NOTE: The new regulations permit the use of the term "catfish" only on labels of fish classified within the family Ictaluridae (9 CFR 541.7(d)(2)). For reference, Attachment 3 of this letter provides a list of acceptable common or usual names for fish in the order Siluriformes.

#### **Notice 24-16 Import Sampling**

<https://www.fsis.usda.gov/wps/wcm/connect/69b5e2bd-1b16-4a74-9e95-4a327943fabb/24-16.pdf?MOD=AJPERES>

#### **CHAPTER V - LABORATORY SAMPLING TOI**

I. GENERAL A. FSIS will conduct sampling for chemical residues speciation, and Salmonella, at OIIEs that have a GOI for Siluriformes fish. This sampling and testing will be conducted to ensure that the product is not adulterated due to the presence of illegal chemical residues; or, based on species testing, the product is not misbranded. In addition, FSIS will begin collecting data to determine the prevalence of Salmonella in raw fish.

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B. For additional guidance not provided in this section of the Notice (e.g., TOIs not performed, sample receipts, discards, positive and failed results), IPP are to refer to FSIS Directive 9900.6, Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products.

## **Request**

The sampling policies put in place for catfish go above and beyond what is done for imported meat?

9 CFR 557.6 - The electronic inspection system will be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

FSIS Directives referenced under the letter to foreign countries identifies that residue sampling will follow FSIS Directive 9900.6.

None of the above are being followed in the current Catfish residue sampling program for imported products. Bien Dong Seafood is being over sampled. The number of samples selected by FSIS is more than any other foreign producer.

***Bien Dong Seafood has no prior violations related to chemical residues based on FSIS sampling. The sampling has been above and beyond what other companies with the same history have exhibited.***

***The sample regiment for normal sampling is based on a statistical random sample selection. Increased or Intensified testing goes above and beyond the normal level of sampling. Bien Dong is being subjected to more samples for no public health reason.***

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## **FSIS National Residue Program**

The Food Safety and Inspection Service (FSIS) works with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to accomplish the responsibilities under the National Residue Program. FSIS's primary mission under the NRP is to verify that establishments control animal drug residues, pesticides, environmental contaminants, and any other chemical hazards in and on meat, poultry, and egg products. The NRP also provides for the collection of national data on the occurrence of residues to support risk assessment, enforcement, and educational

Three principal agencies are involved in the control of residues in meat, poultry, and egg products: FSIS, FDA, and EPA. FDA and EPA establish tolerances (maximum permissible levels) for chemical residues in foods, and FSIS enforces these tolerances through its various residue control programs.

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FDA establishes tolerances for veterinary drugs and food additives under the statutory authority of the Federal Food, Drug, and Cosmetic Act (FFDCA). These tolerances are published in Title 21 of the Code of Federal Regulations (21 CFR). EPA establishes tolerances for registered pesticides under the statutory authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and FFDCA, as modified by the Food Quality Protection Act (FQPA). These are published in 40 CFR. Maximum permissible levels have also been established for residues that are the result of environmental contamination, such as cancelled pesticides that are no longer approved for use but persist in the environment (e.g., DDT), industrial chemicals (e.g., PCBs), and heavy metals. Tolerances for industrial chemicals and heavy metals are established by FDA and published in 21 CFR. For cancelled pesticides, action levels (like tolerances, but less formal) are established by FDA or FSIS, based on recommendations that EPA has published in the Federal Register.

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), FSIS acts to ensure that USDA-inspected meat, poultry and egg products do not contain illegal levels of chemical residues. The cornerstone of FSIS residue prevention activities is the FSIS National Residue Program (NRP), a multi-component analytical testing program for residues in domestic and imported meat, poultry, and egg products. The FSIS NRP, which has been in effect since 1967, provides a variety of sampling plans to prevent residues from entering the food supply, and develops national data on the occurrence of chemical residues to support risk assessment, enforcement and educational activities.

The range of chemical compounds evaluated for inclusion in the various NRP testing programs is comprehensive in scope. It includes approved and unapproved pharmaceutical drugs and pesticides known or suspected to be present in food animals in the U.S. and in countries exporting products to the U.S. It also includes any other xenobiotic or naturally occurring compounds that may appear in meat, poultry, and egg products and that may pose a potential human health hazard.

The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues, and (4) collection, statistical analysis, and reporting of the results of these activities.

When violative residues are detected in **food-producing animals** submitted for slaughter, FSIS notifies the producer and other parties involved in offering these animals for sale. Product found to contain violative levels of residues is considered adulterated and is subject to condemnation. If the product has been distributed into commerce, it may be subject to voluntary recall and/or other actions. In addition, FDA and cooperating state agencies may make on-site visits to these firms.

As per FSIS Directive 9900.6 **LABORATORY SAMPLING PROGRAM FOR IMPORTED MEAT, POULTRY, AND EGG PRODUCTS** ( <https://www.fsis.usda.gov/wps/wcm/connect/a7a9ec1b-5c67-46f3-932d-ce781bcb494/9900.6.pdf?MOD=AJPERES> )

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2. Increased is a LOR above the normal level that is directed by a FSIS management decision. Under increased reinspection, FSIS may hold, on a case-by-case basis, lots of imported meat, poultry, or egg products pending receipt of a laboratory analysis. If FSIS does not place the product on hold, the importer of record is still required to hold product tested for adulterants by FSIS and is not to allow such product to enter commerce unless and until negative results are received; or

3. Intensified is a LOR that is implemented automatically by PHIS when a TOI is reported as "Fail." Under intensified reinspection, FSIS holds the sampled lot at the official import inspection establishment pending receipt of laboratory analysis. The sampled lot is not allowed to move offsite to be held.

#### IV. LOT DISPOSITION

A. For residue test results reported as "Residue Detected – violative," import inspection personnel are to:

1. If the lot is on hold, whether on-site or off-site:

a. If the product is under the IOR's control, confirm that the product is still under the IOR's control and not in commerce. If product is confirmed to be under the IOR's control or is onsite at the import establishment, initiate a refused entry in PHIS from the Lot Manager page for the lot, select Add New Reason on the refused entry page, select Failed Laboratory Analyses, and select the appropriate reason from the drop-down menu.

b. Notify the importer through import establishment management that the lot is refused entry, and if the lot was held off-site, request that the lot be returned to the official import inspection establishment; and

c. Notify RMTAS through the supervisory chain and provide a copy of the inspection certificate (non-eCert countries) and PHIS import inspection application number.

2. If the lot is not on hold:

a. Notify the importer that a sample result was returned violative and request information as to the whereabouts of the lot; and

b. Notify RMTAS through the supervisory chain and provide copy of the inspection certificate (non-eCert countries) and PHIS import inspection application number.

B. For residue test results reported other than "Residue Detected – violative," the lot is eligible for release into commerce when all TOI results for that lot are "Passed." The hold status may be removed.