



## GOLDENQUALITY SEAFOOD CORPORATION

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January 4, 2017

To: USDA FSIS Docket Clerk, Washington, DC

**Subject: PETITION RESIDUE TESTING CATFISH**

Based on the as **per 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. Golden Quality 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 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.

***FROM FINAL RULE - VII. Public Health Considerations: Potential Chemical and***

***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)).***

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

The sample regimen for intensified testing goes above the normal 15 passed lab results averaging 20 to 30 lab samples.

Golden Quality is requesting that the policy for residue sampling be put forth as the regulation states; equivalent to imported meat.

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.

FSIS currently;

- Requires more testing of catfish than meat and poultry at a cost to the importer or producer (Catfish intensified sampling average 10 to 15 more samples more than meat or poultry or domestic follow up testing),
- Requires a country response to get off Catfish Intensified (not the case with meat or poultry),
- Equates a failure to a pond without taking into consideration an animal, the environment, dissipation of a substance, and
- Refuses shipments that are tested and identified as lab sample passed (Other imported residue testing is not handled this way).

We are requesting consistent regulatory policy for all meat (Catfish and Red Meat). The over-regulating of the catfish industry is being instituted above and beyond what is being done for other FSIS regulated products.

We are requesting immediate changes to the non-regulatory policies.

We look forward to a response regarding the issue as soon as possible.

Thank you

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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.

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 <sup>TM</sup>(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> )

#### **IV. REINSPECTION CATEGORIES**

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

#### **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.