



United States Department of Agriculture

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Food Safety and  
Inspection Service

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Mr. Nguyen Nhu Tiep  
Director General  
National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD)  
Ministry of Agriculture and Rural Development  
Hanoi, Vietnam

Dear Director Tiep,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote ongoing verification audit of Vietnam's Siluriformes inspection system March 22 through April 28, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of Vietnam are included as an attachment to the report.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination at [InternationalCoordination@usda.gov](mailto:InternationalCoordination@usda.gov).

Sincerely,

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF  
VIETNAM

MARCH 22–APRIL 28, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
SILURIFORMES FISH AND FISH PRODUCTS  
EXPORTED TO THE UNITED STATES OF AMERICA

September 30, 2021

Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This report describes the outcome of a remote equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), March 22–April 28, 2021. Due to the global COVID-19 pandemic, the audit was conducted remotely using a combination of video conferences and records review. The purpose of the audit was to determine whether Vietnam's food safety inspection system governing Siluriformes fish and fish products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Vietnam currently exports raw intact and raw non-intact Siluriformes products to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards, and Labeling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors concluded that Vietnam's Siluriformes inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. Vietnam has implemented sanitary operating procedures and a HACCP system to ensure controls of hazards in raw Siluriformes products. In addition, Vietnam has implemented a chemical residue testing program that is organized and administered by the national government to verify establishments meet necessary requirements. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Vietnam’s food safety system, March 22–April 28, 2021. The audit began an entrance meeting held via videoconference March 22, 2021 with the Central Competent Authority (CCA) – National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD) in Hanoi, Vietnam. During that virtual entrance meeting the FSIS auditors discussed the audit objective, scope, and methodology. Representatives from NAFIQAD participated throughout the entire audit.

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. Due to the global COVID-19 pandemic, the audit was conducted remotely using a combination of video conferences and records review. The audit objective was to determine whether the food safety inspection system governing Siluriformes remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Vietnam is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products <sup>1</sup>
Raw - Not Intact	Raw Ground Comminuted or Otherwise Non-Intact Siluriformes	Siluriformes – All Products Eligible
Raw - Intact	Raw Intact Meat - Other	Siluriformes – All Products Eligible

Prior to the remote, routine ongoing equivalence verification audit, FSIS reviewed and analyzed Vietnam’s self-reporting tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether Vietnam’s food safety inspection system governing Siluriformes is being implemented as documented in the country’s SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within the applicable equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the SRT.

Determinations concerning program effectiveness during this remote audit focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System

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<sup>1</sup> All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States. For processed meat products, meat includes the following species: beef, goat, lamb, mutton, pork, Siluriformes, and veal.

Operation, Product Standards, and Labeling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed records and conducted interviews related to the administrative functions at CCA headquarters and two regional offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

On November 5, 2019, FSIS published a final rule identifying Vietnam as having an equivalent meat (Siluriformes) inspection system. FSIS typically conducts an onsite audit within one year of a final equivalence determination; this remote audit of Vietnam’s Siluriformes inspection system is in lieu of that onsite audit.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include review of establishments’ conditions or records. A sample of three Siluriformes processing establishments was selected from a total of 13 establishments certified to export to the United States. The products these establishments produce and export to the United States include raw intact and raw non-intact Siluriformes. The FSIS auditors assessed the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR), Section 557.2.

The FSIS auditors also remotely audited one government chemical residue laboratory to verify that this laboratory is capable of providing adequate technical support to the food safety inspection system.

Competent Authority Record Reviews		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>• NAFIQAD Headquarters, Hanoi</li> </ul>
	Regional Agency	1	<ul style="list-style-type: none"> <li>• Southern Regional Agency, Ho Chi Minh City</li> </ul>
	Branch Offices	2	<ul style="list-style-type: none"> <li>• NAFIQAD Branch 4, Ho Chi Minh City</li> <li>• NAFIQAD Branch 6, Can Tho City</li> </ul>
Laboratory		1	<ul style="list-style-type: none"> <li>• Laboratory of NAFIQAD Branch 6 (government chemical residue), Can Tho City</li> </ul>
Siluriformes processing establishments		3	<ul style="list-style-type: none"> <li>• Establishment No. DL 15, Bien Dong Seafood Co., Ltd., Can Tho City</li> <li>• Establishment No. DL 476, Godaco Seafood, My Tho City</li> <li>• Establishment No. DL 500, Workshop 3-Vinh Hoan Corporation, Cao Lanh City</li> </ul>

FSIS performed the remote audit to verify that the food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] Section 601 *et seq.*); and
- United States Code of Federal Regulations, Title 9, Chapter III, Subchapter F, Part 530, *Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish.*

The audit standards applied during the review of Vietnam’s inspection system for Siluriformes included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization’s *Agreement on the Application of Sanitary and Phytosanitary Measures*.

### III. BACKGROUND

From October 1, 2017 to September 30, 2020, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 621,834,136 pounds of meat from Vietnam. This included 621,744,136 pounds of raw intact Siluriformes and 90,000 pounds of raw ground comminuted or otherwise non-intact Siluriformes exported by Vietnam to the United States. Of these amounts, additional types of inspection were performed on 69,878,118 pounds of Siluriformes products. These additional types of inspection included physical examination and chemical residue analysis. As a result of this additional testing, FSIS rejected 221,000 pounds of raw intact and raw non-intact Siluriformes products for issues related to public health, including violations for fipronil, crystal violet, and off-condition product since the previous audit.

The previous FSIS audit in 2018 identified the following findings<sup>2</sup>:

<b>Summary of Findings from the 2018 FSIS Audit of Vietnam</b>
<b>Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards, and Labeling)</b>
<ul style="list-style-type: none"> <li>• Inspectors did not identify the failure to routinely document results of operational sanitation monitoring in all establishments.</li> </ul>
<b>Component 3: Government Sanitation</b>
<ul style="list-style-type: none"> <li>• In one establishment, results of Adenosine-Tri-phosphate testing conducted as a verification of pre-operational sanitation were not recorded on sanitation standard operating procedure documents.</li> <li>• One establishment failed to list scales coming in direct contact with product on their pre-operational monitoring sheet and verification records.</li> <li>• At all establishments audited, results of operational sanitation monitoring were not fully documented.</li> </ul>

<sup>2</sup> Before publishing the final rule to list Vietnam as a country eligible to export Siluriformes fish and fish products to the United States, FSIS reviewed Vietnam’s corrective action plan for all of the audits findings and concluded that all have been satisfactorily addressed.

<ul style="list-style-type: none"> <li>• In one establishment, small blue specks of foreign material were observed in ice being used in the ice glazing area.</li> <li>• In one establishment, employees in the boxing area were observed reaching into bags of product and directly handling frozen fillets of fish after contacting non-food surfaces (boxes).</li> <li>• At two establishments, product rinsing/washing machinery was observed to be constructed with piping which could not be disassembled to enable full inspection to verify sanitation.</li> <li>• In one establishment, the hard-plastic diverter paddles on the sides of a scaling conveyor belt were observed to be in deteriorating condition.</li> </ul>
<p><b>Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System</b></p>
<ul style="list-style-type: none"> <li>• In one establishment the hazard analysis did not identify all potential hazards associated with each step of the process.</li> </ul>

The FSIS final audit reports for Vietnam’s food safety inspection system are available on the FSIS website at: [www.fsis.usda.gov/foreign-audit-reports](http://www.fsis.usda.gov/foreign-audit-reports).

**IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)**

The first of six equivalence components the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The national government of Vietnam organizes and manages the food safety system governing Siluriformes fish and fish products that are exported to the United States. The CCA of Vietnam is NAFIQAD, an organization under the Ministry of Agriculture and Rural Development (MARD) that has the authority to monitor and implement regulations on the quality and food safety of agriculture, forestry, and fisheries, as described in *Decision No. 1120/QĐ-BNN-TCCB*. NAFIQAD is responsible for drafting laws, resolutions and policies governing Siluriformes fish and fish products and developing plans for food safety inspection programs that oversee transport, processing, and export of Siluriformes. NAFIQAD consists of the Central Regional Authority, the Southern Regional Authority (SRA), and branch offices.

The SRA is responsible for implementation of required policies at establishments certified to export to the United States. NAFIQAD Branch Offices 4 and 6 oversee inspection of establishments certified to export Siluriformes fish and products to the United States. The SRA is responsible for issuing new decisions and initiatives, verifying that such policies are implemented in Siluriformes establishments, overseeing food safety programs and enforcing the chemical residue program. The FSIS auditors verified that there have not been any changes in NAFIQAD’s organizational structure since the previous FSIS audit.



The Directorate of Fisheries (D-FISH), also under MARD, is responsible for overseeing the aquaculture locations involved in the raising of live Siluriformes. D-FISH inspects aquaculture rearing and harvest locations and implements regulations that govern the species of fish used in aquaculture, feeds, environmental remediation, and chemical treatments used in aquaculture farms, as described in *Decision No. 27/2017/QĐ-TTg*. D-FISH is responsible for conducting sampling of feed, water, and live fish regularly and in response to residue violations reported by NAFIQAD. D-FISH coordinates with NAFIQAD regarding aquaculture disease monitoring. Vietnam Good Agriculture Practices (VietGAP) is an accreditation body delegated by D-FISH which audits and certifies aquaculture locations for compliance with food safety, environmental integrity, aquatic animal welfare, and traceability requirements.

The FSIS auditors verified the process for certifying establishments as eligible to export to the United States as defined in *Program for Controlling the Food Safety of Siluriformes Fish and Fish Products Exported to the UNITED STATES Market (hereinafter, Program for Food Safety)* and *Circular No. 48/2013*. Siluriformes fish slaughter and processing establishments that intend to export to the United States must first have an understanding of United States requirements and meet food safety conditions required by *Circular Nos. 48/2013/TT-BNNPTNT* and *02/2017/TT-BNNPTNT*, which will then be verified by the SRA during audits. If requirements are met, NAFIQAD will certify the establishment as eligible and designate inspection and supervision for each production shift. If requirements are not met, NAFIQAD will send a written notice to the establishment with detailed reasons regarding the failure of the establishment to meet the requirements. NAFIQAD will also delist establishments based on unsatisfactory food safety inspection results, which will then be required to be corrected and verified by NAFIQAD. The FSIS auditors verified that there have been no delistments since the previous FSIS audit.

Vietnam's *Program for Food Safety* specifies that only source materials from establishments and countries certified as eligible to export to the United States can be used. However, establishments that export Siluriformes to the United States do not receive source material from other countries. The FSIS auditors confirmed that inspection personnel routinely verify that source material originates from only eligible establishments at receiving.

NAFIQAD requires that all establishments have recall plans in place and are able to ensure traceability per *Circular No. 03/2011*. The *Program for Food Safety* additionally requires that establishments eligible to export to the United States notify NAFIQAD within one working day if products have been shipped that have been determined to be adulterated or misbranded and to include information on the traceability of the product. The *Law on Food Safety* identifies the prohibited acts and definitions consistent with adulteration and misbranding. The FSIS auditors verified that there have not been any recalls at the establishments eligible to export to the United States. NAFIQAD will notify FSIS in the event that adulterated or misbranded product is shipped to the United States.

Vietnam's *Program for Food Safety* outlines procedures when noncompliance is identified and the authority of NAFIQAD to take regulatory control actions such as retaining product or rejecting equipment. This also defines provisions for an investigation of an establishment from the branch level if corrective actions are not met or are inadequate and suspension of the issuance of export certificates. The FSIS auditors reviewed examples of noncompliance documented by

inspection personnel on the *Monitoring Sheet for Processing of Siluriformes Fish for Export to the UNITED STATES (hereinafter, Monitoring Sheet)* from the selected establishments and that corrective actions were taken and verified by NAFIQAD. Since the previous FSIS audit, Vietnam has suspended export for five establishments in response to POE violations. NAFIQAD requires establishments to conduct an investigation and will verify their corrective actions prior to allowing them to continue to export to the United States.

The SRA, along with respective branch offices, conducts audits of establishments certified to export to the United States once every 18 months for Class 1 and 2 establishments and once a year for Class 3 establishments, in accordance with *Circular No. 48/2013/TT-BNNPTNT* and the *Program for Food Safety*. Based on the number of deficiencies identified, establishments eligible to export to the United States are categorized in Classes 1, 2, and 3, which then determines the frequency of future audits. The FSIS auditors reviewed SRA's audit reports of and verified that when noncompliance was identified, corrective actions were taken by the establishment and verified by NAFIQAD once implemented. Additionally, NAFIQAD headquarters audits the SRA and branch offices once per year.

Inspection personnel verify requirements for each shipment of product prior to signing export certificates through a review of inspection records, HACCP and sanitation records, and label verification. Export certificates are kept secure by using official seals, are documented on anti-counterfeit paper, and are kept in the sole control of NAFIQAD employees. Additionally, NAFIQAD branch offices conduct a monthly verification of validity of export certificates and prepare a report that documents the inventory of export certificates.

The *Program for Food Safety* requires that establishments notify NAFIQAD branch offices each week of their production schedule for products that are intended to be exported to the United States. NAFIQAD branch offices then set up a staffing plan to ensure inspectors are assigned for each shift to inspect and verify that all FSIS requirements are met for Siluriformes products exported to the United States. Branch offices will then reconfirm that there is staffing for the next day for each shift to ensure coverage is provided for establishments certified to export to the United States. The FSIS auditors reviewed the staffing process shown by NAFIQAD branch offices and found no concerns. The FSIS auditors verified that NAFIQAD inspection personnel are government employees who are paid by the branch offices. The producers and farms pay fees to the branch offices which in turn are paid to the national government.

The FSIS auditors verified that information regarding FSIS requirements is conveyed to inspection personnel and establishments certified to export to the United States through regular trainings and briefings, and through the issuance of circulars or manuals that provide any new updates to requirements of export markets. Additionally, NAFIQAD monitors the FSIS website for policy changes that would warrant the issuance of a circular and will hold internal meetings and workgroups to ensure new requirements are met.

The laboratories that conduct chemical analysis of samples of Siluriformes product used for export to the United States are organized within the NAFIQAD Branch Offices 4 and 6. The CCA conducts annual audits of the NAFIQAD branch laboratories. Each laboratory's quality management system must be accredited according to International Organization for

Standardization 17025:2017, *General Requirements for the Competence of Testing and Calibration Laboratories*, standards, as required by *Joint Circular No. 20/2013/TTLT-BYT-BCT-BNNPTNT*. Accreditation is obtained through the Bureau of Accreditation (BoA) of the Ministry of Science and Technology, which is an accreditation body signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement. The laboratories are audited by the BoA annually, with an extended scope audit and accreditation every three years.

Audits of laboratories are conducted once per year by NAFIQAD. The FSIS auditors reviewed the most recent audit of the NAFIQAD Branch 6 chemical residue laboratory and verified that the laboratories implemented corrective actions when deficiencies were identified. The FSIS auditors verified that the current accreditation certificate for the NAFIQAD Branch 6 laboratory was dated August 27, 2019 and expires on October 2, 2021. The scope of accreditation includes laboratory methods consistent with FSIS' Chemical Laboratory Guidebook methods for chemical residue analyses of products eligible for export to United States.

The laboratories conduct internal proficiency testing annually and external proficiency testing every three years in methods that are used to analyze official samples. The FSIS auditors verified that proficiency testing covers the methods used by laboratory personnel to analyze official samples of products that are destined for the United States and found no concerns. Laboratory technicians are required to hold a Bachelor of Science in chemistry and undergo training in relevant methods, including FSIS methods in the Chemistry Laboratory Guidebook. Each test method must be internationally recognized and NAFIQAD will take into account requirements of export markets prior to approval of methods.

The audit verified that Vietnam's Siluriformes inspection system is organized and administered by the national government, and that NAFIQAD inspection officials are assigned to enforce the laws and regulations governing Siluriformes.

## **V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS, AND LABELING)**

The second of six equivalence components the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for complete separation of fish and fish products of the order Siluriformes at establishments certified as eligible to export to the United States; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors reviewed the hiring process of government inspection personnel and verified that inspection personnel are required to hold a Bachelor of Science degree in order to qualify for their positions. Training for government inspection personnel is held at the headquarters, SRA, and branch level for NAFIQAD for inspection personnel covering inspection requirements including HACCP, Sanitation Standard Operating Procedures (SOP), Sanitation Performance Standards (SPS), Good Manufacturing Practices (GMP), and labeling requirements at least once

per year or whenever there are updates to export requirements. The most recent training was held in July of 2019 for inspection personnel assigned to establishments eligible to export to the United States and reviewed the updated guidance covering United States inspection requirements in the *Program for Food Safety*.

The FSIS auditors verified that NAFIQAD conducts supervisory review visits per instructions in *Circular Nos. 48/2013, 2/2017, and 16/2018* at frequencies of 18 months for Class 1 and 2 establishments and every 12 months for Class 3 establishments. The reviews are conducted by the SRA and branch offices, and are documented on *Form 5b-1* within Annex 5 of *Circular No. 48/2013* and covers the food safety performance of the establishment including HACCP and sanitation SOP requirements outlined in *QCVN 02-01:2009/BNNPTNT* and *QCVN 02-02/2009/BNNPTNT*.

The performance of inspection personnel is evaluated on a yearly basis according to instructions in *Circular No. 48/2013*, to evaluate the performance of government inspection personnel covering United States export requirements including HACCP, sanitation SOPs, GMPs, labeling, residue sampling, and documenting noncompliance.

Establishments certified to export to the United States are required to maintain identity of products, and to control and segregate product destined for the United States from other products. NAFIQAD inspection personnel verify compliance with labeling requirements in accordance with the *Program for Food Safety* and *Circular No. 48/2013*, on a daily basis and additionally for each shipment of product destined for export to the United States. Labels are required to meet FSIS labeling requirements and include the name of the family of fish (e.g., Pangasius), the common name (e.g., Swai, Basa), and percent of added solutions. The FSIS auditors verified that labeling requirements were verified daily by inspection personnel.

The *Program for Food Safety* requires that dead or diseased fish must be promptly disposed of and must be separated and stored in a separate, identified container. NAFIQAD inspection personnel verify proper disposal of condemned materials once per shift. The FSIS auditors verified that condemned materials are removed from production and placed in clearly marked containers through a review of inspection records.

NAFIQAD requires that Siluriformes products destined for the United States be processed on a separate production line from those destined for domestic or other export markets according to the *Program for Food Safety*. Establishments must have the process for separation documented within their GMPs to meet this requirement and the FSIS auditors confirmed that this is verified at least once per shift by inspection personnel.

The FSIS auditors concluded that Vietnam's food safety inspection system governing Siluriformes maintains the legal authority and a regulatory framework that is consistent with criteria established for this component.

## **VI. COMPONENT THREE: GOVERNMENT SANITATION**

The third of six equivalence components the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions; and to include requirements for SPS.

D-FISH is responsible for verifying the implementation of *QCVN 02-20-2014/BNNPTNT* and *Circular No. 38/2018*, which outline the veterinary hygiene and food safety requirements for Siluriformes aquaculture locations including feed, water quality and testing, traceability of breeding stock, and fish health. Water samples are taken by D-FISH every two weeks and fish samples are taken prior to every harvest. When violations are found, NAFIQAD requires aquaculture locations to take immediate corrective actions and conduct a root cause analysis; it does not allow the aquaculture locations to send fish to export markets.

Siluriformes aquaculture locations are also required to adhere to Vietnamese Good Agricultural Practices (VietGAP), outlined in *Circular No. 48/2012* and are audited and certified for meeting these requirements by D-FISH. Farms are designated into three categories to determine frequency of audits, with audits every 18 months for category A farms, every 12 months for category B farms, and every 3 months for category C farms. D-FISH auditors assess aquaculture farm hygiene, records, intake water used, feeds, and veterinary drug usage. During audits, D-FISH will sample feed, water, and fish, and will verify traceability, species identification, aquaculture farm treatments, employee hygiene, water quality, water temperature, and animal health. The FSIS auditors reviewed the most recent audit reports, and water, feed, and fish sampling records and found no concerns.

The *Program for Food Safety* requires that fish must be transported with sufficient oxygen to minimize weak or dead fish during transportation, and dead fish must be removed and placed in designated identified containers. When fish are received at establishments, inspection personnel verify that they originate from aquaculture farms with valid VietGAP certifications. Inspection personnel will also verify transport conditions of fish.

*QCVN 02-01/2009* outlines Vietnam's SPS requirements that establishments are required to meet for ventilation, structure, design and layout, water supply, maintenance, water supply, and personal hygiene. NAFIQAD verifies the establishment addresses condensation control, chemical use and storage, employee hygiene, water potability, pest control, outside premises, and lighting. The FSIS auditors verified through a records review that NAFIQAD conducts a review of SPS on a daily basis.

The FSIS auditors verified that the CCA requires establishments certified to export to the United States to develop, implement, and maintain sanitation SOPs to prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions. The FSIS auditors verified that establishments met requirements prescribed in *QCVN 02-01/2009* and *QCVN 02-02/2009*, which are consistent with 9 CFR Part 416 requirements. The FSIS auditors verified that NAFIQAD's sanitation SOP requirements must be developed to address facility construction and maintenance, equipment maintenance, and pest control consistent with FSIS regulations.

NAFIQAD inspection personnel conduct pre-operational and operational sanitation verification daily, consisting of both direct observation and records review. Inspection personnel document once per shift verification of sanitation SOPs of establishments exporting to the United States on the *Monitoring Sheet*. When deficiencies are identified, NAFIQAD has the authority to restrict an area from operating and to require immediate corrective actions when deficiencies are identified involving direct product contamination or product contact surfaces. The FSIS auditors reviewed records and verified that such deficiencies were identified, documented as noncompliance, corrected by the establishment, and verified by NAFIQAD. Through interviews and remote review of records, the FSIS auditors confirmed that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs and that the CCA continues to maintain requirements.

## **VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM**

The fourth of six equivalence components the FSIS auditors reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

NAFIQAD is responsible for enforcing *QCVN 02-02/2009*, which prescribes the requirements for the development and implementation of a HACCP system. The FSIS auditors verified that NAFIQAD has the authority to take enforcement measures in the event that an establishment does not implement a HACCP system. The FSIS auditors confirmed that NAFIQAD verifies HACCP activities once per shift, including observation of monitoring and verification of all critical control points, verification of corrective actions, and review of pre-shipment records. NAFIQAD also reviews basic HACCP requirements (hazard analysis, flowchart, HACCP plans) initially and when modified. Additionally, NAFIQAD inspection personnel will verify HACCP records for each lot of product prior to shipment.

The FSIS auditors reviewed examples of the *Monitoring Sheet*, where inspection personnel document their verification of HACCP requirements. The review of documents showed that NAFIQAD requires establishments to maintain a written hazard analysis for each step in the slaughter process, flow chart, and HACCP plan. The FSIS auditors reviewed NAFIQAD's audit reports from the selected establishments and verified that the establishments' HACCP systems are further reviewed during their audit process. NAFIQAD documents its review of corrective actions in its *Verification Report of Corrective Actions*.

The FSIS auditors' analysis verification activities indicate that the CCA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs for each processing category. FSIS determined that the HACCP program as described is consistent with criteria established for this component.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS**

The fifth of six equivalence components the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of fish for chemical residues identified by the exporting country's Siluriformes fish products inspection authorities or by FSIS as potential contaminants.

*Circular No. 48/2013* provides instructions for NAFIQAD inspection personnel sample collection for the national residue plan and for each shipment of product destined for export to the United States. NAFIQAD inspection personnel are required to participate in annual sample collection training, conducted by the branch office.

Once a sample is received at the laboratory, the laboratory technician will review the sample and submitted documentation to verify whether it meets receiving criteria. Samples are required to be accompanied by a sample form consistent with the sample request form, have appropriate packaging with an intact seal, meet temperature and minimum volume requirements, and the sample form must be signed by the inspector, establishment, and finally the laboratory technician once received. The sample must be analyzed within 24 hours of receipt at the laboratory.

*The Monitoring Program for Certain Harmful Substances Residues in Aquaculture Fish and Products Thereof* is developed by NAFIQAD in accordance with *Circular No. 31/2015* under the authority of the *Prevention of Undesirable Residues in Meat Act*. Monthly sampling schedules are developed and monitored by the SRA and implemented by the branch offices. The *Program for Food Safety* lists the maximum residue levels for products intended for export to the United States, which are adhered to in the residue monitoring program. Government inspection personnel are responsible for carrying out the sampling plan. If violative residues are identified, the lot is not permitted to be exported to the United States per the *Program for Food Safety* and NAFIQAD ensures appropriate disposition of product through verifying condemnation.

The FSIS auditors verified Vietnam's adherence to the 2021 monitoring plan and reviewed NAFIQAD's progress thus far. NAFIQAD receives laboratory results for official government chemical residue testing directly from the designated laboratories in a timely manner, assesses the data, and takes actions in accordance with the procedures described in their official government chemical residue control program. The FSIS auditors verified through a records review that when residue violations are identified, appropriate corrective actions are taken by establishments and verified by NAFIQAD.

The FSIS auditors reviewed the residue sampling procedures and associated records and verified that samples are collected by NAFIQAD at the aquaculture locations and establishments in accordance with *Circular No. 48/2013*. Residue results are reported to the SRA, and if the sampled lot is designated for export, the branch office will subsequently be notified, and the results will also be sent to the establishment. NAFIQAD inspection personnel are responsible for ensuring proper disposition of product in the case of residue samples exceeding allowable levels. Traceability information is collected on the sampled fish for both routine and targeted residue sampling. The FSIS auditors verified that Vietnam does not conduct retesting of samples.

The FSIS auditors also verified corrective actions taken in response to the FSIS POE violations since the previous FSIS audit, which included violations for fipronil and crystal violet. NAFIQAD determined the fipronil violations were attributed to the use of this pesticide on crops in close proximity to the aquaculture farms used for raising Siluriformes. Vietnam has since removed all pesticides containing fipronil from the list of permissible pesticides, per *Decision No. 501/QZ-BNN-BVTV*. The crystal violet violations were attributed to the use of this compound as a skin treatment used by an employee, and improper use of this compound to treat aquaculture farms used for raising Siluriformes. Corrective actions for these violations included retraining of establishment employees, a meeting held with farmers informing them of prohibited veterinary drugs, and testing of employees' hands as well as raw fish for crystal violet and other prohibited compounds. NAFIQAD verified these corrective actions through official testing for prohibited substances for which they found no violations, in addition to reviewing the investigation and supporting documentation. The FSIS auditors reviewed the corrective actions implemented by the establishments and NAFIQAD and found no concerns.

Prior to the audit, FSIS' residue experts reviewed the *Monitoring Program for Certain Harmful Substances Residues in Aquaculture Fish and Products Thereof in 2019 and Plan for 2020*, associated methods of analysis, and additional SRT responses outlining the structure of Vietnam's chemical residue testing program.

The FSIS auditors' analysis and remote verification indicated that the CCA continues to meet the core requirements for this component.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The sixth equivalence component is Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

Vietnam is currently eligible to export raw Siluriformes fish products to the United States. FSIS does not have any equivalence requirements for microbiological sampling of raw Siluriformes fish products; therefore, government microbiological testing is not required.

## **X. CONCLUSIONS AND NEXT STEPS**

A virtual exit meeting was held with NAFIQAD on April 28, 2021. The FSIS auditors concluded that Vietnam's food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. NAFIQAD routinely verifies implementation of sanitation procedures and establishment HACCP systems to ensure adequate control of food safety hazards. In addition, the FSIS auditors confirmed that NAFIQAD implements an official government chemical residue testing program to verify the effectiveness of its food safety inspection system on an ongoing basis. An analysis of each equivalence component did not identify any deficiencies that represent an immediate threat to public health.



## **Appendix: Foreign Country Response to the Draft Final Audit Report**



**NAFIQAD**

**MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT OF VIETNAM**

**National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD)**

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Ref.: 1261/QLCL-CL1

*Hanoi, 29<sup>th</sup> September 2021*

**Dr. Michelle Catlin**  
**International Coordination Executive**  
**Office of International Coordination**  
**Food Safety and Inspection Service (FSIS)**

Dear Madam,

On behalf of the National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD), under the Vietnamese Ministry of Agriculture and Rural Development, I would like to present its compliments to you and communicate about the following:

1. Regarding comments to the draft final report of remote ongoing verification audit of Vietnam's *Siluriformes* inspection system March 22 through April 28, 2021 conducted by the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA) as requested in the FSIS's official letter dated 12<sup>th</sup> August 2021:

NAFIQAD does agree with content of the draft final report and FSIS's evaluations as well as conclusions on maintaining the equivalence recognition for the food safety hygiene control systems governing *Siluriformes* fish and fish products exported to the United States of America. By this occasion, on behalf of the Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD), the Ministry of Agriculture and Rural Development of Vietnam, I would like to express my sincere thanks to you and your colleagues in the United States Department of Agriculture (USDA) for the support and close coordination throughout the equivalence process of the above-mentioned verification audit.

2. On 27<sup>th</sup> July 2021, NAFIQAD sent its official letter No. 958/QLCL-CL1 for expanding the equivalence of Vietnam's food safety inspection system to include processed *Siluriformes* fish products (frozen, heat treated and not ready to eat). However, we have not received any feedback from FSIS until now, therefore NAFIQAD would like FSIS to consider and accept our above request soon in order to facilitate companies for export fish products/group of frozen, heat treated and not ready to eat *Siluriformes* fish products to US.

Once again, I would like to take this opportunity to wish you and your colleagues health and success. I am looking forward to USDA's and your service continued cooperation and support in the future.

Please accept the assurance of my highest consideration.

Yours sincerely,

A handwritten signature in blue ink is written over an official circular stamp. The stamp contains the text "SOCIALIST REPUBLIC OF VIETNAM" at the top, "NAFIQAD" in the center, and "MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT" at the bottom.

**Nguyen Nhu Tiep**  
**Director General of NAFIQAD**

*cc.*

*Mr. Robert Hanson, Counselor for Agricultural Affairs, U.S. Embassy, Hanoi*