



United States Department of Agriculture

Food Safety and
Inspection Service

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1400 Independence
Avenue, SW.
Washington, D.C.
20250

Mr. Nguyen Nhu Tiep
Director General
National Agro-Forestry-Fishery Quality, Processing and Market Development
Authority (NAFIQPM)
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 an onsite verification audit of Vietnam's inspection system August 7–22, 2023. 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.

Sincerely,

MARGARET

BURNS RATH

Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
Office of International Coordination

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Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF
VIETNAM

AUGUST 7–22, 2023

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

January 23, 2024

Food Safety and Inspection Service
U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Vietnam conducted by the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) August 7–22, 2023. The purpose of the audit was to verify 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 properly labeled and packaged. Vietnam currently exports Siluriformes fish products under the following process categories to the United States: Raw - Intact, Raw - Non Intact, and Heat Treated - Not Fully Cooked - Not Shelf Stable.

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, and Humane Handling); (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.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- Vietnam’s Central Competent Authority—National Agro-Forestry-Fishery Quality, Processing and Market Development Authority (NAFIQPM)—did not ensure that the official chemical residue testing laboratory implemented adequate quality assurance procedures consistent with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards regarding proper labeling of reagents.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- NAFIQPM did not ensure that certified establishments identified all steps in their production process in their flow charts and hazard analyses as required by Vietnam’s national technical regulation QCVN 02-02:2009/BNNPTNT.

During the audit exit meeting, NAFIQPM committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of NAFIQPM’s documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Vietnam’s food safety system August 7–22, 2023. The audit began with an entrance meeting August 7, 2023, in Hanoi, Vietnam, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA)—National Agro-Forestry-Fishery Quality, Processing and Market Development Authority (NAFIQPM). Representatives from NAFIQPM accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference August 22, 2023.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the 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 properly labeled and packaged. Vietnam is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products¹
Raw – Non Intact	Raw Ground Comminuted or Otherwise Non – Intact Siluriformes	Siluriformes – All Products Eligible
Raw – Intact	Raw Intact Meat – Other	Siluriformes – All Products Eligible
Heat Treated – Not Fully Cooked – Not Shelf Stable	Not Ready-To-Eat (NRTE) Otherwise Processed Meat	Siluriformes – All Products Eligible

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Vietnam’s Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue plan and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify whether Vietnam’s food safety inspection system governing Siluriformes fish and fish products 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 six 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 3-year period, in addition to information obtained directly from the NAFIQPM through the SRT.

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g.,

¹ All source Siluriformes fish used to produce products must originate from eligible countries and establishments certified to export to the United States.

Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (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 administrative functions at NAFIQPM headquarters (HQ), one regional authority, two branch offices, ten local inspection offices within the establishments, and five Siluriformes fish farms. 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 documented in the country’s SRT responses and supporting documentation.

A sample of 10 establishments was selected from a total of 26 establishments certified for export to the United States. This included 10 Siluriformes fish slaughter and processing establishments. The products these establishments produce and export to the United States include raw intact, raw non-intact, and NRTE otherwise processed Siluriformes fish products.

During the establishment and fish farm visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed NAFIQPM’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) 557.2, and consistent with requirements in 9 CFR 327.2.

The FSIS auditors also visited one government laboratory conducting microbiological and chemical residue testing to verify that this laboratory can provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• NAFIQPM, Hanoi city
	Regional	1	• NAFIQPM Southern Regional Authority, Ho Chi Minh city
	Branch Offices	2	• NAFIQPM Branch 4, Ho Chi Minh city • NAFIQPM Branch 6, Can Tho city
Laboratory		1	• NAFIQPM Branch 6 Laboratory (government) (microbiological and chemical residue testing), Can Tho city
Siluriformes fish slaughter and processing establishments		10	• Establishment No. DL 15, Bien Dong Seafood Co., Ltd, Can Tho city • Establishment No. DL 61, Workshop 2 - Vinh Hoan Corporation, Cao Lanh city • Establishment No. DL 369, Mekong Delta Food Factory, Can Tho city • Establishment No. DL 408, Atlantic Seafood Freezing Factory N.V, Can Tho city

		<ul style="list-style-type: none"> • Establishment No. DL 461, NTSF Seafoods Joint Stock Company, Can Tho city • Establishment No. DL 500, Workshop 3 - Vinh Hoan Corporation, Cao Lanh city • Establishment No. DL 511, Van Duc Tien Giang Food Export Company, Chau Thanh district • Establishment No. DL 518, Europe Joint Stock Company, My Tho city • Establishment No. DL 810, Bien Dong Hau Giang Seafood Joint Stock Co., Nga Bay city • Establishment No. DL 847, Thanh Binh Dong Thap One Member Company Limited, Thanh Binh district
Siluriformes fish farms	5	<ul style="list-style-type: none"> • Soc Trang 5, Ke Sach district • Tan Phong, Cai Lay district • Tan Thanh, Thanh Binh district • Tan Thuan Dong, Cao Lanh city • Thoi An, Can Tho city

FSIS performed the 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
- The Siluriformes fish and fish products inspection regulations (9 CFR Parts 530-561)

The audit standards applied during the review of Vietnam’s inspection system for Siluriformes fish and fish products 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 (WTO’s) Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From April 1, 2020, to March 31, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 702,729,619 pounds of Siluriformes fish products from Vietnam. Of these amounts, additional types of inspection were performed on 78,150,153 pounds of Siluriformes fish products. These additional types of inspection included physical examination and chemical residue analysis. As a result of these additional inspections, 77,788 pounds of Siluriformes fish products were rejected for issues related to public health, including a POE violation for the presence of chemical residues. FSIS evaluated NAFIQPM’s corrective action response to the POE violation, found it sufficient, and closed the POE violation case.

An additional 228,920 pounds of Siluriformes fish products were refused for other issues not related to public health, including shipping damage, labeling, or other miscellaneous issues.

The previous FSIS audit in 2021 did not identify any systemic findings.

The most recent 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.

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

The first equivalence component 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.

NAFIQPM, under the Ministry of Agriculture and Rural Development (MARD), is the CCA responsible for food safety control during transportation from the farms to the processing establishments, slaughter and processing, and exportation of Siluriformes fish and fish products in accordance with Decision No. 1588/QB-BNN-TCCB. In 2023, the National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD), which was the CCA at the time, merged with the Agro Products Processing and Development Department to form NAFIQPM in accordance with Decision No. 1588/QD-BNN-TCCB. NAFIQAD’s functions and responsibilities related to quality and food safety control of Siluriformes fish and fish products for export were not changed as part of the merger.

NAFIQPM consists of the HQ, regional authorities, branch offices, and local competent authorities (LCAs)—sub-department provincial and municipal offices. The regional authorities, branch offices, and LCAs are independently managed with oversight by NAFIQPM HQ. Currently, there are two regional authorities, but only the Southern Regional Authority (SRA) oversees establishments that process Siluriformes fish and fish products for export to the United States. NAFIQPM has six branch offices, but only Branch 4 and Branch 6 oversee establishments that process Siluriformes fish and fish products for export to the United States. NAFIQPM has 63 LCAs, but currently, only the following 7 have establishments that process Siluriformes fish and fish products for export to the United States: Can Tho city, Dong Thap, Long-An, Vinh Long, Hau Giang, and Tien Giang provinces. NAFIQPM HQ develops annual plans for auditing the regional authorities, branch offices, and LCAs. The annual plan for 2022 required NAFIQPM to audit the regional authorities, branch offices, and LCAs once. The FSIS auditors reviewed reports from the 2022 audits of the SRA, Branch 4, and Branch 6 and verified they were conducted at the required frequency and actions were taken in response to the audit findings.

Oversight of aquaculture farms is coordinated by the Directorate of Fisheries (D-FISH), under MARD, in accordance with Decision No. 1786/QD-BNN-TCCB and the Department of Animal Health (DAH), also under MARD, in accordance with Decision No. 1399/QD-BNN-TCCT. D-FISH is responsible for oversight of Siluriformes fish farms and usage of feed and the chemical

treatment of the aquaculture environment. DAH is responsible for the supervision, prevention and control of aquatic diseases, and they oversee production, distribution, and usage of veterinary drugs.

NAFIQPM requires establishments to develop written traceability and recall programs in accordance with Circular No. 17/2021/TT-BNNPTNT. This circular requires establishments to comply with the “one step back, one step forward” principle to ensure the identification and tracking of the previous production and the following production. This circular requires establishments to notify NAFIQPM within 24 hours of becoming aware of adulterated products being shipped to the United States. NAFIQPM will immediately notify FSIS after receiving notification from the establishment. Circular No. 17/2021/TT-BNNPTNT requires establishments to annually test the effectiveness of their recall plans. The FSIS auditors verified the establishments included in the audit maintained written traceability and recall procedures and annually verified their effectiveness.

NAFIQPM can temporarily suspend an establishment’s eligibility for export to the United States, in accordance with Decision No. 1802/QD-BNN-QLCL, if the establishment does not maintain food safety conditions. NAFIQPM conducts verification of corrective actions, and if satisfactory, the establishment will be permitted to resume exports to the United States. During the audit, NAFIQPM suspended one establishment due to observed insanitary conditions as well as repetitive noncompliances related to sanitation. The FSIS auditors reviewed the associated documentation and verified that NAFIQPM followed their procedures related to temporary suspension of an establishment for not maintaining food safety conditions.

Decision No. 1802/QD-BNN-QLCL requires NAFIQPM to temporarily suspend an establishment’s eligibility for export to the United States after NAFIQPM is notified by FSIS of a POE violation identified through FSIS import reinspection. The establishment is then required to carry out traceability on the affected product, investigate the cause of the violation, perform corrective actions, and submit a report of the results of the investigation and corrective actions to NAFIQPM. NAFIQPM conducts verification of corrective actions, and if satisfactory, the establishment will be permitted to resume exports to the United States. FSIS auditors reviewed documentation associated with a POE violation in 2021 and verified NAFIQPM followed the requirements in Decision No. 1802/QD-BNN-QLCL related to enforcement measures in response to POE violation notifications from FSIS.

NAFIQPM’s export certification process is designed to ensure that Siluriformes fish and fish products intended for export to the United States are not adulterated or misbranded and that only eligible Siluriformes fish and fish products are certified for export to the United States. Decision No. 1802/QD-BNN-QLCL requires physical and sensory inspection of each consignment for export to the United States in accordance with criteria in Appendix I of Decision No. 2864/QD-BNN-QLCL. Physical inspection of each shipment includes verifying the packing list accurately reflects contents of consignment, accuracy of labels, condition of packages, and condition of the shipping container. Branch inspectors submit inspection reports to the branch certificate division for consignments with satisfactory inspection results. Decision No. 1802/QD-BNN-QLCL requires each consignment for export to the United States to be sampled by branch inspectors and tested for *Salmonella* and a limited number of chemical residues. Consignment-specific test

results are submitted to the branch certificate division. Decision No. 1802/QD-BNN-QLCL states that results reported from the designated laboratories are final, and retesting is not allowed. This only applies to testing of fish at slaughter and processing establishments, not testing of fish at farms. Satisfactory results from consignment-specific testing, as well as testing under the national residue monitoring program (NRMP), must be received prior to export certification. Officials from the branch certificate division submit the satisfactory test results and inspection report to the branch directorate for certification. Export certificates and stamps are stored at the branch offices. The FSIS auditors reviewed noncompliant results from consignment-specific testing and verified the branch office notified the establishment of the consignment's ineligibility for export to the United States. The FSIS auditors reviewed export certificates, inspection reports, and consignment-specific sample results and verified that government inspection personnel are performing export certification procedures as per NAFIQPM's requirements and procedures.

Decision No. 1802/QD-BNN-QLCL requires farms supplying Siluriformes fish to processing establishments for export to the United States to have a certificate of aquaculture and to be in an aquaculture area subjected to the NRMP. Decision No. 1802/QD-BNN-QLCL requires Siluriformes fish products to be produced in establishments, whether in Vietnam or an equivalent country, certified as eligible for export to the United States. Currently, Vietnam is not importing Siluriformes fish or fish products for further processing for subsequent export to the United States.

D-FISH is responsible for assessing and certifying Siluriformes fish farms as compliant with food safety regulations through the issuance of certificates of aquaculture in accordance with Circular No. 38/2018/TT-BNNPTNT. SRA auditors are responsible for assessing and certifying Siluriformes fish processing establishments as compliant with food safety regulations through the issuance of certificates of food safety in accordance with Circular No. 32/2022/TT-BNNPTNT. Siluriformes fish processing establishments are required to have a food safety certificate to be eligible to export (hereinafter referred to as the export list). SRA auditors are also responsible for verifying compliance with Decision No. 1802/QD-BNN-QLCL at establishments on the export list that are interested in being certified as eligible for export to the United States. FSIS auditors reviewed documentation from an establishment that was recently certified as eligible for export to the United States and verified SRA auditors evaluated the establishment's ability to comply with equivalent requirements for export to the United States and that all identified deficiencies were corrected prior to the establishment being added to the list of establishments certified to export to the United States.

Official communication between NAFIQPM, DAH, and D-FISH is achieved through the MARD electronic management system. NAFIQPM HQ monitors FSIS websites and receives notifications from the WTO Secretariat on FSIS import requirements. NAFIQPM HQ disseminates information regarding FSIS regulations to SRA auditors and branch inspectors by phone messaging and email. The FSIS auditors verified NAFIQPM distributed the official letter CV 1334/QLCL-CL1 regarding microbiological testing of Heat Treated but Not Fully Cooked-Not Shelf Stable (HT-NFC-NSS) products to branch inspectors via a phone messaging system.

NAFIQPM HQ personnel, SRA auditors, branch inspectors, and LCA officials are public employees and salaries are paid directly by NAFIQPM. The FSIS auditors reviewed earnings and leave statements for an SRA auditor and branch inspector and verified payment was made by NAFIQPM.

Decision No. 1802/QD-BNN-QLCL requires NAFIQPM to provide adequate staffing at Siluriformes fish slaughter and processing establishments to ensure inspection coverage at least once per shift. Establishments must notify the branch offices by Friday of the preceding week of planned production for export to the United States. FSIS auditors reviewed emails from establishments notifying the branches of planned production for export to the United States and verified the establishments were submitting the request within the required timeframe. FSIS auditors reviewed staffing records from the establishments certified for export to the United States and verified they had sufficient branch inspectors to ensure inspection coverage at least once per shift during production for export to the United States.

NAFIQPM officials in charge of food safety and quality assurance are required to have at least a university degree related to food safety and quality of agriculture and fishery products. NAFIQPM HQ organizes initial training for new employees and provides additional training if there are regulatory changes or new food safety issues. NAFIQPM officials receive training on food safety hazards, quality management programs, sampling, and inspection of food safety conditions in fishery processing establishments. NAFIQPM HQ organizes training for LCA officials on collecting samples and implementation of the NRMP. In 2022, NAFIQPM HQ organized training on traceability, recall, and root cause analysis for SRA auditors and branch inspectors. SRA organizes ongoing training for SRA auditors and administrative staff. In 2022, SRA organized training on Decision No. 1802/QD-BNN-QLCL, and in 2023, SRA organized training on Circular No. 32/2022/TT-BNNTNT. Branch offices organize ongoing training for the branch inspectors and administrative staff. In 2022, branch offices organized training on traceability, root cause identification, and handling of food safety incidents. In 2023, the branch offices organized training on monitoring of Siluriformes fish products for export to the United States and training on Circular No. 32/2022/TT-BNNPTNT. Branch inspectors are tested annually on FSIS import requirements and must receive a passing score to be able to inspect product for export to the United States. Branch inspectors who do not receive a passing score must undergo retraining and retesting. The FSIS auditors verified that NAFIQPM officials possess the appropriate educational credentials, training, and experience to carry out their food safety verification tasks.

NAFIQPM has the legal authority and responsibility to designate laboratories for conducting analytical testing of products intended for export to the United States in accordance with Circular No. 20/2013/TTLT-BYT-BCT-BNNPTNT. Branch 4 and Branch 6 are the only official laboratories designated for performing testing of Siluriformes fish and fish products. FSIS audited the Branch 6 microbiological and chemical residue testing laboratory. FSIS' audit scope included sample receipt, timely analysis, analytical methodologies, analytical controls, analyst qualifications, proficiency testing, and recording and reporting of results. Branch 6 laboratory participates in annual proficiency testing for chemical residues organized by Fera Science Limited and RIKILT Food Safety Research. Branch 6 participates in annual microbiological proficiency testing organized by IFM Quality Services, CSIRO, LGC, and Public Health

England. FSIS auditors verified Branch 6 received satisfactory results in international proficiency tests on food safety criteria. Results from official consignment-specific testing for *Salmonella* and chemical residues are provided to the branch and the establishment. Results from the NRMP are provided to SRA. Designated laboratories are audited annually by NAFIQPM HQ as part of government oversight functions over laboratories that perform analyses of official government sampling and testing programs for Siluriformes fish and fish products intended for export to the United States. Laboratories are required to be accredited according to standards consistent with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025. FSIS auditors verified Branch 6 laboratory is ISO/IEC 17025-accredited by the Vietnam Bureau of Accreditation (BoA). Branch 6 laboratory is audited annually by BoA. Additionally, the designated laboratories conduct annual internal audits. FSIS auditors reviewed reports from NAFIQPM HQ, BoA, and internal audits and verified they were performed at the required frequency and verified the laboratory reacted accordingly to audit findings. FSIS auditors reviewed laboratory procedures and analysis from sample receipt to reporting of results and identified the following finding:

- NAFIQPM did not ensure that the official chemical residue testing laboratory implemented adequate quality assurance procedures consistent with ISO/IEC 17025 standards regarding proper labeling of reagents.

FSIS onsite audit verification activities indicate that NAFIQPM's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement for the core regulatory requirements for this component, except for the laboratory finding described above regarding proper labeling of reagents.

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

The second equivalence component FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for complete separation of Siluriformes fish and fish products at establishments certified as eligible for 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.

Employee assessment is handled within each independently managed agency. Performance assessment of branch inspectors is performed once a year by the deputy director of the branch quality assurance division. Branch inspectors are evaluated on knowledge of regulations; adherence to inspection procedures; verification of sanitation standard operating procedures (Sanitation SOP), sanitation performance standards (SPS), good manufacturing practices (GMP), and HACCP systems; adequacy of decision making; record keeping; consignment inspection; and FSIS import requirements. Performance assessment of SRA auditors is performed once a year by the director of the SRA or the head of the quality division. SRA has a team that verifies sampling activities for the NRMP for each province once a year. Performance assessment of NAFIQPM LCA officials involved in developing the monthly NRMP schedule and collecting

samples for the NRMP is based on the Circular No. 31/2015/TT BNNPTNT. The FSIS auditors reviewed reports of employee assessments and verified they were being performed at the required frequency, covered the required evaluation criteria, and addressed unsatisfactory performance.

SRA conducts periodic audits of establishments on the export list to assess food safety conditions at a frequency based on the establishment's grade classification in accordance with Circular No. 32/2022/TT-BNNPTNT. Establishments are graded based on the criteria in Form 5b-1, Guidelines for Inspection, Evaluation, and Classification of Food Safety Conditions of Frozen Fish Processing Establishments. Grade 1 and Grade 2 establishments are audited every 18 months. Grade 3 establishments are audited every 12 months. Grade 4 establishments will have their certificates of food safety revoked. The audits assess the establishment's implementation of their Sanitation SOP programs, SPS requirements, HACCP system, GMPs, labeling, chemical and additive usage, competence of quality assurance staff, sampling, and record keeping. FSIS auditors reviewed the 2022 and 2023 reports from audits of the establishments included in the audit and verified they were performed at the required frequency and the deficiencies were corrected and verified.

Circular No. 17/2021/TT-BNNPTNT requires establishments to utilize a food origin tracing system to ensure identification and tracking of product after every stage of production. QCVN 02-01:2009/BNNPTNT requires that products be arranged in separate lots. Branch offices provide additional guidance for controlling shipments of Siluriformes fish products for export to the United States, which requires verification of segregation of ineligible products from eligible products intended for export to the United States. FSIS auditors verified that products eligible for export to the United States were separated by space within the freezers from products that were not eligible for export to the United States.

Decision No. 1802/QD-BNN-QLCL requires branch inspectors to conduct labeling verification activities before every shipment destined for export to the United States to ensure that information on the product labels is complete, accurate, and meets FSIS labeling requirements. Branch inspectors perform net weight verification on a subset of products from every export consignment to the United States. Branch inspectors perform verification of added solutions once a week. FSIS auditors verified that branch inspectors are reviewing labels as part of pre-shipment review and performing verification of net weights and added solutions at the required frequency. FSIS auditors reviewed labels for export to the United States and verified they contained the required information, including statements on added solutions, net weights, safe handling, and validated cooking instructions, when required. FSIS auditors verified establishments obtained approval from the FSIS Labeling and Program Delivery Staff for products with special claims.

NAFIQPM conducts official species testing when the establishment first becomes certified as eligible for export to the United States. Branch inspectors perform routine species verification using visual inspection of the whole fish. FSIS auditors verified branch inspectors are performing species verification as required.

Decision No. 1802/QD-BNN-QLCL requires branch inspectors to perform daily verification of the handling of dead or diseased fish to ensure they do not enter the food supply and are properly

disposed of and documented. Branch inspectors verify condemned products are stored in containers with recognizable labels and treated in accordance with Decision No. 1802/QD-BNN-QLCL. FSIS auditors observed appropriate identification and segregation of condemned materials and verified inspectors are performing daily verification of the number of dead or diseased fish and verifying they are accurately documented.

FSIS auditors concluded that NAFIQPM continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component FSIS auditors reviewed was Government Sanitation. FSIS auditors verified that NAFIQPM requires each official establishment to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS.

Decision No. 1151/QD-BNN-TCTS describes the 2021-2025 plan for official environmental sampling of source water used for aquaculture farms to ensure fish are being raised under sanitary conditions. D-FISH central office is responsible for collecting samples from the larger sections of the Mekong River and D-FISH LCAs are responsible for collecting samples from the tributaries and canals of the Mekong River. Samples are collected twice a month from January to April and July to October and four times a month from May to June to analyze for environmental parameters, nutrients, bacteria, and toxic algae. Samples are collected twice a year to analyze for heavy metals and pesticides. Periodic reports on the monitoring results are provided to MARD. QCVN 08-MT:2015/BTNMT stipulates limit values for surface water quality parameters. QCVN 02-20:2014/BNNPTNT describes the requirements and frequencies for farms to monitor environmental parameters and nutrients of pond water. The farms sample pond water for heavy metals and pesticides once a year in accordance with Decision No. 1802/QD-BNN-QLCL. The FSIS auditors verified the farms are monitoring the required environmental parameters, nutrients, heavy metals, and pesticides of pond water at the required frequency.

DAH is responsible for monitoring and providing guidance for disease control at farms. DAH collects samples of fish from randomly selected farms for identification of diseases in accordance with Circular 4/1025. Farms are required to conduct daily monitoring for detection of fish that are sick, showing signs of disease or abnormalities, or that die in large numbers, and report them to DAH, in accordance with Circular 04/2016/TT-BNNPTNT. DAH will conduct a disease investigation and perform sampling. DAH reports epidemic situations to MARD. FSIS auditors verified the farms are performing daily surveillance for signs of disease.

Inspectors from D-FISH LCAs conduct inspections at Siluriformes fish farms to verify maintenance of food safety conditions in accordance with Circular No. 38/2018/TT-BNNPTNT. The frequency of inspections is based on the farm's rating. The inspectors document verification of eight food safety criteria as defined on BB 1.3, Inspection Report for Control of Food Safety of Farms. Through records review and interviews, the FSIS auditors verified D-FISH inspectors

are performing inspections at the required frequency and are verifying the required food safety criteria.

Decision No. 1802/QD-BNN-QLCL describes requirements for transportation of Siluriformes fish from the point of harvest to the processing establishment to ensure they are transported in a sanitary manner. Branch inspectors verify the fish compartments of boats and trucks and the equipment for unloading the fish to the receiving area are smooth and easy to clean. Branch inspectors also test the water used to transport the fish for pH, temperature, and dissolved oxygen to minimize the number of weak or dead fish resulting from transportation. FSIS auditors observed branch inspectors at receiving and verified they inspected the fish compartments and unloading equipment for sanitary conditions and tested the water for the required parameters.

QCVN 02-01:2009/BNNPTNT details requirements for food business operators and general food safety conditions. This document addresses requirements for sanitary operations, including handling products in a manner to prevent contamination and performing cleaning at the middle and end of the shift. QCVN 02-02:2009/BNNPTNT requires establishments to develop a written Sanitation SOP program that specifies procedures, measures, and methods of cleaning and disinfection as well as control measures, monitoring, and record keeping. This document also requires establishments to periodically sample to verify hygiene. FSIS auditors reviewed sampling results conducted by the establishment to evaluate sanitary conditions and verified the establishments are conducting sampling at the frequency stated in the Sanitation SOPs. FSIS auditors reviewed Sanitation SOP monitoring records and verified the establishments are monitoring at the frequency stated in the Sanitation SOP programs and they are identifying and documenting deficiencies relating to sanitary conditions.

Decision No. 1802/QD-BNN-QLCL requires branch inspectors to verify maintenance of sanitary conditions and food safety requirements of equipment and infrastructure. This document also requires branch inspectors to verify compliance with SPS requirements and implementation of the establishments' Sanitation SOP programs. Branch inspectors perform monitoring at any stage of production from raw fish transportation through storage and they document their monitoring activities as instructed by NAFIQPM. Branch offices develop weekly monitoring schedules that include verification of SPS requirements and implementation of the establishment's Sanitation SOP program, based on the establishment's planned production in accordance with Decision No. 1802/QD-BNN-QLCL. The monitoring schedule may include verification of post-operational cleaning or pre-operational sanitizing. Branch inspectors use a three-pronged approach to verifying post-operational cleaning and pre-operational sanitizing. Branch inspectors use a combination of observing the cleaning and sanitizing activities, observing establishment quality control personnel perform monitoring activities, and performing hands-on verification. FSIS auditors observed branch inspectors performing verification of pre-operational sanitizing and verified they utilized the three-pronged approach. FSIS auditors verified the branch inspectors were performing verification of pre-operational sanitizing, operational sanitary conditions, and post-operational cleaning at the frequency required by the weekly monitoring schedules. FSIS auditors reviewed noncompliances related to sanitary conditions and verified the branch inspectors are identifying and documenting SPS and Sanitation SOP noncompliances and verifying corrective actions.

FSIS onsite audit verification activities indicate that NAFIQPM requires establishments to develop, implement, and maintain sanitation programs that are consistent with criteria established for this component. FSIS auditors also identified isolated noncompliances related to sanitation which are noted in the individual establishment checklists provided in Appendix A of this report.

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

The fourth equivalence component 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.

FSIS auditors verified that NAFIQPM requires establishments certified for export to the United States to develop, implement, and maintain HACCP systems in accordance with QCVN 02-02:2009/BNNPTNT. The HACCP system must include hazard analysis, flow chart, and HACCP plans that identify, evaluate, and prevent or control food safety hazards in their production processes. NAFIQPM requires establishments' HACCP plans to include activities designed to validate adequacy of controls, monitoring, and verification procedures; records for documenting results of monitoring and verification activities; and corrective actions in response to deviations from critical limits. FSIS auditors reviewed documentation associated with HACCP systems at each audited establishment. FSIS auditors conducted onsite observations of critical control point (CCP) monitoring and reviewed records associated with the establishments' design and implementation of their HACCP systems, including their hazard analyses, flow charts, CCPs, critical limits, monitoring procedures and frequencies, initial validation, ongoing verification, reassessment, records, and pre-shipment reviews. As a result of their review, the FSIS auditors identified the following finding:

- NAFIQPM did not ensure that certified establishments identified all steps in their production process in their flow charts and hazard analyses as required by Vietnam's national technical regulation QCVN 02-02:2009/BNNPTNT.

Decision No. 1802/QD-BNN-QLCL requires establishments to identify and control chemical and antibiotic residues in lots of raw fish and final products. The audited establishments required farms supplying raw materials to conduct preharvest sampling of fish from every pond to test for residues of veterinary drugs, pesticides, and dyes. FSIS auditors reviewed the residue results at the farms and verified they were being conducted at the required frequency and that only ponds with satisfactory results were harvested for processing for export to the United States. FSIS auditors also verified the establishments reviewed the pre-harvest sampling results at raw material receiving.

NAFIQPM requires establishments interested in exporting HT-NFC-NSS products to the United States to reassess their HACCP systems at least annually and whenever changes are needed to identify and establish control measures for hazards associated with these products. FSIS auditors verified the two establishments producing HT-NFC-NSS products intended for export to the United States reassessed their HACCP systems to consider hazards associated with production of

these products. The establishments identified *Salmonella* and *Staphylococcus (S.) aureus* as hazards in non-vacuum packaged HT-NFC-NSS products and *Clostridium (C.) perfringens* and *C. botulinum* as hazards in vacuum packaged HT-NFC-NSS products. FSIS auditors also verified the establishments validated their stabilization process after heat treatment to prevent outgrowth of microbiological pathogens or their toxins.

Decision No. 1802/QD-BNN-QLCL requires branch inspectors to verify the establishments' HACCP system, including evaluating the establishments' written HACCP programs and observing establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. FSIS auditors verified that branch inspectors are performing HACCP verification tasks at the frequency required by the weekly monitoring schedules and are identifying and documenting noncompliances and verifying corrective actions.

FSIS onsite audit verification activities indicate that NAFIQPM requires establishments to develop, implement, and maintain a HACCP system that is consistent with criteria established for this component, except for the HACCP finding described above regarding identification of all steps in the production process in the flow charts and hazard analyses. FSIS auditors also identified isolated noncompliances related to HACCP which are noted in the individual establishment checklists provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component 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 Siluriformes fish for chemical residues identified by the exporting country's Siluriformes fish products inspection authorities or by FSIS as potential contaminants.

Vietnam conducts routine surveillance sampling for chemical residues under the NRMP in accordance with Circular No. 31/2015/TT-BNNPTNT. The NRMP specifies the analytes included in the testing program, the method of analysis to be used, the matrix to be collected, the maximum residue level (MRL), criteria used to determine sampling numbers, and the total number of samples to be collected and tested. Circular No. 31/2015/TT-BNNPTNT requires that aquatic species raised for export meet the chemical residue requirements of the importing country as well as the requirements of Vietnam. Appendix I of Decision No. 1802/QD-BNN-QLCL provides the MRL for residues of veterinary drugs, pesticides, dyes, and metals for Siluriformes fish intended for export to the United States. The implementation and maintenance of the NRMP is carried out by the NAFIQPM LCA. NAFIQPM LCA officials collect samples of Siluriformes fish at hatcheries and farms at different stages of growth as specified in the NRMP. The SRA is responsible for verification and development of the annual NRMP, which is submitted to NAFIQPM HQ for approval. FSIS auditors reviewed the 2023 NRMP monthly schedules and verified the NAFIQPM LCA officials have collected the samples according to the schedule.

Branch 4 and Branch 6 laboratories are responsible for performing chemical residue testing under the NRMP for Siluriformes fish. Circular No. 31/2015/TT-BNNPTNT requires the laboratories to conduct testing and provide the results to the SRA within five days of receipt of the samples. The SRA posts monthly reports of NRMP results to the NAFIQPM website. The laboratories are required to notify the SRA within one day after receiving testing results in excess of the permitted MRL, including screen positive results. The SRA notifies the branch offices, NAFIQPM LCAs, D-FISH, DAH, and the farm of the violative result. The corrective actions depend on the stage of growth of the fish that was sampled. If the fish have not reached commercial size, the SRA request the farm to determine the cause and take appropriate corrective actions. NAFIQPM LCA officials will collect additional samples for enhanced surveillance after a period that allows for excretion of the detected substance. If the fish have reached commercial size, the SRA requests that the establishment temporarily stop harvesting to determine the cause and take appropriate corrective actions. NAFIQPM LCA officials will take additional samples for enhanced surveillance. When the testing results meet the requirements, the SRA will permit the farm to resume harvesting. If the results indicate the use of banned drugs or chemicals, the SRA notifies NAFIQPM LCAs, D-FISH, and DAH for intensive controls in accordance with regulations.

There has been one POE violation related to chemical residues since the previous FSIS audit in 2021. FSIS auditors verified corrective actions as part of the scope of the audit and did not have any concerns. FSIS onsite audit verification activities indicate that NAFIQPM continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in Siluriformes fish and fish products intended for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that Siluriformes fish and fish products prepared for export to the United States are safe and wholesome.

FSIS does not have microbiological sampling and testing requirements for foreign countries that are eligible to export raw or NRTE Siluriformes fish and fish products to the United States. However, Vietnam requires NAFIQPM branch inspectors to verify process control through sampling and testing of Siluriformes fish products for generic *Escherichia (E.) coli* and *Enterococcus* at establishments eligible for export to the United States, as described in Official letter CV 105/QLCL-CL1 and Appendix X of Circular 32/2022/TT-BNNPTNT. The results of generic *E. coli* and *Enterococcus* testing are submitted to the branch offices. FSIS auditors reviewed generic *E. coli* and *Enterococcus* results and verified that the branch offices are sampling at the frequency required by NAFIQPM.

NAFIQM branch inspectors also sample and test each consignment of Siluriformes fish products intended for export to the United States for *Salmonella* as described in Decision No. 1802/QD-BNN-QLCL. The results from consignment-specific *Salmonella* testing are provided to the

branch office. All samples tested for *Salmonella* must be negative before the consignment is certified for export to the United States. FSIS auditors reviewed *Salmonella* results from consignment-specific testing and verified that consignments with positive results were ineligible for export to the United States, in accordance with NAFIQPM requirements. FSIS auditors also verified that the results were reviewed prior to export certification.

Official letter CV 1334/QLCL-CL1 requires NAFIQPM branch inspectors to sample each consignment of HT-NFC-NSS non-vacuum packaged products for *S. aureus* and each consignment of HT-NFC-NSS vacuum packaged products for *S. aureus*, *C. perfringens* and *C. botulinum* for export to the United States. The results from consignment-specific testing for *S. aureus*, *C. perfringens* and *C. botulinum* are provided to the branch division. FSIS auditors reviewed the consignment-specific results from *S. aureus*, *C. perfringens* and *C. botulinum* testing and verified the sampling is being conducted and results are reviewed prior to export certification, as required by NAFIQPM.

FSIS onsite audit verification activities indicate that NAFIQPM maintains overall authority to implement an official microbiological sampling program organized and administered by the national government to verify that Siluriformes fish and fish products intended for export to the United States are unadulterated, safe, and wholesome.

X. CONCLUSIONS AND NEXT STEPS

A remote exit meeting was held August 22, 2023, with NAFIQPM officials. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- NAFIQPM did not ensure that the official chemical residue testing laboratory implemented adequate quality assurance procedures consistent with ISO/IEC 17025 standards regarding proper labeling of reagents.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- NAFIQPM did not ensure that certified establishments identified all steps in their production process in their flow charts and hazard analyses as required by Vietnam's national technical regulation QCVN 02-02:2009/BNNPTNT.

During the audit exit meeting, NAFIQPM committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of proposed corrective actions submitted by NAFIQPM and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Van Duc Tien Giang Food Export Company Dong Hoa hamlet, Song Thuan commune, Chau Thanh district, Tien Giang province	2. AUDIT DATE 8/10/2023	3. ESTABLISHMENT NO. DL 511	4. NAME OF COUNTRY Vietnam
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing
Prepared Products:	Raw intact, raw non-intact, NRTW otherwise processed Siluriformes fish and fish products

60. Observation of the Establishment

22. *Records documenting: the written HACCP plan, monitoring of the CCPs, dates and times of specific event occurrences.*

- Monitoring records for CCP3 were not signed or initialed by the person making the entry as required by QCVN 02-02:2009/BNNPTNT.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/10/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Bien Dong Seafood Co., Ltd Lot II, 18B1-18B2, Tra Noc 2 industrial zone, Phuoc Thoi ward, O Mon district, Can Tho city	2. AUDIT DATE 08/10/2023	3. ESTABLISHMENT NO. DL15	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing
Prepared Products:	Raw intact Siluriformes fish and fish products

60. Observation of the Establishment

15. *HACCP Plan Content*

- The establishment accepts returned products but have not addressed returned products in the flow chart or hazard analysis of the raw intact fish process as required by QCVN 02-02:2009/BNNPTNT.
- The establishment’s critical limit for the only CCP (chemical residues in received raw fish) is not a maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard as required by QCVN 02-02:2009/BNNPTNT.
- The corrective actions for a deviation covered by a critical limit are not consistent with international HACCP standards.

61. AUDIT STAFF OIEA International Audit Staff (IAS)	62. DATE OF ESTABLISHMENT AUDIT 08/10/2023
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United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Europe Joint Stock Company Block 69, My Tho industrial zone, Binh Tao hamlet, Trung An commune, My Tho city, Tien Giang province	2. AUDIT DATE 8/11/2023	3. ESTABLISHMENT NO. DL 518	4. NAME OF COUNTRY Vietnam
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing
Prepared Products:	Raw intact Siluriformes fish and fish products

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/11/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Mekong Delta Food Factory – CASEAMEX Lot 02-12, Tra Noc II industrial zone O Mon district Can Tho city	2. AUDIT DATE 08/11/2023	3. ESTABLISHMENT NO. DL 369	4. NAME OF COUNTRY Vietnam
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes slaughter and processing.
Prepared Products:	Raw intact Siluriformes fish and fish products

60. Observation of the Establishment

15. HACCP Plan Content

- The establishment accepts returned products but have not addressed returned products in the flow chart or hazard analysis of the raw intact fish process as required by QCVN 02-02:2009/BNNPTNT.
- The establishment's critical limit for the only CCP (Chemical residue in received raw fish) is not a maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard as required by QCVN 02-02:2009/BNNPTNT.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/11/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Thanh Binh Dong Thap One Member Company Limited Lot No. 1, Road No.2, Thanh Binh industrial zone, Binh Thanh commune, Thanh Binh district, Dong Thap province	2. AUDIT DATE 8/14/2023	3. ESTABLISHMENT NO. DL 847	4. NAME OF COUNTRY Vietnam
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing
Prepared Products:	Raw intact Siluriformes fish and fish products

60. Observation of the Establishment**15. HACCP Plan Content**

- The establishment accepts returned products but have not addressed returned products in the flow chart or hazard analysis of the raw intact fish process as required by QCVN 02-02:2009/BNNPTNT.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT08/14/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Bien Dong Hau Giang Seafood Joint Stock Company (Bien Dong Seafood Co., Ltd.) Residential Quarter 5, Hiep Thanh ward, Nga Bay city Hau Giang province	2. AUDIT DATE 08/14/2023	3. ESTABLISHMENT NO. DL 810	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing.
Prepared Products:	Raw intact Siluriformes fish and fish products

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT08/14/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Workshop 3 - VINH HOAN CORP 1643, National Road 30, Ward 11, Cao Lanh city, Dong Thap province	2. AUDIT DATE 8/15/2023	3. ESTABLISHMENT NO. DL 500	4. NAME OF COUNTRY Vietnam
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing
Prepared Products:	Raw intact Siluriformes fish and fish products

60. Observation of the Establishment

15. HACCP Plan Content

- The establishment has a program for addressing returned product and the step is included in the flow chart, but it is not addressed in their hazard analysis as required by QCVN 02-02:2009/BNNPTNT.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/15/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION NTSF Seafoods Joint Stock Company Lot C1, C2, C3, C4, C5, Thot Not industrial zone, Thoi Thuan ward, Thot Not district Can Tho city	2. AUDIT DATE 08/15/2023	3. ESTABLISHMENT NO. DL 461	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing.
Prepared Products:	Raw intact Siluriformes fish and fish products

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/15/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Workshop 2 - Vinh Hoan Corporation 1645A, National Road 30, Ward 11, Cao Lanh city, Dong Thap province	2. AUDIT DATE 8/16/2023	3. ESTABLISHMENT NO. DL 61	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing
Prepared Products:	Raw intact, raw non-intact, NRTE otherwise processed Siluriformes fish and fish products

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT08/16/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Atlantic Seafood Freezing Factory N.V Lot A4, industrial zone, Thoi Thuan ward, Thot Not district, Can Tho city	2. AUDIT DATE 08/16/2023	3. ESTABLISHMENT NO. DL 408	4. NAME OF COUNTRY Vietnam
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Siluriformes fish slaughter and processing.
Prepared Products:	Raw intact Siluriformes fish and fish products

60. Observation of the Establishment

13. *SSOP Daily Records*

- SSOP corrective actions in response to product contamination during operations did not the requirements of their written program.

15. *HACCP Plan Content (Flow chart and Hazard analysis)*

- The flow chart and hazard analysis does not accurately reflect product flow because they do not include products with temporary packaging that are taken from freezer to packing room for permanent packaging and then back to the freezer as required by QCVN 02-02:2009/BNNPTNT.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/16/2023

Appendix B: Foreign Country Response to the Draft Final Audit Report



MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT OF VIETNAM
**National Authority for Agro-Forestry-Fisheries Quality, Processing and
Market Development (NAFIQPM)**

Add.: 10 Nguyen Cong Hoan, Ba Dinh, Ha Noi, Viet Nam

Tel: 84.4.38310983; Fax: 84.4.8317221; E-mail: nafiqpm@mard.gov.vn

Ref.No: 1663/CCPT-ATTP

Hanoi, December. 28 , 2023

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

On behalf of the National Authority for Agro-Forestry-Fisheries Quality, Processing and Market Development (NAFIQPM), under the Vietnam Ministry of Agriculture and Rural Development, I would like to present its compliments to you and express my sincere thanks to you and your colleagues in the FSIS for the support and close coordination throughout the evaluations maintaining of the equivalence recognition for the food safety hygiene control systems governing *Siluriformes* fish and fish products exported to the United States of America

In response to your official letter of November 11, 2023 enclosed with the draft final audit report of Vietnam's *Siluriformes* fish inspection system August 7-22, 2023

1. NAFIQPM basically agree with findings on the draft final report. However, NAFIQPM would like to provide comments for the draft report (please see detailed in attached Annex 1).
2. NAFIQPM would like to provide corrective actions taken to the recommendations of the draft report. Please see Annex 2 enclosed.

On the occasion of the New Year 2024, 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.

Thank you for your cooperation./.

Yours sincerely,



Le Ba Anh

Deputy Director General of NAFIQPM


cc. Counselor for Agricultural Affairs, U.S. Embassy, Hanoi.

Annex 1: COMMENTS ON THE DRAFT AUDIT REPORT
 (Attached to NAFIQPM letter No. /CCPT-ATTP dated December , 2023)

No	Content of the draft	NAFIQPM's proposals for modification	Reasons
1.	<p>V. COMPONENT TWO (page 10)</p> <p>Performance assessment of SRA auditors is performed once a year by the deputy director of the SRA quality assurance division. SRA has a team that verifies sampling activities for the NRMP for each province once a year. Performance assessment of NAFIQPM LCA officials involved in developing the monthly NRMP schedule and collecting samples for the NRMP is based on the provincial regulations.</p>	<p>Performance assessment of SRA auditors is performed once a year by the director of the SRA or the head of quality division. SRA has a team that verifies sampling activities for the NRMP for each province once a year. Performance assessment of NAFIQPM LCA officials involved in developing the monthly NRMP schedule and collecting samples for the NRMP is based on Circular No. 31/2015/TT BNNPTNT</p>	<p>More complete and detailed</p>
2.	<p>VI. COMPONENT THREE: GOVERNMENT SANITATION (page 12)</p> <p>Samples are collected twice a month to analyze for environmental parameters, nutrients, bacteria, and toxic algae. Samples are collected three times a year to analyze for heavy metals and pesticides.</p>	<p>“Samples are collected twice a month from January to April and from July to October; four times a month from May to June to analyze for environmental parameters, nutrients, bacteria, and toxic algae. Samples are collected twice a year to analyze for heavy metals and pesticides”.</p>	<p>Consistent with reality</p>
3.	<p>VI. COMPONENT THREE: GOVERNMENT SANITATION (page 12)</p> <p>The inspectors document verification of eight food safety criteria as defined on BB 1.2,</p>	<p>“The inspectors document verification of eight food safety criteria as defined on BB 1.3”</p>	<p>Consistent with reality</p>

ANNEX 2: RESPONSE/CORECTIVE ACTIONS TAKEN TO THE RECOMMENDATIONS OF REPORT
(Attached to NAFIQPM letter No. 1663 /CCPT-ATTP dated December 28 , 2023)

1. By Competent Authorities

Component	Findings	Applied corrective actions	Enclosed documents
<p>COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)</p>	<p>NAFIQPM did not ensure that the official chemical residue testing laboratory implemented adequate quality assurance procedures consistent with ISO/IEC 17025 standards regarding proper labeling of reagents.</p>	<p>NAFIQPM - Branch 6 has Labeled and clearly state the information of 02 bottles of NaOH used to absorb and neutralize acid vapor.</p>	<p>Attached photo</p> 
<p>COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM</p>	<p>NAFIQPM did not ensure that certified establishments identified all steps in their production process in their flow charts and hazard analyses as required by Vietnam’s national technical regulation QCVN 02-02:2009/BNNPTNT</p>	<ul style="list-style-type: none"> - Implementing FSIS recommendations, NAFIQPM notified establishments and disseminated to inspectors to promptly update according to FSIS instructions. - The establishments have adjusted and added missing steps to the production process in their flow charts and hazard analyses table - NAFIQPM disseminates to inspectors and guides establishments in approaching hazard analysis and CCP determination according to FSIS guidance (regulation 9 CFR 417.) 	<ul style="list-style-type: none"> - NAFIQPM has issued its official letter No 711/CCPT-ATTP dated August 30,2023 requesting establishments and NAFQPM’s Branches 4,6 take measures to findings recommended by the FSIS auditors - On December 11-12, 2023, NAFIQPM trained and disseminated to its inspectors about the findings of the FSIS auditors

2. By audited processing the establishments

Establishments	Findings	Applied corrective actions	Enclosed documents	NAFIQPM's verification
Bien Dong Seafood Co., Ltd (DL 15)	The establishment accepts returned products but have not addressed returned products in the flow chart or hazard analysis of the raw intact fish process as required by QCVN 02-02:2009/BNNPTNT	- Revised HACCP, to add the step "Returned products" into the flow chart and hazard analysis of the raw intact fish process. Re-issue HACCP after updating -Re training for QC and relevant staff about the revision	- Revised HACCP plan - Training record (Training Program, HACCP team meeting minutes, Training Effectiveness Evaluation)	satisfactory
	The establishment's critical limit for the only CCP (chemical residues in received raw fish) is not a maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard as required by QCVN 02-02:2009/BNNPTNT.	Updating the hazard analysis table and re-identify CCP. Re-issue HACCP after re-identify CCP. -Re training for QC and relevant staff about the revision		
	The corrective actions for a deviation covered by a critical limit are not consistent with international HACCP standards.	- To add all appropriate content corrective actions for for deviations when CCPs violate international HACCP standards. (full 04 parts) -Re training for QC and relevant staff about the revision		
Mekong Delta Food Factory – CASEAMEX (DL 369)	The establishment accepts returned products but have not addressed returned products in the flow chart or hazard analysis of the raw intact fish process as required by QCVN 02-02:2009/BNNPTNT.	Adding to the flow chart or hazard analysis of HACCP the receiving stage for returned products and refer to the recall products guidance document - HACCP teams refer to FSIS guidance at https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-GD-2022-0006.pdf to add to the quality management program	- the flow chart and hazard analysis of HACCP have been revised	satisfactory

Establishments	Findings	Applied corrective actions	Enclosed documents	NAFIQPM's verification
	The establishment's critical limit for the only CCP (chemical residues in received raw fish) is not a maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard as required by QCVN 02-02:2009/BNNPTNT.	- Adjusting the hazard analysis table and redefine CCP according to regulations		
Atlantic Seafood Freezing Factory N.V (DL 408)	SSOP corrective actions in response to product contamination during operations did not the requirements of their written program.	Training QC to conduct SSOP monitoring to understand and fully record the content of corrective actions according to regulations in SSOP	-The updated and revised monitoring form has full content on corrective actions according to SSOP regulations - Training minutes for QC monitoring SSOP;	satisfactory
	The flow chart and hazard analysis does not accurately reflect product flow because they do not include products with temporary packaging that are taken from freezer to packing room for permanent packaging and then back to the freezer as required by QCVN 02 02:2009/BNNPTNT.	-Adding a description of the step "temporary packaging and changing temporary packaging to main packaging" into the flow chart and HACCP hazard analysis table - Training workers to implement	- the flow chart and hazard analysis table (updated August 17, 2023) - Minutes of training for workers in the temporary packaging process	satisfactory
Workshop 3 - VINH HOAN CORP (DL 500)	The establishment has a program for addressing returned product and the step is included in the flow chart, but it is not addressed in their hazard analysis as required by QCVN 02-02:2009/BNNPTNT.	-Adding hazard analysis for nonconforming product returned in the Hazard Analysis table - Re training for QC and relevant staff about the revision	-the flow chart revised on August 15, 2023 -Hazard analysis table revised on August 15, 2023 - Training records	satisfactory

Establishments	Findings	Applied corrective actions	Enclosed documents	NAFIQPM's verification
Van Duc Tien Giang Food Export Company (DL 511)	<p>Records documenting: the written HACCP plan, monitoring of the CCPs, dates and times of specific event occurrences.</p> <ul style="list-style-type: none"> Monitoring records for CCP3 were not signed or initialed by the person making the entry as required by QCVN 02:2009/BNNPTNT. 	<ul style="list-style-type: none"> -Updating the CCP monitoring form (BM21B/HAF - Form for controlling batches of packaging, allergic ingredients on packaging): Adding a column to record or sign the name of the supervisory inspector for each monitoring content. - Update the revision, issuance date and new validity of the CCP Monitoring Form (BM21B/HAF - Form for controlling batches of packaging, allergic ingredients on packaging). - Retraining for QC staff to monitor and record at the allergen information labeling stage. 	<p>Report on results of correction actions on August 16, 2023;</p> <ul style="list-style-type: none"> - Minutes of meeting dated August 11, 2023; - BM21B/HAF - Form for controlling batches of packaging, allergic ingredients on packaging (CCP), revision: 08 (August 11, 2023); - Notice of training and employee training results dated August 14, 2023; - BM21B/HAF - Form for controlling batches of packaging and allergic ingredients on packaging (CCP) actually implemented from August 15, 2023. 	<p>satisfactory</p>
Thanh Binh Dong Thap One Member Company Limited (DL 847)	<p>The establishment accepts returned products but have not addressed returned products in the flow chart or hazard analysis of the raw intact fish process as required by QCVN 02 02:2009/BNNPTNT.</p>	<p>Adding control of returned non-conforming products to the flow chart and hazard analysis table</p>	<ul style="list-style-type: none"> -the processing flow chart revised on August 15, 2023 -Hazard analysis worksheet revised on August 15, 2023 	<p>satisfactory</p>