



United States Department of Agriculture

Food Safety and
Inspection Service

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March 5, 2024

Mr. Chalermchai Suwannarak
Director General
Department of Fisheries
50 Kasetklang Chatuchak
Bangkok 10900 THAILAND

Dear Mr. Suwannarak,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Thailand's inspection system September 11–22, 2023. Enclosed is a copy of the final audit report. The comments received from the Government of Thailand are included as an attachment to the report.

Sincerely,

MARGARET
BURNS
RATH

Digitally signed
by MARGARET
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Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
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Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF
THAILAND

SEPTEMBER 11–22, 2023

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

SILURIFORMES FISH AND FISH PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 28, 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 Thailand conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) September 11–22, 2023. The purpose of the audit was to verify whether Thailand'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. Thailand currently exports only raw intact Siluriformes fish products to the United States.

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

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

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS, AND LABELING)

- Periodic supervisory reviews are conducted at a frequency of once every three years, which may be insufficient to identify competencies where improvement is needed for government inspection personnel based on findings identified at multiple establishments related to sanitation standard operating procedures (Sanitation SOPs) and HACCP.

GOVERNMENT SANITATION

- Government inspection personnel did not identify deficiencies related to Sanitation SOPs requirements at two establishments.
- Government inspection personnel did not identify deficiencies related to SPS requirements at all three establishments.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- Government inspection personnel did not identify deficiencies related to HACCP requirements at two establishments.

During the audit exit meeting, Thailand's Central Competent Authority – Department of Fisheries (DOF) committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of DOF'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 Thailand’s food safety system from September 11–22, 2023. The audit began with an entrance meeting on September 11, 2023, in Bangkok, Thailand, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Department of Fisheries (DOF). Representatives from DOF accompanied the FSIS auditor throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference on September 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. Thailand 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

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Thailand’s Self-Reporting Tool (SRT) responses and supporting documentation, including their official chemical residue sampling plan and results. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to verify whether Thailand’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 three-year period, in addition to information obtained directly from DOF 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., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards, and Labeling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control

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

Point (HACCP) System, (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative functions at DOF headquarters, one regional office, three local inspection offices within the establishments, and one Siluriformes fish farm. The FSIS auditor 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.

All three Siluriformes fish slaughter and processing establishments certified to export to the United States were audited. The products these establishments produce and export to the United States include raw intact Siluriformes fish products.

During the establishment and fish farm visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor assessed DOF’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 9 CFR 327.2

The FSIS auditor also visited a government chemical residue laboratory to verify that this laboratory can provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Department of Fisheries, Bangkok
	Regional	1	• Fish Inspection and Research Center, Samut Sakhon
Laboratory		1	• Fish Inspection and Quality Control Division (FIQD), (government chemical residue), Bangkok
Siluriformes fish slaughter and processing establishments		3	• Establishment No. 1159, B.S.A. Food Products Co., Ltd., Samut Sakhon • Establishment No. 1173, I.T. Foods Industries Co., Ltd., Samut Sakhon • Establishment No. 1359, C.K. Frozen Fish & Food Co., Ltd., Samut Prakan
Siluriformes fish farm		1	• ML Farm, Ratchaburi

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 Thailand’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 Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From May 1, 2020, to April 30, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 282,228 pounds of raw intact Siluriformes fish products exported by Thailand to the United States. Of these amounts, additional types of inspection were performed on 20,867 pounds of Siluriformes fish products, which included physical examination and chemical residue analysis. As a result of this additional testing, FSIS did not reject any Siluriformes fish product for issues related to public health. However, 44 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 identified the following findings:

Summary of Findings from the 2021 FSIS Audit of Thailand
Component 1: Government Oversight (e.g., Organization and Administration)
<ul style="list-style-type: none"> The CCA conducts residue analysis on primary samples but defers confirmation of results exceeding tolerance levels until they perform analysis on a second extraction from the original fish sample. FSIS does not consider the practice of performing a second analysis to support or refute original results as equivalent.
Component 3: Government Sanitation
<ul style="list-style-type: none"> The CCA does not maintain specific written instructions for Fish Inspection and Quality Control Division (FIQD) inspectors on how to verify sanitation requirements. The current DOF form does not provide FIQD evidence of the methods, process, nor results of specific sanitation verification activities.

The FSIS auditor verified that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

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

The national government of Thailand organizes and manages the food safety inspection system governing Siluriformes fish and fish products. DOF, within the Ministry of Agriculture and Cooperatives, is responsible for ensuring the food safety of Siluriformes fish and fish products. The National Government Organization Act, B.E. 2534 (1991), Section 8, as amended by the National Government Organization Act (No. 4), B.E. 2543 (2000) is the legislation that gives DOF the authority to implement and maintain Thailand's food safety inspection system for Siluriformes fish and fish products. The Royal Ordinance on Fisheries B.E. 2558 (2015) (Chapter 8) provides authority for DOF to require conditions for the hygiene standards of aquatic animals or aquatic products, and to regulate the importation, processing, and export of aquaculture products.

Thailand's Ministerial Regulation on the Organization of the Department of Fisheries, the Ministry of Agriculture and Cooperatives, B.E. 2559 (2016), describes the organization of DOF and the three different divisions within DOF responsible for producing and exporting Siluriformes fish and fish products: the Fish Inspection and Quality Control Division (FIQD), the Inland Aquaculture Research and Development Division (IARDD), and the Fish Quarantine and Inspection Division (FQID). The FSIS auditor verified that there have not been any changes in the DOF organizational structure since the previous FSIS audit in 2021.

FIQD is responsible for regulating, inspecting, and supervising the application of efficient sanitation and food safety measures in establishments producing Siluriformes fish and fish products. Inspection personnel perform government verification activities in establishments to verify compliance with sanitation and HACCP requirements. FIQD is also responsible for certifying and decertifying establishments as eligible to export Siluriformes fish and fish products to the United States. The FIQD headquarters is located in Bangkok, and three fish inspection and research centers are located in Samut Sakhon, Surat Thani, and Songkhla provinces. The centers act as regional competent authorities that provide services for establishment inspection; physical, microbiological and chemical analyses; and research studies.

IARDD is responsible for assessing and standardizing water quality for inland aquaculture and has the authority to regulate, supervise, inspect, and monitor the inland production and breeding of freshwater fish to ensure compliance with national and international standards. IARDD is responsible for registering aquaculture farms when applicable standards are met. IARDD is also responsible for verifying that Siluriformes fish are raised under healthy, suitable conditions, which is achieved through inspection and monitoring of farms and sampling and testing of feed, fish, and water to ensure sanitary conditions are maintained.

FQID is responsible for issuing licenses, permits, and export certificates for Siluriformes fish and fish products and has overall responsibility to control, inspect, and quarantine the import, export, and transit of fish and fishery products through Thailand in accordance with the Royal Ordinance on Fisheries B.E. 2558 (2015) and the Animal Epidemic Act B.E. 2558 (2015).

The Notification of the Ministry of Public Health (No. 385) B.E. 2560 (2017) designates DOF personnel as the competent officers for the execution of the Food Act B.E. 2522 (1979) for aquatic animals and products. The Ministerial Regulation on the Organization of the Department

of Fisheries, The Ministry of Agriculture and Cooperatives, B.E. 2559 (2016) provides the authority to the DOF to regulate and control the food safety and quality systems for fishery products. The regulation also describes the primary tasks of FIQD regarding the regulation, inspection, and control of food safety during processing.

Thailand's Food Act B.E. 2522 (1979), Sections 25–29, prohibits production and distribution of adulterated product and defines food safety and misbranding criteria as anything that might be harmful to health, produced under unhygienic conditions, or food not meeting criteria specified by the Minister, including when samples tested for chemical residues have levels that exceed established limits. Section 43 of the act describes the authority to seize product when there is a suspected violation of the act.

The FSIS auditor verified that DOF provides oversight to ensure that Siluriformes fish and fish products are grown and harvested and that the species is accurately identified. Good manufacturing practices are required to ensure that there is no commingling of other species of fish with Siluriformes fish. When other species of fish are identified, they are removed from the lot. Compliance with these requirements is verified by the government inspection personnel through record reviews and observations at receiving. Additionally, government inspection personnel verify the species and corresponding label on each shipment intended for export to the United States.

Thailand's export certification process requires government inspection personnel to verify eligibility of producing establishments, accurate lotting descriptions, labeling, HACCP and Sanitation SOP records, and acceptable analytical results for all production lots. Inspection personnel will not issue an export certificate unless negative results are received for analyses conducted for chemical residues and microbiological pathogens (e.g., *Salmonella*). The FSIS auditor verified that DOF maintains security of export certificates using a holographic seal and unique identification number that is linked to each certificate.

The establishment must be able to identify the source of raw materials, the production volume, production dates, identifying codes, name of the buyer, distribution date, and the quantity distributed. If DOF determines that a recall is necessary, the establishment is required to provide product details, such as the type of product, production volume, production dates, details of the raw materials, manufacturing process controls, and what the establishment's investigation determined to be the cause for the recalled product. The Aquatic Animal Movement Document (MD) is used as a tool for traceability of Siluriformes fish and fish products as each production lot is given a product code. This coding enables rapid recall if there is a rejection or product violation. The MD specifies the farmer's name, the name and address of the farm, the registration number, and the date and quantity of harvesting. All Siluriformes fish must be sourced from a farm certified by IARDD and must be accompanied by the MD. Establishments certified to export to the United States do not use source materials from any other establishments or from other countries.

The FSIS auditor verified that there have not been any recalls since the previous FSIS audit in 2021. In the event adulterated or misbranded products are shipped to the United States, DOF would inform FSIS of the implicated product through communication between DOF

headquarters and FSIS. Additionally, DOF requires establishments to maintain and implement a recall plan in accordance with HACCP Requirements for Fish and Fishery Products, Section 10.3.

The FSIS auditor verified the process for establishment certification as defined in Criteria for Inspection of Siluriformes Export Establishments to the U.S. and Plant Inspection Procedure, PF-1. This procedure describes inspection verification procedures for ensuring that establishments meet domestic and United States requirements prior to being certified as eligible to export to the United States. A current list of establishments eligible to export Siluriformes fish and fish products to the United States is maintained on the FIQD website. Establishments that submit requests to DOF headquarters for eligibility to export to the United States are required to submit their HACCP manual, Sanitation SOPs, and information on their production processes. Government inspection personnel will then verify that requirements are met. If requirements are not met, government inspection personnel verify that the establishment has implemented corrective actions in response to any noncompliance previously identified.

The procedure requiring establishments to submit corrective actions in response to noncompliances is described in the Plant Inspection Procedure, P-FI. The FSIS auditor reviewed government inspection records, including noncompliance reports at establishments certified to export to the United States, and verified that government inspection personnel are documenting noncompliances and requiring corrective actions to be implemented and documented in writing by the establishment. Corrective actions and preventive measures are required immediately for imminent threats to public health and are then verified by government inspection personnel once implemented. The FSIS auditor verified that there have not been any enforcement measures at the establishments eligible to export to the United States since the previous FSIS audit in 2021.

FSIS import requirements are communicated to establishments, government inspection personnel, and regional offices directly through email, official notifications, or direct meetings, if needed, as well as through the FIQD's website. DOF translates FSIS regulations for government inspection personnel and establishments in Thailand to ensure that the intent of the policy is understood and holds training for government inspection personnel on updated FSIS import requirements. The FSIS auditor verified that information regarding FSIS import requirements is conveyed to government inspection personnel and establishments certified to export to the United States.

The FSIS auditor verified that FIQD inspection personnel are government employees who are paid directly by the regional offices. The Notification of the Ministry of Public Health (No. 385) B.E. 2560 (2017) On Appointment of Competent Officers for the Execution under Food Act B.E. 2522 (1979), Section 11, lists the DOF positions designated as competent inspection personnel under the authority of DOF and the government of Thailand.

The Criteria for Inspection of Siluriformes Export Establishment to the U.S., Section 3, requires government inspection personnel to be present at least once per production shift to perform verification duties. The FSIS auditor verified through review of records and observation that inspection was maintained at the certified establishments at least once per production shift during days when product intended for export to the United States was being processed. Relief staffing

schedules are maintained by regional supervisory government personnel for all government inspection personnel in the event of any planned or unplanned absences.

The FSIS auditor reviewed the hiring process for government inspection personnel and verified that inspectors are required to hold a bachelor's degree in a science-related field to qualify for their positions. DOF verifies that inspectors do not have a conflict of interest before they are hired. Once hired, inspectors are also required to sign a statement indicating they will remain impartial in their decisions. Inspectors are required to undergo on-the-job training, including for FSIS import requirements, for six months. After training is completed, their performance is assessed, and they must receive a passing score before they are allowed to start working.

Government inspection personnel are required to take the "U.S. Import Requirements" training course at least once per year or when changes have been made to FSIS import requirements. This training course focuses on verifying that establishments meet FSIS sanitation requirements, chemical residue sampling requirements for Siluriformes fish and fish products, and labeling requirements. The course also includes information on verification of United States export certificates, and chemical residues that are prohibited in Siluriformes fish and fish products intended for export to the United States. The FSIS auditor verified that the most recent training occurred in September 2023 and covered Sanitation SOP, HACCP, labeling, condemned materials, and FSIS import requirements.

DOF has the authority to approve laboratories that analyze official samples. Authorized laboratories are required to follow the Regulation of the Department of Fisheries on the Registration of Laboratories including submission of validation data for analytical methods, inter- or intra-laboratory proficiency test results, work instructions, and quality assurance information to DOF. Additionally, the Inland Fisheries Research Division is responsible for pesticide testing with the exception for analyses for polychlorinated biphenyls, which are performed by a third-party (private) laboratory. DOF reviews all data collected, and laboratories are approved if requirements are met. DOF conducts annual audits after approval, and if noncompliances are identified, the laboratory's approval can be revoked for one year. The laboratory can request approval again after one year if corrective actions have been implemented to address the noncompliances. The FSIS auditor reviewed the most recent DOF audit report of the central FIQD laboratory and verified that when deficiencies were identified, the laboratory implemented corrective actions and DOF subsequently verified those corrective actions were adequate.

Laboratories must implement quality assurance and quality controls procedures that are consistent with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards. Thailand's Personnel Manual describes the steps taken for ensuring the competency of laboratory technicians. Thailand's Equipment Manual describes the steps taken to ensure that all equipment that is used in the laboratory is calibrated and maintained properly.

Laboratories must also be accredited by the national accreditation body – the Bureau of Laboratory Quality Standards (BLQS) of the Ministry of Public Health. External audits are conducted by BLQS every two years to ensure compliance with ISO/IEC 17025 standards. The

FSIS auditor verified that the laboratory had a valid, current accreditation certificate. The FSIS auditor also reviewed the most recent BLQS audit reports and verified that corrective actions were taken when deficiencies were identified.

The Work Instruction of Quality Assurance for Chemical Laboratory is a guide for the analysts to ensure that the quality and integrity of sample test results are in accordance with ISO/IEC 17025 standards, including the use of a standard calibration curve and positive and negative control samples. Analysts are required to participate in intra- or interlaboratory proficiency testing. All laboratory technicians take part in proficiency testing at least once per year to maintain their competency level. The FSIS auditor verified that proficiency testing covers the methods performed by laboratory personnel to analyze official government samples of products that are intended for export to the United States and found the most recent results were acceptable.

The FSIS auditor verified that DOF's Siluriformes fish and fish products inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of the core regulatory requirements for this component. DOF's Siluriformes fish inspection system continues to meet the core requirements for this component.

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

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

Supervisory reviews are conducted by a chief of inspection of government inspection personnel during their first time performing their inspection duties, and again after three months. The chief of inspection is supervised by the technical manager. Government inspection personnel are evaluated on Sanitation SOP verification activities, HACCP verification activities, economic adulteration and labeling verification activities, export certification, import inspection, and the frequency of all inspection activities. If they pass this evaluation, they are evaluated again after one year and subsequently once every three years. In addition, an auditor from FIQD regional offices will conduct annual audits of export establishments to verify compliance with Sanitation SOP, HACCP, and requirements for export to the United States. The FSIS auditor reviewed the most recent audit report and verified that corrective actions were taken and confirmed when deficiencies were identified. The FSIS auditor verified that supervisory reviews are being conducted as described; however, the following deficiency was identified:

- Periodic supervisory reviews are conducted at a frequency of once every three years, which may be insufficient to identify competencies where improvement is needed for government

inspection personnel based on findings identified at multiple establishments related to sanitation standard operating procedures (Sanitation SOPs) and HACCP.

Thailand ensures prevention of cross-contamination by maintaining requirements for ensuring separation by time and space during production of products intended for export to the United States from products produced for other markets, as described in Operating Practices of Fishery Products and verified by inspectors on Form of Processing Procedure Assessment of Products from Fish of the Order Siluriformes Exported to the U.S. Additionally, raw source material is segregated and product codes are used as identifiers to ensure that there is no commingling of raw source materials eligible for export to the United States with ineligible product.

Establishments certified to export to the United States are required to maintain identity of products and DOF has developed label verification procedures in Criteria for Inspection of Siluriformes Export Establishment to the U.S. (2018) to ensure that the Siluriformes fish and fish products intended for export to the United States meet FSIS labeling requirements. The FSIS auditor confirmed that labeling requirements are verified by government inspection personnel on Form of Processing Procedure Assessment of Products from Fish of the Order Siluriformes Exported to the U.S. for each shipment of product intended for export to the United States. The FSIS auditor verified that labeling requirements were verified by DOF and that establishments maintained copies of all labels used for product intended for export to the United States. Additionally, the DOF Inland Fisheries Research and Development Division has the ability to conduct species testing to verify the species declaration on product labels.

Any fish or parts of fish that are found decomposed or containing harmful or extraneous substances are rejected from processing and segregated. Form of Processing Procedure Assessment of Products from Fish of the Order Siluriformes Export to the U.S. (Attachment No. 15), Section 5.4, lists the requirement to denature fish products with a chemical substance (e.g., charcoal or dye) so the products will not be used for human food. The Operating Practices of Fishery Products, Section 7.1, states that the establishment is required to inspect raw material prior to receiving and are to reject any raw materials that are abnormal or decomposed. The Food Act B.E. 2522, Section 43, requires inspectors to control product that is unfit for human consumption. The FSIS auditor confirmed that daily verification is conducted by the FIQD inspection for handling of condemned animals and parts and inedible products.

The FSIS auditor verified that DOF's Siluriformes fish and fish products inspection system maintains the legal authority to establish regulatory controls over establishments certified to export to the United States. However, deficiencies were identified in implementation of regulatory oversight due to the long time (3 years) between supervisory reviews.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that DOF 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 sanitation performance standards (SPS).

DOF ensures that Siluriformes fish and fish products are transported under sanitary conditions by requiring establishments to verify that Siluriformes fish arrive wholesome and suitable for human consumption as outlined in the Operating Procedures of Fishery Products.

All aquaculture farms that supply Siluriformes fish to establishments for export to the United States are approved and registered by IARDD, as required by the Regulation of Department of Fisheries on Aquaculture Facilities Registration B.E. 2556 and The Royal Ordinance on Fisheries B.E. 2558 (2015).

IARDD officers inspect farms at least once a year to verify the requirements in Good Aquaculture Practices (GAP) for Freshwater Aquatic Animal Farms (Attachment 19.2). IARDD on-farm inspection procedures are outlined in Attachment 19.4, Operational Details of the Activities of Inspection and Fishery Product Quality Certification by IARDD at Farms. Inspection results are recorded on the Checklist for Good Aquaculture Practices on Freshwater Aquatic Animal Farms (Attachment 19.3). The inspection includes verification that aquaculture farms are handling fish hygienically during and after harvest, using clean water and clean and chemical-free ice, and using tools and equipment in a sanitary manner. In addition, aquaculture farmers must immediately inform the IARDD of a fish disease outbreak and appropriately manage the disposal of carcasses and water.

Registered farms must use feed, feed supplements, and vitamins that are registered with DOF. IARDD collects samples of feed, water, and fish for testing of water quality and chemical residues as part of routine inspections to verify ongoing compliance with the aquaculture farm's registration. "For cause" samples will be collected if there is a complaint or if it is deemed that there is a risk associated with the farm. IARDD also has the authority to suspend a noncompliant farm under DOF Regulation Regarding the Certification for Good Aquaculture Practices (GAP) B.E. 2553, Clauses 15 and 16.

DOF ensures that Siluriformes fish that have died outside the controlled circumstances of commercial fishing are separated from eligible Siluriformes fish and fish products. Establishments must handle incoming live or chilled fish in accordance with Sections 5.2 and 5.3 of Attachment 15, Form of Processing Procedure Assessment of Products from Fish of the Order Siluriformes Exported to the U.S., which are consistent with FSIS requirements in 9 CFR 539.1(c), 540.1 and 540.3. Consistent with these requirements, the fish are to be kept in sanitary conditions, dead fish must be condemned, and condemned products must be denatured. Live fish are kept in a tank of ice water before being processed. Government inspection personnel verify that no diseased or dead fish are used in production and the inspection results for every lot of Siluriformes production are recorded appropriately.

Thailand's requirements for establishment construction, facilities, and equipment are specified in Operating Practices of Fishery Products, Parts 1–7, and are consistent with FSIS requirements in 9 CFR parts 416.1–416.5. The FSIS auditor verified that Government inspection personnel conduct a review of SPS once per shift, through record reviews and by observing areas of the establishment. Government inspection personnel monitor the establishments once per shift for condensation control, chemical use and storage, employee hygiene, water potability, pest control, outside premises, and lighting. Government inspection personnel also perform an annual audit to verify compliance according to procedures in Plant Inspection Procedure, P-FI and Work

Instruction of Plant Audit, W-FI-01. When deficiencies are identified, government inspection personnel have the authority to restrict an area from operating and to require immediate corrective actions when deficiencies are identified involving direct product or product contact surface contamination. The FSIS auditor reviewed records and verified that such deficiencies were identified, documented as a noncompliance, corrected by the establishment, and corrective actions were verified by government inspection personnel.

Thailand's HACCP Requirements for Fish and Fishery Products, Section 1, outlines the requirements for developing, implementing, and maintaining Sanitation SOPs. Government inspection personnel perform verification activities during the production of Siluriformes fish or fish products intended for export to the United States including verifying that the establishment implements and monitors its Sanitation SOPs and that corrective actions are implemented when necessary. The FSIS auditor observed an inspector performing pre-operational and operational Sanitation SOP verification at each audited establishment and verified that the inspector conducted pre-operational and operational sanitation verification consisting of both direct observation and record reviews once per shift. Results are documented on Form of Processing Procedure Assessment of Products from Fish of the Order Siluriformes Exported to the U.S., which is used by government inspection personnel to ensure that establishments are appropriately implementing Sanitation SOP requirements. The FSIS auditor's review of documents and observations in the audited establishments indicated that establishments were implementing sanitation requirements; however, the FSIS auditor was able to determine that government inspection personnel did not identify design issues related to monitoring and corrective actions procedures and did not identify that corrective actions were documented after a noncompliance. In addition, government inspection personnel did not identify some structures and equipment in disrepair, nor did they identify areas with condensation. As a result, the following systemic findings were identified:

- Government inspection personnel did not identify deficiencies related to Sanitation SOPs requirements at two establishments.
- Government inspection personnel did not identify deficiencies related to SPS requirements at all three establishments.

The FSIS auditor verified that DOF's food safety inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component. However, the audit findings listed above demonstrate that DOF's food safety inspection system did not effectively verify all SPS and Sanitation SOP requirements at establishments certified to export to the United States. The details of the identified deficiencies related to sanitation 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 the FSIS auditor reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

The FSIS auditor verified that DOF requires establishments certified to export to the United States to develop, implement, and maintain a HACCP system. DOF has the authority to take enforcement measures in the event that an establishment does not implement a HACCP system. The FSIS auditor verified government inspection personnel verify HACCP requirements once per shift in accordance with Thailand's HACCP Requirements for Fish and Fishery Products, which stipulates the detailed rules for the establishment, implementation, and maintenance of the system and procedures based on HACCP principles.

Establishments are required to perform initial validation of their HACCP systems, and government inspection personnel verify that the critical control points are controlling the hazards as identified in the establishment's HACCP plan. Government inspection personnel are trained on HACCP systems and will verify the effectiveness of the HACCP plan. Government inspection personnel conduct ongoing reviews of the HACCP plans and verify their effectiveness every year and whenever there is a new product being produced. Government inspection personnel perform an annual audit to verify compliance according to procedures prescribed in Plant Inspection Procedure, P-FI. DOF requires that establishments maintain a written hazard analysis for each step in the process, flow chart, and HACCP plan. The FSIS auditor verified that the HACCP plan addressed hazards identified as reasonably likely to occur, critical limits, monitoring frequency corrective actions, and verification procedures. The FSIS auditor verified that the HACCP records include HACCP corrective action records in response to deviations from a critical limit and a pre-shipment review to confirm that all HACCP requirements are met prior to export.

Government inspection personnel perform HACCP verification activities during every production shift according to the Criteria for Inspection of Siluriformes Export Establishment to the U.S. (2018) and document results on the Form of Processing Procedure Assessment of Products from Fish of the Order Siluriformes Exported to the U.S. (Attachment 15). FIQD requires that establishments that fail to maintain their HACCP system and correct noncompliances be removed from the DOF's certified establishment list. The FSIS auditor reviewed documents and records to assess the establishments' HACCP monitoring and verification activities and FIQD's implementation of regulatory enforcement. The FSIS auditor's review of documents indicated that establishments prepared written hazard analyses, flow charts, and HACCP plans to identify, evaluate, and prevent or control food safety hazards in their production processes. However, the FSIS auditor determined that government inspection personnel did not verify that a hazard analysis addressed a physical hazard at a packaging step, nor did they verify that an establishment maintained documentation to support a decision in the hazard analysis at the step prior to processing and evisceration. The FSIS auditor also determined that government inspection personnel did not identify that a HACCP record for the critical control point (CCP) at the receiving step was missing an order/lot number and a HACCP record for the CCP at the labeling step was missing the time of the monitoring event. Based on these deficiencies, the following systemic finding was identified:

- Government inspection personnel did not identify deficiencies related to HACCP requirements at two establishments.

The FSIS auditor verified that DOF requires establishments certified to export to the United

States to develop, implement, and maintain HACCP systems. However, the audit findings listed above demonstrate that DOF's food safety inspection system did not effectively implement verification activities to evaluate the adequacy of HACCP systems at some establishments certified to export to the United States. The details of the identified deficiencies related to HACCP are noted in the individual establishment checklists provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The last equivalence component the FSIS auditor 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 internal organs, fat, or muscle of carcasses for chemical residues identified by the exporting country's Siluriformes fish products inspection authorities or by FSIS as potential contaminants.

Thailand's 2023 Residue Monitoring Plan (RMP) specifies the analytes included in the testing program, the method of analysis to be used, the matrix to be collected, and the total number of samples to be collected and tested. Thailand's working committee prepares the annual monitoring plan, controls the effectiveness of the monitoring plan, collects and reviews all the monitoring results, provides enforcement measures when a sample exceeds the maximum residue limit (MRL), and oversees the laboratories responsible for testing to ensure accuracy in line with the international standard. Thailand's RMP is developed consistent with requirements in the European Union's Regulation (EU) 2017/625 and Notification of the Ministry of Public Health, (No. 303) B.E. 2550 (2007) describes veterinary drug residues in food products. Samples are taken from farms registered and approved by DOF and actual numbers are to be based on production volume. Thailand's RMP is revised annually based on the previous year's sample results and production volume. All analytical test methods for analysis of samples collected under the RMP have been validated.

The RMP is developed by DOF and distributed to sampling officers at the regional level. FIQD sampling officers are responsible for carrying out the sampling plan. If a screened positive sample is found, DOF will confirm through additional analysis of the sample. The established tolerance or action levels for each chemical residue included in the testing program are consistent with established FSIS MRLs. The FSIS auditor verified through a review of documentation that no chemical residue samples have exceeded established tolerances since the previous FSIS audit in 2021. The FSIS auditor additionally verified Thailand's adherence to the 2023 RMP.

The FSIS auditor reviewed the residue sampling procedures and associated records and verified that samples are collected by sampling officers from the respective FIQD regional office for each production lot intended for export to the United States. Sample results are reported to the sampling officer, the government inspection personnel, and the regional offices. FIQD receives laboratory results for official government chemical residue testing directly from the laboratory in a timely manner, assesses the data, and takes actions in accordance with the procedures described in the RMP. Thailand does not allow the export of product to the United States until acceptable

test results are available. Any product that has a violative level of a chemical residue detected is not allowed to be exported. Retesting of product that has returned a violative level of a chemical residue is prohibited. Additionally, each establishment collects a fish sample for each shipment to the United States and tests for residues, which must also be negative prior to shipment.

IARDD will randomly collect Siluriformes fish samples at the farm of no less than 500 grams and the condition of the samples is checked upon arrival at the laboratory for chemical residue analysis. The laboratory has official procedures for sample handling, protection, storage, retention, and disposal of samples. For violative results, the laboratory immediately notifies IARDD, which then issues a warning letter for the first offense and investigates the farm/hatchery. The possible sources of the contamination are identified, and a traceback is conducted to the supplier of the source of contaminating substances (e.g., feed, drug, or chemical substances). If a second offense occurs, IARDD will suspend the hatchery/farm from the DOF approved farm list. FIQD requires that establishments implement a traceability system to ensure that finished products can be traced to their origin. Establishments can only buy Siluriformes fish from GAP certified farms.

The FSIS auditor verified that DOF's comprehensive chemical residue program includes sampling of Siluriformes fish from certified aquaculture farms and establishments certified to export to the United States prior to export. The FSIS auditor's verification indicated that DOF continues to meet the core requirements for this component. There have not been any POE violations related to this component since the previous FSIS audit in 2021.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component is 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.

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

X. CONCLUSIONS AND NEXT STEPS

A remote exit meeting was held September 22, 2023, with DOF officials. At this meeting, the FSIS auditor 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 auditor identified the following findings:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS, AND LABELING)

- Periodic supervisory reviews are conducted at a frequency of once every three years, which may be insufficient to identify competencies where improvement is needed for government inspection personnel based on findings identified at multiple establishments related to sanitation standard operating procedures (Sanitation SOPs) and HACCP.

GOVERNMENT SANITATION

- Government inspection personnel did not identify deficiencies related to Sanitation SOPs requirements at two establishments.
- Government inspection personnel did not identify deficiencies related to SPS requirements at all three establishments.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- Government inspection personnel did not identify deficiencies related to HACCP requirements at two establishments.

During the audit exit meeting, DOF committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of DOF's documentation of proposed corrective actions 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 B.S.A. Food Products Co., Ltd. 1278 Wichienchodok Rd., Amphur Muang Samut Sakhon	2. AUDIT DATE 09/14/2023	3. ESTABLISHMENT NO. 1159	4. NAME OF COUNTRY Thailand
	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	X	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 .	X	41. Ventilation	X
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	X
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 processing.
Prepared Products:	Raw Intact Siluriformes fish and fish products

60. Observation of the Establishment

7. The SSOP plan did not include procedures for the monitoring of employee handling of product and prevention of cross-contamination from insanitary objects to food, food packaging material, as required by DOF in "HACCP Requirements for Fish and Fishery Products".

14. The establishment is unable to support the decision in the hazard analysis that microbiological hazards are not likely to occur at the "defect" step, prior to processing and evisceration. The hazard analysis indicates fish are less than 10 degrees Celsius at this step in order to control microbiological hazards, however, during the monitoring of this prerequisite program, a fish exceeded this temperature at 10.8 degrees Celsius at the start of processing. The corrective actions for this deficiency were insufficient to address microbiological hazards (adding more ice to product that exceeds the required temperature). Additionally, fish are processed at an ambient room temperature of 30 degrees Celsius over a period of 3.5 hours.

41. Government inspection personnel did not identify condensation in the tunnel from the packaging room to the freezer and in a room between the packaging room and the freezer.

45. Government inspection personnel did not identify a vacuum pack machine that was in disrepair with peeling rubber around the seal.

*No fish were being processed that were destined for export to the United States.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

09/14/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION I.T. Foods Industries Co.,Ltd. 39/108 Moo 2 Bangkrajao Muang Samut Sakhon	2. AUDIT DATE 09/13/2023	3. ESTABLISHMENT NO. 1173	4. NAME OF COUNTRY Thailand
	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	X	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.	X	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.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
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.	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 processing.
Prepared Products:	Raw Intact Siluriformes fish and fish products

60. Observation of the Establishment

7. The establishment's SSOP plan does not include a description of all monitoring procedures, as required by DOF in "HACCP Requirements for Fish and Fishery Products", however the establishment is monitoring all required elements of the SSOP requirements.

10. Government inspection personnel did not identify the following deficiencies during pre-operational sanitation verification: Residue from previous days production on top of a drain adjacent to processing line.

12. The establishment's SSOP corrective actions did not include procedures to ensure appropriate disposition of products that may be contaminated or measures to prevent the recurrence of direct contamination or adulteration of product.

12. An SSOP record that identified multiple deficiencies (a contaminated curtain between product transit areas, and cracked tile on the floor), did not document corrective actions.

15. The establishment did not document a hazard analysis at the "pack in nylon bag" step for physical hazards.

22. One HACCP record for the receiving CCP was missing the order/lot number, as required by the HACCP form.

22. One HACCP record for the labeling CCP was missing the time of the monitoring event.

39. Government inspection personnel did not identify the following deficiencies during pre-operational sanitation verification: caulking and rust flaking off nozzles used for washing fish at the start of the processing line, a hole in the ceiling around hose that goes up through ceiling in evisceration room, and chipping plastic belt in fish receiving room.

41. Government inspection personnel did not identify beaded condensate between the processing area and blast chill freezer area.

*No fish were being processed that were destined for export to the United States.

61. AUDIT STAFF OIEA International Audit Staff (IAS)	62. DATE OF ESTABLISHMENT AUDIT 09/13/2023
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United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION C.K. Frozen Fish & Food Co., Ltd. 109/1 Moo 21 Bangplee-Tamru Rd. Samut Prakan	2. AUDIT DATE 09/15/2023	3. ESTABLISHMENT NO. 1359	4. NAME OF COUNTRY Thailand
	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	X
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	X
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 processing.
Prepared Products:	Raw Intact Siluriformes fish and fish products

60. Observation of the Establishment

38. Government inspection personnel did not identify that plastic curtains could provide the opportunity for the entrance of pests into the establishment from the exterior.

41. Government inspection personnel did not identify condensation on plastic curtains in the transit area between the processing room and freezer.

*No fish were being processed that were destined for export to the United States.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT09/15/2023

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

No. 0508.3/1726



Department of Fisheries
Paholyothin Road, Kaset-Klang
Chatuchak, Bangkok 10900
Thailand

12 February B.E. 2567 (2024)

Dear Dr. Michelle Catlin,

**Re: Draft Final Report of the Audit Conducted in Thailand
On 11-22 September 2023**

With reference to the USDA letter dated 15 December 2023, sharing a copy of the draft final report of the Thailand's Siluriformes fish inspection system, in particular, the deficiencies detected during the audit, and inviting the Government of Thailand to inform the USDA of the corrective actions we have taken.

In this connection, attached herewith please find the corrective action plans and comments on the draft report for your consideration.

Should you need additional information, please do not hesitate to contact us. Your kind consideration of these corrective action plans and details would be much appreciated.

Yours sincerely,



(Mr. Taworn Thunjai)
Deputy Director-General
For Director-General

Enclosure: As stated

Michelle Catlin, Ph.D.
International Coordination Executive
Office of International Coordination

Fish Inspection and Quality Control Division
Email: fiqd@dof.mail.go.th

Comments on the Draft Report of an Audit Carried Out in Thailand from 11 September 2023 to 22 September 2023

Page No.	Title of draft audit report	Texts Referred to	DOF Comment
8	V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCTS STANDARDS, AND LABELING)	<u>Paragraph 2, lines 1-2</u> Supervisory reviews are conducted by a chief of inspection or technical manager from the regional office of government inspection personnel during their first time performing their inspection duties, and again after three months.	Rewrite as follows: Supervisory reviews are conducted by a chief of inspection of government inspection personnel during their first time performing their inspection duties, and again after three months. Chief of inspection was supervised by the technical manager (TM).

**Response of the Draft Final Report of an Audit Conducted under Thailand's Siluriformes Fish
and Fish Product Inspection System on 11-22 September 2023**

No.	Recommendation	Action conducted by the DOF
1	Periodic supervisory reviews are conducted every three years, which may not be enough to identify areas where government inspection personnel need to improve based on findings at multiple establishments related to Sanitation Standard Operating Procedures (Sanitation SOPs) and Hazard Analysis and Critical Control Point (HACCP).	The periodic supervisory frequency in SRT has been revised from once every three years to every year which will be done by each respective inspection unit (central and regional inspection units).
2	<p>2.1 Government inspection personnel fortunately did not find any discrepancies concerning Sanitation SOPs requirements at two establishments</p> <p>2.2 Government inspection personnel fortunately did not find any discrepancies concerning SPS requirements at all three establishments.</p> <p>2.3 Government inspection personnel fortunately did not find any discrepancies concerning HACCP requirements at two establishments.</p>	<p>1. The meeting with all government inspection personnel had been promptly convened to fully comprehend and address the FSIS' observations made on 22 September 2023, and 9-10 October 2023.</p> <p>2. The Department of Fisheries (DOF) has taken steps to develop corrective action measures as follows;</p> <p>2.1 Arranged re-training course focused on inspection techniques for Good Manufacturing Practice (GMP) and Hazard Analysis and Critical Control Point (HACCP). The details are as follows;</p> <p>(1) GMP training courses encompassed the following topics:</p> <ul style="list-style-type: none"> - GMP principles covered construction and design, equipment and tools, chemicals and packaging, sanitation control, sanitation facilities, personnel hygiene, and operation control. Furthermore, the course covered the Sanitation Performance Standard (SPS) guidelines established by the FSIS. This was completed on 4 October 2023.

No.	Recommendation	Action conducted by the DOF
2 (cont.)		<p>- GMP inspection techniques related to methods for gathering evidence during audits, audit principles, and audit guidelines. This was completed on 14 November 2023.</p> <p>(2) HACCP training courses included HACCP principles, sanitation standard operating procedures (SSOPs) and HACCP system verification. This was completed on 14 November 2023.</p> <p>Moreover, the DOF has provided on-site training on GMP and HACCP systems to the government inspection personnel since November 2023.</p> <p>2.2 After the training in 2023, the DOF has arranged a harmonization meeting for all government inspection personnel from 12 – 16 February 2024. This aims to ensure the harmonization and equivalent competence of inspection procedures and systems among inspection personnel, sharing the objective of promoting uniformity in inspection, and alignment of inspection guidelines and other quality standards, including those of the FSIS requirement.</p> <p>2.3 Following a comprehensive performance evaluation of a government inspection personnel's oversight of Siluriformes fish and fish products exported to the US, the DOF initiated an evaluation of these government inspection personnel in January 2024 due to no fish production prior to January 2024. The DOF intends to complete the evaluation for all government inspection personnel by June 2024.</p>