



United States Department of Agriculture

Food Safety and
Inspection Service

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

Dr. Adisorn Promthep
Director General
Department of Fisheries
50 Kasetklang Chatuchak
Bangkok 10900 Thailand

Dear Dr. Promthep,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site initial and follow up equivalence verification audit of Thailand's inspection system governing Siluriformes fish and fish products from May 7-11, 2018, and August 27-31, 2018. 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.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at InternationalCoordination@fsis.usda.gov.

Sincerely,

for Janell 

Janell Kause
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
THAILAND
MAY 7-11, 2018

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

WITH THE
FOLLOW-UP REPORT OF THE AUDIT CONDUCTED IN
THAILAND
AUGUST 27-31, 2018

September 14, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an initial on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from May 7-11, 2018. The purpose of the initial on-site audit was to verify whether Thailand's food safety inspection system governing fish of the order Siluriformes and their products provides a level of public health protection equivalent to that achieved by FSIS in the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

In addition, this report also includes Appendix C which describes the outcome of a follow-up audit to the initial on-site equivalence verification audit conducted by the FSIS from August 27-31, 2018. The purpose of the follow-up audit was to observe the actual production process in all certified establishments operating and implementing FSIS requirements. The follow-up audit also served to further verify that Thailand's food safety inspection system is being implemented as documented in its self-reporting tool (SRT) responses and verify the adequacy of the corrective actions in response implemented by Thailand to the May 7-11, 2018, initial on-site audit findings.

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

During the initial on-site audit, the FSIS auditors identified several deficiencies for Thailand to address within its food safety inspection system. Specifically, the FSIS auditors identified the following findings during the initial on-site audit:

Government Oversight

- The Department of Fisheries (DOF) does not have regulatory requirements for:
 - Certified establishments to maintain daily records documenting the monitoring of the sanitation standard operating procedures (sanitation SOPs), though the facility did maintain records.
 - Certified establishments to develop HACCP verification procedures for direct observations of monitoring activities and corrective actions, resulting in no performance of the procedure by an establishment.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The DOF failed to verify that the pre-harvest operation (i.e., farm) maintain a tracking log of the movement of fish (per the DOF regulations), and the farm did not maintain a tracking log of fish movements to facilitate traceability.
- The DOF does not have regulatory requirements to ensure that product labels include special handling statements and safe handling instructions, with labels at one facility not having the items required by FSIS.

Government Sanitation

- The FSIS auditors observed that product contact surfaces were soiled due to breakage of intestines during the establishments' evisceration process. No immediate actions were taken by the establishment or the government inspector to restore sanitation conditions or prevent cross contamination.

Government Hazard Analysis and Critical Control Points (HACCP) System

- The DOF does not require certified establishments to identify in their hazard analysis the specific potential biological, chemical, or physical hazards to be prevented or controlled, with one facility not identifying all potential hazards.

The audit findings did not represent a potential to endanger public health because most of them involved recordkeeping and necessary technical clarifications. In addition, the sanitation issues observed during fish production are unlikely to lead to problems that will cause human illness.

During the initial on-site audit exit meeting, the DOF committed to address the preliminary audit findings as presented within the next 30 days. The FSIS auditors visited all four certified establishments eligible by the DOF to export Siluriformes fish products to the United States during the initial on-site audit. The FSIS auditors could only observe the actual production process in two of the four establishments to verify implementation of the food safety system that Thailand represented in its SRT responses. In the other two establishments, FSIS auditors were able to review documents and records associated with previous production. In view of these facts, FSIS scheduled a follow-up audit to, in part, observe all three currently certified establishments while operating to verify that Thailand's food safety inspection system is being implemented as documented in its SRT responses. In addition, FSIS verified the adequacy of the DOF's corrective actions taken in response to the initial on-site audit findings.

From August 27-31, 2018, FSIS performed a follow-up audit of Thailand's food safety system governing fish of the order Siluriformes and their products. The FSIS auditors visited all establishments currently certified at the time by the DOF to export products to the United States. During this audit, all certified establishments were processing Siluriformes fish and performing other related operations as per the SRT responses submitted by Thailand. The FSIS auditors were able to observe the production of Siluriformes fish, in addition to the implementation of corrective actions to the deficiencies noted during the initial on-site audit.

The FSIS audit determined that Thailand's food safety inspection system governing fish of the order Siluriformes and their products is being implemented as documented in the SRT and according to the corrective actions taken in response to the deficiencies noted during the initial audit. FSIS auditors reviewed and analyzed each component and the corrective actions undertaken by Thailand and did not identify any findings that represented a potential to endanger public health. Appendix C of this report describes the outcome of the August 27-31, 2018, follow-up audit.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Thailand's food safety inspection system governing Siluriformes fish and fish products from May 7-11, 2018. The audit began with an entrance meeting held on May 7, 2018, in Bangkok, Thailand, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – The Department of Fisheries (DOF).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was an initial equivalence verification audit. The audit objective was to verify whether Thailand's food safety system governing fish of the order Siluriformes and their products are functioning in a manner equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Thailand has certified establishments that are eligible to export Siluriformes fish and fish products by HACCP process categories: raw non-intact, raw intact, and thermally processed/commercially sterile products to the United States. Since March 1, 2016, Thailand has been exporting only raw intact Siluriformes products to the United States.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, 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 from March 1, 2016 to December 31, 2017, in addition to information obtained directly from the CCA through self-reporting tool (SRT) responses and supporting documentation.

Representatives from the CCA accompanied the FSIS auditors throughout the entire audit. 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, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs. The evaluation of all six equivalence components included a review and analysis of Thailand's SRT responses and supporting documentation. The FSIS on-site audit included record reviews, interviews, and observations made by the FSIS auditors.

Administrative functions were reviewed at CCA headquarters, one regional office, and four local inspection offices. The FSIS auditors evaluated the implementation of control systems in place to verify whether the national system of inspection, verification, and enforcement is being implemented as documented.

The FSIS auditors visited each of the four establishments certified to export Siluriformes fish and fish products to the United States. The selected certified establishments included four slaughter

and processing establishments and one cold storage facility that was connected to Est. 1079. However, during the visits to the certified establishments, no certified establishment was producing Siluriformes fish products for export to the United States. (Note: A follow-up audit was conducted in August 2018 to observe operations. See Appendix C.)

Additionally, FSIS audited three laboratories to verify their ability to provide adequate technical support to the food safety inspection system. During the establishment and pre-harvest operations visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety and public health. The FSIS auditors examined the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with the FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §557.2.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Department of Fisheries (DOF), Bangkok
	Regional	1	• Regional Office, Samut Sakhon
Laboratories		3	<ul style="list-style-type: none"> • Fish Inspection and Quality Control Division (FIQD, government physical, microbiological and chemical residue), Bangkok • Regional Laboratory (FIQD, government physical, microbiological and chemical residue), Samut Sakhon • Inland Aquaculture Research and Development Division, Region 8, Phra Nakorn Sri Ayutthaya
Siluriformes fish slaughter and raw processing establishments		4	<ul style="list-style-type: none"> • Establishment No. 1173, Samut Sakhon • Establishment No. 1079, Samut Prakarn • Establishment No. 1159, Samut Sakhon • Establishment No. 3185, Phra Nakorn Sri Ayutthaya
Siluriformes fish cold storage		1	• Establishment No. 1079, Samut Prakarn
Pre-harvest operation		1	• Suphattora Farm, Ratchaburi

FSIS performed the audit to verify whether Thailand’s food safety inspection system governing Siluriformes fish and their products meet requirements equivalent to those under the specific provisions of United States’ laws and regulations, specifically:

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

The audit standards applied during the review of Thailand's inspection system for fish of the order Siluriformes and their products included all applicable legislation originally determined by FSIS as equivalent as part of the initial review process.

III. BACKGROUND

On December 2, 2015, FSIS published the final rule, *Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish*. The final rule established an 18-month transitional period from March 1, 2016 to August 31, 2017. FSIS began fully enforcing all regulatory requirements on September 1, 2017.

From March 1, 2016 to December 31, 2017, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 48,424 pounds of raw intact Siluriformes fish products exported by Thailand to the United States. FSIS also performed reinspection for additional types of inspection, including testing for chemical residues and refused 2,337 pounds due to public health reasons related to the presence of furazolidone in the product.

During the planning phase of the audit, the DOF informed FSIS that the number of eligible establishments initially certified to export Siluriformes fish products to the United States had been reduced from eight establishments to four establishments.

The FSIS final audit report for Thailand's food safety inspection system will be available on the FSIS website at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

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

The DOF is the government agency within Thailand's Ministry of Agriculture and Cooperatives that serves as the CCA for the system of inspection of fish of the order Siluriformes fish and fish products. Three divisions within the DOF provide regulatory oversight to establishments that produce and export fish products (i.e., 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 FIQD is responsible for controlling and ensuring that Siluriformes fish and fish products exported from Thailand are safe, wholesome, and meet standards and requirements of the importing countries by regulating, inspecting, and controlling the sanitation of the establishments

as well as the safety and traceability of fish products from processing through reaching the consumers. The IARDD is responsible for the study, research, and development of technologies of freshwater aquaculture and farm management and providing those technologies to farmers, and the surveillance program to prevent diseases in freshwater fish. The IARDD is also responsible for the inspection, certification, and monitoring of the operations of farms and hatcheries. The FQID is responsible for the importation and exportation of Siluriformes fish and fish products to and from Thailand.

The FSIS auditors verified through direct observation and records review that the FIQD inspect operations at all four certified establishments that process Siluriformes fish products for export to the United States. The FIQD also assesses the eligibility of establishments that request inclusion on the list of establishments certified to export to the United States and has legal authority to remove establishments from the listing due to noncompliance with export requirements or voluntary withdrawals initiated by the establishments. However, the FSIS auditors were only able to see the FIQD inspection procedures being performed according to United States export requirements at two of the four establishments because there was no production or products being produced at two establishments. Additionally, there was no production that could be directly observed where product was intended for export to the United States.

The FIQD inspectors are government employees that are permanent, or under renewable contracts with the DOF. The basic qualifications to become the FIQD inspectors include at least a bachelor's degree in the sciences, and successful completion of training sessions on the DOF's requirements for good manufacturing practices (GMP), good aquaculture practices (GAP), HACCP systems, fish handling, and fish products standards. Additionally, before the beginning of their inspection assignments, the FIQD inspectors must successfully complete training on inspection requirements for Siluriformes fish processing, and the requirements for exporting Siluriformes fish products to the United States. Once at their assigned stations, the FIQD provides yearly training to its inspectors on United States requirements.

The FIQD inspectors are required to pass training prior to their assignment. Additional training is provided on FSIS regulations and requirements. Periodic supervisory reviews are conducted on the FIQD inspection staff's performance at least once every three years. During supervisory reviews, the DOF will review inspection reports to verify that inspection verification activities of the establishment takes place at least once per production shift in all establishments producing product for export to the United States. In addition, the DOF will include a direct observation in evaluation of the proficiency of inspection personnel after they receive training on assessments of HACCP verification, sanitation performance standards (SPS), sanitation standard operating procedures (sanitation SOP) verification, economic adulteration controls, labeling verification activities, export certification, and imported product inspection.

The FSIS auditors reviewed hiring and human resource records kept on the FIQD employees. The FSIS auditors verified that all the DOF employees are government employees and paid by the government. Records of training revealed that all employees are required to undergo ongoing training on HACCP verification, SPS, sanitation SOP verification, economic adulteration controls, labeling verification activities, export certification, and imported product

inspection, including specific requirements for production of product to be export to the United State.

The DOF stated that the FIQD inspectors verify that establishments adequately implement and monitor their sanitation SOP and HACCP systems to ensure food safety. The FSIS auditors observed the FIQD inspectors performing daily inspection verification checks to ensure that establishments are implementing and monitoring their sanitation SOP and HACCP systems as written. These reports are collected and sent to the FIQD headquarters and kept on file to be used for export certification and traceback in case of recalls. However, the FSIS auditors were only able to see the FIQD inspection being performed at two of the four establishments because there was no production or products being produced at two establishments. Additionally, there was no products that could be directly observed that were for export to the United States. The FSIS auditors' records review and interviews with the FIQD resulted in the following finding:

- The Department of Fisheries (DOF) does not have regulatory requirements for:
 - Certified establishments to maintain daily records documenting the monitoring of the Sanitation SOP's, though the facility did maintain records.
 - Certified establishments to develop HACCP verification procedures for direct observations of monitoring activities and corrective actions, resulting in no performance of the procedure by an establishment.

The establishments assign lots based on the production day, or a lot is assigned based on the shipments from the fish farms received on the day of production. The FSIS auditors verified through records review at four establishments and observations in two establishments that the FIQD in-plant inspectors ensure that production lots have correct documentation from the farm through the processing steps, including labeling information, and receive certification for export from the DOF headquarters in Bangkok.

The FIQD inspectors certify that Siluriformes fish products have been processed in an eligible establishment and verify that the product lot identification correlates with the identity of product samples analyzed at the laboratories. If source materials are imported, only Siluriformes fish products from foreign establishments certified to export to the United States are eligible by the FIQD for the establishments to use as suppliers. The FSIS auditors verified that the FIQD inspector verifies that establishments use an eligible foreign source supplier for imported product intended for export to the United States. The FIQD inspector checks the list of approved suppliers in addition to the list of eligible establishments available on the FSIS website.

The FSIS auditors verified through records review and interviews with the FQID officers, the specific duties of the FQID inspection staff related to certification of Siluriformes fish products exported to the United States. The FQID inspectors ensures that at the time of certification of product for United States export, the exporter shall present all documentation to the fish quarantine officer at the site of export. The FIQD inspector issues the Health Certificate. Export documents generated by the establishment are then reviewed by the FQID fish quarantine officer to verify information including species, size, and quantity of the exported Siluriformes fish and fish products. The FQID examines cargo for cause if any issues are identified during their

review and a ten percent physical and visual verification check. After review of documentation and inspection of the shipment, if needed, the FQID issues an export permit for the shipment.

The FSIS auditors interviewed the FIQD officials and verified that a shipment of dried Siluriformes fish product exported to the United States containing desiccant packets was not intended for export to the United States. The product was rejected at the border by FSIS. The DOF further explained that the shipment was fraudulent since the health certificate was from a different establishment, which only indicated the product was free of *vibrio* spp., and did not have all information required by FSIS. As a result of the DOF investigation, a procedural change to the FQID review process was implemented. The FQID procedure now dictates that documentation for all shipments to the United States are reviewed prior to issuance of the export permit. The DOF affirmed the adequacy of the updated certification process, which is regularly evaluated by supervisory officials during the annual internal audits.

The FSIS auditors interviewed and verified the DOF activities in response to a POE violation (2017-TH-1173-01) due to the presence of AOZ (3-amino-2-oxazolidinone), which is a metabolite of furazolidone. Documentation provided for review revealed that the investigation identified that the producing establishment received Siluriformes fish from an unregistered farm. The FIQD indicated that as of the date of production of product, they were not sampling all consignments for export as implementation of the FIQD sampling of each consignment occurred at the end of March 2017. The FIQD provided documentation of the producing establishment's suspension until corrective actions were fully implemented. The FIQD indicated that follow-up sampling of the establishment's subsequent production has been ongoing with no repeat violations; upon completion of all verification sampling by the FIQD, the establishment may be reinstated.

The FSIS auditors verified through direct observations at the farm that pre-harvest operational activities are under the regulatory oversight of the IARDD, an agency within the DOF that assesses compliance of producers with regulatory requirements for in-land aquaculture, and supervises, inspects, and monitors in-land production and breeding of freshwater fish. Officials from the IARDD monitor and sample feed, fish, and water to verify the compliance of producers with regulatory standards. The IARDD works with the Ministry of Health to notify farmers of potential outbreaks in fish diseases and potential contaminants in the area and surrounding waters. The IARDD is also in charge of registering eligible farms that supply establishments certified to export to the United States and ensures that pre-harvest operational activities take place under sanitary conditions.

The DOF defines adulterated products as those products that are decomposed, contain pathogens, or those for which laboratory results indicate the presence of prohibited chemicals or the presence of chemical residues that exceed established tolerance levels. The FSIS auditors verified that the DOF has described adulterated products through a review of the *Royal Ordinance Fisheries B.E. 2558 (2015)* document and in interviews with the DOF personnel.

In interviews conducted during the audit, the DOF stated that it does not perform species testing. The DOF also stated that any importation of Siluriformes products to be used in processing for export is conducted under the oversight of the DOF, which includes review of export documents

and labels to ensure the imported product is from eligible countries and is derived from fish of order Siluriformes. Thailand establishments may use imported Siluriformes fish from other countries to produce products for export to the United States. The DOF states that product may be received from countries determined by FSIS as equivalent, and establishments listed as eligible on the FSIS website. These products must be accompanied by the health certificate issued by the foreign government and an additional document identified as an Imported Aquatic Animal Raw Material Movement Document (IMD).

The IMD is issued by government authorities at certified establishments from an eligible country and contains the name of the country that has been determined eligible to export Siluriformes fish products. The product must also be properly labeled describing the common name and scientific name of the type of Siluriformes fish and identifying from where the products were derived. The information on the IMD document must match the information appearing on the health certificate. Through a review of records, the FSIS auditors verified that the DOF officials in Bangkok must verify the acceptability of every shipment of Siluriformes fish that comes into Thailand.

The establishments certified by the DOF to export to the United States have access to FSIS's internet notification system and are encouraged by the DOF to remain well informed on policy changes by obtaining information from FSIS and review the updated information on the IARDD, FIQD, and FQID websites. The IARDD and FIQD also contact the establishments directly through email, official letters, and meetings as needed. The FSIS auditors reviewed communications that occurred at each level of the inspection system to relay new FSIS requirements, directives, notices or information on POE violations including emails and official letters. The FIQD inspectors also document in their daily reports when they have notified the establishment about updates and changes to import and export requirements.

The FSIS auditors directly observed that analyses of products for official verification are conducted by laboratories that the DOF authorizes for that function. All laboratories that are approved to analyze samples of product for export to the United States must be accredited in accordance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005 (General Requirements for the Competence of Testing and Calibration Laboratories) or comply with good laboratory practices (GLP) standards. The DOF stated in interviews that laboratories that are approved to analyze samples of product destined for the United States must be ISO/IEC 17025:2005 accredited and certified, the FSIS auditor was able to view a copy of the accreditation during the visit to the laboratory. Laboratories in Thailand that are used for official analytical testing are government owned and operated, with the exception of the pesticides laboratory, which is privately owned.

The FSIS auditors reviewed records documenting that the laboratories are accredited by the national accreditation body of the Bureau of Laboratory Quality Standards (BLQS), Ministry of Public Health. Evaluation of the proficiency of the analysts occurs at least once per year, and the DOF officials receive the results of such testing. The DOF can utilize private laboratories to conduct official sample analysis on products eligible for export to the United States. These approved private laboratories, in addition to being accredited to ISO/IEC 17025:2005 must be registered with the DOF. Furthermore, the analytical methods they use must be validated to

ensure that they are fit for the purpose. Private laboratories submit the analytical methods along with their validation data, analysts' proficiency, or inter-laboratory testing results, work instructions and laboratory quality assurance procedures to the DOF officials. The DOF verifies that laboratories undergo both internal and external audits to ensure that analytical work meets established standards and that such work is in alignment with the needs of the inspection system.

The FSIS auditors verified through records reviewed that internal audits are completed by the laboratories once per year to ensure continued compliance with ISO/IEC 17025:2005 standards. External audits are conducted by BLQS every two years to verify that the laboratories meet accreditation requirements of ISO/IEC 17025:2005. The DOF performs audits of the laboratories annual. If there are noncompliances found during the audit, the approval can be revoked for one year, after which the laboratory will have to apply for registration again.

The DOF organizes and administers the country's Siluriformes fish and fish products food safety inspection system. The DOF official personnel enforce laws and regulations governing the production and export of Siluriformes fish and fish products at certified establishments. However, the DOF does not have a written regulatory requirement that establishments develop the verification procedure of direct observation of monitoring of CCPs, or direct observation of corrective actions. In the absence of verification procedures, there is no assurance that controls in place are working as intended.

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

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The food safety inspection system is to provide for regulatory controls, including but not limited to, control over condemned materials; complete separation of eligible Siluriformes fish products from ineligible products; government inspection of production activities at least once per production shift when producing products for export to the United States; and periodic supervisory visits to certified establishments to evaluate the performance of inspection personnel.

In interviews conducted during the audit, the DOF stated that it has issued government regulatory requirements for establishments certified to export to the United States to maintain complete separation of Siluriformes fish products from Siluriformes fish products produced for other markets. Certification of products for export to the United States will only be authorized by the DOF. The FSIS auditors reviewed the regulatory documentation and interviewed the establishment personnel to verify that products produced for export to the United States are separated by time and/or space.

To provide adequate inspection coverage ensuring that a government inspector be present and performing verification activities at least once per production shift when producing Siluriformes product for export to the United States, the DOF requires certified establishments to provide their production schedules, including volumes and times, two weeks in advance of the production start time. The FSIS auditors reviewed inspection records and interviewed the FIQD inspection staff

during the establishment visits to verify the presence of an inspector at the establishments at least once per production shift. Establishments that fail to provide production schedules to the DOF do not receive inspection service and those products are ineligible for export to the United States.

The FSIS auditors reviewed copies of letters that establishments had given to the FIQD inspectors and emails to the DOF requesting inspection with times, dates, production types, and volumes. The FIQD uses the establishments' filed documents as part of their tracking and traceback ability of all products produced for export to the United States. The FIQD inspectors complete and file an on-site inspection report, daily inspection report, and monthly inspection report to the FIQD headquarters, which includes results of inspection, as well as product information including amount produced, and lot identifier codes. Consequently, the Siluriformes fish products from those establishments that are not eligible for export or did not have inspection coverage will be identified when the FIQD cannot confirm the production schedule and volume of products produced from reports on file.

The IARDD is responsible for inspections of fish raising facilities and has regulatory authority to ensure requirements are met. While reviewing records and responsibilities of the IARDD personnel at the visited farm, the FSIS auditors determined the following:

- The pre-harvest operation (i.e., farm) did not maintain a tracking log of the movement of Siluriformes fish per the DOF's regulations. The DOF did not verify that the farm maintained a log of Siluriformes fish movements to facilitate traceback.

Occasionally, Siluriformes fish will be sorted and moved from one pond to another based on growth rate or size of the fish. Based on responses provided by the farm management, the FSIS auditors concluded that the farm was not maintaining a tracking log of movement of Siluriformes fish from one pond to another, thereby preventing full traceability of source material from processor to farm, and farm to fingerling (fry) producer.

The FSIS auditors verified through records review and observations that the regulatory controls of the DOF's food safety system mandate that establishments certified to export to the United States inspect Siluriformes fish and raw materials (including other ingredients prior to receiving) and reject any materials that are abnormal or decomposed. Siluriformes fish that are rejected and segregated as inedible are handled to ensure that those materials are not used in the manufacture of products for human consumption. In interviews conducted during the audit, the DOF stated that dyes are not allowed to be used in its establishments; therefore, inedible products were not denatured, only labeled, and removed from the premises under establishment control. The FSIS auditors verified through the establishment's HACCP records and flow chart that inedible materials are removed from the establishment and not allowed to be used for human consumption. However, the FSIS auditors were not able to directly observe inedible materials being removed because of the lack of production of products produced for export to the United States. Only the collection of the inedible material into a labeled bucket without denaturant was observed.

The FSIS auditors verified through records review that the FIQD records show that each lot of raw material has a unique product code used as an identifier to ensure that there is no

commingling of raw materials. The FIQD personnel document amounts of products produced with each identifier lot code and report the information to the FIQD headquarters via on-site reports, daily reports, and monthly reports. The FIQD headquarters will then use the data reported by field inspectors to verify submitted requests for health certificates made by establishments. The FIQD inspection staff also verify proper and accurate labeling of products at establishments certified to export to the United States. These procedures are verified by internal audits that are conducted once per year by trained auditors of the FIQD. While reviewing labeling intended for use on products for export to the United States, the FSIS auditors identified the following finding:

- The DOF does not have regulatory requirements to ensure that product labels include special handling statements and safe handling instructions.

The DOF has established a food safety inspection system to provide regulatory controls over Siluriformes fish and fish products. However, in the absence of traceability and proper label verification, the food safety inspection system lacks the regulations and inspection procedures to ensure that only product meeting FSIS requirements is exported to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the DOF requires each official establishment to develop, implement, and maintain a written sanitation SOP program to prevent direct product contamination or insanitary conditions.

The DOF has sanitation SOP requirements described within its document entitled *HACCP Requirements for Fish and Fishery Products, Amendment No. 3*. The document states that a processor must first meet prerequisite requirements specified in *General Criteria and Conditions for Inspection and Certification of Exported Fishery Product*, which provides a blueprint for certification of an establishment. Establishments are then required to develop a written sanitation SOP program, implement it effectively, and monitor the resulting conditions of hygiene during processing at a sufficient frequency.

The written sanitation SOP includes requirements for hygienic processing in relation to the establishment's structure; safety of water used; cleanliness of food contact surfaces (including gloves and outer garments); prevention of cross contamination; maintenance of handwashing and toilet facilities; protection of food from adulteration from fuel, lubricants, pesticides, cleaning compounds, condensate or other physical, biological or chemical hazards; proper labeling and storage of chemicals and toxic compounds; monitoring of employee health conditions; and exclusion of pests from the establishment. If a noncompliance is observed, the establishment must correct the issue in an appropriate timeframe.

The FIQD inspectors perform daily inspection and verification of the adequacy of sanitation programs at slaughter and processing establishments certified to export to the United States, following uniform procedures to ensure compliance with regulatory requirements. Results of

official inspection and verification of the adequacy of the sanitation program are documented using standardized forms in accordance with the DOF's instructions.

Consistent with the DOF's regulations, the FIQD inspectors verify the acceptability of Siluriformes fish at the point of delivery at the certified establishments and document inspection results for each lot of Siluriformes fish inspected. The FIQD inspectors verify that sanitary handling, rapid transport, and efficient handling of live or chilled Siluriformes fish, are adequately implemented by inspecting and documenting the receiving activities at the establishments for each lot of Siluriformes fish. The FIQD inspectors also ensure that diseased and adulterated Siluriformes fish and parts are controlled and segregated as inedible materials during receiving, slaughter, and processing operations.

The adequacy of the sanitation program in certified establishments is audited yearly to determine their ability to remain eligible to export their products. The DOF issues a GMP certificate upon a successful evaluation of hygiene inspection that is valid for one year. When deficiencies are identified, renewal of certification is granted if the corrective action plan was completed in the required timeframe as approved by the FIQD. The FIQD inspectors perform at least one yearly audit in order to verify ongoing compliance with the GMP certificate; noncompliance may result in revocation of their GMP certification.

The FSIS auditors reviewed sanitation plans and records related to design, implementation, and record keeping at all four audited establishments. The DOF requirements for sanitation outlined in the document *Operating Practices of Fishery Products-Amendment No. 3* are consistent with FSIS regulatory requirements in 9 CFR Part 416.1 - 416.5. The FIQD requirements specify intensity of lighting (foot-candles), positive airflow from certain areas of the facility, the use of foot dips at every entrance, and number of toilets according to the number of workers. The FIQD inspectors perform the regular daily inspection required when products are produced for export to the United States at certified eligible establishments. If an establishment is not in compliance, they may be removed as eligible to export until a corrective action plan is approved, occurs, and has been verified by the FIQD inspector.

The FIQD inspectors perform verification activities during the production of products intended for export to the United States to ensure the establishment implements and effectively monitors activities according to their written sanitation SOP, and the firm takes corrective actions when necessary. Results of these activities are recorded on the *Form of Processing Procedure Assessment of Products from Fish of the Order Siluriformes Export to the U.S.*

The FSIS auditors directly observed at two of the four establishments the sanitary conditions of live Siluriformes fish when received at establishments, and observed that the FIQD inspection staff verify good sanitation, rapid transport, efficient handling, that Siluriformes fish are live or chilled, and documented with the *Form of Processing Procedure Assessment of Products from Fish of the Order Siluriformes Export to the U.S.* Results of the FIQD inspection were recorded for every lot of Siluriformes fish production. The FSIS auditors observed that the FIQD inspectors ensure diseased or otherwise adulterated Siluriformes fish carcasses or parts are separated from product fit for human consumption during all steps in the processing operations.

However, the FSIS auditors were not able to directly observe two of the four establishments because of the lack of production of products produced.

The FSIS auditors verified through records review and observations that the FIQD inspectors performed daily pre-operational and operational sanitation inspections according to the procedural form referenced above with results documented as compliant or noncompliant. The findings discovered during daily inspection are communicated to responsible establishment personnel to initiate corrective actions and implement measures to prevent recurrence of the problem.

Pre-operational inspection adequacy was verified through observation of the FIQD inspection personnel performing their review after the establishment personnel had completed their pre-operational inspection. The FSIS auditors followed the FIQD inspectors and observed verification of operational sanitation procedures, however, the FSIS auditors were not able to directly observe two of the four establishments because of the lack of production of products produced. The FSIS auditor observed the following finding:

- The FSIS auditors observed that product contact surfaces were soiled due to breakage of intestines during the establishment's evisceration process. No immediate actions were taken by the establishment or the government inspector to restore sanitation conditions or prevent cross contamination.

The FSIS auditors visited one registered farm located in Ratchaburi province to observe and review records of the verification of sanitation requirements at the harvest sites. The registered farms are to comply with the IARDD established GAP which outline the requirements for growers for sampling and analysis of feeds/feed additives, water and/or live fish as applicable, and actions in response to disease outbreaks or observation of nonconformance with the IARDD requirements. Through records reviewed at the farm, the FSIS auditors were able to review an IARDD inspection report and verify that the IARDD officers inspect farms at least once every three years to ensure requirements are met. During this inspection, the IARDD officer verifies that the farm continues to meet the GAP with certification valid for a timeframe of three years. Inspection includes review of provisions related to farm management, sanitation, feed and drug/chemical usage, harvesting (records of sales), data collection/records to ensure traceability, source of fish (fry), and fish production parameters (stocking density, health, growth rate, etc.).

In interviews conducted during the audit at the farm with the IARDD, the FSIS auditors verified that the IARDD samples feed, water for quality purposes, and fish for drug and chemical residues. "For Cause" samples may be taken based on a complaint or an item of risk is identified with a specific farm including notification by FSIS of a POE violation. If chemical residues are detected, samples of fish feed and aquatic animals (fish) are taken by the IARDD and undergo chemical residue analysis.

The IARDD officers identify noncompliant conditions and a letter of warning is issued requiring corrective actions within one month or their certification may be suspended; upon suspension, the IARDD notifies the FIQD of the action. The IARDD verifies that farms handle fish

hygienically during and after harvest using clean water, tools, equipment, and trucks. Only fish that are alive and not diseased, or otherwise unsound, are permitted to be loaded for harvest.

The FSIS auditors reviewed documentation at the farm from the IARDD as evidence that the IARDD is also responsible for inspection of feed manufacturers, visiting twice per year. The IARDD inspectors also take samples of feed for quality testing as well as presence of pathogens, antibiotics, mycotoxins, and melamine. The FIQD inspector stated that feed manufacturers are required to send formulations to the FIQD headquarters prior to the manufacture and sale of any products for usage.

The reviews, analysis, and on-site verification activities conducted by the FSIS auditors indicate that Thailand's Siluriformes food safety inspection system requires that all certified establishments develop, implement, and maintain sanitation programs to prevent the creation of insanitary conditions and direct product adulteration. However, the audit finding listed above demonstrates that the FIQD has not effectively ensured the adequacy of the sanitation SOP systems employed at establishments eligible to export product to the United States.

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

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

The DOF outlines HACCP requirements within the document *HACCP Requirements for Fish and Fishery Products*, with requirements for a hazard analysis, HACCP plan, contents of the HACCP plan (list food safety hazards, CCPs, critical limits, and procedures and frequency of monitoring), corrective actions (development of corrective actions, segregation of affected product, verification and recordkeeping of corrective actions), verification (reassessment of the HACCP plan, ongoing verification consisting of review of consumer complaints, calibration of instruments, and testing of products, and review of records), validation (scientific validation of critical limits and validation of the systems adequacy to comply with the HACCP plan), documentation and recordkeeping (maintenance of records, information on records, and record retention).

The FSIS auditors verified through records review that an establishment wishing to produce Siluriformes fish products must first submit a full HACCP program to the FIQD for review, which must meet the criteria of HACCP regulations for Siluriformes fish product processing. In interviews conducted during the audit, the DOF stated that the FIQD officials conduct verification of the acceptability of the certified establishments' written HACCP programs in accordance with Codex Alimentarius HACCP principles. Once the HACCP documents are found acceptable, the DOF officials issue a HACCP certificate that is initially valid for six months, with subsequent certificates valid for one year upon completion of successful implementation of a HACCP system. Renewal of certification is contingent upon the outcome of an evaluation and the adequacy of any corrective actions required to be implemented in a timeframe specified by the FIQD.

In interviews conducted during the audit, the DOF stated that the approval status of an establishment would be suspended if, but not limited to, product testing results do not meet importing countries standards. Additionally, in instances when product rejection from an importing country occurs (POEV), the DOF will conduct additional investigations. The FIQD inspectors perform traceback of random production lots to ensure the firm's record keeping system is adequate.

The FSIS auditors reviewed all four visited establishments' HACCP system records including hazard analysis, the HACCP plan, and supporting documentation. The following isolated observations were noted:

- The DOF does not require certified establishments to identify in their hazard analysis the specific biological, chemical, or physical hazards to be prevented or controlled.

Whenever an establishment or the FIQD inspection personnel identify noncompliance for the HACCP system, the establishment must present a corrective action plan within established timeframes from the date of inspection depending on the public health significance of the deficiency. The FIQD policy indicates that approval status of an establishment will be suspended if product testing does not pass importing countries' standards, or HACCP noncompliances are observed which would have an impact on food safety. The FIQD will also perform additional investigations when a product rejection from an importing country occurs.

The analysis and on-site verification activities of the FSIS auditors indicate that Thailand's Siluriformes food safety inspection system requires that all certified establishments develop, implement, and maintain a HACCP system to prevent the production of adulterated or misbranded product. However, the audit findings listed above provide an indication that the FIQD has not effectively ensured the adequacy of the HACCP systems employed at establishments eligible to export product to the United States.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

The FSIS auditors verified that the DOF developed the National Residue Control Program (NRCP). The NRCP is designed by a committee comprised of representatives of different fishery sectors, including the Coastal Fisheries Research Division; the Inland Fisheries Research Division; Fishery Quarantine Division; the DOF experts representing, the Aquatic Animal Feed and Research Division, Legal Affairs Division, Planning Division, and the FIQD. The program, which runs from January 1 to December 31 of each year, is revised annually based on the

previous year's sample results and expected production volume. This committee designs and controls the effectiveness of the monitoring plan, reviews monitoring results, provides oversight to the laboratories and initiates enforcement when sample results exceed maximum limits.

Samples of muscle of young and adult fish are randomly collected by the IARDD and the FIQD officials at the registered pre-harvest sites and certified establishments respectively. The collected samples are used for screening and for confirmation of chemical analyses. Chemical compounds that are tested represent stilbenes, synthetic steroids, chloramphenicol, nitrofurans, antibiotics, anthelmintic coccidiostats, organochlorines including polychlorinated biphenyl (PCB), heavy metals, and dyes and their metabolites. Sampling frequency is established by the DOF auditors based on the establishments' HACCP performance. Documents reviewed in conjunction with the interview conducted at the IARDD chemistry laboratory by the FSIS auditors indicated that the maximum tolerance limits for these residues follows Codex standards.

The FSIS auditors verified through records review that confirmed violative results from samples collected at aquaculture production farms are reported to the IARDD officials, who issue official notification to the producer, and result in an investigation of the farm and/or hatchery to identify the source of the contamination. Subsequent violations from the same farm and/or hatchery lead to suspension of the noncompliant producer from the list of approved farms. The FIQD officials receive notification of the suspension action to ensure that any of the eligible establishments do not use those farms as sources of raw materials.

The FSIS auditors confirmed that the DOF verifies that the analytical methods used by the laboratories are validated and remain in compliance with international standards. The FSIS auditors reviewed the most recent reports for accreditation audits conducted by BLQS at three chemical laboratories that included the FIQD's laboratories in Bangkok and in Samut Sakhon, and at the IARDD regional laboratory in Phra Nakorn Sri Ayutthaya. The DOF laboratories received accreditation for a variety of in-house methods based on methods recognized by the Association of Analytical Communities (AOAC) to detect chemicals in fishery products.

The FSIS auditors reviewed the laboratories' quality manuals and the standard operating procedures for equipment calibration and validation of test methods. Additionally, the FSIS auditors requested records pertaining to staff qualifications, credentials, and training, internal audits, noncompliance, and corrective actions. The FSIS auditors also reviewed proficiency testing program for all audited laboratories, with no concerns noted.

The DOF relies on private laboratories for analytical testing for the presence of pesticide residues in Siluriformes fish products. The FSIS auditors verified that private laboratories interested in testing pesticides in fishery products must register with the DOF and comply with requirements and ISO/IEC 17025:2005 standards. The FSIS auditors verified the procedures of sample transportation to laboratories by the DOF personnel. The procedures include sample identity with an assignment of unique sample number while maintaining the anonymity of the client. All analytical tests are reported directly to the DOF electronically. The DOF requires private laboratories to maintain their current accreditation. The FSIS auditors reviewed a sample of analytical results for the presence of PCB conducted at the private laboratory during the audit of the IARDD laboratory, with no concerns noted.

The FSIS auditors confirmed that Thailand has a system to define a production lot as being raw material from a single farm on a single production day. The lot product code, assigned to product destined for United States export, enable eligible establishments to initiate rapid identification of production lots if a product recall is necessitated. The product lots that are sampled are required to remain on hold until non-violative results for their testing are received from the laboratory.

The analysis and on-site verification activities of the FSIS auditors indicate that Thailand has developed and implemented a chemical residue testing program that is organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The 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 currently has presented four establishments certified as eligible to export Siluriformes fish products to the United States. These establishments do not produce any low-acid canned or ready to eat Siluriformes fish products for export to the United States; therefore, government microbiological verification testing for *Listeria monocytogenes* and *Salmonella* is not required. FSIS does not have any regulatory requirements for microbiological sampling of raw intact Siluriformes fish products. As a result, FSIS concluded that the DOF has developed and implemented a microbiological testing program that meets FSIS criteria for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on May 11, 2018, in Bangkok, Thailand, with the DOF. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component identified several deficiencies for the CCA to address within their food safety system within the next 30 days. The FSIS auditors identified the following findings:

Government Oversight

- The DOF does not have regulatory requirements for:
 - Certified establishments to maintain daily records documenting the monitoring of the Sanitation SOP's.
 - Certified establishments to develop HACCP verification procedures for direct observations of monitoring activities and corrective actions.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The DOF does not have regulatory requirements to ensure that product labels include special handling statements and safe handling instructions.
- The DOF failed to verify that the pre-harvest operation (i.e., farm) maintain a tracking log of the movements of fish (per the DOF regulations), and the farm did not maintain a tracking log of fish movement to facilitate traceability.

Government Sanitation

- The FSIS auditors observed that product contact surfaces were soiled due to breakage of intestines during the establishments' evisceration process. No immediate actions were taken by the establishment or the government inspector to restore sanitation conditions or prevent cross contamination.

Government Hazard Analysis and Critical Control Points (HACCP) System

- The DOF does not require certified establishments to identify in their hazard analysis the specific potential biological, chemical, or physical hazards to be prevented or controlled.

The audit findings did not represent a potential to endanger public health because most of them involved recordkeeping and necessary technical clarifications. In addition, the sanitation issues observed during fish production are unlikely to lead to problems that will cause human illness.

During the initial on-site audit exit meeting, the DOF committed to address the preliminary audit findings as presented within the next 30 days. The FSIS auditors visited all four certified establishments eligible by the DOF to export Siluriformes fish products to the United States during the initial on-site audit. The FSIS auditors could only observe the actual production process in two of the four establishments to verify implementation of the food safety system that Thailand represented in its SRT responses. In the other two establishments, FSIS auditors were able to review documents and records associated with previous production. In view of these facts, FSIS scheduled a follow-up audit to, in part, observe all three currently certified establishments while operating to verify that Thailand's food safety inspection system is being implemented as documented in its SRT responses. In addition, FSIS verified the adequacy of the DOF's corrective actions taken in response to the initial on-site audit findings.

From August 27-31, 2018, FSIS performed a follow-up audit of Thailand's food safety system governing fish of the order Siluriformes and their products. The FSIS auditors visited all establishments currently certified at the time by the DOF to export products to the United States. During this audit, all certified establishments were processing Siluriformes fish and performing other related operations as per the SRT responses submitted by Thailand. The FSIS auditors were able to observe the production of Siluriformes fish, in addition to the implementation of corrective actions to the deficiencies noted during the initial on-site audit.

The FSIS audit determined that Thailand's food safety inspection system governing fish of the order Siluriformes and their products is being implemented as documented in the SRT and according to the corrective actions taken in response to the deficiencies noted during the initial audit. FSIS auditors reviewed and analyzed each component and the corrective actions undertaken by Thailand and did not identify any findings that represented a potential to endanger

public health. Appendix C of this report describes the outcome of the August 27-31, 2018, follow-up audit.

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 I.T. Foods Industries Co.,Ltd. 39/108 Moo2, Bang Krachao Amphoe Mueang, Samut Sakhon	2. AUDIT DATE May 8, 2018	3. ESTABLISHMENT NO. No. 1173	4. NAME OF COUNTRY Thailand
	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.	X	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 SSOPs 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.	X	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. Enforcement	X
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)	O	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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

- 8) During review of establishment SSOP records it was noted that no records of monitoring of operational sanitation were documented. After further discussion, it was revealed that the CCA does not currently have a requirement for documentation of operational monitoring.
- 15,51) Establishment Hazard Analysis did not identify potential chemical hazard related to use of chlorine at steps where chlorinated water is used in direct contact with product. Additionally, the firm did not identify the potential hazard of foreign material contamination in ice; during walk-through, it was noted that foreign material was embedded within ice which was used as part of the production process.
- 19) The CCA does not require certified establishment to include observation as part of the verification of monitoring of critical limit.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

May 8, 2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sethachon Co., Ltd. 225 Moo 12 Bangpri Yai, Amphoe Bang phli, Samut Prakarn	2. AUDIT DATE May 9, 2018	3. ESTABLISHMENT NO. No. 1079	4. NAME OF COUNTRY Thailand
	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.	X	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.	X	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. Enforcement	
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)	O	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. Monthly Review	O
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

- 8) During review of establishment SSOP records it was noted that no records of monitoring of operational sanitation were documented. After further discussion, it was revealed that the CCA does not currently have a requirement for documentation of operational monitoring.
- 19) The CCA does not require certified establishment to include observation as part of the verification of monitoring of critical limit.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

May 9, 2018

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 Road Maha Chai, Amphoe Mueang Samut Sakhon	2. AUDIT DATE May 9, 2018	3. ESTABLISHMENT NO. No. 1159	4. NAME OF COUNTRY Thailand
	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.	X	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	
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.	X	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. Enforcement	X
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)	O	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. Monthly Review	O
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

- 8) During review of establishment SSOP records it was noted that no records of monitoring of operational sanitation were documented. After further discussion, it was revealed that the CCA does not currently have a requirement for documentation of operational monitoring.
- 19) The CCA does not require certified establishment to include observation as part of the verification of monitoring of critical limit.
- 38, 51) Containers of unidentified chemicals/ingredients stored at the outside premises of the establishment.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

May 9, 2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sanhara Foods Co., Ltd. 128 Moo 3 Ban Khwang, Amphoe Maha Rat Phra Nahon Si Ayutthya	2. AUDIT DATE May 10, 2018	3. ESTABLISHMENT NO. No. 3185	4. NAME OF COUNTRY Thailand
	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.	X	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	X
19. Verification and validation of HACCP plan.	X	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	X	51. Enforcement	X
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)	O	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. Monthly Review	O
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

8) During review of establishment SSOP records it was noted that no records of monitoring of operational sanitation were documented. After further discussion, it was revealed that the CCA does not currently have a requirement for documentation of operational monitoring.

15, 51) The establishment processes include a step where frozen fish are thawed using water at an elevated temperature (note: temperature unknown as it was not directly observed). Review of process records reveal no tracking of time of thawing, or temperature of the water used for the thawing process. Based on these observations, it is not clear if the establishment adequately controls the potential hazard of microbial growth.

19) The CCA does not require certified establishment to include observation as part of the verification of monitoring of critical limit.

23, 51) The establishment produces a dried Siluriformes product, which is considered not Ready-to-Eat based on normal consumer preparation practices. It was observed that the product does not include an adequate handling statement, nor does the product include Safe Handling Instructions

46, 51) During observation of establishment evisceration process of fish, it was noted that surface of the table, employee gloves, and knives were soiled due to breakage of intestines during the process. No actions were observed to be taken by establishment employees to clean food contact surfaces to prevent potential cross contamination. Further, FIQD inspection personnel took no action to stop the process or require establishment employees to take actions as necessary to restore sanitary conditions. FIQD inspection indicated that once the establishment starts the process of evisceration, they are permitted to continue operating as observed, and do not perform any routine cleaning of equipment or surfaces until a break period occurs for lunch or the end of production.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDITMay 10, 2018

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

No. 0508.3/ 8072



Department of Fisheries
Phaholyothin Road,
Kaset-klang, Chatuchak,
Bangkok 10900, Thailand
Tel. (662) 558 0142
Fax. (662) 558 0142

26 July B.E. 2561 (2018)

Dear Mr. Kause,

Thailand's response to FSIS Draft final report of an audit
conducted in Thailand (May 7-11, 2018)

This is with reference to your letter dated June 27, 2018 providing the draft final audit report conducted from May 7-11, 2018. Thank you very much for opportunity to comment the draft final audit report.

The Department of Fisheries, Thailand (DOF) would like to present our response comprised of two tables (comments of the findings identified in the draft final audit report and DOF's corrective actions). Enclosed herewith is the detail of Thailand's response.

Should you need any additional information or clarification, please do not hesitate to contact us.

Yours sincerely,

(Mr. Bunchong Chumnongsittathum)
Deputy Director-General
For Director-General

Janell Kause
Acting International Coordination Executive
Office of International Coordination
1400 Independence Avenue, SW.
Washington, D.C.
20250



No. 0508.3/ 8071

Department of Fisheries
Phaholyothin Road,
Kaset-klang, Chatuchak,
Bangkok 10900, Thailand
Tel. (662) 558 0142
Fax. (662) 558 0142

26 July B.E. 2561 (2018)

Dear Mr. Kause,

Thailand's response to schedule a follow up on-site audit

This is with reference to your letter dated June 27, 2018 regarding the planning to verify full implementation of Thailand's inspection system. In response to your request, the Department of Fisheries, Thailand (DOF) proposes the schedule for follow up on-site audit from August 27-31, 2018. For your information, there is some concern that it may be unable to observe full implementation or specific operating for United States market at the time of your follow up on-site audit due to there is no order for export Siluriformes fish products to USA.

Furthermore, regarding your letter dated June 19, 2018, it was stated that "Thailand is not interested in exporting thermally processed Siluriformes fish and fish products to the United States". DOF would like to clarify that we are interested in exporting thermally processed but no order of thermally processed products at that time.

In this connection, we are pleased to submit the amended "list of establishment eligible to export Siluriformes fish to the United States" by addition of one establishment, deletion of one establishment. Enclosed is the amendment on the list of establishments as of July 26, 2018.

We look forward to hearing from you. Should you need more information please do not hesitate to contact us.

Yours sincerely,

(Mr. Bunchong Chumnongsittathum)
Deputy Director-General
For Director-General

Janell Kause
Acting International Coordination Executive
Office of International Coordination
1400 Independence Avenue, SW.
Washington, D.C.
20250

Establishment Eligible to Export Siluriformes Fish to the United States

Approved Number	Establishment Name	Address	Province
1159	B.S.A. Food Products Co., Ltd.	1278 Wichienchodok Road, Maha Chai , Amphoe Mueang Samut Sakhon Tel.0 3441-2824	Samut Sakhon
1173	I.T. Foods Industries Co., Ltd.	39/108 Moo2 ,Bang Krachao Amphoe Mueang Samut Sakhon Tel. 0 3440 90461-4	Samut Sakhon
3185	Sanhara Foods Co., Ltd.	128 Moo 3 Ban khwang, Amphoe Maha Rat Tel.093-4959-296	Phra Nakhon Si Ayutthya
1359	C.K. Frozen Fish & Food Co., Ltd.	109/1 Moo 21 Soi Bangpleeyai Bang phli Samut Prakan	Samut Prakan

Deletions : Number of deletion : 1

Approved Number	Establishment Name	Address	Province
1079	Sethachon Co.Ltd.	225 Moo 12 Bangpri Yai , Amphoe Bang phli Tel. 02-3160421-8	Samut Prakan

Additions : Number of addition : 1

Approved Number	Establishment Name	Address	Province
1359	C.K. Frozen Fish & Food Co., Ltd.	109/1 Moo 21 Soi Bangpleeyai Bang phli Samut Prakan	Samut Prakan



Criteria for Inspection of Siluriformes Exported Establishment to US

This document states the criteria and conditions for inspection and certification of Siluriformes exported establishment in order to make sure that the Siluriformes establishment under Fish Inspection and Quality Control Division, Department of Fisheries comply to the United States' Standard

Siluriformes establishment inspection shall be done with The Good Manufacturing Practices (GMPs) and Hazard Analysis Critical Control Point (HACCP), DOF, 2004, in order to control the significant hazards and reduce the risk of cross contamination. Those controls are under the DOF's policies emphasized in control the food safety every step in the food chain from the growing areas, aquaculture sites, point of transportation throughout the processing step to make the customer the best confidence both in quality and safety.

Criteria and FSIS Standard for Inspection of Siluriformes Exported Establishment

1. A non-DOF list establishment who would like to export Siluriformes products, could get contact to a DOF officer to inspect by the DOF's GMP and HACCP, 2004. Then, it may request for the US export afterward.
2. The applying producer shall use the DOF application form attached with requested documents as follow,
 - (1) Copy of corporate body certificate from The Ministry of Commerce. In case of natural person, copy of identification card and copy of house registration are used.
 - (2) Copy of company registration from The Ministry of Commerce.
 - (3) Copy of food processing facility license from The Ministry of Public Health.
 - (4) Copy of licenses of factory establishing and business engagement from The Ministry of Industry or the certificate showing as not being in the scope of licensing.
 - (5) Copy of the register for fishery entrepreneur licentiate from DOF Provincial Office.
 - (6) HACCP manual.
 - (7) Map.
 - (8) Copy of the power of attorney with revenue stamp required by law for certification applying.

Contact points

- (1) Establishment in the area of Samut Songkhram, Samut Sakhon, Nakhon Pathom, Ratchaburi, Petchaburi, Kanchanaburi, and Prachuabkeerikan could contact to Samut Sakhon Fish Inspection and Research Center (SSFIC) located in 127 Moo 8 Tambol Kokkham, Ampur Muang, Samut Sakhon 74000 Tel. 6634-857282, 6634-457423., Fax. 6634-857-192.
- (2) Establishment in the area of the upper Southern part of Thailand as Chumphon, Ranong, Phang-nga, Krabi, Phuket, Suratthani, and Nakhon Sri Thammarat could contact to Suratthani Fish Inspection and Research Center (SRFIC) located in 20/62 Moo 7 Tambol Thakham, Ampur Punpin, Suratthani 84130 Tel. 6677-286-943, 6677-274232., Fax. 6677-274-231.
- (3) Establishment in the area of the lower Southern part of Thailand as Patthalung, Songkla, Trang, Saton, Pattani, Yala, and Narathivas could contact to Songkla Fish Inspection and Research Center (SKFIC) located in 79/2 Wichianchom Rd., Tambol Bo yang, Ampur Muang, Songkla 90000 Tel. 6674-312-037., Fax. 6674-314-797.



(4) Establishment located in the rest of the areas could contact to Inspection System Development Group of Fish Inspection and Quality Control Division (FIQD) located in Preeda Kannasuta Bld., Kaset klang, Chatuchak, Bangkok 10900 Tel. 6625-580-150-5 int. 13406-7., Tel/Fax. 6625-580-142.

3. A DOF list Establishment who would like to export Siluriformes products, could get contact to a DOF officer attached with production manual comply with the US's standards. DOF officer would provide inspection before making the permit decision.

4. Conditions for the approval

4.1 Only raw material Siluriformes fish from DOF aquaculture farm approved could be received and used to be produced. In case of imported, shall only be from the US approved establishments and countries.

4.2 Production plan of each lot shall be informed to a DOF officer prior at least 2 weeks in order to be inspected every lot of the production.

4.3 Product label shall be complied with the Siluriformes Fish Import Labelling Requirements (9 CFR 557.14 and 557.15). The details of FSIS labeling requirements appear in annex.

4.3.1 Labels for immediate container

The 9 required features are as follows:

- Name of product
- Name of country origin, preceded by the words "Product of" placed immediately under the product name
- Ingredients statement (if product contains two or more ingredients)
- Foreign establishment number (the foreign inspection legend would also need to appear on the immediate container)
- Handling statement for products that are perishable and require special handling to maintain their wholesomeness (e.g., "keep refrigerated", "keep frozen")
- Net quantity of contents (for products sold at retail)
- Manufacturer's or distributor's name and address
- Nutrition labeling (if applicable, FSIS regulations provide for certain exemption)
- Safe Handling Instructions (if product is not-ready-to-eat and destined for consumers, hotels, restaurants and similar institutions)

4.3.2 Labels for shipping/outside container

The 5 required features are as follows:

- Name of country of origin
- Foreign establishment number
- Name of product
- Shipping or identification mark (a number or mark used to link the product to the foreign inspection certificate - 9 CER 557.4)
- Handling statement for products that are perishable and require special handling to maintain their wholesomeness (e.g., "keep refrigerated", "keep frozen")

4.4 GMP and HACCP documents and related records such as quality control record, employee health record, water and ice analysis result, raw material and product analysis result, and GMP and HACCP records have to be kept for at least 2 years and not less than the product's shelf-life.



Department of Fisheries' Inspection Procedure

New producer

Since Department of Fisheries acquired the contact from a Siluriformes establishment exported to the US, the DOF officer shall provide actions as,

1. All requested document and HACCP manual shall be checked, DOF officer would come to inspect the producer when all of the document and control plan comply to the FSIS's standard.
2. In case of a non-DOF list establishment, GMP and HACCP shall be fully inspected with the Siluriformes produced standard exported to the US included.
3. If the establishment complies with the requirements, the name of the approved establishment would be added in the DOF list and be notified to the US.
4. A non-approved producer shall be informed to be improved and get re-inspection.

Existing approved Siluriformes establishment

1. GMP and and HACCP system shall be fully checked with Siluriformes exported standard on-site at least once a year.
2. When a establishment could not maintain its system and standard, the establishment shall correct the non-compliances in time stated. Those establishments shall have revocation out of the DOF list if a non-compliance has not been effectively corrected.
3. When received a production plan from a approved Siluriformes establishment, DOF officer shall provide actions as the procedure as,
 - 3.1 Provide inspector(s) to inspect every step of production against FSIS's standard every production shift, record the inspection result in the DOF checklist, and notify it's to chief accordingly.
 - 3.2 Name, type, and amount of the product shall be notified to the DOF's sampling staff and certification staff.
 - 3.3 The product shall be sampling follow the US regulations. A health certificate shall be issued when the analysis result has been satisfied.
 - 3.4 In case of water, ice, raw materials, and food contact surfaces result are not satisfied, producer's corrective actions shall be checked and verified.
 - 3.5 A revised FSIS standard shall be informed and notified to an approved Siluriformes producer.

.....



Annex

Labels for Siluriformes fish export to the United States

Labels for Siluriformes fish export to the United States must comply with the requirements of the Siluriformes Fish Import Labelling Requirements (9 CFR 557.14 and 557.15)

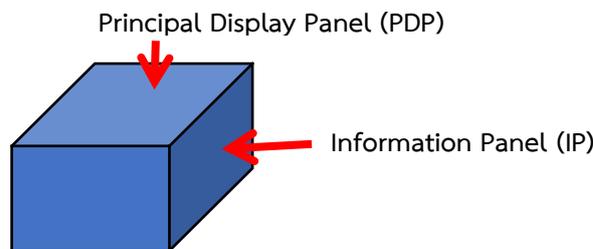
1. Immediate containers

The immediate container is the receptacle or other container that is ordinarily sold to or purchased by a consumer *or* any other container in which the food product is directly contained or enclosed.

FSIS regulations specify where some of these required features must be located on the immediate container: Principal Display Panel (PDP) and Information Panel (IP).

The PDP is the part of the label most likely to be displayed or presented to the purchaser when the product is offered for sale.

The IP is any portion of a label (typically to the right of the PDP) that displays certain mandatory features.



Labels for immediate containers must have up to nine (9) required features. All required features must be in English

1.1 Name of product (PDP)

- "Catfish" may only be used to label products that contain fish in the family Ictaluridae
- Non-Ictaluridae fish products must be labeled with their common or usual name (e.g., "Basa," "Swai," "Giant Pangasius")
- Labels for raw Siluriformes fish products containing added solution must include a descriptive designation (e.g., "contains 10% added solution of water, salt, phosphates.....")

1.2 Name of country of origin, preceded by the words "Product of" placed immediately under the product name (PDP)

1.3 Ingredients statement (if product contains two or more ingredients) (PDP or IP)

- If the ingredients are two or more, indicate the word "Ingredients" followed by the ingredient list
- Show all ingredients in descending order

1.4 Foreign establishment number (the foreign inspection legend would also need to appear on the immediate container) (PDP)

- used to identify status for inspection legend, DOF has designed the inspection legend which is Inspected and passed
- May be any size but must be legible
- The DOF model is





- 1.5 Handling statement for products that are perishable and require special handling to maintain their wholesomeness (e.g., “keep refrigerated” or “keep frozen”) (PDP)
- 1.6 Net quantity of contents (for products sold at retail) (PDP)
 - The terms “net weight” or “net wt.” shall be used when stating the net quantity of contents in terms of weight
 - The term “net content” or “content” when stating the net quantity of contents in terms of fluid measure
- 1.7 Manufacturer’s or distributor’s name and address (PDP or IP)
- 1.8 Nutrition labeling (if applicable, FSIS regulations provide for certain exemptions) (PDP or IP)
- 1.9 Safe Handling Instructions (if the product is not-ready-to-eat and destined for consumers, hotels, restaurants, and similar institutions) (PDP or IP). The sample of safe handling instructions is

Safe Handling Instructions

This product was prepared from inspected and passed fish. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

	Keep refrigerated or frozen. Thaw in refrigerator or microwave.
	Keep raw fish separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish.
	Cook thoroughly.
	Keep hot foods hot. Refrigerate leftovers immediately or discard.

2. Shipping/Outside Container

Shipping/outside containers need to have sufficient label space for application of the USDA mark of import inspection and need to bear the following labeling features:

- 2.1 Name of country of origin
- 2.2 Foreign establishment number

The number of the foreign establishment where the product within the container was last processed (i.e., any step in the process up to and including packaging and labeling).
- 2.3 Name of product
- 2.4 Shipping or identification mark (a number or mark used to link the product to the foreign inspection certificate - 9 CFR 557.4)
- 2.5 Handling statement (e.g., “keep refrigerated” or “keep frozen”) for products that are perishable and require special handling to maintain their wholesomeness

3. In some cases, the immediate container is also the shipping/outside container because the product inside is not fully labeled. In this case, the outside container needs to bear all of the required features of an immediate container (items 1.1 – 1.9) and of a shipping/outside container (items 2.1 - 2.5).

Executive Summary

Page Number	Title	Report Text	DOF comments
1	II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY	<p>Paragraph 4</p> <p>Administrative functions were reviewed at CCA headquarters, one regional office, <u>and four local inspection offices</u>. The FSIS auditors evaluated the implementation of control systems in place to verify whether the national system of inspection, verification, and enforcement is being implemented as documented.</p>	<p>During the onsite audit, the FSIS auditors visited only one local inspection offices at IARDD Region 8, Phra Nakorn Sri Ayutthaya.</p>
5	IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)	<p>Paragraph 4</p> <p>The FIQD inspector issues the Health Certificate. Export documents generated by the establishment are then reviewed by the FQID fish quarantine officer to verify information including species, size, and quantity of the exported Siluriformes fish and fish products. The FQID examines cargo for cause if any issues are identified during their review and a ten percent physical and visual verification check. After review of documentation and inspection of</p>	<p>DOF would like to request to change the paragraph as follow:</p> <p>The FIQD issues the Health Certificate and performs physical and visual verification during loading goods to cargo at least ten percent.</p> <p>The FQID is authorized to verify information including species, size, and quantity of the exported Siluriformes fish and fish products in the cargo prior to issues export certificate</p>

		the shipment, if needed, the FQID issues an export permit for the shipment.	for the shipment. The FQID also authorized to examine the cargo for cause if any issues are identified during their review.
6		<p>Paragraph 3</p> <p><i>The IARDD works with” the Ministry of Health” to notify farmers of potential outbreaks in fish diseases and potential contaminants in the area and surrounding waters.</i></p>	In case of potential disease outbreak, the IARDD work with the Aquatic Animal Health Research and Development Division (AAHRDD) to monitor and control outbreak. AAHRDD is a division under Department of Fisheries who responsible to control fish disease. The IARDD notifies farmers of potential outbreaks in fish diseases and potential contaminants in the area and surrounding waters.
7		<p>Paragraph 2</p> <p>The IMD is issued by <u>government authorities at certified establishments from an eligible country.</u> and contains the name of the country that has been determined eligible to export Siluriformes fish products. The product must also be properly labeled describing the common name and scientific name of</p>	<p>DOF would like to explain the paragraph as follow:</p> <p>The Imported Aquatic Animal Raw Material Movement Document (IMD) is a document for traceability of imported product into Thailand, issued by FQID.</p> <p>The IMD contains name of importer, import</p>

		<p>the type of Siluriformes fish, and identifying from where the products were derived. The information on the IMD document must match the information appearing on the health certificate. Through a review of records, the FSIS auditors verified that the DOF officials in Bangkok must verify the acceptability of every shipment of Siluriformes fish that comes into Thailand.</p>	<p>permit number, origin of the product and date of imported.</p> <p>DOF inspectors must verify the acceptability of every shipment of Siluriformes fish that comes into Thailand at every port of entry. The FIQD inspector will also verify the document during inspection at processing plant and prior to issue health certificate.</p>
13		<p>Paragraph 1</p> <p>The FIQD inspector stated that feed manufacturers are required to send formulations to the FIQD headquarters prior to the manufacture and sale of any products for usage.</p>	<p>DOF would like to clarify that;</p> <p>The IARDD is authorized to approve the formulations of feed prior to the manufacture and sale of any products for usage.</p>

Corrective action

Component	Deficiency	Corrective Actions
<p>Government Oversight</p> <ul style="list-style-type: none"> The Department of Fisheries (DOF) does not have regulatory requirements for: 	<p>(1) Certified establishments to maintain daily records documenting the monitoring of the Sanitation SOP's, though the facility did maintain records.</p>	<p>DOF has regulatory requirements for certified establishments to maintain daily records documenting the monitoring of the Sanitation SOP's as stated on SECTION 1 page 3 issued date: April 2004 of <u>HACCP Requirements for Fish and Fishery Products</u>. The details are as follow;</p> <p>No. 7. Records of SSOP monitoring and corrective actions must be maintained for a period as specified in;</p> <p style="padding-left: 40px;">(3) Record retention. All records required by this part must be retained at the processing facility at least</p> <p style="padding-left: 80px;">(i) 1 year after the date they were prepared in the case of refrigerated products and traditional product.</p> <p style="padding-left: 80px;">(ii) 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.</p>
	<p>(2) Certified establishments to develop HACCP verification procedures for direct observations of monitoring activities and corrective actions, resulting in no performance of the procedure by an establishment.</p>	<p>To comply with FSIS requirement,</p> <ol style="list-style-type: none"> DOF HACCP requirement was revised to add the direct observations of monitoring activities and corrective actions as a verification procedure. DOF notified the certified establishments to amend their HACCP verification procedures addressing direct observations of monitoring activities and corrective actions via the official letter and FIQD's website. The new version of HACCP Plan of each establishment is required to submit to DOF within August 10, 2018 for approval. DOF officers will stringently verify the activity of HACCP verification on August 2018 onward

<p>Government Statutory Authority and Food Safety and Other Consumer Protection Regulations</p>	<p>(1) The DOF failed to verify that the pre-harvest operation (i.e., farm) maintain a tracking log of the movement of fish (per the DOF regulations), and the farm did not maintain a tracking log of fish movements to facilitate traceability</p>	<ol style="list-style-type: none"> 1. DOF has notified the certified farms to maintain a tracking log of the movement of Siluriformes fish since June 1, 2018. 2. DOF has revised audit procedures to add more detail about a tracking log of the movement of Siluriformes fish from one pond to another since July 20, 2018. 3. In order to ensure the fully traceability of source material from farm to fingerling (fry) producer, DOF will perform inspection of FSIS’s finding farm to verify corrective action on August 2018. The other farms will be subjected to verify the tracking on September, 2018 onwards.
	<p>(2) The DOF does not have regulatory requirements to ensure that product labels include special handling statements and safe handling instructions, with labels at one facility not applying the items required by FSIS.</p>	<ol style="list-style-type: none"> 1. The regulatory requirement, Criteria for Inspection of Siluriformes Exported Establishment to US is amended by addressing the clarity of labeling requirements. The required features both for immediate container and shipping/outside container are shown in topic 4.3. (Attachment no. 1) <p>The new Criteria for Inspection of Siluriformes Exported Establishment to US has been notified to processing establishments via the official letter and FIQD’s website. This new criteria is expected to apply in August, 2018.</p> <ol style="list-style-type: none"> 2. To ensure that product label include special handling statements and safe handling instructions items is complied with the Siluriformes Fish Import Labelling Requirements, DOF has improved the procedure for label inspection at the process of establishment inspection, product inspection and Health certificate. The improved procedure is as follows:

		<p>2.1 During processing, plant inspection officers will conduct inspection by using the checklist for inspection. The key inspection items include imported aquatic animal control, local aquatic animal raw material control, sanitation standard operating procedures, HACCP system, processing control, sampling and testing program, official inspection legend and labeling of food product. The item of labeling of food products is amended in order to be clearer for plant inspection officers for example the safe handling instructions is required for not-ready-to-eat and destined for consumers, hotels, restaurants and similar institutions. FIQD plans to implement the new checklist in August 2018.</p> <p>2.2 The FIQD product sampling group will take samples at the establishment which intending to export to the US of only the lot informed to have process inspected from plant inspection officers. The samples taken will be analyzed for microbiological, chemical and physical qualities including label inspection.</p> <p>2.3 During the issuance Health certificate process, label will be verified again by FIQD Fishery Product Certification Group prior to issue Health certificate.</p>
<p>Government Sanitation</p>	<p>(1) The FSIS auditors observed that product contact surfaces were soiled due to breakage of intestines during the establishments’</p>	<p>DOF strengthened control by</p> <ol style="list-style-type: none"> 1. DOF has arranged training session on July 2018 for DOF inspectors and establishments as regard to prevent cross contamination and how to set up proper control. Clean up process shall perform immediately if the process has possibility of cross contamination. 2. To ensure effective control of the processing plant, DOF will perform follow up inspection at the

	<p>evisceration process. No immediate actions were taken by the establishment or the government inspector to restore sanitation conditions or prevent cross contamination</p>	<p>processing plant that FSIS found the deficiency by August, 2018. The processing plant has stopped producing any product since June 2018 due to the renovation the structure. The renovation will complete by July 2018.</p>
<p>Government Hazard Analysis and Critical Control Points (HACCP) System</p>	<p>(1) The DOF does not require certified establishments to identify in their hazard analysis the specific potential biological, chemical, or physical hazards to be prevented or controlled, with one facility not identifying all potential hazards.</p>	<p>DOF have requirement to identify all potential hazard; biological, chemical, or physical hazards as stated in <u>HACCP Requirements for Fish and Fishery Products</u>, issued date: April 2004, Section 2 No. 3 The content of HACCP plan, page 3-4: The details are as follow;</p> <p>No.3. The contents of the HACCP plan. The HACCP plan must, at a minimum: List the food safety hazards that are reasonably likely to occur.</p> <p>To ensure the effective implementation, DOF strengthening control measures are as follow</p> <ol style="list-style-type: none"> 1. Training session was generated on July 2018 for the inspectors as regards to how to evaluate the hazards analysis particularly all potential hazards. 2. The establishment was notified to correct the hazards analysis on July 2018 and the deficiency was already fixed. 3. To ensure the competency of inspectors, DOF supervisors will perform on site witness the inspectors from August 2018 onward

Appendix C: Follow-up Audit Conducted in Thailand on August 27-31, 2018

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I. INTRODUCTION

FSIS conducted a follow-up on-site equivalence verification audit of Thailand’s food safety inspection system from August 27-31, 2018. The audit began with an entrance meeting held on August 27, 2018, in Bangkok, Thailand, during which the FSIS auditors discussed the audit objectives, scope, and methodology with representatives from the Central Competent Authority (CCA) – Department of Fisheries (DOF).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

Administrative functions were reviewed at CCA headquarters and three local establishment inspection offices. The FSIS auditors evaluated the implementation of control systems in place to ensure the national system of inspection, verification, and enforcement were being implemented as intended. The FSIS auditors visited all three establishments certified to export to the United States. In between the May 2018 audit and the follow-up audit Thailand delisted one establishment because the plant was not exporting to the United States and no longer had orders or interest in exporting. The selected certified establishments were processing establishments producing fish of the order Siluriformes and their products.

During the establishment visits, the FSIS auditors focused attention on the extent to which industry and government interacted to control hazards and prevent noncompliances with the potential to impact food safety and endanger public health. The FSIS auditors examined the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with the FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §557.2.

Competent Authority Visits	#	Locations
Central Competent Authority	1	<ul style="list-style-type: none">Department of Fisheries (DOF), Bangkok
Siluriformes fish slaughter and processing establishments	3	<ul style="list-style-type: none">Establishment No. 1173, Samut SakhonEstablishment No. 1159, Samut SakhonEstablishment No. 3185, Pranakorn Sri Auttaya

FSIS performed this follow up audit to verify whether Thailand’s food safety inspection system governing Siluriformes fish and their products meet requirements equivalent to those under the specific provisions of United States’ laws and regulations, specifically:

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

The audit standards applied during the review of Thailand's inspection system for fish of the order Siluriformes and their products included all applicable legislation originally determined by FSIS as equivalent as part of the initial review process.

III. BACKGROUND

There were no changes noted in the background information provided since the May 7-11, 2018, initial on-site FSIS audit. Each component below includes a description of the equivalence criteria, the findings from the May 7-11, 2018, initial on-site audit, and the FSIS auditors' verification results and observations from the August 2018 follow-up audit.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

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

During the May 7-11, 2018, initial on-site audit, the FSIS auditors found:

- The Department of Fisheries (DOF) does not have regulatory requirements for:
 - Certified establishments to maintain daily records documenting the monitoring of the Sanitation SOP's, although the facility did maintain records.
 - Certified establishments to develop HACCP verification procedures for direct observations of monitoring activities and corrective actions, resulting in no performance of the procedure by an establishment.

In response to this finding, the DOF explained that they do have regulatory requirements for certified establishments to maintain daily sanitation SOP records. The FSIS auditor verified that the requirement is included in the document titled "HACCP Requirements for Fish and Fishery Products". The document explicitly requires documentation and recordkeeping related to HACCP and sanitation. DOF personnel further responded that to ensure maintenance of adequate records and to allow for improved verification by Fish Inspection and Quality Control Division (FIQD) inspectors, an official letter was sent to all certified establishments requiring them to create an additional summary listing of all sanitation SOPs, including the frequency of monitoring. The FSIS auditors were able to review the letter issued to each certified establishment, in addition to updated records at all certified establishments.

The DOF corrective action stated that they would revise their regulations to require establishments to amend their HACCP verification procedures to include procedures for direct observation of monitoring and corrective actions. FSIS auditors verified this through records reviews at all certified establishments and an official DOF letter was issued to all certified establishments informing them of the change in regulatory requirements.

During site visits to certified establishments, FSIS auditors verified through a review of written programs that certified establishments updated their HACCP plans to include procedures and a frequency for verification by direct observation of monitoring and corrective actions. The FSIS auditors also verified through review of records, that certified establishments listed all sanitation SOP procedures with frequency of monitoring for each procedure. Each certified establishment was conducting monitoring of the sanitation SOPs at the identified frequency and recording results on designated forms as observed by FSIS auditors.

The FSIS auditors verified that Thailand's updated system of government oversight and DOF personnel enforcement of the laws and regulations ensuring the food safety system of exported Siluriformes fish and fish products has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory 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 AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The food safety inspection system is to provide for regulatory controls, including but not limited to, control over condemned materials; complete separation of eligible Siluriformes fish products from ineligible products; government inspection of production activities at least once per production shift when producing products for export to the United States; and periodic supervisory visits to certified establishments to evaluate the performance of inspection personnel.

During the May 7-11, 2018, initial on-site audit, the FSIS auditors found:

- The pre-harvest operation (i.e., farm) did not maintain a tracking log of the movement of Siluriformes fish per the DOF's regulations. The DOF did not verify that the farm maintained a log of Siluriformes fish movements to facilitate traceback.

In response to this finding, the DOF explained that additional training and revision of DOF audit procedures of fish growing farms would occur. The FSIS auditors verified through records review that training of the Inland Aquaculture Research and Development Division (IARDD) inspectors has since occurred. The FSIS auditors also reviewed updated audit verification forms to be used by IARDD inspectors when conducting site visits and audits of registered fish farms. The FSIS auditors also reviewed a letter of notification issued to all fish farms to reinforce the DOF requirement of maintaining a tracking log of movement of any fish to ensure traceability of movement from hatchery to finished product.

During the May 7-11, 2018, initial on-site audit, the FSIS auditors found:

- The DOF does not have regulatory requirements to ensure that product labels include special handling statements and safe handling instructions.

In response to this finding, the DOF explained that they would issue new criteria in the form of regulatory requirements for establishments to include mandatory labeling features for the immediate container and shipping container. Through a review of a letter issued to each certified establishment, the FSIS auditors verified that the DOF provided notification to all certified establishments that indicated the change in regulatory requirements. The FSIS auditors also reviewed the DOF's updated inspection verification procedures that now include FIQD inspectors to verify labeling requirements have been met while performing routine inspections during production. FIQD inspectors also verify labeling requirements by taking a sample of the finished packaged product for label inspection/verification, and during the Health Certificate issuance inspection process.

The FSIS auditors verified that Thailand's updated statutory requirements and improvements to inspection verification procedures ensures the traceability and proper labeling of exported Siluriformes fish and fish products. Thailand's government has the legal authority to establish regulatory controls over certified establishments that export their products to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the DOF requires each official establishment to develop, implement, and maintain a written sanitation SOP program to prevent direct product contamination or insanitary conditions.

During the May 7-11, 2018, initial on-site audit, the FSIS auditors found:

- Product contact surfaces were soiled due to breakage of intestines during the establishments' evisceration process. No immediate actions were taken by the establishment or the government inspector to restore sanitation conditions or to prevent cross contamination.

In response to this finding, the DOF explained that to address this finding, a training session would be held for DOF inspectors and certified establishments' to ensure sanitary conditions are reinforced and maintained. To ensure improvement by establishments, DOF inspectors were assigned to perform follow-up inspection to verify controls and corrective actions were effective. The FSIS auditors reviewed DOF inspection reports to verify that planned measures were implemented, and follow-up inspections occurred with acceptable results. Through a document review and the tour of each audited facility, the FSIS auditors affirmed that documentation occurred and certified establishments operated in such a manner as to prevent the creation of insanitary conditions, and that sanitation SOP programs being effectively implemented, monitored, and documented.

The FSIS auditors verified that Thailand's response to previous identification of insanitary conditions has resulted in improvements by certified establishments, as well as DOF inspectors' verification of establishment sanitary conditions. The analysis and onsite verification activities of the FSIS auditors indicate that the Siluriformes fish inspection system of Thailand requires that all certified establishments develop, implement, and maintain sanitation programs to prevent the creation of insanitary conditions and direct product adulteration.

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

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

During the May 7-11, 2018, initial on-site audit, the FSIS auditors found:

- The DOF does not require certified establishments to identify in their hazard analysis the specific potential biological, chemical, or physical hazards to be prevented or controlled, with one facility not identifying all potential hazards.

In response to this finding, the DOF explained that they do have regulatory requirements for certified establishments to identify all potential hazards at each step. The FSIS auditor verified that the requirement for the hazard analysis is included in the document titled “HACCP Requirements for Fish and Fishery Products,” which explicitly requires a hazard analysis and a listing of food safety hazards. DOF personnel indicated that to ensure compliance and to enhance application of improved verification by FIQD inspectors, inspection verification forms were updated and put in place to be used by FIQD inspectors. The FSIS auditors confirmed that the DOF provided notification to all certified establishments through a review of the letter issued, review of the updated FIQD inspection verification forms, and observation of revised programs at certified establishments.

The FSIS auditors verified that Thailand’s updated system of government oversight and DOF personnel are enforcing laws and regulations ensuring the safety of exported Siluriformes fish and fish products intended for export to the United States. The analysis and onsite verification activities of the FSIS auditors indicate that the Siluriformes fish inspection system of Thailand requires that all certified establishments develop, implement, and maintain a HACCP system to prevent the production of adulterated or misbranded product.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The DOF develops and implements a chemical residue testing program that is organized and administered by the national government. The program includes random sampling of muscle from Siluriformes fish and fish products, for chemical residues identified by Thailand’s inspection authorities or by FSIS as potential contaminants.

There were no changes, new information, or additional observations in this component during the current FSIS follow-up audit from the information reported during the May 7-11, 2018, initial on-site FSIS audit.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The 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.

There were no changes, new information, or additional observations in this component during the current FSIS follow-up audit, from information reported during the May 7-11, 2018, initial on-site audit.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on August 31, 2018, in Bangkok, Thailand, with the DOF. At this meeting, the FSIS auditors presented the observations from this follow-up audit.

The FSIS auditors visited all establishments certified by the DOF to export products to the United States. During this audit, all certified establishments were able to perform operations. The FSIS auditors were able to see production of Siluriformes fish and fish products, in addition to the corrective actions presented to FSIS and issued to the establishments.

The FSIS audit determined that Thailand's food safety inspection system governing fish of the order Siluriformes and their products is being implemented as documented in the SRT and according to the corrective actions taken in response to the deficiencies noted during the initial audit. FSIS auditors reviewed and analyzed each component and the corrective actions undertaken by Thailand and did not identify any findings that represented a potential to endanger public health.

APPENDICES

Appendix D: Individual Foreign Establishment Audit Checklists

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 Moo2, Bang Krachao Amphoe Mueang, Samut Sakhon	2. AUDIT DATE 08-27-2018	3. ESTABLISHMENT NO. No. 1173	4. NAME OF COUNTRY Thailand
	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 SSOPs 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. Enforcement	
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)	O	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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment
No findings to report

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08-27-2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sanhara Foods Co., Ltd. 128 Moo 3 Ban Khwang, Amphoe Maha Rat Phra Nahon Si Ayutthya	2. AUDIT DATE 08-28-2018	3. ESTABLISHMENT NO. No. 3185	4. NAME OF COUNTRY Thailand
	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	X	51. Enforcement	
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)	O	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. Monthly Review	O
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

No findings to report

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 Road Maha Chai, Amphoe Mueang Samut Sakhon	2. AUDIT DATE 08-29-2018	3. ESTABLISHMENT NO. No. 1159	4. NAME OF COUNTRY Thailand
	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	X
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. Enforcement	
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)	O	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. Monthly Review	O
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

48/51

Establishment failed to adequately identify (mark or label) the container used for collection of fish which died during transport in order ensure adequate control of materials.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08-29-2018

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

No. 0508.3/ ๑๘๙๒



Department of Fisheries
50 Paholyothin Road, Kaset-klang,
Chatuchak, Bangkok 10900 Thailand
Tel. 66 2 562 0600-14
Fax. 66 2 5580142

๑๗ September B.E. 2561 (2018)

Dear Ms. Kause,

Thank you for your letter dated 12 September 2018 in which you provided the draft final audit report for an initial audit on Thailand's inspection system governing Siluriformes fish and fish products conducted from 7 – 11 May 2018 with updated the follow up audit conducted from 27 – 31 August 2018.

The Department of Fisheries (DOF) appreciates the efforts of FSIS in conducting the audit and is grateful for the opportunity to comment on the Draft Final Report. There is no objection on the provided report. The DOF notes the overall finding meets the core criteria for all six components to maintain its equivalence with the United States' system.

Please find enclosed information about the corrective action of B.S.A. Food Products Co., Ltd. taken by the DOF to address the audit findings.

Should you need additional information, please do not hesitate to let us know.

Yours sincerely,

(Mr. Bunchong Chumnongsittathum)
Deputy Director-General
For Director- General

CC. FAS Counselor, Bangkok

Janell Kause
International Coordination Executive
Office of International Coordination

Corrective action of B.S.A. Food Products Co., Ltd. (1159)

Deficiency	Corrective Actions
<p>Keep the dead fish and undersize in the same basket for return to supplier. Then can't identify that dead fish before catching ,or Transportation.</p>	<p>- The establishment fixed the deficiency immediately by clearly identified the container for dead fish.</p> 