



United States Department of Agriculture

Food Safety and  
Inspection Service

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Mr. Meesak Pakdeekong  
Director General  
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Dear Mr. Pakdeekong,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote ongoing verification audit of Thailand's Siluriformes inspection system from May 4 through June 1, 2021. Enclosed is a copy of the final audit report. Comments received from the Government of Thailand are included as an attachment to the final report.

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

Sincerely,

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF  
THAILAND

MAY 4–JUNE 1, 2021

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

November 12, 2021

Food Safety and Inspection Service  
United States Department of Agriculture

## **Executive Summary**

This report describes the outcome of a routine equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) May 4–June 1, 2021. Due to the global COVID-19 pandemic, FSIS conducted the audit remotely using a combination of videoconferences and records review. The purpose of the audit was to determine whether Thailand's food safety inspection system governing *Siluriformes* fish and fish products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Thailand currently exports raw-intact *Siluriformes* products to the United States.

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

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

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

- The Central Competent Authority (CCA) conducts residue analysis on primary samples but defers confirmation of results exceeding tolerance levels until they perform analysis on a second extraction from the original fish sample. FSIS does not consider the practice of performing a second analysis to support or refute original results as equivalent.

### **GOVERNMENT SANITATION**

- The CCA does not maintain specific written instructions for Fish Inspection and Quality Control Division (FIQD) inspectors on how to verify sanitation requirements. The current Department of Fisheries (DOF) form does not provide FIQD evidence of the methods, process, nor results of specific sanitation verification activities.

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

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Thailand's food safety inspection system. The audit began with an entrance meeting on May 4, 2021, held via videoconference, 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). Representatives from DOF participated throughout the entire audit.

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that FSIS conducted remotely. The audit objective was to determine whether the food safety inspection system governing Siluriformes products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Thailand is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products <sup>1</sup>
Raw – Non-Intact	Raw ground comminuted or otherwise non-intact Siluriformes	Siluriformes – All products eligible
Raw – Intact	Raw intact meat - other	Siluriformes – All products eligible

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

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

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control

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

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

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

The FSIS auditors selected the only two Siluriformes processing establishments certified to export to the United States for the remote audit. The products these establishments produce and export to the United States include raw intact Siluriformes.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include review of establishments' conditions or records. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) Section 557.2.

The FSIS auditors also remotely reviewed records and conducted interviews with laboratory personnel associated with a government residue laboratory to verify that the approved laboratories are capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	• Department of Fisheries (DOF), Bangkok
	Regional	1	• Fish Inspection and Research Center, Samut Sakhon
Laboratory		1	• Fish Inspection and Quality Control Division (FIQD), (government chemical residue), Bangkok
Siluriformes slaughter and processing establishments		2	• Establishment No. 1159, B.S.A. Food Products Co., Ltd., Maha Chai • Establishment No. 1173, I.T. Foods Industries Co., Ltd., Muang

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

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

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

### **III. BACKGROUND**

From September 1, 2017 to August 31, 2020, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 57,148 pounds of raw intact Siluriformes exported by Thailand to the United States. Of these amounts, FSIS performed additional types of inspection on 8,600 pounds of Siluriformes product, including testing for chemical residues. As a result of this additional testing, FSIS did not reject any Siluriformes product for issues related to public health.

The previous FSIS audit from August 27-31, 2018, did not identify any systemic findings.

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

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

The first equivalence component 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.

DOF, within the Ministry of Agriculture and Cooperatives, is the CCA responsible for ensuring the food safety of Siluriformes fish and fish products. The *National Government Organization Act B.E. 2534* (1991), as amended by the *National Government Organization Act (No. 4) B.E. 2543* (2000), is the legislation that gives DOF the authority to implement and maintain Thailand's national inspection system for Siluriformes fish and fish products.

Thailand's *Ministerial Regulation on the Organization of the Department of Fisheries, The Ministry of Agriculture and Cooperatives B.E. 2559* (2016), describes the organization of DOF. The three different divisions within DOF responsible for regulatory oversight of Siluriformes fish and fish products include the Fish Inspection and Quality Control Division (FIQD), the Inland Aquaculture Research and Development Division (IARDD), and the recently renamed Fish Quarantine and Fishing Vessel Inspection Division (FQFVID).

FIQD is responsible for establishing and maintaining the fishery product quality inspection system in accordance with international standards including regulating, inspecting, and supervising the application of food safety requirements in establishments producing Siluriformes

fish. FIQD is also responsible for certifying and decertifying establishments as eligible to export Siluriformes fish products to the United States. The *Food Act B.E. 2522*, Chapter 6, delineates the regulatory and enforcement authorities of competent officers. The FSIS auditors verified that there have not been any enforcement actions associated with the two establishments certified to export to the United States since the previous FSIS audit.

The FIQD headquarters (national center) is in Bangkok. The three FIQD regional centers are in the Samut Sakhon, Surat Thani, and Songkhla provinces. The centers act as regional competent authorities. Each regional center provides services in establishment inspection, laboratory analyses, and research studies. Currently, the Samut Sakhon Regional Center provides oversight of both establishments certified to export to the United States.

IARDD is responsible for assessing and standardizing water quality for inland aquaculture. In addition, IARDD has the authority to regulate, supervise, inspect, and monitor the inland production and breeding of freshwater fish to ensure compliance with national and international standards. IARDD is responsible for registering aquaculture farms that meet applicable standards.

FQFVID is responsible for issuing licenses, permits, and certificates related to the export of Siluriformes product. FQFVID has overall responsibility to control, inspect, and quarantine the import, export, and transit of fish and fishery products through Thailand.

DOF implements a “farm to table” approach to prevent the adulteration and misbranding of Siluriformes product. IARDD verifies that Siluriformes fish are raised under healthy, suitable conditions by inspecting and monitoring grow-out farms and by sampling and testing feed, fish, and water to ensure sanitary conditions are maintained. Once Siluriformes fish are transported from the farms to the establishments, FIQD inspection personnel verify that establishments implement and monitor the required quality control and HACCP programs. Thailand’s *Food Act B.E. 2522*, prohibits the production and distribution of foods that are impure, adulterated, or substandard. These definitions include food safety and misbranding criteria, including production under unhygienic conditions of any food that might be harmful to health, and food not meeting specified criteria, including those that have levels of chemical residues exceeding specific limits. Section 43 of the *Food Act B.E. 2522* describes the authority to seize product when there is a suspected violation of the Act.

Thailand’s export certification process requires FIQD government inspection personnel to verify the source of Siluriformes fish, accurate lotting descriptions, compliance with requirements including labeling, and acceptable analytical results for each production lot. FIQD certifying officers in the Health Certification Unit at one of three FIQD offices in Bangkok, Samut Sakhon, and Songkhla issue export certificates. Government inspectors from the regional center perform lot inspection, collect fish samples for chemical residue analysis, and provide the information to the Health Certification Unit. The Health Certification Unit receives the sample request, analytical results, and lot inspection reports. If all results are acceptable, FIQD issues the export certificate. Once issued, FIQD provides a copy of the health certificate to FQFVID for export permission.



DOF ensures the security and integrity of the export certification process by applying a hologram seal with unique number on original export certificates, storage and use of all export certification materials in secure government offices, and official tracking records. The FSIS auditors reviewed establishment export requests, inspection reports, sampling requests, analytical results, and loading reports to verify the export certification process and did not identify any concerns.

FIQD requires that establishments develop written recall procedures and implement a traceability system to ensure that establishment or DOF personnel can trace finished products back to their origin in the event a product recall is necessary. The FSIS auditors verified through interviews that there have not been any product recalls of Siluriformes fish or fish products since the previous FSIS audit in 2018.

FIQD representatives stated that no imported Siluriformes fish or fish products are used to produce product for export to the United States. DOF requires that all Siluriformes fish originate from an aquaculture farm certified by IARDD and that the aquaculture farm acquire an Aquatic Animal Movement Document (MD) that accompanies fish in transport. DOF personnel and industry use the MD for traceability of Siluriformes fish. MDs specify the origin of the fish including the farm and farmer's name, address of farm, registration and certification number, harvest date, species, and quantity harvested. IARDD officers issue MDs after review of documentation provided by the aquaculture farm prior to transportation of fish. IARDD officers randomly verify loading of Siluriformes at aquaculture farms. FIQD inspectors at the certified establishments verify the MD for receiving every lot of raw Siluriformes source material and document verification results on *Form F-FI-12, Processing Procedure Assessment of Siluriformes Fish Products Exported to the U.S.* The FSIS auditors verified through interviews and review of documents and records that the CCA is implementing the procedures as described.

DOF ensures that the same laws, regulations, and policies apply to all certified establishments. The *Food Act B.E. 2522*, applies the same level of scrutiny to domestic establishments as those that are eligible to export. DOF documents requirements specific to establishments certified to export to the United States in specific written policies and procedures, primarily the *Criteria for Inspection of Siluriformes Establishments Exporting to US*. FIQD holds accreditation to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17020 standards, *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*, and accordingly has established oversight systems. The FIQD National Center provides oversight of the regional centers and conduct annual audits. The FSIS auditors reviewed the July 16-17, 2020, annual *Audit checklist for CCA HQ evaluation of Samut Sakhon Regional Center* that documented the verified implementation of policies, procedures, and oversight provided by the regional center. Section 3.12 of the audit checklist documented implementation of oversight procedures for Siluriformes products for export to the United States. The FSIS auditors did not identify any concerns.

FIQD is responsible for ensuring that establishments meet requirements before certifying them as eligible to export to the United States. The *Criteria for Inspection of Siluriformes Export Establishments to the U.S.* describes the process, including review of written Good Manufacturing Practices (GMPs) and HACCP system documentation. If FIQD determines an establishment's written food safety programs are compliant, FIQD performs an on-site audit.

FIQD identifies establishments meeting all requirements as eligible to export to the United States and written notification is provided to FSIS.

DOF disseminates information regarding United States requirements from headquarters to inspection personnel and certified establishments by sending letters directly to establishments, other DOF departments, and regional centers. In addition, DOF maintains information on their website providing details of requirements for export to the United States.

DOF ensures that government inspection personnel assigned to certified establishments exporting Siluriformes products to the United States are employed and paid by the national government. The *Notification of the Ministry of Public Health (No. 385) B.E. 2560, On Appointment of Competent Officers for the Execution under Food Act B.E. 2522*, Section 11, lists DOF positions designated as competent officers for aquatic animals, processed aquatic animals, and products from aquatic animals. DOF inspection personnel are either government inspectors under contract with DOF or permanent government employees. Interviews with DOF representatives during the audit confirmed that DOF renews employment contracts annually. The FSIS auditors verified that the Samut Sakhon Regional Center, providing oversight of certified establishments, includes six permanent government inspectors and ten contract government inspectors, all employed as food technologists. DOF issues identification cards identifying employees as either permanent civil servants or contract employees. Regardless, DOF pays all government employees by direct deposit using funds from the national government budget as verified by the FSIS auditors. DOF representatives stated that Thailand does not charge industry fees for inspection.

The *Criteria for Inspection of Siluriformes Export Establishment to the U.S.*, Section 3, requires that there be an inspector present at least once per production shift to perform verification duties. FIQD requires establishments to provide a written request for inspection two weeks in advance of planned production. The standard request form includes the planned source of fish, production schedule, and production volume. The establishment sends the request form to the Samut Sakhon Regional Center where a food technologist reviews and signs the form to indicate acceptance of the inspection dates. The regional center assigns at least one, but typically two FIQD food technologists to provide inspection during production for the United States. The FSIS auditors reviewed all associated records, including a scheduling calendar produced by the Samut Sakhon Regional Center demonstrating planned inspection during production intended for export to the United States.

In addition, FIQD has established oversight procedures to confirm the presence of assigned FIQD inspector(s). The Regional Center Section Chief or other authorized individual either visits the establishment to observe and confirm inspection or alternately they may call the establishment to ensure the presence of assigned government inspectors. The FSIS auditors reviewed records demonstrating verification of the presence of assigned government inspectors including the date and time range the Section Chief or designee was present at the establishment, the name of the assigned inspector(s), and the method by which inspection coverage was verified (e.g., direct observation or telephone).

DOF ensures that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to carry out their inspection tasks. Thailand requires that

all food technologists have a Bachelor of Science degree in a related field prior to employment. The FSIS auditors reviewed Samut Sakhon Regional Center documentation demonstrating the list of food technologists and their associated degrees. DOF provides for initial and ongoing training designed to ensure the knowledge and competence of inspection personnel. The FSIS auditors verified that training conducted since the last FSIS audit includes ISO/IEC 17020; GMP/HACCP requirements and inspection technique; fish handling; fishery product standards and DOF requirements; and specific training for FSIS requirements. DOF holds annual FSIS requirements training and requires that all inspection staff assigned to certified establishments participate in the annual training. The FSIS auditors reviewed records for the 2020 FSIS requirements training and verified that it documented the participation of all 16 food technologists from the Samut Sakhon Regional Center by name, the training dates, method of assessment (e.g., written exam), and whether each employee passed the training.

DOF has the legal authority and responsibility to approve laboratories that perform analyses for official government sampling and testing programs for Siluriformes products exported to the United States. Laboratories are required to follow the *Regulation of the Department of Fisheries on the Registration of Laboratories B.E. 2561* (2018) governing registration of laboratories. Currently a total of 26 laboratories are registered including 11 government (four FIQD, seven IARRD) and 15 private laboratories. DOF has authorized all 26 laboratories to perform chemical residue analyses on official government samples.

Registered laboratories must comply with ISO/IEC 17025:2017 standards and Good Laboratory Practices and be accredited by the National Accreditation Body of the Bureau of Laboratory Quality Standards (BLQS) under the Ministry of Public Health. DOF does not receive accreditation audit reports but, according to interviews, will review the accreditation body audit reports during the annual DOF audit. The FSIS auditors reviewed the current accreditation certificate issued by BLQS for the FIQD Bangkok laboratory and verified that the certificate expires in January 2022. The FSIS auditors also reviewed the most recent BLQS accreditation audit report, dated July 10-11, 2019, documenting a total of nine findings and the associated laboratory corrective action plan. The FSIS auditors reviewed the letter from BLQS dated March 19, 2020, notifying the laboratory of the accreditation but there was no indication from BLQS that the accrediting body reviewed the corrective actions and found them acceptable.

DOF is responsible for conducting annual audits of all registered laboratories. DOF headquarters or DOF regional center personnel conduct the annual oversight audits and assess compliance with ISO/IEC 17025 standards. The FSIS auditors reviewed an annual audit report (*Form F-8-06, ISO 17025:2017 checklist*) conducted by DOF headquarters of the FIQD Samut Sakhon laboratory in March 2021. The FSIS auditors verified written corrective actions addressing audit findings. The laboratory quality assurance manager reviews and approves the corrective actions. The corrective action plan developed by registered laboratories in response to audit findings is not provided to the original DOF auditors but acceptability of the corrective actions by DOF is evaluated during the next annual audit.

The FSIS auditors reviewed evidence for laboratory personnel qualifications and training, calibration of equipment, proficiency testing, internal quality controls for analyses, and the most recent internal laboratory audit report for the FIQD Bangkok laboratory. The FIQD Bangkok

2020 proficiency testing for chemical residues in fish consisted of FAPAS<sup>®</sup> standards for crystal violet and leucocrystal violet and results were acceptable. The FSIS auditors determined through interviews that DOF requires personnel hired by the laboratories to have Bachelor of Science degrees. The FSIS auditors reviewed the personnel profile form for an analyst that documented the educational background and initial and ongoing training records.

DOF personnel, either IARDD inspectors at registered aquaculture farms or FIQD personnel at establishments certified to export to the United States, collect all official government chemical residue samples. DOF ensures sample identification and security at the time of sampling, during sample storage, and during transport by DOF personnel to laboratories. The FSIS auditors verified the sample receipt process at the FIQD Bangkok laboratory, including verification of information in the sample form, sample integrity and identification, and sample condition. Once received, the laboratory assigns a unique sample identification number to each sample that ensures anonymity throughout the analytical process.

IARDD laboratories report analytical results from aquaculture farm sampling to the local IARDD office. FIQD laboratories and private laboratories report analytical results of samples obtained at certified establishments to the appropriate regional center. Laboratories do not distribute analytical results reports to DOF headquarters. The FSIS auditors reviewed multiple analytical results reports from IARDD, private, and FIQD laboratories and did not identify any concerns.

The FSIS auditors determined, through interviews with FIQD representatives, that in response to analytical results exceeding the tolerance or maximum residue level (MRL), the laboratory does not consider the result final. FIQD's standard practice is to perform a second extraction from the fish sample, perform a second analysis, and if the results are acceptable, the laboratory reports the final sample result as acceptable. The FSIS auditors identified the following systemic finding:

- The CCA conducts residue analysis on primary samples but defers confirmation of results exceeding tolerance levels until they perform analysis on a second extraction from the original fish sample. FSIS does not consider the practice of performing a second analysis to support or refute original results to be equivalent.

The FSIS auditors verified that DOF's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component. However, DOF must address the audit finding described above.

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

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

FIQD requires the regional center to perform annual audits of establishments to evaluate compliance with requirements as described in *Plant Inspection Procedure, P-FI*. The Plant Inspection Unit, including at least one supervisor, from the regional center evaluates regulatory compliance of establishments at least once a year with a full inspection. The Plant Inspection Unit performs the full inspection according to procedures in *Establishment Inspection Procedures (W-FI-01)*. The annual audits include verifying compliance with all regulatory requirements including GMP, HACCP, and specific export market requirements. FIQD personnel document results of the full inspection on multiple forms including *Form F-FI-01, Hygiene Inspection Checklist*, and *Form F-FI-02, HACCP Checklist*. *Form F-FI-02* includes sanitation standard operating procedures (sanitation SOP) requirements. The regional center provides the establishment with a cover letter and *Form F-FI-05, On-site Report*, documenting the results of the inspection including all identified noncompliance and requesting corrective actions. Establishments must respond to the regional center with written corrective actions. The regional center performs initial review of the corrective actions and if acceptable, assigns inspectors to conduct an on-site follow-up inspection to further evaluate effectiveness of corrective actions. The FIQD personnel document results from the follow-up inspection on *Form F-FI-07, Follow-up Inspection Report*. The regional center provides the establishment with a final, complete audit report using *Form F-FI-06, GMP and HACCP Inspection Report*.

The FSIS auditors reviewed the most recent annual audits for each certified establishment. In addition, the FSIS auditors reviewed establishment corrective action reports, follow-up inspection reports, and final reports issued to the establishments. The remote audit confirmed that DOF is conducting comprehensive audits of establishment compliance annually and ensuring adequate corrective actions in response to findings.

DOF provides for supervisory evaluation of the performance of government inspection personnel. The team leader from the relevant regional center is responsible for conducting evaluations of assigned personnel. The FIQD supervisory performance evaluation for new inspectors is initially conducted after three months and thereafter annually. After the first annual evaluation, the team leader assesses performance every three years. The FIQD supervisors document results of the performance assessment on the *FIQD Report of Inspector Performance*, a standard form. The FSIS auditors reviewed performance evaluations for two permanent government inspectors and two contract government inspectors assigned to provide inspection

coverage of the two establishments certified eligible to export to the United States. The FSIS auditors verified that DOF is performing the process as described in the SRT.

DOF ensures separation of production of Siluriformes products destined for export to the United States through either time or space. The *Operating Practices of Fishery Products* requires segregation of raw material lots and lot identification to ensure traceability and prevent mixing of products. FIQD inspectors verify adequate separation of products during every production intended for export to the United States and document results on *Form F-FI-12*. In practice, FIQD representatives advised the FSIS auditors that both certified establishments produce products destined for export to the United States during the entire day of operations. The FSIS auditors reviewed multiple records documenting verification and compliance with segregation requirements.

DOF specifies labeling requirements for Siluriformes fish products exported to the United States in *Criteria for Inspection of Siluriformes Export Establishment to the U.S.* (2018). FIQD inspection personnel verify labeling requirements during every production. In addition, FIQD inspectors verify compliance with labeling requirements during the pre-export and export certification process to include verification of shipping marks. FIQD documents results of daily inspection on *Form F-FI-12*. The FSIS auditors reviewed daily verification records and determined DOF is implementing verification procedures as described. During the remote audit, FIQD representatives advised the FSIS auditors that Thailand requires annual certification of scale accuracy by the National Food Institute or National Institute of Metrology. Establishments must display certificates of accuracy on each scale. The *Work Instruction for Inspecting Weights of Frozen Aquatic Products (W-PH-3)* provides instructions for verification of net weights. FIQD inspectors document the results of net weight verification on *Form F-PH-02, Physical and sensory evaluation report*. The FIQD representatives stated that neither certified establishment glazes nor adds solution to Siluriformes products destined for export to the United States. The FSIS auditors reviewed daily verification records and net weight verification records and did not identify any concerns.

DOF requires establishments to segregate and control condemned and inedible products. The *Operating Practices of Fishery Products*, Section 7.1, requires the establishment to inspect raw material prior to receiving, and reject any raw materials that are abnormal or decomposed. During the remote audit, FIQD representatives stated that establishments are required to segregate inedible products into differently colored and labeled containers. The *Food Act B.E. 2522*, Section 43, provides the authority for inspectors to control product that is unfit for human consumption. FIQD inspectors verify the segregation of inedible products daily during production and document results on *Form F-FI-12*. In Thailand, establishments do not use denaturant for inedible or condemned materials. According to interviews during the remote audit, establishments may sell inedible products as fertilizer, but they must maintain evidence of the transactions and FIQD inspectors reportedly verify the weights and disposition of inedible products. However, DOF has not provided FSIS with written instructions describing this activity. DOF needs to ensure written instructions and corresponding government verification records reflect actual activities performed to ensure compliance with requirements. The FIQD representatives agreed that the current *Form F-FI-12* does not document the results of these verification activities.

The FSIS auditors concluded that Thailand's food safety inspection system governing Siluriformes provides for separation of Siluriformes, maintains controls over condemned materials, ensures compliance with labeling requirements, and provides for periodic supervisory visits to establishments certified to export to the United States.

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

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

DOF ensures that Siluriformes fish and fish products are raised and transported under sanitary conditions. IARDD evaluates Good Aquaculture Practices (GAPs) for aquaculture farms, issuing GAP certificates for compliant aquaculture farms, as required by the *Regulation of Department of Fisheries on Aquaculture Facilities Registration B.E. 2556*. The *Department of Fisheries Regulation on the Certification of Good Aquaculture Practices for Aquaculture (GAPs)*, B.E. 2553 details the requirements and process for GAP certification and provides the authority for DOF to suspend certification in the event of aquaculture farm noncompliance with requirements.

IARDD officers inspect aquaculture farms at least once a year to verify the requirements in *Good Aquaculture Practices (GAP) for Freshwater Aquatic Animal Farms*. The inspection includes verification of mandatory requirements including registration of the farm, effluent standards, prohibition on use of animal manure in rearing fish, use of registered feed and supplements within expiration dates, production inputs free from drugs and contaminants prohibited by the government, hygienic production processes that are safe for aquatic animals and consumers, proper use of registered animal drugs according to the label, use of properly registered chemicals (in case the chemical substance is required to be registered), avoidance of use of prohibited drugs and chemicals, and assurance that harvested aquatic animals do not contain prohibited drugs or exceed specified tolerances. Additional criteria assessed during audits include hygienic handling of fish during and after harvest, use of clean water, use of clean chemical-free ice, maintaining tools and equipment in a sanitary manner, and maintaining accurate aquaculture farm records.

During the annual inspection, IARDD officers also perform on-site analyses of water quality parameters and perform a chemical residue screening test on aquatic animal feed. In addition, IARDD officers collect samples of fish that official IARDD laboratories analyze for chemical residues. IARDD also has the authority to perform investigations and collect additional chemical residue samples from aquaculture farms where warranted, including detection of prohibited drugs or chemical residues exceeding established tolerances.

IARDD officers document inspection results on *Form F-AU-16, Evaluation form for freshwater animal farm in ponds according to GAP standards*. IARDD provides GAP certificates to aquaculture farms that comply with the requirements, valid for three years. The FSIS auditors determined that currently there are four registered aquaculture farms providing Siluriformes fish to the establishments certified to export to the United States. The FSIS auditors reviewed

IARDD audit records, sampling records, analytical results, and GAP certificates issued to aquaculture farms and did not identify any concerns.

DOF requires establishments to verify that Siluriformes fish arrive wholesome and suitable for human consumption as outlined in the *Operating Procedures of Fishery Products*. The FSIS auditors reviewed establishment records documenting the condition of fish at receiving, including water and fish temperature, segregation of unacceptable Siluriformes fish, and sanitary conditions. The FIQD inspectors verify sanitary handling, rapid transport, and efficient handling of Siluriformes fish by inspecting each lot of Siluriformes fish at receiving. In addition, FIQD inspectors verify traceability for every lot of received fish through review of the MD required to accompany every lot of fish in transport. FIQD inspectors document verification results on *Form F-FI-12*. The FSIS auditors reviewed verification records and did not identify any concerns.

DOF ensures that establishments separate Siluriformes fish that have died other than under the controlled circumstances of commercial fishing from eligible Siluriformes fish and fish products. The *Operating Practices of Fishery Products* describes the requirements for receiving of raw materials (e.g., fish). Each certified establishment must document the source of the fish and inspect the fish for wholesomeness. The establishment must dispose of rejected fish in labeled and color-coded containers. The FIQD inspectors verify that the establishments properly identify, control, segregate, and dispose of diseased and adulterated Siluriformes fish and parts during receiving and processing operations. FIQD inspectors document verification results on *Form F-FI-12*. The FSIS auditors reviewed verification records and did not identify any concerns.

DOF ensures that the condition of certified establishments' construction, facilities, and equipment is adequate to prevent the contamination or adulteration of Siluriformes products. The *Royal Ordinance on Fisheries*, Chapter 8, provides the legislative authority for DOF to develop hygiene standards for the rearing, transportation, and processing of aquatic animals and aquatic animal products consistent with international standards. DOF specifies sanitation requirements for establishment construction, facilities, equipment, and operations in the *Operating Practices of Fishery Products*, Parts 1-6. The requirements are consistent with the FSIS SPS requirements in 9 CFR Part 416.1-416.5 and include construction and design, equipment and instruments, chemicals and packaging material, cleaning and sanitation, hygiene requirements, employees, and control of operations.

DOF has not provided FIQD inspectors with written instructions applicable to the daily verification of the requirements outlined in the *Operating Practices of Fishery Products*, outlined above. During the remote audit, FIQD representatives confirmed there are not specific instructions for verifying sanitation and GMP requirements during daily inspection but stated that the inspectors know what to verify. FIQD inspectors reportedly document verification results on *Form F-FI-12*, under line item 3.2, implementation of sanitation SOPs. The FSIS auditors reviewed daily FIQD verification records for both certified establishments. The FIQD inspector provides the establishment with a written *Form W-FI-01, Daily Summary Report*, including any identified noncompliance. The FSIS auditors reviewed documented noncompliance, establishment corrective actions, and signatures documenting inspector



verification of the corrective actions. The FIQD Regional Center sends a letter to the establishment acknowledging acceptability of corrective actions once they are verified as acceptable.

The FSIS auditors verified that daily inspection has resulted in documented noncompliance with specific SPS requirements. However, DOF needs to issue specific written instructions for verification of the requirements in the *Operating Practices of Fishery Products* and revise Form *F-FI-12* to document evidence of the performance and results of corresponding verification activities. On this point, the FIQD representatives again agreed that the current *Form F-FI-12* does not document the results of these verification activities.

DOF's *HACCP Requirements for Fish and Fishery Products*, Section 1, outlines the requirements for developing, implementing, and maintaining sanitation SOPs. FIQD inspection personnel perform verification activities during the production of Siluriformes product destined for export to the United States, including verifying that the establishment implements and monitors its sanitation SOPs and performs corrective actions when necessary. During the remote audit, the FIQD representatives stated that FIQD inspectors conduct pre-operational sanitation verification during every production intended for export to the United States. The FSIS auditors determined that DOF has not provided FIQD inspectors with written instructions for verifying sanitation SOP requirements, including pre-operational sanitation. FIQD inspection personnel record the results of sanitation SOP verification activities on *Form F-FI-12*. The form includes one line item for verifying sanitation SOP requirements. As a result, the current DOF forms do not provide FIQD evidence of the methods, process, nor results of specific sanitation SOP requirements. FSIS identified the following systemic finding:

- The CCA does not maintain specific written instructions for FIQD inspectors on how to verify sanitation requirements. The current DOF form does not provide FIQD evidence of the methods, process, nor results of specific sanitation verification activities.

The FIQD Samut Sakhon Regional Center performs annual audits of certified establishments as previously described, including verification of establishment sanitation, GMP, and sanitation SOP compliance. The FSIS auditors reviewed the most recent annual audit records for each certified establishment and confirmed verification of requirements, documentation of sanitation noncompliance, and verification of the effectiveness of corrective actions. The FSIS auditors did not identify any concerns.

The FSIS auditors confirmed that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs. However, as noted above, the CCA must address the finding by providing specific written instructions for daily verification procedures and revising the daily verification records to document evidence of verification of specific requirements.

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

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

The CCA requires establishments to design, implement, and maintain HACCP systems consistent with United States requirements. Thailand's *HACCP Requirements for Fish and Fishery Products* stipulates the detailed rules for the development, implementation, and maintenance of a HACCP system.

The FIQD Samut Sakhon Regional Center performs annual audits of certified establishments as previously described, including assessment of HACCP system compliance according to the *Plant Inspection Procedure, P-FI* and *Establishment Inspection Procedures, W-FI-01. Form F-FI-02, HACCP audit checklist*, includes assessment of the HACCP plan, hazard analysis, flow chart, critical control points (CCP), corrective actions, monitoring, verification, records and recordkeeping, HACCP training of establishment personnel, written recall procedures, and commitment to the HACCP plan. The FSIS auditors reviewed the most recent annual audits of both certified establishments and did not identify any concerns.

FIQD inspectors perform daily HACCP verification activities according to the *Criteria for Inspection of Siluriformes Export Establishment to the U.S. (2018)* and document results on *Form F-FI-12*. The form identifies daily verification of monitoring, verification, corrective actions, and records documenting monitoring of CCPs. The FSIS auditors reviewed inspection records that document daily verification of HACCP requirements. In addition, the FSIS auditors reviewed documented noncompliance and records documenting verification of corrective actions.

The FSIS auditors confirmed that the CCA requires each official establishment develop, implement, and maintain a HACCP system.

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

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

Prior to the remote audit, FSIS' residue experts reviewed Thailand's 2020 Residue Monitoring Plan (RMP), methods of analysis, and additional SRT responses outlining the structure of Thailand's national program. There have not been any POE violations related to this component since the previous FSIS audit.

DOF develops, implements, and maintains an official government chemical residue control program designed to verify proper control and use of veterinary drugs, chemicals, and pesticides in Siluriformes production. A working committee consisting of representatives from different fishery sectors in Thailand has duties and responsibilities including development of an annual RMP, controlling the effectiveness of the RMP, reviewing all results, providing enforcement measures when samples exceed the allowable levels, and overseeing laboratories responsible for analysis.

The annual RMP is comprised of samples collected from Siluriformes fish at registered and approved aquaculture farms. IARDD officers are responsible for official chemical residue sampling at randomly selected aquaculture farms. IARDD officers document sample collection on a standard form, including specific identifying information relevant to the location and samples. IARDD officers collect samples, place samples into bags, securely seal the bags, and label the samples with identification numbers before placing them into an insulated box with ice for transport to the local IARDD office. IARDD typically freezes samples overnight and IARDD officers deliver samples to the laboratory the following day. The FSIS auditors reviewed sample records and verified traceability, sample identification, sample collection date and sample receiving date at the laboratory and concluded DOF maintains chain of custody for all official samples.

FSIS' residue experts concluded that all chemical test methods used under the RMP have been validated and comply with ISO/IEC 17025:2017 standards. IARDD and FIQD laboratories perform all official residue analyses except for polychlorinated biphenyls, which is performed by one of the private laboratories in Thailand accredited to ISO/IEC 17025:2017 for this scope. The established tolerance or action level for each chemical included in the testing program is consistent with FSIS requirements.

The FSIS auditors reviewed results demonstrating progress in collecting and analyzing samples according to the 2021 RMP. IARDD personnel in headquarters track RMP sample collection and analytical results to ensure sampling progress as expected. IARDD representatives stated that for the 2020 and 2021 RMP sampling, laboratories did not identify any results as exceeding allowable levels. IARDD performs an on-site inspection of the aquaculture farm if the laboratory identifies the detection of prohibited drugs or analytical results were above allowable tolerances. In addition, if the laboratory identifies prohibited drugs then IARDD removes GAP certification for the aquaculture farm. In either case, IARDD performs follow-up sampling at the identified aquaculture farm to ensure compliance. If IARDD rescinded GAP certification, they will only reinstate GAP certification after determining the corrective actions were adequate to prevent recurrence.

In addition to the RMP, DOF requires sampling of every lot of Siluriformes intended for export to the United States. Samut Sakhon Regional Center supervisors assign FIQD inspectors to the certified establishment to collect samples. FIQD inspectors submit samples to either FIQD or private laboratories for analysis. FIQD ensures lot traceability throughout the process by using unique lot identification numbers and sample numbers assigned by FIQD inspectors. The export certification process is not complete until FIQD receives acceptable analytical results. The FSIS auditors reviewed lot inspection results from the certified establishments and identified that the

chemical residue analyses differed between those reported by a private laboratory versus those reported by a FIQD laboratory. The FIQD laboratory analyzed for “sum of oxytetracycline, tetracycline, and chlortetracycline”, mercury, cadmium, and lead. FIQD representatives advised the FSIS auditors that the FIQD laboratories analyzed for the required elements whereas the private laboratory performed a more extensive suite of chemical analyses. The FSIS auditors reviewed sampling records, traceability records, and analytical results associated with establishment verification sampling and did not identify any concerns.

In summary, DOF comprehensive chemical residue program includes sampling of fish from certified aquaculture farms during the annual GAP certification audit, sampling of fish from randomly selected certified aquaculture farms under the RMP, and sampling of fish from certified establishments prior to export to the United States. The FSIS auditors’ analysis and remote audit verification indicated that the CCA continues to meet the core requirements for this component.

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

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

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

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

A remote exit meeting was held on June 1, 2021, with DOF. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. FSIS identified the following findings:

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

- The CCA conducts residue analysis on primary samples but defers confirmation of results exceeding tolerance levels until they perform analysis on a second extraction from the original fish sample. FSIS does not consider the practice of performing a second analysis to support or refute original results as equivalent.

### **GOVERNMENT SANITATION**

- The CCA does not maintain specific written instructions for FIQD inspectors on how to verify sanitation requirements. The current DOF form does not provide FIQD evidence of the methods, process, nor results of specific sanitation verification activities.

FSIS will evaluate the adequacy of the CCA's proposed corrective actions and base future equivalence verification activities on the information provided.

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

No. 0508.1/ 0785



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8 September B.E. 2564 (2021)

Dear Dr. Catlin,

Thailand's response to FSIS for draft final report of a remote audit conducted of Thailand during 4 May - 1 June 2021

This is with reference to your letter dated 20 August 2021, regarding the draft final report of a remote audit conducted of Thailand during 4 May - 1 June 2021 to evaluate the food safety system governing siluriformes fish and fish products exported to the United States of America.

In this regard, the Department of Fisheries (DOF), Thailand would like to submit the comments to the findings identified in the draft final report of a remote audit conducted of Thailand during 4 May - 1 June 2021 as in attachment 1 and DOF's corrective actions as in attachment 2.

Should you need any additional information or clarification, please do not hesitate to contact us. Your kind consideration on our comments and corrective actions would be much appreciated.

Yours sincerely,

(Dr. Vicharn Ingsrisawang)  
Deputy Director-General  
For Director-General

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination  
1400 Independence Avenue, SW.  
Washington, D.C. 20250

# ATTACHMENT 1

## Comments of the findings identified in the draft final report of a remote audit conducted of Thailand during 4 May - 1 June 2021

Page No.	Title of draft report	Report Text	DOF comments
6	IV. Component One: Government oversight (e.g., Organization and Administration)	<u>Paragraph 3, lines 7-9</u> ....Interviews with DOF representatives during the audit confirmed that DOF renews employment contracts annually but the duration of employment is <u>seven years</u> , after which DOF may issue a new contract.	DOF would like to amending the text to this following;  Government employees who work under the contracts of DOF will be renewed employment contracts annually when their contracts are ended. The DOF representative who was interviewed during the remote audit has worked as an inspector with DOF for seven years.
15	VIII. Component Five: Government Chemical Residue Testing Programs	<u>Paragraph 4, lines 2</u> The FSIS auditors reviewed results demonstrating progress in collecting and analyzing samples according to the 2021 <u>NRP</u> .	Correct name is " <u>RMP</u> " not NRP.
16	VIII. Component Five: Government Chemical Residue Testing Programs	<u>Paragraph 1, lines 2-5</u>  .....The FIQD laboratory analyzed for "sum of oxytetracycline, tetracycline, and chlortetracycline", mercury, cadmium, and lead. FIQD representatives advised the FSIS auditors that the FIQD laboratories analyzed for the required elements whereas the private laboratory performed a more extensive suite of chemical analyses. The FSIS auditors .....	DOF would like to amending the text to this following:  ..... The FIQD laboratory can analyze all testing parameters according to the FSIS requirements including tetracycline group (oxytetracycline, tetracycline, and chlortetracycline), nitrofur group, fluoroquinolones group, mercury, cadmium, and lead. However, during the remote audit, the LC-MS/MS of FIQD laboratory was undergoing for maintenance, therefor, the testing of nitrofur group and fluoroquinolone group were done by private laboratory which its performance is equivalent to DOF laboratory. The FSIS auditors.....
		<u>Paragraph 2, lines 3</u> .....randomly selected certified aquaculture farms under the <u>NRP</u> , and sampling of fish.....	Correct name is " <u>RMP</u> " not NRP.



## ATTACHMENT 2

### DOF's corrective actions

Component	Deficiency	Corrective Actions
Government oversight (e.g., Organization and Administration)	The Central Competent Authority (CCA) conducts residue analysis on primary samples but defers confirmation of results exceeding tolerance levels until they perform analysis on a second extraction from the original fish sample. FSIS does not consider the practice of performing a second analysis to support or refute original results as equivalent.	DOF will change the procedure to not doing the second analysis to support or refute original results.
Component Three: Government Sanitation	The CCA does not maintain specific written instructions for FIQD inspectors on how to verify sanitation requirements. The current DOF form does not provide FIQD evidence of the methods, process, nor results of specific sanitation verification activities.	To comply with FSIS requirement, the SOP for verifying sanitation requirements and the checklist which provides FIQD evidence of the methods, process and results of specific sanitation verification activities will be written and submitted to FSIS within 20 <sup>th</sup> October 2021.