



United States Department of Agriculture

AUG 27 2018

Food Safety and
Inspection Service

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Avenue, SW.
Washington, D.C.
20250

Dr. Bi Kexin
Director General
Import and Export Food Safety Bureau
The General Administration of China Customs of the People's Republic of China
(GACC)

Dear Dr. Bi,

The United States Department of Agriculture (USDA), Food Safety Inspection Service (FSIS) conducted an on-site initial equivalence verification audit of China's Siluriformes fish and fish products inspection system from May 28 through June 4, 2018. Enclosed is a copy of the final audit report. The comments received from The General Administration of China Customs (GACC) of the People's Republic of China 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,

A handwritten signature in blue ink that reads "Janell Kause".

Janell Kause
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

THE PEOPLE'S REPUBLIC OF CHINA

MAY 28 - JUNE 4, 2018

EVALUATING THE FOOD SAFETY INSPECTION SYSTEMS GOVERNING

FISH AND FISH PRODUCTS OF THE ORDER SILURIFORMES

EXPORTED TO THE UNITED STATES OF AMERICA

August 24, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an initial onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from May 28 through June 4, 2018. The purpose of the audit was to verify whether the People's Republic of China's (PRC) food safety inspection system governing fish and fish products of the order Siluriformes provides a level of public health protection equivalent to the level achieved by FSIS in the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The PRC currently only exports raw intact Siluriformes fish and fish products.

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, and Product Standards and Labeling); (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.

An analysis of the findings within each component identified several deficiencies for the Central Competent Authority (CCA) – The General Administration of Customs of the PRC (GACC) to address within their food safety system within the next 60 days. The FSIS auditors identified the following findings:

Government Oversight

- In one audited provincial office, the GACC inspection personnel did not document all noncompliances identified during their verification activities.

Government Sanitation

- In one establishment, rusted pipes and loose silicone were observed on the overhead structures on the ceiling over exposed products in the production areas.
- In another establishment, beaded condensate was observed over exposed product in several production areas.

Government Hazard Analysis and Critical Control Points (HACCP) System

- In all six establishments audited, establishment ongoing verification activities did not include direct observations of monitoring activities.
- In five out of six establishments audited, establishment verification records did not include the times or results of the verification activities.
- In four out of six establishments audited, establishment corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit.
- In two out of six establishments audited, establishment monitoring records did not include the initials or signature of the establishment employee making the entry.

These findings do not endanger public health because most of them involve recordkeeping and necessary technical clarifications. If the GACC addresses these findings, FSIS would be able to find the system equivalent to FSIS's inspection.

During the audit exit meeting, the GACC committed to address the preliminary audit findings as presented. The FSIS auditors visited a sample of six establishments from 14 slaughter and raw processing establishments currently certified as eligible by the GACC to export Siluriformes fish products to the United States. FSIS noted that most of the certified establishments could only receive Siluriformes fish from November to March of each year due to the geographical locations of their pre-harvesting farms. There are only two out of the 14 certified establishments that receive Siluriformes fish all year from their contracted pre-harvesting farms. Therefore, the FSIS auditors were only able to observe the actual production process in two establishments to verify implementation of FSIS requirements. The two establishments are the ones that operate year-round and are the largest and fourth largest exporters accounting for about 63 percent of Siluriformes fish product shipped to the United States since October 2016. In the other four establishments, FSIS auditors were able to review documents associated with previous production.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of the People's Republic of China's (PRC) food safety inspection system governing fish and fish products of the order Siluriformes from May 28 through June 4, 2018. The audit began with an entrance meeting held on May 28, 2018, in Beijing, PRC, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – The General Administration of Customs of the PRC (GACC); representatives from the Certification and Accreditation Administration of the PRC (CNCA); and the USDA's Foreign Agriculture Service (FAS). Representatives from the GACC accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was an initial onsite equivalence verification audit. The audit objective was to verify whether the PRC's food safety inspection system governing fish of the order Siluriformes and their products provides a level of public health protection equivalent to the level achieved by FSIS in the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The PRC 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, the PRC has been exporting only raw intact Siluriformes fish products to the United States.

FSIS applied a risk-based procedure that included an analysis of the PRC's 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 GACC through the self-reporting tool (SRT) responses and supporting documentation.

Representatives from the GACC 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); (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 the PRC's SRT responses and supporting documentation. The FSIS onsite audit included record reviews, interviews, and observations made by the FSIS auditors.

Administrative functions at the GACC headquarters, one provincial Custom Administration (CA) office, six local inspection offices located at the audited establishments, and two pre-harvesting farms. 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 a sample of six establishments from 14 slaughter and raw processing establishments currently certified as eligible by the GACC to export Siluriformes fish and fish products to the United States. FSIS noted that most of the certified establishments could only receive Siluriformes fish from November to March of each year due to the geographical locations of their pre-harvesting farms. There are only two out of the 14 certified establishments that receive Siluriformes fish all year from their contracted pre-harvesting farms. Therefore, the FSIS auditors were only able to observe the actual production process in two establishments to verify implementation of FSIS requirements. The two establishments are the ones that operate year-round and are the largest and fourth largest exporters accounting for about 63 percent of Siluriformes fish product shipped to the United States since October 2016. In the other four establishments, FSIS auditors were able to review documents associated with previous production. The FSIS auditors visited two pre-harvesting farms that provide raw fish to two of the audited establishments.

During the establishment and farm 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. The FSIS auditors focused on the GACC’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §557.2.

Additionally, the FSIS auditors visited one government laboratory conducting chemical residue analyses as part of the national chemical residue control plan to verify its ability to provide adequate technical support to the inspection system and to ensure compliance with the GACC’s requirements.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> GACC Headquarters Office, Beijing
	Provincial	1	<ul style="list-style-type: none"> Zhaoqing Provincial Custom Administration Office, Zhaoqing
Laboratory		1	<ul style="list-style-type: none"> Hubei Inspection and Quarantine Technology Center, Wuhan <ul style="list-style-type: none"> Chemical Residue Division
Siluriformes fish slaughter and raw processing establishments		6	<ul style="list-style-type: none"> Establishment 4500/02050 / Gain Ocean Food Co., Ltd., Beihai City, Guangxi Establishment 4400/02223 / Zhenye Aquatic (Huilong) Ltd., Zhaoqing City, Guangdong Establishment 4200/02026 /Hubei Qianjiang Huashan Aquatic Food and Product Co., Ltd., Qianjiang City, Hubei

		<ul style="list-style-type: none"> • Establishment 4200/02058 / Hubei Shengli Foodstuff Co., Ltd., Xiantao City, Hubei • Establishment 4200/02020 / Deyan Aquatic Products and Food Co., Ltd., Honghu City, Hubei • Establishment 4200/02011/ Qingjiang Baolong Aquatic Products & Foodstuffs Co., Ltd., Qianjiang City, Hubei
Pre-harvest operations	2	<ul style="list-style-type: none"> • Establishment 4200/Y0024 / Gangbeiyuan Farm, Honghu City, Hubei • Establishment 4500/Y0237 / Dongxing Jiangyuan, Dongxing City, Guangxi

FSIS performed the audit to verify whether the PRC’s food safety inspection system governing Siluriformes fish and fish products met requirements equivalent to those under the specific provisions of United States’ laws and regulations, in particular:

- 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 Federal Meat Inspection Act (FMIA) (21 United States Code [U.S.C.] 601, *et seq.*

The audit standards applied during the review of the PRC’s food safety inspection system for fish and fish products of the order Siluriformes 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 4,615,526 pounds of raw Siluriformes fish products and 74,052 pounds of thermally processed-commercially sterile Siluriformes fish products exported by the PRC to the United States. FSIS also performed reinspection for additional types of inspection, including testing for chemical residues and refused 210,877 pounds because of POE violative test results. Currently, the PRC does not have any certified establishments eligible to export thermally processed-commercially sterile Siluriformes fish products to the United States. The PRC delisted the only thermally processed-commercially sterile establishment certified as eligible to export Siluriformes fish products to the United States on April 1, 2017. At the time of the audit, the PRC presented 14 certified as eligible establishments producing raw Siluriformes fish and fish products for export to the United States.

The FSIS final audit report for the PRC'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 FSIS auditors noted that the PRC's food safety inspection system governing fish and fish products of the order Siluriformes is going through a re-organization process that will be fully implemented by September 30, 2018. Currently, the GACC, an independent administrative institution at the ministerial level directly under the State Council, is the CCA. The central headquarters of GACC is located in Beijing. GACC is in charge of the administrative functions at the national customs, entry-exit commodity inspection, entry-exit health quarantine, entry-exit animal and plant quarantine, and safety of imported-exported products. The Import and Export Food Safety Bureau, a department of GACC, is in charge of managing national control over the safety of import and export of fishery products, including fish and fish products of the order Siluriformes for export to the United States.

The FSIS auditors verified that the GACC has the ability and the responsibility to certify or revoke the certification of any establishment that has requested to export products to the United States, in accordance with the *Administrative Provisions for the Records of Export Food Production Establishments*. During the planning phases of the audit, the GACC informed FSIS that the number of eligible establishments certified to export fish and fish products of the order Siluriformes to the United States had been reduced from 20 to 14 establishments.

At the provincial level, there are 42 Custom Administration (CA) Districts throughout the PRC that oversee 268 laboratories for inspection and quarantine testing of imported and exported food; 700 local customs houses and offices; and 6,000 personnel working on food inspection of imported and exported products. Currently, there are five provincial CA offices located in Guangdong, Guangxi, Hubei, Anhui, and Jiangsu that oversee the inspection operations at 14 certified establishments presented by the GACC as eligible for exporting products to the United States. At the local level, the local CA offices are responsible for providing inspection coverage at the registered farms and slaughter and raw processing establishments certified as eligible to export products to the United States.

The FSIS auditors verified through interviews and record reviews that all inspection personnel are government employees who are paid by the national government. The government inspectors are required to have a professional degree in veterinary science, aquatic products, or food science. The GACC provides initial and annual ongoing training in relevant laws and regulations to new and/or current inspection personnel. The government inspectors are required

to pass an exam prior to their assignment and take additional training specific to FSIS requirements for product intended for export to the United States.

The FSIS auditors reviewed the current ongoing training records that included training materials for United States specific import requirements such as verification of receiving raw fish, good manufacturing practices (GMP), HACCP, sanitation, traceability, labeling, and export certification. The FSIS auditors noted that the GACC has a mechanism in place to conduct at minimum an annual performance appraisal to assess its inspection personnel's knowledge, skills, and abilities. The annual assessment includes interviews, reviews of inspection-generated records, and direct observation of inspection personnel while conducting their inspection activities.

The GACC disseminates inspection regulations including FSIS's import requirements via an intranet system known as the Office Administration (OA) notification system to provide instructions to provincial and local levels. The FSIS auditors observed the application of the OA notification system in one of the audited establishments and found no concerns.

During the audit of Zhaoqing Provincial CA office, the FSIS auditors reviewed the control procedures for proper implementation of the national system of inspection, verification, and enforcement in the only certified establishment located in this province. The FSIS auditors conducted interviews and reviewed inspection generated records including a sample of the noncompliance reports. The FSIS auditors identified the following:

- The GACC inspection personnel did not document all noncompliances identified during their HACCP verification activities.

The FSIS auditors explained that failure to document all noncompliances in an establishment can ultimately impact the GACC's ability to assess noncompliances, conduct accurate analyses of trends, and ensure that requirements related to United States export are continuously implemented. During the exit meeting, the GACC stated that the *Instruction of Exporting Food Establishments Registration Management (CNCA 2011-61)* provides instructions to the inspection personnel to identify and document any noncompliance findings on the *No Compliance Traceability Report*. The establishment is required to take corrective actions and preventive measures in response to a noncompliance within an appropriate timeframe in accordance with the GACC's *Administrative Provisions for the Records of Export Food Production Establishments* requirements.

The GACC requires farms that provide raw fish to slaughter and raw processing establishments certified as eligible to export fish and fish products of the order Siluriformes to the United States to implement a traceability program throughout the process. At the farm level, the FSIS auditors noted that the Ministry of Agriculture and Rural Affairs (MARA) is responsible for the national aquatic disease prevention, and for the control of all registered farms producing fish for human consumption. In addition to MARA's farm registration requirements, the GACC also requires additional registration for export oriented farms that provide raw fish for those slaughter and raw processing establishments that are certified as eligible to export to the United States. These farms must submit their application for approval to export to the corresponding provincial CA pending that they meet the GACC and the importing country's requirements.

The FSIS auditors verified through interviews and record reviews that the local CA inspectors conduct at minimum an annual inspection of farms to verify compliance with the GACC and FSIS import requirements. This includes review of the farm's traceability program and production records, as well as hands on inspection verification of the farm's sanitation condition; inventory of chemical and veterinary drugs consumption; and collecting water, feed, and fish samples for chemical residue analysis. The CA inspector delivers the sealed samples to the designated government laboratory. In the event of a positive chemical residue result, the provincial CA suspends the export qualification of the registered farm. At the establishment level, the FSIS auditors verified that the establishment's production process can be traced back to the farm through the establishment's production lot management system. The production lot is defined as one day's production demonstrating the year, month, date, and farm lot number in accordance with the GACC requirements.

The GACC's *Regulatory Requirements for the Export of Siluriformes Fish Products to the United States* provides a regulatory definition for adulteration and misbranding. This document also provides instructions to the inspection personnel on enforcement actions when they identify adulterated or misbranded products. The in-plant inspection personnel verification begins with the receiving of the raw fish in the slaughter and raw processing establishments. The FSIS auditors verified that upon arrival of the Siluriformes fish to the establishments, the in-plant inspection personnel verify the source of the fish (only from farms eligible to export to the United States), species, and sanitation of the transport vehicle. The GACC informed the FSIS auditors that the establishments certified as eligible to export to the United States do not receive Siluriformes fish from any other country and solely utilizes their own contracted registered farms for product that is destined for export to the United States.

The in-plant inspection personnel also verify the production process from the receiving of Siluriformes fish to the issuance of an export certificate. This includes verification of proper implementation of sanitation, HACCP, sampling, traceability, and labeling requirements. The FSIS auditors noted that the audited establishments have a system in place to distinguish between the Siluriformes fish products destined for export to the United States and other fish products destined for other markets. This includes complete separation of the production process for the United States during receiving, processing, and storage by time, space, and a lot management system. In addition, the establishments are required to apply a label that clearly indicates that the product is only for export to the United States.

The FSIS auditors reviewed an export certificate package in one of the audited establishments. This package included documents generated by the establishment's employees and inspection personnel. The establishment's document included such information as the identification of the registered farm, species of fish, size of fish, country of destination, and pre-shipment review record associated with the production lots of the exported Siluriformes fish products. The inspection personnel's document included verification of sanitation records, HACCP records, labeling requirements, traceability documents, and residue sampling results associated with the production lot for the exported batch. The GACC has implemented a hold and test policy that is intended to keep product under government control until test results indicate that there are no violative levels of chemical residue in the product. The GACC requires this compulsory

chemical residue analysis of each consignment prior to issuance of the export certificate for Siluriformes fish product destined for export to the United States.

The FSIS analysis and onsite audit verification activities indicate that the GACC has an organizational structure and sufficient administrative support to implement the PRC's Siluriformes fish and fish products inspection system. The GACC enforces laws and regulations governing production and export of Siluriformes fish products at the establishments certified as eligible by the GACC to export to the United States.

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 system is to provide for regulatory controls over condemned materials; complete separation of fish and fish products of the order Siluriformes at establishments certified as eligible to export to the United States, inspection of production activities at least once per shift, and periodic supervisory visits to official establishments.

The GACC requires that a government inspector is to be present at least once during an 8-hour production shift when producing fish and fish products of the order Siluriformes for export to the United States. In order to provide sufficient staffing to meet FSIS requirements, the GACC requires that eligible establishments provide their production schedules at least three days prior to the start of their production. This requirement allows the GACC to provide sufficient inspection coverage including a relief inspector if needed for each production shift. The FSIS auditors verified the implementation of this requirement through interviews and record reviews.

The FSIS auditors reviewed a number of in-plant inspection generated records to verify the daily implementation of inspection verification of the GACC requirements for HACCP, sanitation, chemical residue control, condemned material, traceability, labeling, and recall. The daily inspection verification activities cover the entire production shift that includes the receiving of Siluriformes fish, processing, storage, packaging, and export of the products to the United States. The in-plant inspection personnel document the results of their daily verification procedures in a standard form, the *Official Inspection Record*.

The GACC requires establishments certified as eligible to export to the United States to separate and appropriately dispose of condemned and/or inedible fish and fish products of the order Siluriformes. The FSIS auditors verified that audited establishments maintain daily records documenting disposal of condemned Siluriformes fish. During the onsite audit of two slaughter and raw processing establishments, the FSIS auditors observed designated containers that were marked for condemned and inedible Siluriformes fish throughout the slaughter and raw processing areas. These establishments have a procedure in place to identify, separate, and dispose of dead or abnormal Siluriformes fish at the receiving stations. The FSIS auditors confirmed through interviews and record reviews that the in-plant inspection personnel verify

collection, segregation, storage, and disposal of condemned Siluriformes fish at least once per production shift documenting their verification results on the *Official Inspection Record*.

The GACC requires establishments certified as eligible to export to the United States to maintain complete separation of Siluriformes fish products for export from those produced for other markets. The FSIS auditors verified in two of the audited establishments that the actual separation starts from receiving Siluriformes fish in designated transport vehicles from eligible farms. These establishments maintain complete separation throughout the entire process by having clearly marked designated processing lines and storage areas. In addition, the establishments are required to produce Siluriformes fish products for export to the United States on specific days in coordination with the CA inspection officials. The FSIS auditors confirmed through interviews and record reviews that in-plant inspection personnel are verifying the proper implementation of the establishment's procedure separating the United States production operations from other markets by space and time.

The GACC requires that the provincial CA inspection personnel conduct periodic supervisory visits. The FSIS auditors verified through interviews and record reviews that these visits are conducted annually, at minimum, by the provincial technical department. The GACC's annual supervisory visits evaluate and document in-plant inspection personnel knowledge, skills, and abilities for proper implementation of the GACC requirements in regard to production and export of Siluriformes fish products to the United States. The FSIS auditors reviewed one annual performance review conducted in 2017 in the Zhaoqing CA office and found no concerns.

The FSIS analysis and onsite audit verification activities indicate that the GACC's Siluriformes fish product inspection system provides regulatory controls over condemned materials; complete separation of establishments certified as eligible to export to the United States, inspection of production activities at least once per production shift, and periodic supervisory visits to official establishments.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The inspection system is to require that each official establishment develop, implement, and maintain written sanitation standard operating procedures (SSOP) to prevent direct product contamination or insanitary conditions.

The GACC requires that registered farms that provide Siluriformes fish to certified slaughter and raw processing establishments that export to the United States maintain sanitary conditions of the growing ponds and water source. The FSIS auditors visited two registered farms and did not identify any concerns.

The FSIS auditors noted that the GACC's sanitation requirements are consistent with FSIS regulatory requirements described in 9 CFR Part 416. The GACC requires each official establishment to develop, implement, and maintain written sanitation programs to prevent direct product contamination or the creation of insanitary conditions. The establishment's sanitary procedures must include the required frequency for pre-operational inspection and operational

inspection, the list of the establishment's personnel accountable for conducting sanitary procedures, and the records to document the results of the sanitation inspection. The establishments are required to take necessary measures to prevent direct product contamination or creation of insanitary conditions.

The GACC's *Food Safety Law of People's Republic of China* provides instructions to the inspection personnel for verifying that the establishments certified as eligible to export products to the United States have adequately implemented prerequisite programs such as GMPs, SSOPs, and sanitation performance standards (SPS). The FSIS auditors verified through the interviews and records that the inspection personnel conduct and document the result of their verification activities in accordance with the GACC's sanitation requirements.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs at the audited establishments. The FSIS auditors assessed the adequacy of the pre-operational inspection verification by observing the in-plant inspection personnel conducting pre-operational sanitation verification in one of the audited establishments. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification inspection. The in-plant inspection personnel conduct pre-operational sanitation verification on a daily basis when the establishment is producing *Siluriformes* fish products for export to the United States. The FSIS auditors noted that the in-plant inspector took regulatory control action, notified the establishment personnel, and documented his findings in accordance with GACC requirements.

The FSIS auditors reviewed the daily sanitation records generated by the establishment's personnel. The FSIS auditors noted that establishments were not documenting the initials or signature of the establishment personnel who conducted the sanitation operational inspection. The establishment's personnel stated that the same person conducts both the pre-operational and operational inspection; therefore, there is only one signature or initial on the establishment operational form.

The GACC's *Safety and Sanitation Requirements for Export Food Manufacturers of the Announcement on the Release of Safety and Sanitation Requirements and Product Catalog for Export Food Manufacturers* requires an establishment certified as eligible to export *Siluriformes* fish products to the United States to maintain the facility in good condition in order to prevent direct product contamination or creation of insanitary conditions. The FSIS auditors identified the following sanitation findings in two of the audited establishments:

- In one establishment, rusted pipes and loose silicone were observed on the overhead structures on the ceiling over exposed products in the production areas.
- In another establishment, beaded condensate was observed over exposed product in several production areas.

These findings create insanitary conditions and may cause direct product contamination. The GACC inspectors instructed the establishment's personnel to take immediate corrective actions.

The FSIS analysis and onsite audit verification activities indicate that the GACC requires that all certified establishments develop, implement, and maintain sanitation programs to prevent the creation of insanitary conditions and direct product contamination.

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 plan.

The FSIS auditors noted that the GACC's HACCP requirements are consistent with FSIS regulatory requirements cited in 9 CFR Part 417. The GACC's *Safety and Sanitation Requirements for Export Food Manufacturers of the Announcement of the Release of Safety and Sanitation Requirements and Product Catalog for Export Food Manufacturers* requires that each establishment certified as eligible to export Siluriformes fish products to the United States to develop, implement, and maintain a HACCP system.

The FSIS auditors verified that the audited establishment's HACCP plans included a flow diagram, hazard analysis, monitoring and verification activities of critical control points, corrective actions, and record keeping requirements supporting the implementation of the HACCP system. The FSIS auditors noted that, on an annual basis, the GACC and CNCA evaluates the design and proper implementation of the HACCP system in each of the establishments certified as eligible to export Siluriformes fish products to the United States.

The FSIS auditors reviewed in-plant inspection personnel HACCP verification records and noted that they documented the results of their daily verification tasks in accordance with the GACC's requirements. The FSIS auditors' HACCP verification activities also included interviews with establishment and inspection personnel and review of the establishments' HACCP records. The FSIS auditors identified the following HACCP findings in the audited establishments:

- In all six establishments audited, establishment ongoing verification activities did not include direct observations of monitoring activities.
- In five out of six establishments audited, establishment verification records did not include the times or results of the verification activities.
- In four out of six establishments audited, establishment corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit.
- In two out of six establishments audited, establishment monitoring records did not include the initials or signature of the establishment employee making the entry.

The FSIS analysis and onsite audit verification activities indicate that the GACC requires that all certified establishments develop, implement, and maintain a HACCP system in order 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 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 such as pesticides, veterinary drug residues, and environmental pollutants identified by the GACC or FSIS as potential contaminants.

Prior to the onsite audit, FSIS's residue experts thoroughly reviewed the PRC's National Residue Program (NRP) and its sampling plans for 2016 and 2017, associated methods of analysis, and additional SRT responses outlining the structure of the PRC's chemical residue testing program. FSIS reviewed the GACC's chemical residue related laws including the *Food Safety Law of China*, the *Agricultural Product Quality Safety Law*, and the *Regulations on Veterinary Drug Administration* that address the limits on pesticides, veterinary drugs, and heavy metals.

The GACC's laws including the *Food Safety Law of China*, the *Agricultural Product Quality Safety Law*, and *The Regulations on Veterinary Drug Administration* demonstrate that the GACC has the legal authority and responsibility to regulate, plan, and execute its NRP in order to prevent and control the presence of residues of veterinary drugs and other contaminants in Siluriformes fish products intended for human consumption. The GACC has assembled a regulatory task force with representatives from MARA to design the annual NRP. The FSIS auditors noted that the GACC is primarily responsible for implementation of the residue sampling plans covering production of Siluriformes fish products intended for export markets and MARA is responsible for implementation of the residue sampling plans covering the domestic market.

The GACC's *Implementation Rules for Import and Export Safety Supervision Sampling and Risk Monitoring for Food and Cosmetics* provides instructions to inspection personnel assigned in the slaughter and raw processing establishments for sample selection, proper handling of samples, and secure transportation of samples to the designated government laboratories.

The FSIS auditors verified that in-plant inspection personnel who collect the residue samples of raw fish and finished products have received adequate training in accordance with the GACC's NRP sampling protocol. This protocol includes sampling methodology, identification of a production lot, sample size, sampling frequency, traceability, and secure delivery of residue samples to designated government residue laboratories. All collected samples are traceable to their production lot in the establishment and farms. In order to ensure that residue samples are under government control during the entire process from sampling to testing results, the inspection personnel who collect the samples also seal and deliver them to the designated government residue laboratory. The laboratory reports the results of the analytical testing to inspection personnel. In case of violative levels of residues, the in-plant inspection personnel are required to detain the product and verify the effectiveness of the establishment's corrective actions that include segregation of affected lots and identification of the root cause of the violation. In accordance with the CA requirements, the affected lots with violative residue levels are not eligible for export to the United States.

The CNCA is responsible for certification of the technical competency of the GACC's laboratories by following *Laboratory Accreditation Guidelines* and *Laboratory Accreditation Rules* that have been developed by China's National Accreditation Service for Conformity (CNAS). The Laboratory Accreditation Rules stipulate procedures and requirements for running the CNAS laboratory accreditation system, including accreditation conditions, accreditation processes, application acceptance requirements, and review requirements. Laboratory compliance is assessed using International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, ISO/IEC17020, ISO/IEC Guide 17034, and ISO/IEC17043.

The FSIS auditors visited the Hubei Inspection and Quarantine Technology Center, a government laboratory located in Wuhan. This is an official government laboratory that conducts chemical residue testing as part of the national chemical residue control plan to ensure compliance with requirements of the GACC and importing countries. The laboratory is ISO 17025 accredited by CNAS. The FSIS auditors reviewed records and interviewed the laboratory manager to assess the staff's technical competency, training, and knowledge of the analytical methods used to detect chemical residues. The results of the review demonstrate that laboratory personnel are qualified and adequately trained to perform analytical methods for the detection of residues of concern.

The FSIS analysis and onsite verification activities indicate that the GACC 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 and final equivalence component 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.

The PRC currently has 14 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 GACC 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 June 4, 2018, in Beijing, China, with the GACC. 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, although some findings could lead to product contamination if the concerns identified are not adequately addressed. The FSIS auditors identified the following findings:

Government Oversight

- In one audited provincial office, the GACC inspection personnel did not document all noncompliances identified during their verification activities.

Government Sanitation

- In one establishment, rusted pipes and loose silicone were observed on the overhead structures on the ceiling over exposed products in the production areas.
- In another establishment, beaded condensate was observed over exposed product in several production areas.

Government Hazard Analysis and Critical Control Points (HACCP) System

- In all six establishments audited, establishment ongoing verification activities did not include direct observations of monitoring activities.
- In five out of six establishments audited, establishment verification records did not include the times or results of the verification activities.
- In four out of six establishments audited, establishment corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit.
- In two out of six establishments audited, establishment monitoring records did not include the initials or signature of the establishment employee making the entry.

These findings do not endanger public health because most of them involve recordkeeping and necessary technical clarifications. In addition, the sanitation problems observed are unlikely to lead to problems that will cause illness. If the GACC addresses these findings, FSIS would be able to find the system equivalent to FSIS's inspection.

During the audit exit meeting, the GACC committed to address the preliminary audit findings as presented. The FSIS auditors visited a sample of six establishments from 14 slaughter and raw processing establishments currently certified as eligible by the GACC to export Siluriformes fish products to the United States. FSIS noted that most of the certified establishments could only receive Siluriformes fish from November to March of each year due to the geographical locations of their pre-harvesting farms. There are only two out of the 14 certified establishments that receive Siluriformes fish all year from their contracted pre-harvesting farms. Therefore, the FSIS auditors were only able to observe the actual production process in two establishments to verify implementation of FSIS requirements. The two establishments are the ones that operate year-round and are the largest and fourth largest exporters accounting for about 63 percent of Siluriformes fish product shipped to the United States since October 2016. In the other four establishments, FSIS auditors were able to review documents associated with previous production.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gain Ocean Food Co., Ltd., Beihai City, Guangxi	2. AUDIT DATE 05/29/2018	3. ESTABLISHMENT NO. 4500/02050	4. NAME OF COUNTRY The People's Republic of China
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. 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)		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. Periodic Supervisory Reviews	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

15/51: The establishment's ongoing verification activities did not include direct observations of monitoring activities.

39/51: The FSIS auditors observed rusted pipes and loose silicone on the overhead structures on the ceiling over exposed products in the production areas.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Deyan Aquatic Products and Food Co., Ltd. Honghu, Hubei	2. AUDIT DATE 06/01/2018	3. ESTABLISHMENT NO. 4200/02020	4. NAME OF COUNTRY The People's Republic of China
5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	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)		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. Periodic Supervisory Reviews	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

15/51: The establishment's ongoing verification activities did not include direct observations of monitoring activities.

22/51: The establishment's verification records did not include time or result of the verification activities.

22/51: The establishment's corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Hubei Shengli Foodstuff Co., Ltd. Xiantao City, Hubei	2. AUDIT DATE 05/31/2018	3. ESTABLISHMENT NO. 4200/02058	4. NAME OF COUNTRY The People's Republic of China
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	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)		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

15/51: The establishment's ongoing verification activities did not include direct observations of monitoring activities.

22/51: The establishment's verification records did not include time or result of the verification activities.

22/51: The establishment's corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit.

22/51: The establishment's monitoring records did not include for each entry initial or signature of the establishment employee making the entry.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Hubei Qianjiang Huashan Aquatic Food and Product Co., Ltd. Qianjiang City, Hubei	2. AUDIT DATE 06/01/2018	3. ESTABLISHMENT NO. 4200/02026	4. NAME OF COUNTRY The People's Republic of China
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	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)		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

15/51: The establishment's ongoing verification activities did not include direct observations of monitoring activities.

22/51: The establishment's verification records did not include time or result of the verification activities.

22/51: The establishment's corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Qingjiang Baolong Aquatic Products & Foodstuffs Co., Ltd. Qianjiang City, Hubei	2. AUDIT DATE 06/1/2018	3. ESTABLISHMENT NO. 4200/02011	4. NAME OF COUNTRY The People's Republic of China
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	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)		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. Periodic Supervisory Reviews	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

15/51: The establishment's ongoing verification activities did not include direct observations of monitoring activities.

22/51: The establishment's verification records did not include time or result of the verification activities.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Zhenye Aquatic (Huilong) Ltd. Zhaoqing City, Guangdong	2. AUDIT DATE 05/30/2018	3. ESTABLISHMENT NO. 4400/02223	4. NAME OF COUNTRY The People's Republic of China
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. 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)		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

- 15/51: The establishment's ongoing verification activities did not include direct observations of monitoring activities.
- 22/51: The establishment's verification records did not include time or result of the verification activities.
- 22/51: The establishment's corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit.
- 22/51: The establishment's monitoring records did not include for each entry initial or signature of the establishment employee making the entry.
- 41/51: The FSIS auditors observed beaded condensate over exposed product in several production areas.

Appendix B: Foreign Country Response to Draft Final Audit Report

Letter from the General Administration of Customs (Division)

Food Safety Letter (2018) NO. 52

Letter with regards to the comments in response to the report drafted by U.S.-led inspection on the safety and supervision system for Siluriformes fish exports from China to U.S.

To: Food Safety and Inspection Service (U.S.)

With respect to the draft inspection report on the safety and supervision system for Siluriformes fish exports from China to U.S., dated June, 29th, we confirm our receipt of the aforementioned report on July 2nd.

After in-depth research into your draft inspection report, we have prepared the corresponding comments. To facilitate our communication, we have provided comments on each issue outlined in your draft inspection report in sequential order and have made rectifications to the existing problems. We hereby submit our comments (please refer to the attachment). We hope that you can verify the compliance of the safety and supervision system for Siluriformes fish exports from China to U.S. at your earliest convenience.

Yours Sincerely

Attachment: Comments in response to the report drafted by the U.S. auditors



China Food & Drug Administration

August 3rd, 2018

Attachment 1:

Comments in response to the report drafted by the U.S. auditors

I. Component 1 (page 4 of report)

1. The FSIS auditors noted that the PRC food safety inspection system governing fish and fish products of the order Siluriformes is undergoing a re-organization process that will be fully implemented by September 30th, 2018

Comment: In March 2018, the import/export supervising function and supervision team had been re-organized from the China National Quality Supervision and Inspection Bureau to the Chinese Customs. This is only a change in affiliation.

As of now, there are no changes to the inspection system for the export of Siluriformes fish from China to U.S. and we are able to ensure the quality and safety of exported Siluriformes fish.

2. The GAGC inspection personnel did not document all non-compliances identified during their HACCP verification activities. The FSIS auditors explained that failure to document all non-compliances in an establishment can ultimately impact the GAGC's ability to assess non-compliances, conduct accurate analyses of trends, and ensure that requirements related to United States export are continuously implemented.

Comment: The 'Work Guidance for Establishments Processing Food for Export' (State Notice (2011) No. 61) requires official inspectors to verify and record all non-compliances in the 'Non-compliance Tracking Report'. We shall intensify the trainings for official inspectors and put more stringent requirements in place for official inspectors to record all non-compliances during the HACCP verification of establishments processing Siluriformes fish for export to the U.S.

II. Component 3 (page 6 of report)

3. In one establishment, rusted pipes and loose silicone were observed on the overhead structures on the ceiling over exposed products in the production areas.

Comment: The Chinese establishment has dealt with and removed the rusted pipes and loose silicone on the overhead structures on the ceiling over exposed products in the production areas. The Chinese establishment has also enhanced daily inspection to prevent the occurrence of loose silicone.

4. In another establishment, beaded condensate was observed over exposed product in several production areas.

Comment: The Chinese establishment has upgraded the ventilation system to prevent the formation of beaded condensate in production areas.

III. Component4 (page 7 of report)

5. In all six establishments audited, ongoing verification activities did not include direct observations of monitoring activities.

Comment: Reviewers in the inspected establishments had verified the absence of CCP anomalies with their signatures but did not leave specific comments on the monitoring activities. With regards to this, the 6 Chinese establishments had implemented a revised CCP log format and added fields for operator's signature and reviewer's comments. They have also conducted training for reviewers to learn about the 'Record Management System'.

At the same time, inspections had been conducted on other establishments to ensure strict compliance to the CCP verification record, as required by the U.S.

6. In five out of six establishments audited, verification records did not include the times or results of the verification activities.

Comment: Reviewers in the inspected establishments had verified qualified results with their signatures but did not note the specific times and results of the verification activities. With regards to this, the Chinese establishments had revised the 'Record Management System', revised and implemented the CCP log format with added fields for operator's signature and reviewer's comments. They have also conducted training for reviewers to learn about the 'Record Management System'.

At the same time, inspections had been conducted on other establishments to ensure strict compliance to the CCP verification record, as required by the U.S.

7. In four out of six establishments audited, corrective action records did not include all four parts of the corrective actions to be followed in response to a deviation from a critical limit.

Comment: The corrective action records in the inspected establishments did not include the analysis of reasons. With regards to this, the Chinese establishments had revised the description of corrective action in the CCP2 'Metal Detection' log, Added the description of reason analysis step. They have also conducted training on FSIS regulations for members of the HACCP group.

At the same time, inspections had been conducted on other establishments to ensure strict compliance to all four parts of the corrective actions, as required by the U.S.

8. In two out of six establishments audited, monitoring records did not include the initials or signatures of establishment employees making the entry.

Comment: Personnel in the inspected establishments can be identified with their employee tags and they are required to pass through hygiene inspection before entering production areas. Therefore, we had not required every employee to sign at the entrance. With regards to this, the Chinese establishments had added an attendance log at the entrance for entering employees to sign off. They have also conducted training for administrators to learn about the 'Food Protection Plan'. At the same time, inspections had been conducted on other establishments to ensure strict compliance to the employee entry record, as required by the U.S.