



United States Department of Agriculture

Food Safety and
Inspection Service

SEP 25 2019

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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 and Inspection Service (FSIS) conducted an on-site equivalence verification audit of China's Siluriformes fish inspection system from November 26 through December 13, 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 final report.

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

Sincerely,


for Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
THE PEOPLE'S REPUBLIC OF CHINA
NOVEMBER 26 – DECEMBER 13, 2018

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

August 15, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a follow-up initial on-site equivalence verification audit of Siluriformes fish and fish products conducted by the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) from November 26 through December 13, 2018 in the People's Republic of China (PRC). The previous FSIS initial on-site audit was conducted from May 28 through June 4, 2018. During the initial audit, FSIS was only able to observe the actual production process in two out of the seven audited establishments due to the seasonal production of fish of the order Siluriformes. The purpose of the current follow-up audit was to observe the actual production process in all seven establishments and two pre-harvest sites for the audit; to verify the proper implementation of the proffered corrective actions in response to previous audit findings; and to verify whether the PRC's food safety inspection system governing Siluriformes fish and fish products maintains 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 FSIS auditors visited seven out of ten establishments certified by the PRC to export Siluriformes fish and fish products to the United States. During this audit, all seven certified establishments were processing Siluriformes fish and performing other related operations as per the self-reporting tool (SRT) responses submitted by the PRC. The FSIS auditors were able to observe the production of Siluriformes fish and the implementation of corrective actions to the deficiencies noted during the initial on-site audit. The PRC currently only exports raw intact Siluriformes fish and fish products to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, 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 equivalence component did not identify any deficiencies that represented an immediate threat to public health. However, the FSIS auditors identified several isolated Sanitation and HACCP findings that are noted in the individual establishment checklist provided in Appendix A of this report. During the audit exit meeting, the Central Competent Authority (CCA) committed to addressing the preliminary audit findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions and base future equivalence verification activities on those and any other information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the People's Republic of China's (PRC) food safety inspection system governing fish and fish products of the order Siluriformes from November 26 through December 13, 2018. The audit began with an entrance meeting held on November 26, 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) 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 a follow-up audit to an initial on-site equivalence verification audit conducted earlier in the year. The audit objective was to verify whether the PRC's food safety inspection system governing fish of the order Siluriformes provides a level of public health protection equivalent to the level achieved by the 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 to the United States by HACCP process categories: raw non-intact and raw intact products.

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 August 31, 2018, in addition to information obtained directly from the GACC through the self-reporting tool (SRT) responses and supporting documentation.

The FSIS auditors were accompanied throughout the audit by representatives from the GACC. 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 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. The evaluation of all six equivalence components included a review and analysis of the PRC's SRT responses and supporting documentation. The FSIS on-site audit included record reviews, interviews, and observations made by the FSIS auditors.

The FSIS auditors reviewed administrative functions at the GACC headquarters, four district Custom Administration (CA) offices, seven local inspection offices located at the audited establishments, and two pre-harvesting farms. The FSIS auditors evaluated the implementation of control systems to verify whether the national system of inspection, verification, and enforcement is being implemented as documented.

The FSIS auditors visited seven establishments out of the 10 slaughter and raw processing establishments currently certified as eligible by the GACC to export Siluriformes fish and fish products to the United States. The FSIS auditors visited two pre-harvesting operations that provide live 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 interact 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 the 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 two government laboratories that conduct chemical residue analyses as part of the national chemical residue control plan to verify that they can 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
	District Offices	4	<ul style="list-style-type: none"> Zhaoqing Custom Office of Guangzhou Custom District, Zhaoqing Yuncheng Custom Office of Nanjing Custom District, Yuncheng Beihai Custom Office of Nanning Custom District, Beihai Xiantao Custom Office of Wuhan Custom District, Xiantao
Chemical Residue Laboratories		2	<ul style="list-style-type: none"> The Nanjing Customs Laboratory, Nanjing. The Zhaoqing Customs Laboratory, Zhaoqing.
Siluriformes Fish Slaughter and Raw Processing Establishments		7	<ul style="list-style-type: none"> Est. No. 3200/02512, Jiangsu Haitian Sea-Beach Aquatic Foods Co., Ltd., Yancheng. Est. No. 3400/02027, Anhui Fuhuang Sungem Foodstuff Group Co., Ltd., Chaohu City. Est. No. 4400/02223, Zhenye Aquatic (Huilong) Co., Ltd., Zhaoqing. Est. No. 4200/02026, Hubei Qianjiang Huashan Aquatic Food and Product Co., Ltd., Qianjiang. Est. No. 4200/02041, Changyang Qingjiang Pengbo Development Co., Ltd., Yichang City. Est. No. 4200/02020, Deyan Aquatic Products and Food Co., Ltd., Honghu City. Est. No. 4500/02050, Gain Ocean Food Co., Ltd., Beihai.

Pre-Harvest Operations	2	<ul style="list-style-type: none"> • Chaohu Sungem Breeding Improvement Farms - No. 3411/Y0003, Chaohu City. • Moshi Doubaoahu Agriculture Development Co., - No. 4200/Y0064, Yichang City.
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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, specifically:

- United States Code of Federal Regulations, Title 9, Chapter III, Subchapter F, Part 530. *Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish*
- 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 August 31, 2018, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 11,876,445 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 on 2,227,732 pounds for additional types of inspection, including testing for chemical residues and refused 211,824 pounds of Siluriformes fish from PRC 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 10 certified as eligible establishments producing raw Siluriformes fish and fish products for export to the United States.

FSIS conducted its initial on-site equivalence audit of the PRC for Siluriformes fish and fish products from May 28 through June 4, 2018. During that audit, the FSIS auditors visited six establishments and identified record keeping and operational deficiencies related to HACCP and sanitation. During the current follow-up audit, the FSIS auditors visited a total of seven establishments that included visits to four of the same establishments that were previously audited during May 28 through June 4, 2018. FSIS auditors were able to verify that proffered corrective actions to all previous audit findings had been adequately implemented and resolved in these four establishments.

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 there have been no major changes in the CCA's organizational structure or inspection procedures governing fish and fish products of the order Siluriformes since the FSIS initial equivalence audit conducted in May-June 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 oversees 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.

At the central level, 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 intended for export to the United States. At the provincial level, there are 42 Custom Administration (CA) districts throughout the PRC. Currently, there are five district CA offices located in Guangdong, Guangxi, Hubei, Anhui, and Jiangsu that oversee the inspection operations at the 10 certified establishments eligible for exporting Siluriformes fish and fish products to the United States. At the local level, the Import and Export Food Safety Division of local CA offices are responsible for providing inspection coverage at the registered farms and slaughter and raw processing establishments certified as eligible to export Siluriformes fish and fish products to the United States.

The FSIS auditors verified through interviews and record reviews that all inspection personnel are permanent 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 to 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 aquaculture practices (GAPs), good manufacturing practices (GMPs), HACCP systems,

sanitation, traceability, labeling, fish products standards, and export certification. The FSIS auditors noted that the GACC has a mechanism in place to conduct at a 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 import requirements via an intranet system known as the Office Administration (OA) notification system to provide instructions to district and local levels. The FSIS auditors observed the application of the OA notification system in three of the local CA offices and found no concerns.

The FSIS auditors verified that the GACC's Department of Enterprise Management and Audit-based Control has the legal authority and responsibility to certify or delist 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*. The GACC may revoke an establishment certification when the establishment is not meeting PRC or importing country's requirements. 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 14 to 10 establishments.

The FSIS auditors verified that the GACC has provided instructions to its inspection personnel to identify and document any noncompliance findings on the *No Compliance Traceability Report* (NCTR). The FSIS auditors reviewed in-plant inspection generated NCTRs at all audited establishments. The FSIS auditors verified that inspection personnel had identified and documented noncompliance findings in NCTRs in accordance with the GACC's requirements. Inspection personnel closed the NCTRs after verifying the adequacy and effectiveness of the establishment's preventive and corrective actions. The FSIS auditors' verification of this documentation also confirmed the corrective actions the GACC put in place based on findings of the FSIS initial equivalence audit for Siluriformes fish and fish products conducted in May-June of 2018.

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, 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, GACC also requires additional registration for farms that provide raw fish to those slaughter and raw processing establishments that are certified as eligible to export fish to the United States. These farms must submit their application for approval to export to the corresponding local CA pending, approval is granted after verification that they meet the GACC and the importing country's requirements. The FSIS auditors visited two registered farms and through observation and record review verified that these farms are required to comply with both MARA and GACC requirements. These requirements include regulatory requirements for growers regarding the farm's sanitary conditions, sampling and analysis of feeds/feed additives, water, live fish, and necessary actions in response to disease outbreaks.

The FSIS auditors verified through interviews and record reviews that the local CA inspectors conduct at a minimum an annual inspection of farms to verify compliance with the GACC and FSIS import requirements. This annual inspection 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 collection of 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 live 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 (that the fish originated only from registered 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 utilize their own contracted registered farms for product destined for export to the United States.

The in-plant inspection personnel also verify the production process from the receiving of Siluriformes fish through 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 product intended for export to 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 export certificate packages in the audited establishments. Such packages included documents generated by the establishment's employees and inspection personnel. The establishment's documents included such information as the identification of the registered farm, species of fish, size of fish, country of destination, pre-shipment review record, and microbiological and chemical residue sampling results associated with the production lot for the exported Siluriformes fish products. The inspection personnel's document review, prior to issuance of the export certificate, included verification of each establishment's sanitation and HACCP records, establishment's microbiological and chemical residue sampling results, as well as a review and verification of labeling, and traceability documents.

The CNCA, a department under State Administration for Market Regulation, 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 Nanjing Customs Laboratory, located in Nanjing, Jiangsu, and the Zhaoqing Customs Laboratory, located in Zhaoqing, Guangdong. These are both official government laboratories that conduct chemical residue testing as part of the national chemical residue control plan to ensure compliance with requirements of the GACC and importing countries. These laboratories are ISO 17025 accredited by CNAS. The FSIS auditors reviewed records and interviewed the laboratories managers 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 on-site 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 the production and export of Siluriformes fish and 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 AND 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 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. To provide sufficient staffing to meet FSIS inspection 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 review.

The FSIS auditors reviewed 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 on 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 on-site audit of seven 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 review 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 all audited establishments that the actual separation begins at 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 review 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 district CA inspection personnel conduct periodic supervisory visits. The FSIS auditors verified through interviews and record review that these visits are conducted annually, at a minimum, by the district Food Safety Division's inspection personnel. 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 review of documented periodic supervisory visits conducted in 2018 did not identify any public health or food safety concerns.

The FSIS analysis and on-site audit verification activities indicate that the GACC's Siluriformes fish product inspection system provides regulatory controls over condemned materials; complete separation of fish and fish products at 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 (sanitation SOPs) 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. Good Aquaculture Practices serve as a guide for sanitary practices employed by farms including records documenting the monitoring and sampling of live fish for health conditions, monitoring and sampling feed and feed additives, in addition to monitoring and sampling the water of the ponds. The FSIS auditors visited two registered farms to review the documentation and observe conditions of the environment. The FSIS auditors 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 GAPs, sanitation SOPs, and sanitation performance standards (SPS). The FSIS auditors verified through interviews and record reviews 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 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. However, the FSIS auditors identified SPS findings isolated to individual establishments not observed by the GACC inspectors that are described in the individual establishment checklist provided in Appendix A of this report. These SPS findings may create insanitary conditions and may cause direct product contamination. The GACC inspectors instructed the establishment's personnel to take immediate corrective actions based on these FSIS auditor observations.

The FSIS analysis and on-site 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. Isolated sanitation performance standards issues that were observed are noted in the individual establishment checklist in the back of the report and were corrected immediately by GACC inspectors.

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 on 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's inspection personnel from Department of Enterprise Management and Audit Based-Control 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 results of these evaluations are recorded on the "HACCP Verification Form".

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 findings isolated to individual establishments HACCP record keeping that are noted in the individual establishment checklist provided in Appendix A of this report.

There were no products affected by these HACCP findings. During the exit meeting, the GACC committed to address the HACCP findings.

The FSIS analysis and on-site 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 on-site audit, FSIS residue experts thoroughly reviewed the PRC's National Residue Program (NRP) and its sampling plans for 2017 and 2018, associated methods of analysis, and additional SRT responses outlining the structure of the PRC's chemical residue testing program. FSIS also 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 noted that the GACC has implemented a test and hold policy intended to keep product under government control until test results indicate that there are no violative levels of chemical residue in the product. The FSIS auditors verified that in-plant inspection personnel who collect the residue samples of raw fish 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. To ensure that residue samples are under government control during the entire process from sampling to receipt of 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. If violative levels of residues are detected, 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 FSIS analysis and on-site verification activities indicate that the GACC has developed and implemented a chemical residue testing program, that includes testing of Siluriformes fish products intended for export to the United States 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 10 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 December 13, 2018, in Beijing, China, with the GACC. At this meeting, the FSIS auditors presented the preliminary findings from the audit. These findings do not represent an immediate threat to public health because most of them involve HACCP recordkeeping or SPS requirements. During the audit exit meeting, the GACC committed to address the preliminary audit findings as presented. FSIS will evaluate the adequacy of the GACC's proposed corrective actions and associated documentation and base future equivalence verification activities on the information provided.

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 Zhenye Aquatic (Huilong) Ltd. Zhaoqing City, Guangdong	2. AUDIT DATE 12/03/2018	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	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.		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

The FSIS auditors observed the following Sanitation Performance Standards findings. Although no direct product contamination was observed, the following may create insanitary conditions and a potential for product contamination.

39/51: Rusted areas on the overhead structures (cooling units) above exposed products in the production areas.

39/51: Small holes in the ceiling and open gaps between ceiling and pipes protruding from overhead structures over exposed products in the production areas.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

05/30/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Jiangsu Haitian Sea-Beach Aquatic Foods Co., Ltd. Yancheng	2. AUDIT DATE 11/30/2018	3. ESTABLISHMENT NO. 3200/02512	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 SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	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

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

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

05/29/2018

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 12/07/2018	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 SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	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

22/51: The establishment's HACCP plan did not include returned product in the flow chart or hazard analysis.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

06/01/2018

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 12/05/2018	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 SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	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.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		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

22/51: The establishment's HACCP monitoring records did not document the time of monitoring activity for each entry.

The FSIS auditors observed the following Sanitation Performance Standards findings. Although no direct product contamination was observed, the following may create insanitary conditions and a potential for product contamination.

38/51: Deteriorated seal around a shipping door did not provide a tight seal when door was closed (potential vermin entrance).

39/51: The establishment used silicone type material to fill a gap in the internal surfaces of the ice making machine.

46/51: The interior surfaces of the lids of fish transport water tank were not cleaned adequately in accordance with the establishment's sanitary requirement.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

05/29/2018

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 12/07/2018	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 SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	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.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
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

22/51: The establishment's HACCP plan did not include returned product in the flow chart or hazard analysis.

The FSIS auditors observed the following Sanitation Performance Standards findings. Although no direct product contamination was observed, the following may create insanitary conditions and a potential for product contamination.

39/51: Small holes in the ceiling and walls, exposed insulation, and open gaps between ceiling and pipes protruding from overhead structures over exposed products in the production areas.

45/51: Rusted areas in the interior surfaces of the ice making machine.

46/51: During the pre-operational sanitation inspection verification, residue buildups from the previous days' operation were observed on the food contact surfaces of several cutting boards in the production area.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Changyang Qingjiang Pengbo Development Co., Ltd. Yichang	2. AUDIT DATE 12/10/2018	3. ESTABLISHMENT NO. 4200/02041	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.		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

22/15: The establishment's HACCP plan did not include the frequency of direct observation of verification procedures.

22/51: The establishment's HACCP verification records did not document the type of verification (record review or direct observation) activities.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Anhui Fuhuang Sungem Foodstuff Group Co., Ltd. Chaohu City	2. AUDIT DATE 11/27/2018	3. ESTABLISHMENT NO. 3400/02027	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.		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

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

The FSIS auditors observed the following Sanitation Performance Standards finding. Although no direct product contamination was observed, the following may create insanitary conditions and a potential for product contamination.

39/51: Small holes in the ceiling and exposed insulation around cooling units attached to the ceiling over exposed products in the production area.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

05/29/2018

Appendix B: Foreign Country Response to Draft Final Audit Report

中华人民共和国海关总署食品局便函

加 急

海关总署食品局关于提交对美国考察中国输美 鲶鱼监管体系最终报告草案评议意见的函

美国农业部食品安全检验局：

贵方2019年6月11日提交的对中国输美鲶鱼监管体系考察最终报告草案收悉。

中方对贵方考察最终报告草案进行了认真研究，针对贵方考察报告草案提出的问题，逐一进行了整改。现将整改措施提交贵方（见附件）。希望贵方继续确认中国输美鲶鱼监管体系与贵方等效，保障中国输美鲶鱼贸易顺畅。

顺致敬意。

附件：中方整改措施



内部抄送：企管司、国际司

外部抄送：美利坚合众国驻华大使馆农业处

Letter from the Bureau of Food from the General Administration of Customs of the People's Republic of China

Urgent

Letter from Bureau of Food of the General Administration of Customs Regarding the Submission of Comments and Opinions on the Draft of the Final Report of Due Diligence by the U.S. regarding China's Regulatory System of Siluriform for Export to the U.S.

Bureau of Food Safety Inspection Services of the U.S Department of Agriculture:

We have received the Draft of the Final Report of the Due Diligence by the U.S. of China's Regulatory System of Siluriform for Export to the U.S. that you have submitted on 11 Jun 2019.

We have carried out a conscientious study of draft of the final report of the due diligence and have made corrections to each of the problems raised in the draft of your due diligence report. We hereby submit the corrective measures to you (see attachment). We hope that you will continue to ensure that China's regulatory system of siluriform for export to the U.S. has equivalent effect with that of your country, so as to ensure successful trade of China's siluriform exported to the U.S.

Yours sincerely.

Attachment: Corrective Measures Proposed by China

General Administration of Customs (stamp: Bureau of Import/Export Food Safety of the General Administration of Customs)

10 Jul 2019

Internal cc: Department of Enterprise Management, Department of International Cooperation

External cc: Agricultural Service of the U.S. Embassy in China

附件

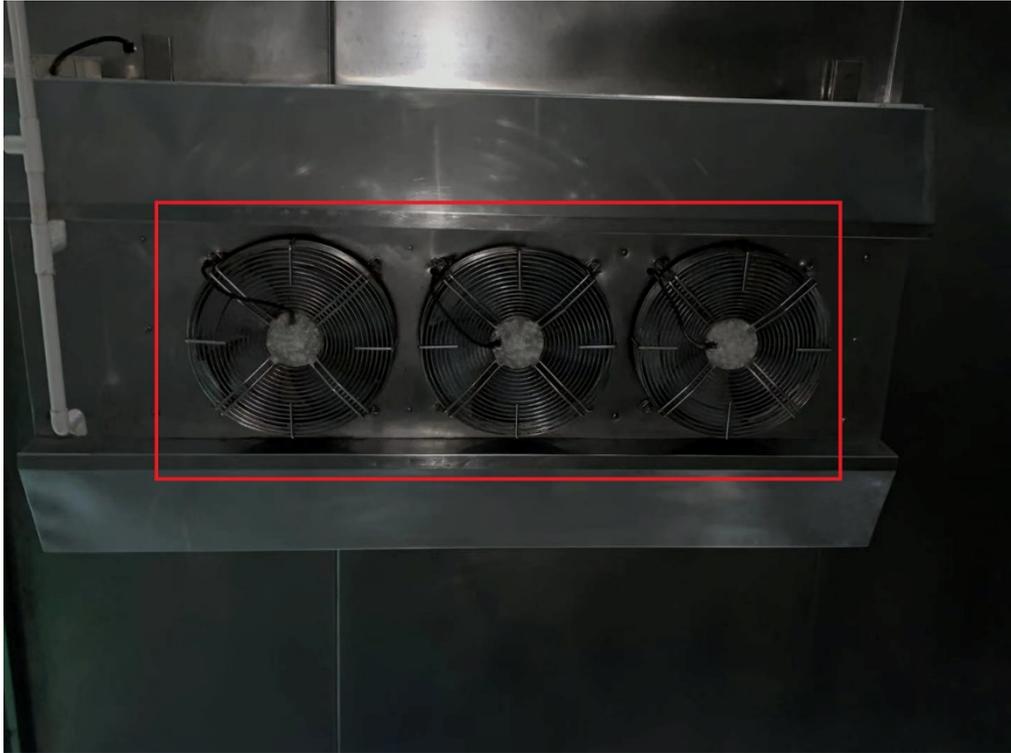
中方整改措施

一、肇庆市振业水产冷冻有限公司，备案号：
4400/02223（1. Zhenye Aquatic (Huilong) Ltd. ,
Establishment No.: 4400/02223)

（一）车间内产品暴露位置上方的制冷机有锈迹。（1.
Rusted areas on the overhead structures (cooling units)
above exposed products in the production areas.）

整改措施：已清除制冷机上的锈迹。

整改后制冷机照片如下：



(二) 车间内产品暴露位置上方天花板有小洞，天花板与水管接口之间有缝隙。(2. Small holes in the ceiling and open gaps between ceiling and pipes protruding from overhead structures over exposed products in the production areas.)

整改措施：已封闭天花板上的小洞和天花板与水管之间的接口。

整改后的天花板照片如下：



二、江苏海天滩涂水产有限公司, 备案号: 3200/02512
(2. Jiangsu Haitian Sea-Beach Aquatic Foods Co.,Ltd.,
Establishment No.: 3200/02512)

(三) 企业的 HACCP 验证记录缺少验证活动的时间或
结果。(3. The establishment's HACCP verification
records did not document the time or the result of
verification activities.)

整改措施：该企业已修改 HACCP 验证记录的格式，并在记录中填写验证活动的时间和结果。

修改后的 HACCP 验证记录如下：

原料验收记录表 CCPI

关键限值：原料鱼必须来自备案的养殖场，有供货证明，经检测合格。

监控方法：原料监控员检查每一批原料是否来自备案的养殖场，收购前是否经检测合格，核对供货证明，不符合的拒收。

产品名称：斑点叉尾鲴鱼

供应商：东台市金贯特种水产养殖场

日期	2018.10.12	2018.10.12				
检查内容						
供货证明号	20170224	20170225				
原料是否经检测合格	√	√				
原料批号	0602Y	0602Y				
塘口号	2#	2#				
车牌号码	<input checked="" type="checkbox"/> 苏 JD3381 <input checked="" type="checkbox"/> 苏 JL6711	<input type="checkbox"/> 苏 JD3381 <input checked="" type="checkbox"/> 苏 JL6711	<input type="checkbox"/> 苏 JD3381 <input type="checkbox"/> 苏 JL6711			
数量 (KG)	7021	7876				
规格大小	<input checked="" type="checkbox"/> 500 克以上 <input type="checkbox"/>	<input checked="" type="checkbox"/> 500 克以上 <input type="checkbox"/>	<input type="checkbox"/> 500 克以上 <input type="checkbox"/>			
物种验证：是否是斑点叉尾鲴	<input checked="" type="checkbox"/> 是 <input type="checkbox"/> 否	<input checked="" type="checkbox"/> 是 <input type="checkbox"/> 否	<input type="checkbox"/> 是 <input type="checkbox"/> 否			
感官	病变	无	无			
	寄生虫	无	无			
	污染	无	无			
	活力	正常	正常			
	外来杂质	无	无			
	其它缺陷	无	无			
评定意见	合格	合格				
验收人/时间	陈同峰 09:48	陈同峰 12:40				
监督检查结果	合格	合格				
监督检查人/时间	苏林华 14:20	苏林华 17:30				

审核人 (Checker):

陈同峰

日期 (Date): 2018.10.13

8:52

三、湖北省潜江市华山水产食品有限公司，备案号：

4200/02026 (3. Hubei Qianjiang Huashan Aquatic Food and Product Co., Ltd., Establishment No.: 4200/02026)

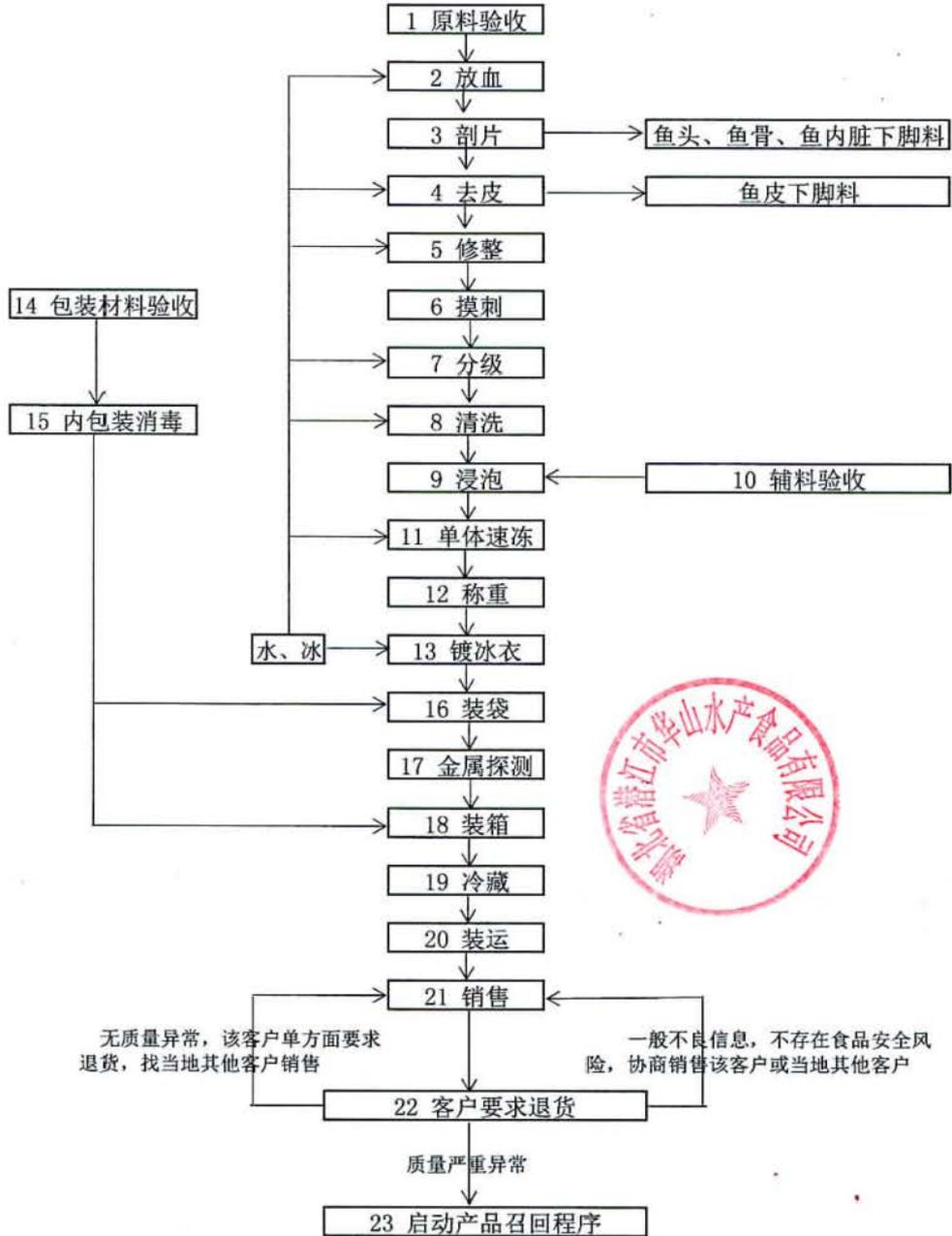
(四) 企业 HACCP 计划的工艺流程图或危害分析中未涉及退回产品。(4. The establishment's HACCP plan did not include returned product in the flow chart or hazard analysis.)

整改措施：该企业已在 HACCP 计划工艺流程图和危害分析表中增加了对退回产品的处置。

修改后的工艺流程图和危害分析表如下：

附件1:

华山公司输美鮰鱼制作工艺流程图



危害分析工作单

危害分析工作单					
公司名称：华山水产食品有限公司			产品描述：去头、去内脏、去皮、去刺单冻鲟鱼片		
公司地址：湖北省潜江市熊口镇潜熊路 23 号			储存和销售方式：冷冻（-18℃以下）、分发、出售		
			预期用途和消费者：烹饪、烧烤、煎炸后食用。一般公众（对鲟鱼过敏者禁食）		
(1) 加工步骤	(2) 食品安全危害	(3) 可能合理发生？	(4) 理由	(5) 如第 3 列为是，可采取哪些措施预防、消除或将危害降至可接受水平？	(6) 关键控制点
冷藏	生物方面——微生物生长	否	冷藏温度保持在-18 度以下。		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
装运	生物方面——致病菌生长，毒素形成	否	监控冷藏集装箱温度		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
销售	生物方面——致病菌生长，毒素形成	否	监控冷藏集装箱温度		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
客户要求退货	生物方面——致病菌生长，毒素形成	否	客户要求-18 度以下保存		
	化学方面	否	客户通知发现危害	对结果进行第三方实验室验证确认	
	物理方面	否	客户通知发现危害	对结果进行第三方实验室验证确认	
无质量异常或一般不良信息销售给其他客户	生物方面——致病菌生长，毒素形成	否	按照要求-18 度以下保存		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
质量严重异常	生物方面——致病菌生长，毒素形成	否	按照要求-18 度以下保存		
	化学方面	否	客户通知发现危害	对结果进行第三方实验室验证确认质量异常	
	物理方面	否	客户通知发现危害	对结果进行第三方实验室验证确认质量异常	
启动产品召回程序	生物方面——致病菌生长，毒素形成	否	监控冷藏集装箱温度		
	化学方面	否	确认质量异常	做不合格品处理	
	物理方面	否	确认质量异常	做不合格品处理	

四、广西金海盈食品有限公司，备案号：4500/02050

(Gain Ocean Food Co., Ltd., Establishment No.: 4500/02050)

(五) 企业的 HACCP 监控记录未记录每次监控活动的时间。(The establishment's HACCP monitoring records did not document the time of monitoring activity for

each entry)

整改措施：该企业已修改 HACCP 监控记录格式，以记录每次监控活动的时间。

修改后的 HACCP 监控记录如下：

广西金海盈食品有限公司 GAIN OCEAN FOOD CO., LTD.						表号: GO-RE-C-F24 NO.: GO-RE-C-F24			
输美鲶鱼类原料验收记录(CCP 点) Raw Fish Receiving Record of Siluriformes Fish Products Exporting to the US						版本/修订: 1/0 Version/revision:1/0			
关键 限值 Critical limit	1. 养殖药物残留符合要求 1. Drug residue meet the requirement. 2. 提供合格的养殖场供货证明 2. Provide the qualified supply proof.			监控内容 Monitoring contents	1. 合格原料检验报告单 qualified test report Y <input type="checkbox"/> N <input type="checkbox"/> 2. 合格供货证明 Qualified supply proof Y <input type="checkbox"/> N <input type="checkbox"/>				
纠偏措施: 拒收无供货证明或供货证明不符合要求的原料 Corrective action: reject the raw material without supply proof or that do not meet the requirement.				监控频率: 每批原料 Monitoring frequency: each lot of raw material		监控人: 原料验收 QC Monitor people: QC of raw material receiving			
原料名称: Name of fish:		原料来源地: Source:			运输方式: Type of transportation:				
日期: Date:		原料批次: The raw material lot:			供货证明号: NO. of supply proof:				
每车原料质量抽查情况 Spot check of each truck of raw material									
车次 Truck NO.		1	2	3	4	5	6	7	8
项目 Item									
运输车牌号 Plate number									
原料到厂时间 Arriving time									
运输车和水箱卫生清洁检查 Sanitation of truck and water tank									
运输车温度监控检查和水温测试 Check of temperature monitoring of transport vehicle and temperature check									
原料物种鉴定 (是打√, 不是打×) Species verification of raw material(yes tick √, no tick ×)									
煮后口感和感官判定 taste after cooked and Sensory judgment									
阳台质检 规格抽查 Spot check of size	总重 (斤) Total weight(1/2 kilogram)								
	300g-500g								
	500g-800g								
	800g-1250g								
	其他 others								
平均 (斤) Average(1/2 kilogram)									
原料鱼总重 (斤) Total weight of available fish(1/2 kilogram)									
死鱼/畸形鱼重量 (斤) Weigh of dead/deformed fish(1/2 kilogram)									
纠正措施 Corrective actions									
评定结果 Evaluation results									
验收人/时间 Acceptance person/time									
监督检查结果 Supervision and inspection results									
监督检查人/时间 Supervisor/time									
1、物种判定依据: 见各物种的标准图片; Basis for species determination: see the standard pictures of each species. 2、死鱼/畸形鱼/濒临死亡的鱼/污染的鱼的处理办法是退回客户或者做下脚料处理; Dead/deformed/dying/contaminated fish are to be returned to the customer or treated with offal; 3、鲶鱼运输水温要求控制在 20 摄氏度以下; 装鱼量要求适中, 减少原料鱼运输过程死鱼的产生; Temperature of Catfish transportation water should be controlled less than 20 degrees Celsius. Moderate loading quantity is required to reduce the production of dead fish during the transportation of raw fish									
复核人 Reviewers::					日期 Date::				

(六) 出货月台卷闸门封条老化, 门无法紧闭密封 (可能导致虫害进入)。 (6. Deteriorated seal around a shipping door did not provide a tight seal when door was closed (potential vermin entrance).

整改措施: 该企业已在出货月台的卷闸门底部增加1.2cm 厚的软胶, 确保密封。

整改前后对比的照片如下:

整改前:



整改后:



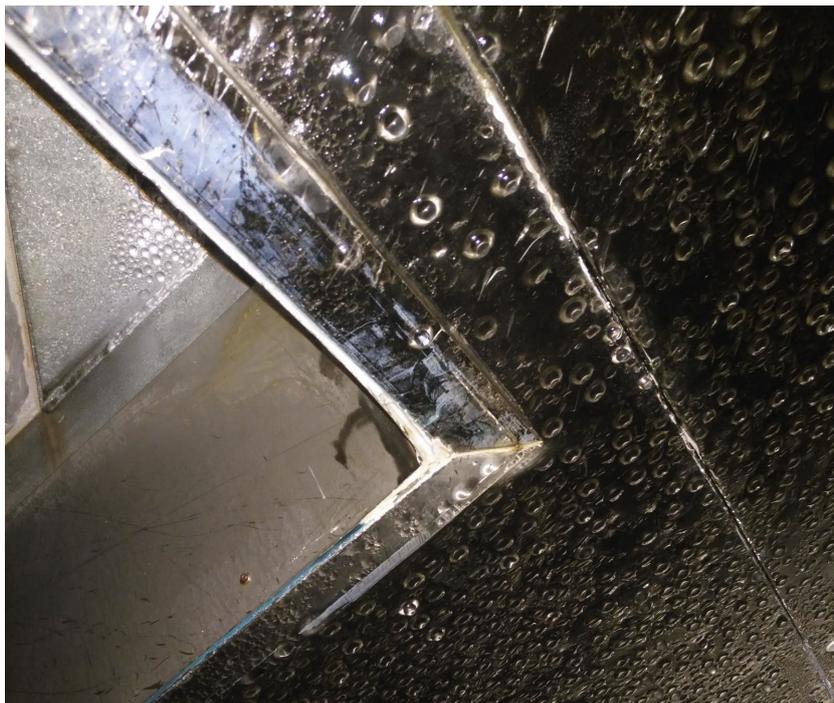
(七) 企业使用硅胶材料修补制冰机内表面缝隙。(7.

The establishment used silicone type material to fill a gap in the internal surfaces of the ice making machine.).

整改措施: 该企业已将制冰机内部的硅胶去除干净。

整改前后对比的照片如下:

整改前:



整改后:



(八) 运鱼水箱顶盖内表面未按照企业的卫生要求充分清洗。(8. The interior surfaces of the lids of fish transport water tank were not cleaned adequately in accordance with the establishment's sanitary requirement.)

整改措施: 该企业采取了以下整改措施: 一是清洗运鱼水箱顶盖内表面; 二是与原料运输车签订了运输协议, 要求运输车鱼箱在装车前要彻底清洗干净, 不能有青苔等污渍; 三是对原料验收和监管人员培训关于运输车辆的卫生要求

和监控要求。

运鱼水箱顶盖内表面清洗前后对比的照片如下：

整改前：



整改后：



与原料运输车签订的运输协议如下：

鲶鱼运输协议

Siluriformes Fish transport agreement

甲方 Party A: 广西金海盈食品有限公司 Gain Ocean Food Co., Ltd.

乙方 Party B: 陈尚富

经甲乙双方友好协商, 就甲方委托乙方运输车装运原料达成以下协议:

After friendly negotiation, party A and party B have reached the following agreement on party A's entrusting party B's transport vehicle to ship the raw materials

一、 鲶鱼原料运输车为打氧鲜活运输车, 运输用水必须为洁净的井水或者淡水, 其水质符合《国家渔业水质标准》(GB 11607-89)的规定, 运输过程必须定期监控水温, 温度控制在 20 度以下(水温根据运输距离适当调整控制), 运输用冰必须来自符合出口食品生产卫生要求的制冰企业;

1. Siluriformes Fish raw material transporter is an oxygen fresh transporter. The water used for transportation must be clean well water or fresh water. Its water quality meets the requirements of National Fishery Water Quality Standard (GB 11607-89). During transportation, water temperature must be monitored regularly and controlled below 20 degrees (water temperature should be adjusted and controlled properly according to transportation distance). Ice for transport must come from ice-making enterprises that meet the hygienic requirements of food production for export.

1. The vehicle transporting the siluriformes fish must be fresh oxygen vehicle, transport water must be clean well water or fresh water, the water quality conforms to the national fishery water quality standard "(GB 11607-89). During transportation, water temperature must be monitored regularly and controlled below 20 degrees (water temperature should be adjusted and controlled properly according to transportation distance). Ice for transport must come from ice-making enterprises that meet the hygienic requirements of food production for export.

二、 运输车装载容器采用常用的塑料箱, 重复使用的装载容器要能方便清洗以及具备装好良好的进排水装置;

2. The containers used in the transport vehicles are usually plastic boxes. The reusable containers should be easy to clean and equipped with good inlet and drainage device.

三、运输车及装运工具要保持清洁、无污染、无异味, 密封且备有防雨、防尘、防虫害设施;

卫生要求如下: 装载原料鱼用的塑料箱, 每次使用前(装鱼前)都要清洗干净, 包括清洗干净鱼箱内部的污垢, 鱼箱外部的卫生, 及鱼箱盖子上的污垢和青苔。每次卸鱼后, 也要清洗干净鱼箱的卫生, 清洗干净鱼残留的污垢, 以便下次使用时便于清洗。

3. The transport vehicle and the means of transport shall be kept clean, pollution-free and odor-free, sealed and equipped with rain-proof, dust-proof and pest-proof facilities;

The sanitation requirements are as follows: the plastic containers should be cleaned before loading the fish every time, including sanitation inside the fish box, the sanitation outside the fish box, and the dirt and moss on the lid of the fish box. After unloading of fish, clean the container as well, so that the next time the use is easy to clean.

四、运输车装运鲢鱼原料时，根据鲢鱼的生活习性，控制装运密度，正常情况下，一个水箱体积为1m³，装运鱼量不超过2500斤；

4. When transporting Siluriformes Fish, the transporting density should be controlled according to the living habits of catfish. Normally, the volume of a water tank is 1 m³, and the quantity of transported fish should not exceed 1250kgs.

五、本运输车为专用水产品鲜活运输车，不得使用任何违禁药品来控制鱼的死亡率；

5. This transport vehicle is a special aquatic product fresh and fresh transport vehicle, and shall not use any illegal drugs to control the death rate of fish.

六、运输人员应加强对鲢鱼的防护，确保不被污染和掺杂；

6. Transportation personnel should strengthen the protection of catfish, to ensure that is not contaminated and adulterated

七、装运前检查装运容器无破损并清洁干净，并进行消毒；

7. Check the containers before loading to ensure without breakage and clean, and sterilize it.

八、甲方会委派人员跟车监督，会进行装车前的车辆卫生检查以及运输过程的监督，一旦发现运输车辆和鱼箱不干净的会立即要求司机进行清洗，直到清洗干净才可装车。

8. Party A will appoint personnel to supervise with the vehicle, carry out vehicle sanitation inspection before loading and the supervision of transportation process. Once the vehicle and fish containers are found to be not clean, the driver will be asked to clean them immediately, and the vehicle can not be loaded until they are cleaned.

九、合同日期从2018年12月7日到2019年12月7日止。

9. Duration of agreement: from 2018.12.7 to 2019.12.7

甲方 PartyA: 广东海益食品有限公司 乙方 PartyB: 陈岗富

代表人 Representatives: 李中胜 代表人 Representatives: 陈岗富

日期 date: 2018.12.7 日期 date: 2018.12.7

对原料验收和监管人员的培训记录如下：

培训记录

Record of training

GO/RE-C-F32

培训起止时间 Training time	2018.12.7		培训地点 Training place	三楼会议室		
培训对象 Training object	原料验收、监管人员、冷库工、车间卫生管理人员(食堂)		培训人数 Personnel be trained	26	缺勤人数 Personnel absent	0人
授课人 Teaches	尤子奇		单位 Department	品质、仓储、生产		
培训内容 Training content	1. 原料验收和监管人员对原料运输车辆卫生要求和监管要求 2. CCP1点的监管要求和记录填写要求 4. <<SSOP>>卫生标准操作程序-饮用水、用水 3. 冷库及食堂卫生要求 卫生要求(与水和的清洗消毒卫生要求)					
培训目的 Objective for training	让相关人员熟悉原料运输车辆卫生要求, 监管要求在保证运输车辆卫生要求, 让CCP1点的操作人员及监管人员了解和填写新的原料验收记录填写要求和监管要求 让冷库工了解冷库卫生要求, 填写冷库工卫生要求 让食堂和卫生管理人员了解冷库卫生要求, 填写冷库工卫生要求, 填写冷库工的卫生要求					
Sign in List						
葛远山	黄小波					
黄非豪	何国朋					
周月艳	梁四华					
李水林	周新					
何梅强	梁敏					
陈志子	高永平					
陈子引	梁金					
山文	黄斌					
梁作	谭德文					
刘重安	陈其志					
梁	孙轻武					
葛远山	梁敏					
梁峰	秦培彩					
评价方法	考试 <input type="checkbox"/> 提问 <input checked="" type="checkbox"/> 操作 <input type="checkbox"/>					
评价结果	合格					
备注 Remarks	验证由所在部门负责人: 梁峰 负责对其所从事岗位是否胜任的考核。 Workshop director responsible for the verification and text the required qualification of the employee 考核时间 Examination time: 2018.12.8					

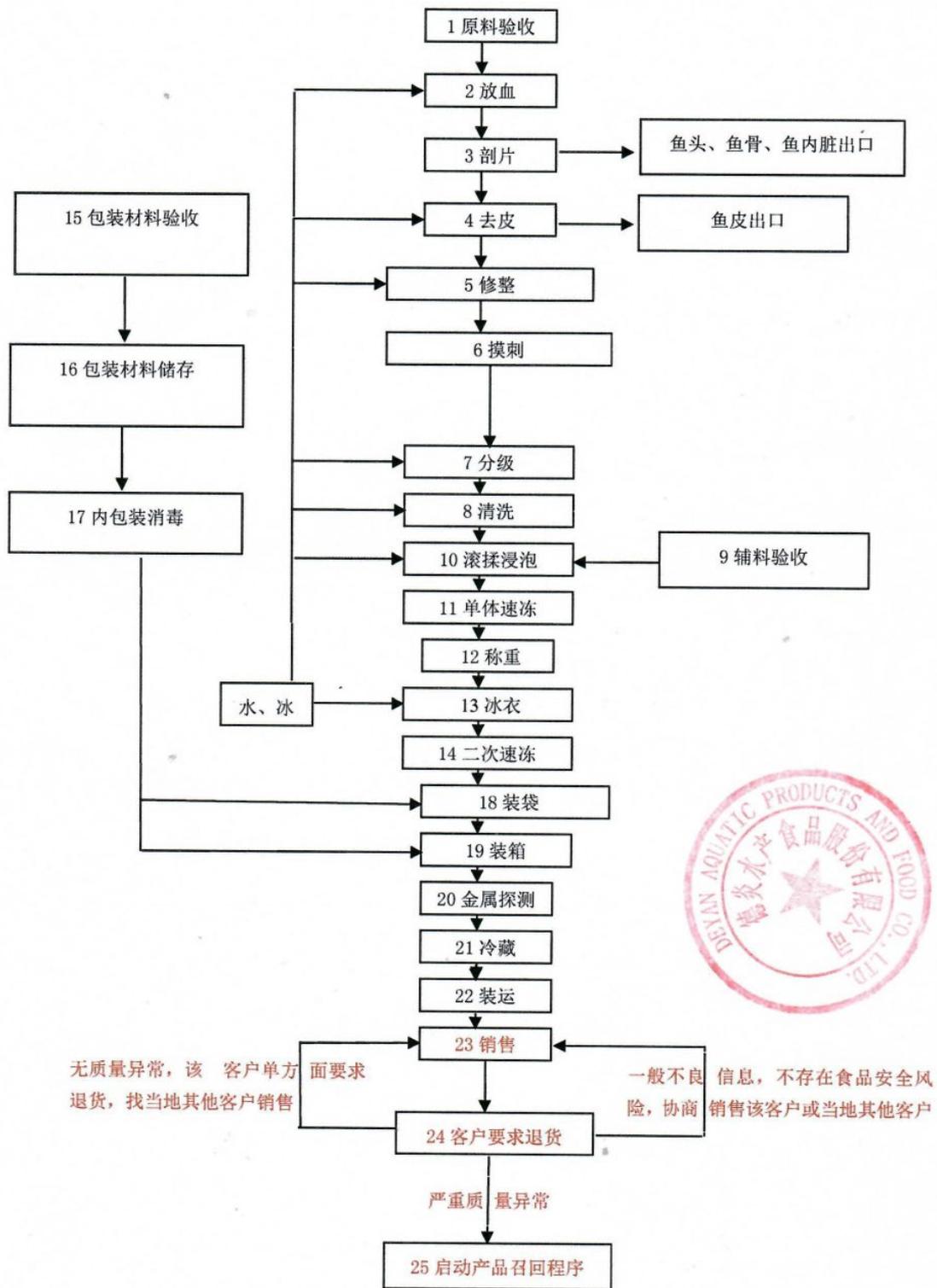
复核/日期: 2018.12.8

五、德炎水产食品股份有限公司, 备案号: 4200/02020
(5. Deyan Aquatic Products and Food Co., Ltd.,
Establishment No.: 4200/02020)
(九) 企业 HACCP 计划的工艺流程图或危害分析中未

涉及退回产品。(9. The establishment's HACCP plan did not include returned product in the flow chart or hazard analysis.)

整改措施：该企业已在 HACCP 计划工艺流程图和危害分析表中增加了对退回产品的处置。

修改后的工艺流程图和危害分析表如下：



危害分析工作单

危害分析工作单					
公司名称: 德炎水产食品股份有限公司			产品描述: 去头、去内脏、去皮、去刺单冻叉尾鲷鱼片		
公司地址: 湖北省洪湖市新堤大道1号			储存和销售方式: 冷冻(-18℃以下)、分发、出售		
			预期用途和消费者: 烹饪、烧烤、煎炸后食用。一般公众(对鲷鱼过敏者禁食)		
(1) 加工步骤	(2) 食品安全危害	(3) 可能合理发生?	(4) 理由	(5) 如第3列为是,可采取哪些措施预防、消除或将危害降至可接受水平?	(6) 关键控制点
18 内包装消毒	生物方面—微生物污染	否	紫外线消毒1小时以上		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
19 装袋	生物方面—微生物污染	否	SSOP实施到位,内包材使用前消毒处理。		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
20 装箱	生物方面—微生物污染	是	鲷鱼是一种已知的食品过敏原	对鲷鱼进行准确的标签说明	1B
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
21 金属探测	生物方面	否	未发现危害		
	化学方面	否	未发现危害		
	物理方面—物理污染	是	产品可能与设备或传送带的金属碎片一起包装起来	包装好的产品通过运行中的金属探测仪,探测金属碎片	1P
22 冷藏	生物方面—微生物生长	否	冷藏温度保持在-18度以下		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
23 装运	生物方面—致病菌生长,毒素形成	否	监控冷藏集装箱温度		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
24 销售	生物方面—致病菌生长,毒素形成	否	温度保持在-18度以下		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
25 客户要求退货	生物方面—致病菌生长,毒素形成	否	温度保持在-18度以下		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		
26 启动产品召回程序	生物方面—致病菌生长,毒素形成	否	温度保持在-18度以下		
	化学方面	否	未发现危害		
	物理方面	否	未发现危害		



(十) 车间内产品暴露位置上方天花板、墙壁有小洞,有隔热材料暴露,天花板与水管接口之间有缝隙。(10. Small holes in the ceiling and walls, exposed insulation, and open gaps between ceiling and pipes protruding from

overhead structures over exposed products in the production areas.)

整改措施： 已对车间进行了升级改造，封闭天花板和墙上的小洞、暴露的隔热材料和天花板与水管之间的接口。

改造后的天花板和墙壁照片如下：





(十一) 制冰机内表面有锈迹。(11. Rusted areas in

the interior surfaces of the ice making machine.)

整改措施： 已对制冰机进行了除锈处理。

处理后的制冰机内部照片如下：



(十二) 开工前卫生验证时，在车间多个切鱼板的食物接触面发现粘有先前加工时产生的残渣。(12. During the pre-operational sanitation inspection verification, residue buildups from the previous days' operation were observed on the food contact surfaces of several cutting boards in the production area.)

整改措施： 已清洗切鱼板，清除残留物。对员工开展关

于食品接触面卫生操作的培训。

清洗后的切鱼板照片如下：



对员工的培训记录如下：

Name of Co.: DeYAN Aquatic Products & Food Co., Ltd
Address of Co.: No.1 Xindi Avenue, Honghu City, Hubei Province, P. R. China

员工培训记录

培训对象	鱼苗车间管理人员、车间卫生清洁人员																																													
培训时间	2018.12.10	培训地点	公司二楼会议室																																											
培训目的	让员工熟悉掌握车间设备设施的清洁消毒操作要求及日常卫生检查要点																																													
培训性质	内部培训																																													
培训内容	科目名称	内容简述	授课时数	培训讲师																																										
	公司文件《SSOP》	食品接触面的清洁与消毒	2 hrs	柯建东																																										
培训方式																																														
人员签到:	<table border="0"> <tr> <td>万桃喜</td> <td>胡娥新</td> <td>胡华英</td> <td>王中平</td> <td>柯建东</td> <td>王志明</td> </tr> <tr> <td>朱思园</td> <td>胡享林</td> <td>蒋山珍</td> <td>胡春华</td> <td>曹万国</td> <td>冯金兰</td> </tr> <tr> <td>叶四翠</td> <td>彭定忠</td> <td>宋敬雷</td> <td>刘三管</td> <td>张运东</td> <td>董书亮</td> </tr> <tr> <td>余本玉</td> <td>钟克</td> <td>吴凤城</td> <td>范思红</td> <td>张发久</td> <td>蔡历志</td> </tr> <tr> <td>刘美娟</td> <td>刘长兴</td> <td>范思红</td> <td>朱敬香</td> <td>刘元红</td> <td>胡砚平</td> </tr> <tr> <td>朱应姣</td> <td>熊晓</td> <td>曹通方</td> <td>张永军</td> <td>张平刚</td> <td></td> </tr> <tr> <td>王明德</td> <td>阎德凤</td> <td>张保凤</td> <td></td> <td></td> <td></td> </tr> </table>				万桃喜	胡娥新	胡华英	王中平	柯建东	王志明	朱思园	胡享林	蒋山珍	胡春华	曹万国	冯金兰	叶四翠	彭定忠	宋敬雷	刘三管	张运东	董书亮	余本玉	钟克	吴凤城	范思红	张发久	蔡历志	刘美娟	刘长兴	范思红	朱敬香	刘元红	胡砚平	朱应姣	熊晓	曹通方	张永军	张平刚		王明德	阎德凤	张保凤			
万桃喜	胡娥新	胡华英	王中平	柯建东	王志明																																									
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余本玉	钟克	吴凤城	范思红	张发久	蔡历志																																									
刘美娟	刘长兴	范思红	朱敬香	刘元红	胡砚平																																									
朱应姣	熊晓	曹通方	张永军	张平刚																																										
王明德	阎德凤	张保凤																																												
考核评价方式:	<input type="checkbox"/> 书面测试 <input checked="" type="checkbox"/> 问答测验 <input type="checkbox"/> 技能评定 <input type="checkbox"/> 其它																																													
培训结果:	大家基本掌握食品接触面、设备设施的清洁消毒操作标准。 考核人: 柯建东																																													

六、长阳清江鹏搏开发有限公司, 备案号: 4200/02041

(6. Changyang Qingjiang Pengbo Development Co., Ltd., Establishment No.: 4200/02041)

(十三) 企业 HACCP 计划中未写明直接观察验证程序的频率。(13.The establishment's HACCP plan did not include the frequency of direct observation of verification procedures.)

整改措施: 该企业已修订 HACCP 计划, 增加了直接观察验证程序的频率。

修改后的 HACCP 计划如下:

刘美 曾政后

长阳清江鹏搏开发有限公司

单冻叉尾鲌鱼片 HACCP 计划书

HACCP-12-2017 B/0 版

HACCP 计划表

工厂名称：长阳清江鹏搏开发有限公司

工厂地址：湖北省宜昌市长阳经济开发区长阳大道 168 号

品名：单冻叉尾鲌鱼片

销售与贮藏方法：冷冻-18℃以下、分发、出售

预期用途和消费者：烹饪、烧烤、煎炸后食用。一般大众（对鲌鱼过敏者禁食）

日期：

签名：

关键控制点编号和位置	关键限值	监控程序和频率	HACCP 记录	验证程序和频率	纠偏措施
1C 原料验收	官方备案养殖场的供货证明	品控员每车验收供货证明	原料验收记录， 供货证明 纠偏记录	每年对养殖用水的环境化学污染物、氯霉素和杀虫剂进行检测；在原料捕捞前 1-2 周抽样检测药物残留；对每天进厂的鲌鱼原料按池塘号进行抽样检测药物残留；对每批次成品抽样检测药物残留；每周一次审核监测、纠偏和验证记录。监督员每班 2 次验证检查。验证检查内容：1、原料验收人员是否按文件要求的重新进行验收操作；2、是否按文件如实按时规范填写验收记录	拒收非官方备案养殖场的原料
1P 金属探测	所有产品均应通过运行中的金属探测器；通过金属探测器的产品未发现可探测的金属杂质（注：铜Φ1.5mm，铁Φ2.0mm，不锈钢Φ1.5mm，每 1 小时校准一次）	经培训的操作员在开始作业前、生产过程中每半小时和生产结束时对金属探测器进行目视检查根据灵敏度标准进行测试，所有产品应通过持续工作的金属探测器，以确认产品中是否存在金属杂质。	金属探测记录 纠偏记录	每班开始时、生产结束时和生产过程每 1 小时用标准检测板通过金属探测器，以评估其灵敏度；在需要时重新校验；每周审核监控、纠偏和验证记录一次。监督员每班 2 次验证检查，检查内容：1、金探操作员是否按文件规定对每件产品进行金探操作并按文件规定的频率进行灵敏度检测；2、；是否按文件规定如实按时规范填写金属探测记录。	1. 如果产品没有经过金属探测，封存后进行金属探测； 2. 校正操作程序以确保产品未经金属探测之前不会被处理；如果金属探测器调节失灵，应搁置产品，直至金属探测器正常工作，再使产品通过金属探测器； 3. 对产品进行返工，以去除被金属探测器驳回的任何产品所含金属碎片； 4. 查证在产品中发现金属的来源和修理损坏的或受影响的设备。
1B 装箱	所有成品包装标签中有鲌鱼的声明	品控员在每一批次开始生产时抽一个成品包装，之后每小时抽查一个目测纸箱标签，确认是否有鲌鱼声明	成品纸箱标签关键控制点监控记录 纠偏记录	品控员核对纸箱标签检查记录，审核监控、纠偏和验证记录，每周一次。监督员每班 2 次验证检查，检查内容：1、装箱操作人员是否逐箱在规定的位置张贴过敏源申明的变迁；2、是否按文件如实填写变迁记录	1. 隔离并搁置任何不含过敏源（鲌鱼）标签的产品，使用纠正的标签对产品进行重新贴标或者重新制作纠正后的包装； 2. 品控员应确定出现偏差的原因并防止改情况重演。

(十四) 企业的 HACCP 验证记录中未记录验证活动的类型 (审核记录或直接观察)。(14.The establishment's HACCP verification records did not document the type of verification (record review or direct observation) activities.)

整改措施: 该企业已修订 HACCP 验证记录格式, 以记录验证活动的类型。

修订后的 HACCP 验证记录格式如下:

七、安徽富煌三珍食品集团, 备案号: 3400/02027 (7. Anhui Fuhuang Sungem Foodstuff Group Co., Ltd, Establishment No.: 3400/02027)

(十五) 企业的 HACCP 验证记录缺少验证活动的时间或结果。(15. The establishment's HACCP verification records did not document the time or the result of verification activities.)

整改措施: 该企业已修改 HACCP 验证记录的格式, 并在记录中填写验证活动的时间和结果。

修改后的 HACCP 验证记录如下:

公司名称: 安徽富煌三珍食品集团有限公司 Firm Name: Anhui Fuhuang Sun gem Foodstuff Group CO., Ltd
 包装标签检查监控记录 (CCP3)

Packaging label inspection monitoring record

产品名称 Product Name 玫瑰叉尾鱼翅包 监控频率 Monitoring Frequency: 每批 记录编号 NO: SZ/D62-13

验收日期	2018.12.11		
生产批次	20181211		
追溯代码	20181211102Y		
包材名称	0.69 包装纸膜		
包材批次	20181211-1		
标注清晰	合格		
运输工具清洁	合格		
无破损、无异味	合格		
过敏原标识	合格		
冷冻标识	合格		
验收人/时间	周子杰 9:05 分	验收结果评定	合格
监督检查人/时间	张秋菊 11:20 分	监督检查结果	合格
纠偏	无		

审核人: 

日期: 2018.12.12. 10:30 分

(十六) 车间内产品暴露位置上方天花板有小洞，天花板上加挂的制冷机周边有暴露的隔热材料。(16. Small holes in the ceiling and exposed insulation around cooling units attached to the ceiling over exposed products in the production area.)

整改措施：已封闭天花板上的小洞，清除制冷机周围暴露的隔热材料。

改造前后的天花板和制冷机照片如下：

整改前：



整改后：

