



United States Department of Agriculture

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Food Safety and  
Inspection Service

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

Dear Dr. Bi,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote verification audit of the PRC's Siluriformes fish and fish products and poultry products inspection system from July 26 to September 7, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of the PRC are included as an attachment to the report

Sincerely,

A handwritten signature in black ink, appearing to read "Michelle Catlin".

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF  
THE PEOPLE'S REPUBLIC OF CHINA  
JULY 26–SEPTEMBER 7, 2021

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

February 17, 2022

Food Safety and Inspection Service  
United States Department of Agriculture

## **Executive Summary**

This report describes the outcome of a routine ongoing equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from July 26 to September 7, 2021. Due to the global COVID-19 pandemic, the audit was conducted remotely using videoconferences and records review. The purpose of the audit was to determine whether the People's Republic of China (PRC) food safety inspection system governing Siluriformes fish and fish products and poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The PRC currently exports raw intact Siluriformes fish products and ready-to-eat fully cooked chicken to the United States.

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

The remote audit demonstrated that the PRC's food safety inspection system for Siluriformes fish and fish products and poultry products is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Central Competent Authority (CCA) has required that establishments certified as eligible to export products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their exported products. In addition, the CCA has implemented microbiological and chemical residue testing programs to verify its food safety inspection system. An analysis of each component did not identify any findings that represented an immediate threat to public health.

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of the People’s Republic of China (PRC) food safety system from July 26 to September 7, 2021. The audit began with an entrance meeting via videoconference on July 26, 2021, with representatives from the Central Competent Authority (CCA)–the General Administration of Customs of the People’s Republic of China (GACC). Representatives from GACC participated throughout the audit.

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

<b>Process Category</b>	<b>Product Category</b>	<b>Eligible Products<sup>1</sup></b>
Raw – Non-Intact	Raw Ground Comminuted or Otherwise Non-Intact Siluriformes	Siluriformes - All Products Eligible
Raw – Intact	Raw Intact Meat - Other	Siluriformes - All Products Eligible
Fully Cooked - Not Shelf Stable	Ready-to-Eat (RTE) Fully cooked Poultry	Chicken and Duck - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Poultry Fully cooked Without Subsequent Exposure to the Environment	Chicken and Duck - All Products Eligible

The USDA’s Animal Plant Health Inspection Service (APHIS) determined that the PRC is affected with highly pathogenic avian influenza and Newcastle disease. Consequently, the PRC is eligible to export only processed poultry products that meet the requirements described in Title 9 of the Code of Federal Regulations (9 CFR) 94.6(b)(4).

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed the PRC’s Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether the PRC’s food safety inspection system governing Siluriformes fish and poultry products is being implemented as documented in the country’s SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government

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<sup>1</sup> All source Siluriformes fish and poultry used to produce products must originate from eligible countries and establishments certified to export to the United States.

offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from GACC through the SRT.

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed records related to administrative functions at GACC headquarters and three local customs offices, in addition to government verification records from four local inspection offices. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to two meetings each week over an eight-week period. Through record reviews, the FSIS auditors evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditors selected a sample of four establishments from a total of 15 establishments, certified as either eligible to export processed poultry or raw Siluriformes fish products directly to the United States, or to provide raw poultry as source material for further processing. This included one poultry (chicken) slaughter establishment; one poultry processing establishment, producing RTE fully cooked chicken; and two Siluriformes fish slaughter and raw processing establishments.

The remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. The FSIS auditors assessed GACC’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 381.196 and 557.2.

The FSIS auditors also remotely audited two government laboratories to verify their ability to provide adequate technical support to the food safety inspection system. One laboratory was conducting both microbiological and chemical residue testing and the other laboratory was conducting solely microbiological testing.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>General Administration of China Customs (GACC) Headquarters, Beijing</li> </ul>
	Customs Offices	3	<ul style="list-style-type: none"> <li>Hebi Customs Office of Zhengzhou Custom District, Hebi</li> <li>Luzhou Customs Office of Hefei Custom District, Luzhou</li> </ul>

			<ul style="list-style-type: none"> <li>• Zhaoqing Customs Office of Guangzhou Custom District, Zhaoqing</li> </ul>
Government Laboratories		2	<ul style="list-style-type: none"> <li>• Zhaoqing Customs Comprehensive Technology Center (microbiological and chemical testing)</li> <li>• Hefei Customs Technology Center Food Microbiological Laboratory (microbiological testing)</li> </ul>
Poultry Slaughter Establishment		1	<ul style="list-style-type: none"> <li>• Establishment No. 3400/03042, Cargill Animal Protein Co. Ltd., Chuzhou</li> </ul>
Poultry Processing Establishment		1	<ul style="list-style-type: none"> <li>• Establishment No. 4100/03078, Hebi Yongda Meiyuan Food Co. Ltd., Hebi</li> </ul>
Siluriformes Fish Slaughter and Raw Processing Establishments		2	<ul style="list-style-type: none"> <li>• Establishment No. 3400/02027, Anhui Fuhuag Sungem Foodstuff Group Co., Ltd., Chaohu City</li> <li>• Establishment No. 4400/02223, Zhenye Aquatic (Huilong) Co., Ltd., Zhaoqing</li> </ul>

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

- Federal Meat Inspection Act (21 United States Code [U.S.C.] Section 601 et seq.);
- 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;
- Poultry Products Inspection Act (21 U.S.C. Section 451 et seq.); and
- poultry products inspection regulations (9 CFR 381).

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

**III. BACKGROUND**

From July 1, 2018 to June 30, 2021, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 40,912,139 pounds of meat and 96,090 pounds of poultry exported by the PRC to the United States. This included 37,983,168 pounds of raw intact Siluriformes - Ictaluridae (catfish); 2,928,971 pounds of raw intact Siluriformes (other than catfish); 47,818 pounds of RTE fully cooked chicken without subsequent exposure to the environment; and 48,272 pounds of RTE fully cooked chicken. Of these amounts, additional types of inspection were performed on 6,991,767 pounds of Siluriformes and 96,030 pounds of poultry (6,553,700 pounds of raw intact Siluriformes - Ictaluridae (catfish); 438,067 pounds of raw intact Siluriformes (other than catfish); 47,818 pounds of RTE fully cooked chicken without subsequent exposure to the environment; and 48,212 pounds of RTE fully cooked chicken). These additional types of inspection included physical examination, chemical residue analysis,

and testing for microbiological pathogens (*Listeria monocytogenes* [Lm] and *Salmonella* in RTE chicken). As a result of this additional testing, 285,750 pounds of Siluriformes fish product were rejected for the presence of chemical residues in analyzed samples. This included the presence of atrazine (an herbicide) and semicarbazide (a potential metabolite of the antibiotic nitrofurazone). In accordance with FSIS procedures for evaluating and verifying implementation of corrective actions in response to rejected product, FSIS conducted a review of GACC’s written responses to these violations, including the results of on-farm investigations, and determined these responses acceptable. In addition, as part of FSIS risk-based audit methodology, the FSIS auditors selected two of these implicated establishments (i.e., both of the selected Siluriformes establishments) in this remote audit, for which no further concerns were identified.

The previous FSIS onsite audit conducted in December of 2018 identified the following systemic findings related to the poultry inspection system (with only isolated findings identified for Siluriformes fish):

<b>Summary of Systemic Findings (Poultry) from the Prior FSIS Audit of the PRC</b>
<b>Component 1: Government Oversight (e.g., Organization and Administration)</b>
<ul style="list-style-type: none"> <li>At the streamlined inspection system (SIS) establishment, government inspectors were not manually reflecting the flap (pulling the cut skin and muscle back) from the opening cut and observing the inner surfaces of the carcass as would be required in a SIS poultry slaughter establishment because the establishment was considering transitioning to the new poultry inspection system (NPIS).</li> </ul>
<b>Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System</b>
<ul style="list-style-type: none"> <li>At the NPIS establishment, not all the records documenting 100% carcass monitoring of the critical control point (zero tolerance for visible feces, septicemia, and toxemia) included the time that each deviation from the critical limit occurred. Furthermore, while adequate corrective actions were taken, corrective action records did not include specific measures to prevent recurrence of the deviation and did not identify the cause of the deviation.</li> </ul>
<b>Component 6: Government Microbiological Testing Programs</b>
<ul style="list-style-type: none"> <li>At the NPIS establishment, the pre-chill microbiological testing program for poultry carcasses did not include clearly defined process control criteria because the sampling data being collected was to establish the process control criteria.</li> </ul>

In this current audit, the FSIS auditors verified through review of records that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The most recent FSIS final audit reports for the PRC’s food safety inspection system are available on the FSIS website at: [www.fsis.usda.gov/inspection/import-export/international-reports/foreign-audit-reports](http://www.fsis.usda.gov/inspection/import-export/international-reports/foreign-audit-reports).



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

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

The FSIS auditors verified that there have been no major changes in GACC's organizational structure governing both Siluriformes fish and fish products and poultry products since the previous FSIS equivalence verification audit conducted in 2018. GACC continues to oversee 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.

Within GACC, the Bureau of Import and Export Food Safety is the primary department responsible for ensuring the safety of Siluriformes fish and fish products and poultry products exported to the United States. The Bureau's functions include developing the safety, inspection and quarantine systems, undertaking record filing and registration, supervision and administration of imported food and cosmetics; and risk analysis. The Bureau operates in a three-tier vertical fashion, originating from GACC headquarters in Beijing, through provincial and local customs offices situated throughout the country.

The FSIS auditors verified through interviews and record reviews that all inspection personnel are permanent government employees who are hired and paid by the national government. The FSIS auditors also confirmed direct payment of GACC inspection personnel by reviewing Administrative Personnel Salary Spreadsheets presented by the local GACC offices.

Inspection personnel in Siluriformes fish establishments are required to have a professional degree in veterinary science, aquatic products, or food science. These individuals are responsible for conducting inspection verification activities at the registered aquaculture farms and slaughter and raw processing establishments certified to export Siluriformes fish and fish products to the United States. Inspection personnel in poultry establishments are required to have a professional degree in veterinary science, food or public health science, or veterinary assistance degree. For certified poultry establishments, each customs office is comprised of four veterinarians, supervisory veterinarians, and food inspectors. The four veterinarian is responsible for supervisory guidance, daily management, assessment, and training of supervisory veterinarians. Supervisory veterinarians are assigned to certified establishments where they provide overall supervisory inspection of poultry products intended for export to the United States.

Inspection personnel who are supervised by supervisory veterinarians are responsible for enforcement of GACC requirements. GACC's inspection and certification activities are further supported by veterinarians from the Ministry of Agriculture and Rural Affairs (MARA), who are responsible for conducting ante-mortem and post-mortem inspection of poultry at the slaughter

establishments. The FSIS auditors verified through interviews and record reviews that the inspection personnel have appropriate educational credentials to conduct inspection activities at the four establishments selected for this audit.

The PRC's Civil Servant Law requires that all newly appointed inspection personnel receive proper training when they assume their post for the first time. GACC provides continuous training in the form of centralized lectures, online education, video meetings, and practical on the job training. The FSIS auditors reviewed GACC's training schedules and inspectors' training records since the previous FSIS audit in 2018. This included training of the newly hired inspection personnel in establishments certified to export to the United States. The training materials included verification of good aquaculture practices, good manufacturing practices (GMP), good commercial practices (GCP), HACCP systems, sanitation, traceability, labeling, poultry and fish products standards, and export certification. The FSIS auditors verified that 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, review of inspection-generated records, and direct observation of inspection personnel while conducting their assigned inspection activities.

The FSIS auditors verified that GACC's Department of Enterprise Management and Audit-based Control has the legal authority and responsibility to certify or delist any establishment in accordance with the Administrative Provisions for the Records of Export Food Production Establishments. GACC has authority to revoke an establishment export certification when the establishment is not meeting the PRC or importing country's regulatory requirements. All poultry or Siluriformes fish establishments that are interested in exporting eligible products to the United States must apply for export certification in accordance with GACC requirements.

Concerning the use of raw source materials, the FSIS auditors verified through interviews and record reviews that certified Siluriformes establishments do not receive Siluriformes fish from any other country and solely utilize their own contracted registered farms as source materials for products destined for export to the United States. The FSIS auditors also verified that the raw materials for all processed poultry currently exported to the United States are derived exclusively from slaughter establishments within the United States. This point will be revisited under subsequent components of the report in that, as GACC is the competent authority for exports, its oversight activities at the audited poultry slaughter establishment had been limited by the fact that this facility currently produces predominately for the PRC's domestic market. This slaughter facility was included in the audit scope as it is the only slaughter establishment currently certified to export to the United States, thereby representing a potential source of raw materials should the PRC decide to source its slaughtered poultry domestically. In order to demonstrate an ongoing ability to enforce relevant requirements, GACC conducted a documented trial on August 11, 2020, which included verification of all requirements related to the use of slaughtered raw poultry as source materials for processed products destined for export to the United States.

Chicken and duck imported from the PRC is subject to APHIS highly pathogenic avian influenza and Newcastle Disease requirements specified in 9 CFR 94.6. Consequently, the PRC is currently eligible to export only cooked poultry to the United States. Additional measures to prevent and control these diseases are provided by Chapter VI of the PRC's Administrative

Measures on Animal Inspection, which identifies requirements for suspect animals and animal products that are imported or transported intra-country to disease-free zones. Animals and animal products that are not legally transported or inspected as required will be penalized per Chapter VIII of this document. All poultry presented at certified poultry establishments must be accompanied by appropriate health certificates issued by MARA.

The FSIS auditors verified through interviews and record reviews that GACC has provided instructions to its inspection personnel to identify and document any noncompliance findings on the Noncompliance Traceability Report (NCTR). The FSIS auditors reviewed inspection generated NCTRs for the four selected establishments. The FSIS auditors verified that inspection personnel had identified and documented noncompliance findings in NCTRs in accordance with 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 confirmed the proper implementation of GACC's proposed corrective actions in response to the previous onsite FSIS audit findings. The FSIS auditors also verified through record reviews that GACC has provisions in place for elevated enforcement actions, including withdrawal of inspection, suspension of issuance of export certificates, or imposed fines when an exporting establishment does not meet the importing country's or the PRC's regulatory requirements. The FSIS auditors verified through interviews that there have not been any elevated enforcement actions associated with certified poultry and Siluriformes fish slaughter and processing establishments since the previous onsite FSIS audit in 2018.

The supervision and administration of food recalls is organized by the State Administration for Market Regulation (SAMR) at the national level and carried out by the certified establishments. The FSIS auditors verified through interviews and record reviews that GACC requires each certified establishment maintains recall procedures in accordance with the SAMR's Measure for the Administration of Food Recall (2020), as well as traceability records sufficient to conduct traceback activities if adulterated product were exported to the United States. As indicated previously, GACC's oversight activities are limited to that of imported and exported products; not products intended for the domestic market.

GACC has a regulatory definition for adulteration and misbranding and developed specific instructions to the inspection personnel on enforcement strategies when they identify adulterated or misbranded products. These definitions include food safety and misbranding criteria, including production under unhygienic conditions of any food that might be harmful to health, and any food not meeting specified criteria, including those that have levels of chemical residues exceeding specific limits. The FSIS auditors verified through interviews that there have not been any product recalls of exported poultry or Siluriformes fish products since the previous onsite FSIS audit in 2018.

The FSIS auditors reviewed export certification "packages" for the selected Siluriformes fish and poultry 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 poultry or aquaculture farms, species (for Siluriformes fish), country of destination, pre-shipment review record, and microbiological and chemical

residue sampling results associated with the production lot for the exported products. Prior to issuance of the export certificate, signing officials routinely verify each establishment's sanitation and HACCP records, microbiological and chemical residue sampling results, as well as a review and verification of labeling, and traceability documents.

The China National Accreditation Service for Conformity Assessment (CNAS) operates the national accreditation system for certifying laboratories that test official government verification samples of products destined for the United States. Provincial GACC offices oversee government laboratories within each province. Inspection personnel at certified establishments collect and send required samples to assigned government laboratories within their respective province for analysis.

CNAS audits government laboratories against the standards laid out in Guobiao/Tuǐjiàn (GB/T) 27025-2019 to verify conformance with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 standards. GACC requires a hold and test policy within the context of its government chemical residue and microbiological verification testing programs. GACC stated that sampled Siluriformes fish and poultry shipments are stored in GACC approved cold storage warehouse pending laboratory analysis.

During the audit of the two government laboratories, the FSIS auditors verified the PRC's ability to coordinate evaluations of laboratory performance, including proficiency testing schemes for analysts and evaluations of the quality controls maintained by laboratory managers. FSIS also verified that laboratory staff possess relevant academic credentials and experience in their specialty areas.

The FSIS auditors verified that GACC's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

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

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

GB 12694-2016 requires that establishments certified to export or provide source materials for products exported to the United States follow the regulations on animal welfare during primary production, transport, and slaughter. This includes requirements to ensure that live poultry are

slaughtered in accordance with GCPs, in a manner that will result in thorough bleeding of the poultry carcass and will ensure that breathing has stopped before scalding. Article 23 of Order No. 26 (2002) requires that government veterinarians conduct ante-mortem inspection at certified establishments prior to slaughter. Poultry ante-mortem inspection includes both document review and clinical examinations of live poultry in accordance with Section 3.3.2.2 of GACC's Poultry Inspection and Quarantine and Supervision Handbook for Poultry Exported to the United States (hereafter referred to as The Poultry Handbook). Articles 25 and 26 of Order No. 26 (2002) require that poultry originate from registered farms accompanied by a Certificate of Passing the Quarantine of Origin of Animals.

The FSIS auditors reviewed documents associated with the verification trial for slaughtered poultry intended for export to the United States conducted on August 11, 2020. These documents indicated that inspection personnel conducted ante-mortem inspection on each lot of live poultry and verification of GCPs twice per shift.

The government veterinarians conduct post-mortem inspection at certified poultry establishments in accordance with Article 23 of Order No. 26 (2002). The FSIS auditors interviewed inspection personnel to verify that proper presentation, examination, and disposition of carcasses and parts are being implemented when a certified establishment intends to export to the United States. The FSIS auditors reviewed documents related to the August 11, 2020 verification trial at the selected poultry slaughter establishment for which no concerns were identified.

The FSIS auditors verified through interviews and record reviews that the selected establishments have a system in place to distinguish between the Siluriformes fish and fish products or poultry products destined for export to the United States from products destined for other markets. This includes complete separation of the entire 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 distinguishing label to clearly indicate that the product is only for export to the United States. The FSIS auditors confirmed that inspection personnel are verifying the proper implementation of the establishment's procedures and did not identify any concerns.

GACC requires establishments certified to export to the United States to separate and appropriately dispose of condemned and/or inedible fish and fish products of the order Siluriformes. This included inspection verification of certified establishments' procedures to identify, separate, and dispose of dead or abnormal Siluriformes fish from the receiving of live fish to packaging stations. The FSIS auditors confirmed through interviews and record reviews that the inspection personnel conduct daily, at least once per production shift, verification of certified establishments' procedures to ensure proper collection, segregation, storage in designated containers and rooms, and disposal of condemned Siluriformes fish in accordance with the GACC's requirements. The FSIS auditors remotely reviewed the results of in-plant inspection daily verification activities and did not identify any concerns.

Article 18 of the Administrative Measures on Animal Inspection states that when birds and poultry products fail inspection, government inspection veterinarians may issue a notice of disposal and oversee disposal. The Notice of the Ministry of Agriculture on Printing and

Distributing the Technical Specifications for the Harmless Treatment of Dead and Diseased Animals (2017) states that disposal of sick birds and poultry products that may cause harm to the health of humans and other animals shall be shipped in closed and impermeable containers. During the audit, the FSIS auditors reviewed the August 11, 2020 government verification trial records demonstrating that the relevant portions of these requirements were applied, including appropriate segregation of condemned materials in specially marked or otherwise secure containers and final disposal of these materials at nearby rendering facilities.

The FSIS auditors remotely 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. These verification activities cover the entire production shift that includes the receiving of raw materials, processing, storage, packaging, and export of the products to the United States. The inspection personnel document the results of their daily verification procedures on a standard form, the Official Inspection Verification Record. The FSIS auditors' review of these records did not identify any concerns.

GACC requires that inspection personnel be present at least once during each production shift when processing poultry or Siluriformes fish establishments are producing products for export to the United States. In order to provide sufficient staffing, GACC requires that certified establishments submit their production schedules several days prior to the start of their production for export. This requirement allows the GACC to provide sufficient inspection coverage, including a relief inspector, if needed, for each production shift. The FSIS auditors verified through interviews and record reviews that this requirement has been implemented as intended in both poultry and Siluriformes fish establishments.

The GACC requires that the district custom administration (CA) inspection personnel conduct at a minimum an annual periodic supervisory visit of establishments certified to export to the United States. The GACC's annual supervisory visits include evaluation of certified establishments' HACCP, GMP, and sanitation compliance, as well as evaluation of inspection personnel knowledge, skills, and abilities for proper implementation of the GACC requirements in regard to production and export of poultry or Siluriformes fish products to the United States. The FSIS auditors' review of documented annual supervisory visits conducted in 2020 and 2021 did not identify any public health or food safety concerns and confirmed that these visits and any related follow-up visits were conducted in accordance with the GACC's requirements.

The FSIS auditors verified that GACC has the legal authority to establish regulatory control over meat and poultry establishments that are certified to export their products to the United States.

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

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

GACC has requirements for certified poultry and Siluriformes fish establishments to develop, implement, and maintain written sanitation programs to prevent direct product contamination or the creation of insanitary conditions consistent with FSIS regulatory requirements cited in 9 CFR Part 416.

At the aquaculture farm level, MARA is responsible for the national aquatic disease prevention, sanitary measures, and for the control of all registered aquaculture farms producing fish for human consumption. The GACC provides additional requirements for registration of those aquaculture farms that provide raw fish to certified slaughter and raw processing establishments. The GACC's Regulation Requirements for Siluriformes Fish Products for Export to the United States provides regulatory requirements for breeding farms regarding the farm's sanitary conditions, sampling and analysis of feeds/feed additives, water, live fish, and necessary actions in response to disease outbreaks. GACC's Requirements for Transportation of Raw Materials for Siluriformes Fish Products for Export to the United States provides regulatory requirements regarding transport vehicle's sanitation condition and required vehicle's equipment including water filters, temperature control systems, and oxygen supply devices.

The FSIS auditors verified through interviews and record reviews that the local CA inspection personnel conduct at a minimum an annual inspection of aquaculture farms to verify compliance with the GACC and FSIS import requirements. This annual inspection includes review of the MARA's monitoring of aquaculture farms, traceability of breeding stock, and aquaculture farm hygienic production records. The inspection personnel also conduct hands on inspection verification of the aquaculture farm's sanitary condition; inventory of registered chemical and veterinary drugs consumption; and monitoring of the collection of water, feed, and fish samples for chemical residue analysis. The FSIS auditors' review of related records did not identify any concerns.

GACC's Regulation Requirements for Siluriformes Fish Products for Export to the United States includes the specific sanitation requirements. Each certified establishment's sanitary procedures must include the required frequency for pre-operational inspection and operational inspection, list establishment personnel accountable for conducting sanitary procedures, and document the results of the sanitation inspection. The Certification and Accreditation Administration of China's (CNCA) Requirements on Safety and Sanitation Requirements for Manufacturers of Food for Export and Product Catalogue of Manufacturers of Food for Export requires certified establishments to maintain the facility in good condition in order to prevent direct product contamination or creation of insanitary conditions. The document includes requirements for establishments' design and structure, maintenance, water supply, ventilation, pest control, lighting, and personnel hygiene.

Poultry establishments certified to export to the United States are required to meet hygiene requirements of Order No. 23 (2011) and GB 12694-2016. These articles and sections include the requirements for the premises outside the certified establishment; pest control; water potability and water waste; garbage handling; facility construction and equipment; toxic and harmful materials control; packing, storage and transportation sanitation; and personnel hygienic requirements.

The FSIS auditors confirmed through the review of inspection records that the inspection personnel are verifying pre-operational and operational Sanitation SOP, SPS, and establishment procedures to control contamination throughout the slaughter and dressing operation in accordance with the GACC's requirements as applicable for poultry or Siluriformes fish slaughter.

The reviews, analysis, and remote verification activities conducted by the FSIS auditors indicated that GACC's food safety inspection system requires that all establishments certified to export to the United States develop, implement, and maintain sanitation protocols that are consistent with the criteria established for this component.

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

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

GACC has specific requirements for certified poultry and Siluriformes fish establishments to develop, implement, and maintain HACCP systems consistent with FSIS requirements cited in 9 CFR Part 417.

For Siluriformes fish and fish products, the CNCA's Requirements on Safety and Sanitation Requirements for Manufacturers of Food for Export and Product Catalogue of Manufacturers of Food for Export include the detailed rules for the development, implementation, and maintenance of a HACCP system. The FSIS auditors confirmed that, on an annual basis, the inspection personnel from Department of Enterprise Management and Audit Based-Control evaluate the design and proper implementation of the HACCP system in each of the certified establishments eligible to export Siluriformes fish products to the United States. The results of these evaluations are recorded on a form entitled Record of HACCP System Verification for Manufacturer of Food for Export. The annual audit includes an assessment of the HACCP plan, hazard analysis, flow chart, critical control points (CCP), corrective actions, monitoring, verification, records and recordkeeping, HACCP training of establishment personnel, and written recall procedures. In addition, the FSIS auditors reviewed daily inspection personnel HACCP verification records and noted that they documented the results of their verification tasks in accordance with the GACC requirements.

Per Articles 6 through 8 of Bulletin No. 3 (2002), establishments intending to export poultry products to the United States are to develop their HACCP system by conducting a hazard analysis and identifying the preventive measures, determining the CCPs, establishing critical limits for CCPs and associated monitoring procedures, performing corrective actions and recordkeeping and documentation procedures, and performing verification procedures. Article 4 of this Bulletin identifies inspection personnel as responsible for verifying the implementation of each certified establishment's HACCP system.



In accordance with The Poultry Handbook, poultry slaughter establishments intending to export to the United States are to maintain a written program to control fecal and ingesta contamination and ensure that fecal contaminated carcasses do not enter the chiller. The FSIS auditors reviewed documents associated with GACC's August 11, 2020 verification trial for slaughtered poultry intended for export to the United States. These documents indicated that inspection personnel documented the results of their verification tasks in accordance with the GACC requirements, including hands-on verification of zero tolerance requirements for feces (10 poultry carcasses) at a frequency of twice per shift.

Poultry processing establishments certified to export RTE products to the United States are required to control *Lm* in the post-lethality environment, as well as *Clostridium perfringens*, *Clostridium botulinum*, and *Bacillus cereus* during stabilization, within the scope of their HACCP systems. Documents reviewed by the FSIS auditors for the poultry processing establishment demonstrated that inspection personnel routinely verify that this establishment has developed a HACCP system that addresses the temperature of products during cooking and stabilization, with all poultry products reaching a minimum temperature of 74° C (165° F) throughout to meet the relevant APHIS requirements.

The FSIS auditors verified through interviews and record reviews that GACC requires certified establishments to develop, implement, and maintain HACCP systems for each processing category.

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

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

Prior to the remote audit, FSIS residue experts reviewed the PRC's National Residue Program (NRP) for both poultry and Siluriformes fish, including its sampling plans for calendar years 2020 and 2021; calendar year 2020 results; associated methods of analysis; and additional SRT responses outlining the structure of the PRC's chemical residue program.

The implementation of the NRP is based on the PRC's Technology Specifications of Residues Monitoring of Animal & Animal-origin Foodstuffs for Export (2012), which includes poultry and Siluriformes fish. This standard outlines the organizations and responsibilities for the technology specifications of residues monitoring of animals & animal-origin foodstuffs for export plan, the basic procedure for residue monitoring, formulation and publication of the plan, implementation of the plan, delivery of results, handling of non-compliant results, analysis and reporting of results, as well as the procedure and requirements of supervisory inspection and control measures. Export of Siluriformes fish products is further supplemented by GACC's Measures for the Administration of Import and Export Food Safety, which instructs inspection

personnel to conduct onsite investigation of the aquaculture farm when the laboratory reports the presence of prohibited drugs or analytical results are above tolerance level.

The FSIS auditors verified through interviews and record reviews that trained inspection personnel randomly collect poultry or Siluriformes fish samples; freeze, label, and securely seal sampling containers; and submit samples to assigned government laboratories in accordance with GACC's instructions. The FSIS auditors reviewed inspection sampling forms generated at the audited poultry slaughter establishment, in addition to two Siluriformes fish establishments and corresponding aquaculture farms. The sampling forms captured information, such as name and address of certified establishment (or aquaculture farm), sample collector's name, weight of sample, condition of sample, sample collection date, mode of transport to the laboratory, traceability, and a list of targeted compounds for testing. These documents also indicated that inspection personnel routinely ensure that poultry or Siluriformes fish received at the slaughter establishments come from approved farms. The FSIS auditors' review of these forms did not identify any concerns.

The FSIS auditors verified that inspection personnel receive the results of government monitoring chemical residue testing in a timely manner, assess the results, and take appropriate actions in accordance with GACC's requirements. The FSIS auditors confirmed that GACC has implemented a hold and test policy for Siluriformes fish products, set forth with the intent to keep product under government control until test results indicate that there are no violative levels of chemical residue in the product. Concerning poultry, section 6.4 of The Poultry Handbook also requires that product be held pending laboratory testing results when product is intended for export to the United States. However, as indicated in previous sections of the report, raw materials for all processed poultry exported to the United States were derived exclusively from slaughter establishments within the United States at the time of the audit.

The FSIS auditors interviewed government personnel from an official government laboratory that conducts chemical residue testing as part of the PRC's NRP to verify their ability to provide adequate technical support to the inspection system. These interviews included a review of records documenting sample receipt, application of equivalent testing methods, adherence to maximum residue limits, and reporting of results. No concerns arose from interviews held with laboratory personnel.

The result of the remote audit activities indicated that GACC is implementing the NRP as intended.

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

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

The PRC currently has 11 establishments certified as eligible to export Siluriformes fish and fish products to the United States. These establishments do not produce any RTE 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.

In accordance with the PRC's Monitoring Program for Microbes in Exported Poultry Products (MoPMEPP), poultry slaughter establishments certified to export to the United States are required to develop a sampling and testing program to verify sanitary dressing process control for indicators of intestinal and fecal contamination. Establishments are to maintain this program in either a HACCP plan, sanitation SOP, or other prerequisite program. The program is to contain a description of the sampling process, including identifying designated personnel, sample sites, sampling frequency, preserving and handling samples, and reporting samples with nonconformities. Samples are to be collected randomly, at pre-evisceration and at post-chill, one carcass per production line. For chickens, one sample is collected for every 22,000 carcasses or at least weekly. Establishments have the option to test for either generic *Escherichia coli* (*E. coli*), aerobic plate count, total coliforms, or Enterobacteriaceae. Establishments certified to export to the United States are instructed to evaluate test results using statistical process control techniques, and to maintain records of test results for two years.

The MoPMEPP also establishes a program equivalent to FSIS's program for *Salmonella* testing of chicken carcasses, with specific instructions to ensure that sampling is performed randomly by inspection personnel. Carcass rinse samples are submitted to designated government laboratories that analyze them using methods outlined in the MoPMEPP. Results are reported directly to GACC at the provincial and local levels by means of an electronic laboratory reporting system. The FSIS auditors reviewed government sampling results from the August 11, 2020 trial conducted at the audited slaughter establishment and concluded that GACC maintains the ability to implement this microbiological carcass testing program as intended.

The Poultry Handbook contains instructions that specifically require certified establishments to recognize *Lm* and *Salmonella* as pathogens of concern in RTE products. GACC requirement stipulates a zero tolerance for the presence of *Lm* and *Salmonella* in RTE fully cooked poultry products for export to the United States. The export requirements also mandate that all certified processed poultry establishments implement controls for *Lm* in post-lethality exposed products and in the processing environment. The export requirements further specify the analytical methods and sample sizes to be used by the laboratories conducting microbiological analysis of products for either pathogen.

The FSIS auditors interviewed inspection personnel assigned to the selected poultry processing establishment to determine the level of knowledge that they possess on the protocols to be followed to conduct government verification sampling to detect *Lm* and *Salmonella* in product, as well as *Lm* on product contact surfaces and the environment at establishments certified to export PLE RTE products to the United States. The inspection personnel demonstrated a sound knowledge of the instructions contained in the microbiological sampling manual and their responsibility to verify that the establishment has developed and implemented verification sampling programs.

All RTE sampling protocols include hold and test measures. If a positive sample were found, either by government verification testing or by establishment monitoring testing, GACC would initiate additional follow up testing of food contact and environmental surfaces. Poultry product that tests positive would not be eligible for export and would be under GACC control either to be destroyed or reprocessed. Subsequently, GACC would require the establishment to initiate intensified cleaning and sanitizing of the environment and food contact surfaces. GACC also requires its inspection personnel to conduct an in-depth verification assessment of the design and implementation of the establishment's HACCP system.

Inspection generated records demonstrated that inspection personnel routinely verify that the establishment is implementing its sampling and testing programs to verify that *Lm* and *Salmonella* are being effectively controlled in its processes, and that these programs are being administered effectively. Routine product sample testing conducted by the inspection personnel or the establishment's employees has not yielded any positive *Lm* or *Salmonella* results from the audited poultry processing establishment.

The FSIS auditors interviewed personnel at the Hefei Customs Technology Center Food Microbiological Laboratory, which conducts testing of official samples for *Salmonella* from chicken carcasses serving as raw materials for processed product exported to the United States. These interviews included review of records for each phase of the analytical process, including sample receipt, application of equivalent testing methods, and reporting for these pathogens. The FSIS auditors reviewed laboratory staff training records for those individuals conducting microbiological testing in conjunction with exports to the United States. The review determined that all analysts received required training to conduct analytical testing.

There have not been any POE violations related to this component since the previous FSIS audit in 2018. The remote audit activities indicated that the PRC maintains the legal authority and technical ability to regulate, plan, and execute activities of the food safety inspection system aimed at controlling the presence of microbiological pathogens in poultry products exported to the United States.

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

An exit meeting was held September 7, 2021, by videoconference with GACC. The FSIS auditors concluded that the PRC's food safety inspection system for Siluriformes fish and poultry products is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has required that establishments certified as eligible to export products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their exported products. In addition, the CCA has implemented microbiological and chemical residue testing programs to verify its food safety inspection system. An analysis of each component did not identify any findings that represented an immediate threat to public health.

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



中华人民共和国海关总署  
GENERAL ADMINISTRATION OF CUSTOMS OF THE P. R. CHINA

食品函〔2022〕48号

## 海关总署进出口食品安全局关于提交对自产 熟制禽肉和鲶形目鱼类输美考察报告评议 意见的函

美国驻华大使馆农业处：

贵方关于《中国自产熟制禽肉输美考察报告》收悉。经研究，现提供报告评议意见（见附件）。

顺致敬意。

附件： 自产熟制禽肉和鲶形目鱼类产品输美考察报告评议意见



Address: No.6, Jian Guo Men Nei Avenue, Beijing 100730, People's Republic of China  
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中华人民共和国海关总署  
GENERAL ADMINISTRATION OF CUSTOMS OF THE P. R. CHINA

## 附件

### 自产熟制禽肉和鲶形目鱼类产品 输美考察报告评议意见

一、在报告正文第2页审核范围部分,审核的主管机构“河南海关所属鹤壁海关”应为“郑州海关所属鹤壁海关”,“安徽海关所属合肥海关”应为“合肥海关所属庐州海关”。

二、报告下方第3页审核范围部分,审核的政府实验室“肇庆出入境检验检疫局检验检疫综合技术中心”应为“肇庆海关综合技术中心”。

三、在报告正文第5页政府监管部分,海关总署进出口食品安全局的英文应为“Bureau of Import and Export Food Safety”。

四、在报告正文第7页政府监管部分,提及的“国家市场和药品监督管理局(CFDA)”应为“国家市场监督管理总局(SAMR)”。

五、在报告正文第8页政府监管部分,中国合格评定国家认可委员会(CNAS)是由国家认证认可监督管理委员会(CNCA)设立并授权的国家认可机构,而非由海关总署(GACC)设立并授权。





中华人民共和国海关总署

GENERAL ADMINISTRATION OF CUSTOMS OF THE P. R. CHINA

六、报告中引用的部分部门规章已进行了更新、修订，具体为《食品召回管理办法》(2015年版)已更新为《食品召回管理办法》(2020年修订版);《进出境肉类产品检验检疫管理办法》、《进出口水产品检验检疫监督管理办法》已废止，由《中华人民共和国进出口食品安全管理办法》(海关总署第249号令)替代。

六、报告中引用的部分标准已更新，具体为：GB/T 20094-2006《屠宰和肉类加工厂企业卫生注册管理规范》已废止，由GB 12694-2016《食品安全国家标准 畜禽屠宰加工卫生规范》替代；GB 16548-2006《病害动物和病害动物产品生物安全处理规程》已废止，由《农业部关于印发<病死及病害动物无害化处理技术规范>的通知》(农医发[2017]25号)替代；GB/T 27025-2008《检测和校准实验室能力的通用要求》已废止，由GB/T 27025-2019《检测和校准实验室能力的通用要求》替代。

七、在报告正文第2页中，关于中国在美注册的企业数量应为15家而不是14家，即：中国在美国注册的鲶鱼企业11家，禽肉加工企业3家，禽肉屠宰企业1家，总计15家。



A letter from the Import and Export Food Safety Bureau of GACC on Submitting Comments on the Audit Report on China Origin Cooked Poultry and Siluriform Fish Exported to the United States

FSIS China Office;

Your Audit report on China origin Cooked Poultry Exported to the United States" has been received. After research, comments on the report are now provided (see attachment). Best regards.

Attachment: Comments on the Audit Report on China Origin Cooked Poultry and Siluriform Fish Exported to the United States

Food Safety Bureau

Jan 25<sup>th</sup> 2022

## Comments on the Audit Report on China Origin Cooked Poultry and Siluriform Fish Exported to the United States

1. In the audit scope section on page 2 of the main body of the report, “Hebi Customs affiliated to Henan Customs” should be “Hebi Customs affiliated to Zhengzhou Customs”, and “Hefei Customs affiliated to Anhui Customs” should be “Luzhou Customs affiliated to Hefei Customs”.
2. In the audit scope section on the third page below the report, the audited government laboratory "Zhaoqing Entry-Exit Inspection and Quarantine Bureau Inspection and Quarantine Comprehensive Technology Center" should be "Zhaoqing Customs Comprehensive Technology Center".
3. In the government supervision section on page 5 of the main body of the report, the English name of the Import and Export Food Safety Bureau of the General Administration of Customs should be "Bureau of Import and Export Food Safety".
4. In the section on government regulation on page 7 of the main body of the report, the “China State Administration for

Market and Drug Administration (CFDA)” mentioned should be “the State Administration for Market Regulation (SAMR)”.

5. In the government supervision section on page 8 of the main body of the report, the China National Accreditation Service for Conformity Assessment (CNAS) is a national accreditation body established and authorized by the National Certification and Accreditation Administration (CNCA), not by the General Administration of China Customs (GACC) established and authorized.

6. Some departmental regulations cited in the report have been updated and revised. Specifically, the Measures for the Administration of Food Recalls (2015 Edition) have been updated to the Measures for the Administration of Food Recalls (Revised in 2020); Measures for the Administration of Import and Export Meat Product Inspection and Quarantine and Measures for the Supervision and Administration of Inspection and Quarantine of Import and Export Aquatic Products are replaced by Measures for the Administration of Import and Export Food Safety of the People's Republic of China (Order No. 249 of the General Administration of Customs)

7. Some of the standards cited in the report have been updated, specifically: GB/T 20094-2006 "Administrative Specifications for Hygienic Registration of Slaughtering and Meat Processing Plants" has been abolished, and is replaced by GB 12694-2016 "National Food Safety Standard - Livestock and Poultry Slaughtering" "Processing Hygiene Code" to replace; GB 16548-2006 "Procedures for biosafety treatment of Diseased Animals and Diseased Animal Products Production" has been abolished and replaced by the Notice of the Ministry of Agriculture on Printing and Distributing the Technical Specifications for the Harmless Treatment of Dead and Diseased Animals[2017] No. 25); GB/T 27025-2008 "Testing and Calibration" General Requirements for Laboratory Competence" is obsolete and replaced by GB/T 27025-2019 "General Requirements for the Competence of Testing and Calibration Laboratories".

7. On page 2 of the main body of the report, the number of Chinese companies registered in the United States should be 15 instead of 14. That is; 11 Chinese siluriform fish companies, 3 poultry processing companies, and 1 poultry slaughtering company registered in the United States, 15 in total.