FINAL REPORT OF AN AUDIT CONDUCTED IN THE PEOPLE'S REPUBLIC OF CHINA

NOVEMBER 26 TO DECEMBER 13, 2018

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

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Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) in the People's Republic of China (PRC) from November 26 to December 13, 2018. The audit objective was to determine whether the food safety system governing poultry products provides a level of public health protections equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The audit included an assessment of both the poultry processing and slaughter food safety inspection systems, the latter of which was conducted because of the publication of a recent FSIS proposed rule to amend the inspection regulations to permit the import of poultry products originating from birds slaughtered in the PRC.

Currently, the PRC is eligible to export only fully cooked poultry (chicken and duck) that is derived from approved sources, i.e., product slaughtered and sourced from official establishments in the United States or establishments certified to export to the United States in countries with an equivalent poultry slaughter inspection system. At this time, because of USDA's Animal and Plant Health Inspection Service (APHIS) restrictions, should the aforementioned FSIS rule become final, the PRC would only be allowed to export cooked poultry products to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, 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 did not identified any findings for processed poultry; however, the following findings were identified for slaughtered poultry (two establishments audited):

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- 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).

Government Hazard Analysis and Critical Control Point (HACCP) System

- 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.

Government Microbiological Testing Programs

- 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.

The audit findings related to PRC's poultry slaughter establishments are not significant. They do not represent a potential to endanger public health because the findings involved recordkeeping and necessary technical clarifications that do not impact product safety. The FSIS audit determined that PRC's poultry slaughter and processed products inspection systems are being implemented as documented in the self-reporting tool (SRT). Additionally, during the on-site audit exit meeting, the Central Competent Authority (CCA) committed to immediately address the audit findings presented by providing the necessary clarifications to the government inspection personnel and establishment management. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided There were no systemic audit findings identified during the 2015 audit of PRC's poultry slaughter inspection system or the 2016 audit of PRC's processed poultry inspection system, and the audits supported that PRC's poultry inspection systems met equivalence requirements.

Currently, the rulemaking pertaining to the eligibility of poultry products originating from birds slaughtered in the PRC for export to the United States is in process, i.e., a proposed rule has issued. Until a final rule is issued all source materials used to produce fully cooked poultry products for export to the United States must come from an approved source outside the PRC.[1] As a result, the findings related to PRC poultry slaughter establishments described in this report have no bearing on product currently or previously exported to the United States. Additionally, isolated findings concerning the audited processed poultry facilities are included on the individual establishment checklists within Appendix A of this report.

[1] The final rule has been published since the preparation of this audit report.

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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 (PRC) food safety system from November 26 to 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 People's Republic of China (GACC).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to determine whether the food safety system governing poultry products in the PRC 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 audit included an assessment of both poultry processing and slaughter food safety inspection systems, the latter of which was conducted as a result of the publication of the recent FSIS proposed rule to amend the inspection regulations to permit the import of poultry products originating from birds slaughtered in the PRC. The PRC is eligible to export the following category of product to the United States: ready to eat (RTE) fully cooked-not shelf stable chicken and duck that is derived from approved sources, i.e., establishments certified to export to the United States in countries with an equivalent poultry slaughter inspection system. Currently, the PRC has only exported RTE fully cooked-not shelf stable chicken product derived from an approved source, and does not have any RTE fully cooked-not shelf stable duck product establishments certified as eligible to export to the United States.

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

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

Administrative functions were reviewed at CCA headquarters and three local customs offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The PRC currently has three establishments certified to export processed poultry that is sourced from poultry slaughtered in the United States or in other countries eligible to slaughter and export poultry to the United States. All three establishments produce fully cooked chicken. In addition, two of these processing establishments presented sister slaughter facilities from which they intend to receive raw materials, once publication of the final rule permitting the use of poultry products from birds slaughtered within the PRC occurs.

One of the slaughter establishments operates under the streamlined inspection system (SIS) for poultry described in Title 9 of the United States Code of Federal Regulations (9 CFR) §381.76. The other slaughter establishment operates under the New Poultry Inspection System (NPIS) described within stated regulation. All five facilities, i.e., three processing establishments and two slaughter establishments, were included within the current audit scope. During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR §381.196.

Additionally, the microbiology and chemical residue sections of two government laboratories were audited to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• General Administration of China Customs (GACC) Headquarters, Beijing
	Local Customs Offices	3	• Hebi Customs Office of Henan Custom District, Hebi • Chuzhou Customs Office of Nanjing Custom District, Chuzhou • Nanping Customs Office of Fuzhou Custom District, Nanping
Government Microbiology and Chemical Testing Laboratories		2	• Hefei Customs Laboratory, Hefei • Fuzhou Customs Laboratory, Fuzhou
Poultry Processing Establishments (fully cooked chicken)		3	• 3400/03045, Cargill Animal Protein Further Processing Co., Ltd., Chuzhou • 3500/03066, Fujian Sunner Food Co., Ltd. (The sixth factory), Nanping, Guang Ze County • 4100/03078, Hebi Yongda Meiyuan Food Co. Ltd., Hebi
Poultry Slaughter Establishments		2	• 3400/03042, Cargill Animal Protein Co. Ltd., Chuzhou (SIS) • 3500/03036, Fujian Sunner Development Co., Ltd., Number 4 Slaughter House, Nanping, Guang Ze County (NPIS)

FSIS performed the audit to verify that the PRC's food safety inspection systems for poultry processing and slaughter meet requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Poultry Products Inspection Act (21 United States Code [U.S.C.] 451 *et seq.*); and
- The Poultry Products Inspection Regulations (9 CFR Part 381).

The audit standards applied during the review of the PRC's inspection systems for processed and slaughtered poultry 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 (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures*.

III. BACKGROUND

The PRC is currently eligible to export processed poultry (chicken and duck) to the United States. However, until the final rule recognizing the PRC's system for slaughtered poultry as equivalent is published, source materials used to produce finished poultry products for export to the United States must come from an approved source. An approved source is poultry carcasses or products from an equivalent, eligible country and certified establishment including carcasses and products slaughtered in an official establishment in the United States.

FSIS has conducted multiple on-site audits of the PRC's inspection system for processed poultry products since the 2006 publication of its final rule entitled *Addition of the People's Republic of China to the List of Countries Eligible to Export Processed Poultry Products to the United States*, which included on-site reviews in 2010, 2013, and most recently in July 2016. Each of these follow-up audits concluded that the PRC's processed poultry inspection system continues to meet equivalence requirements and the reports for each audit have been published on the FSIS website. Additionally, there were no findings during this current audit of the processed poultry inspection system. Nevertheless, the PRC has exported only limited quantities of processed poultry to the United States to date. From September 01, 2015 to August 31, 2018, FSIS import inspectors performed 100 percent re-inspection for labeling and certification, as well as testing for microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella*) on 110 pounds of ready-to-eat (RTE) fully cooked chicken from the PRC. No product was rejected during this time.

FSIS has conducted multiple on-site audits of the PRC's inspection system for slaughtered poultry (2010, 2013, and 2015). There were no systemic audit findings identified during the 2015 audit of PRC's poultry slaughter inspection system, and the audit supported that PRC's poultry slaughter inspection system met equivalence requirements. On June 16, 2017, FSIS proposed to amend the poultry products inspection regulations to list the PRC as eligible to export to the United States poultry products produced from birds slaughtered in the PRC. FSIS has completed its review and evaluation of comments received on the proposed rule and has a final rule in clearance. Although the PRC may be listed in the FSIS regulations as eligible to export poultry products to the United States, the products must also comply with all other applicable requirements of the United States, including those of USDA's Animal and Plant Health Inspection Service (APHIS) before any products can enter the United States. At this

time, because of APHIS restrictions for Newcastle disease and highly pathogenic avian influenza (HPAI), should the FSIS rule become final, the PRC would continue to only be permitted to export fully cooked poultry products to the United States.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed the PRC's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether the PRC's food safety inspection system governing processed and slaughtered poultry is being implemented as documented in the country's SRT submission.

The FSIS final audit reports for the PRC's food safety inspection system are 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; ensures 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 confirmed that GACC is the CCA for matters related to the export of poultry products to the United States. In March 2018, the PRC's State Council announced a government reorganization aimed at improving efficiency and customer service in many parts of the Chinese government. The reorganization merged the former CCA, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), into GACC. This merger included the integration of all former China Inspection and Quarantine (CIQ) offices located at Chinese ports into GACC's existing import/export inspection structure. In early September 2018, the State Council published the *Regulations on the Allocation of Functions, Internal Bodies and Staffing of the General Administration of Customs*, which outline GACC's organization and functions. Article 3 of this regulation assigns GACC with the responsibility to enforce the requirements outlined in the PRC's *Food Safety Law (2015)*.

In terms of food safety and agriculture, the former AQSIQ Import and Export Food Safety Bureau (FSB) and Plant and Animal Health Department have largely retained their titles, functions, structure, and personnel. The assigned functions of the FSB under GAC include developing the safety, inspection and quarantine systems, undertaking record filing and registration, and inspection, quarantine, supervision and administration of imported food and cosmetics; and risk analysis. The FSB is designed to operate in a three-tier vertical fashion, originating from GACC headquarters in Beijing, through provincial and local customs offices situated throughout the country.

Oversight of the entire production process, from ante-mortem to finished product packaging and distribution, of all poultry intended for export to the United States is performed by government inspectors. As described in Appendix 1 of GACC's *Poultry Inspection and Quarantine and Supervision Handbook for Poultry Exported to the United States* (hereafter referred to as *The Handbook*), each customs office is comprised of tour veterinarians, supervisory veterinarians, and inspectors. The tour veterinarian is responsible for supervisory guidance, daily management, assessment, and training of supervisory veterinarians. Supervisory veterinarians are assigned by GACC to a certified establishment where they provide overall supervisory inspection of poultry products intended for export to the United States. Government inspectors (all veterinarians) are responsible for enforcement of general sanitation requirements and sampling and are supervised by supervisory veterinarians.

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. While on-site, the FSIS auditors verified the educational background of the government inspection personnel, noting that these individuals maintain documentation demonstrating their veterinary credentials. The FSIS auditors also confirmed direct payment of GACC inspection personnel by reviewing *Administrative Personnel Salary Spreadsheets* at local GACC offices.

Chapter X of the Civil Servant Law requires that all newly appointed government inspection personnel receive training when they assume their post for the first time. Continuous training is provided in the form of centralized lectures, remote online education, off-job intensive training, video meeting, and practical training (training outlined in 5.3 of *The Handbook*). Employee training plans are routinely reviewed and updated at least annually. The FSIS auditors confirmed that GACC and MARA personnel stationed at the establishments have been trained to conduct verification and inspection in a uniform manner, and that they have the ability to evaluate the implementation of HACCP, sanitation, and other prerequisite programs maintained by the establishments.

The FSIS auditors noted five documented training sessions held between 2017-2018 that included attendees from both GACC and MARA. Topics included implementation of *FSIS Directive 5000.1*, *Verifying an Establishment's Food Safety System*; Import and Export of Poultry Products; United States Poultry Regulation Updates; Completion of the FSIS SRT Questionnaire; and Ante-mortem and Post-mortem Inspection of Poultry. The FSIS auditors also noted that government inspection personnel, in the NPIS establishment audited, were provided with a translated copy of *FSIS Directive 6500.1*, *New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-To-Cook Requirements*.

The Handbook specifies the instances when government inspectors can require establishments certified to export to the United States to take corrective actions. GACC has the authority to initiate enforcement activities when corrective actions are not effective, or the certified establishment continues to not comply with PRC requirements (i.e., withdrawal of establishment certification) per *Order No. 20 (2002)*. Article 3 of *Decree No. 503 (2007)* specifies enforcement actions and fines that may be imposed on establishments which do not meet PRC requirements.

APHIS considers PRC to be affected with highly pathogenic avian influenza (HPAI) and Newcastle disease. Chapter VI of the *Administrative Measures on Animal Inspection* 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 establishments certified to export to the United States must be accompanied by appropriate health certificates issued by MARA.

Establishments interested in exporting poultry products to the United States apply for certification with GACC at the local level. Farms that supply live poultry intended as source materials for poultry product exports to the United States are also required to apply for certification. Establishments interested in becoming certified shall meet requirements in *Order No. 20* and *Order No. 142*. While on-site, the FSIS auditors reviewed the documents associated with the three processing facilities certified for export to the United States in October of 2017. This review indicated that the aforementioned procedures were followed appropriately through the initial application, on-site visit, and final certification phases.

Relative to the use of raw materials, Articles five and six of *Order No. 26 (2002)* states that the PRC will only receive imported poultry products from establishments certified to export to the United States in eligible countries recognized by GACC. At approved entry ports, inspection personnel will perform inspection as per Article 12. Imported products that do not meet requirements per Article 13 shall be returned or destroyed and will not be allowed to enter the country. Imported products that pass inspection will be sampled and analyzed for sensory, chemical, microbiology (including bacteria count, *Salmonella*, *Campylobacter*, *Lm,* and *Staphylococcus aureus*) and relevant pathogenic and parasitic testing depending on the country-of-origin. Sampled inspected shipments are stored in GACC approved cold storage warehouse pending laboratory analysis. Per Articles 18 and 19, imported shipments are not allowed to be moved or processed until a *Certificate of Inspection and Quarantine for Entry Goods* is issued.

The supervision and administration of food recalls is managed by the PRC's Food and Drug Administration (CFDA) at the national level and carried out by the certified establishment that produced food products identified as harmful to human health. The FSIS auditors noted that each audited establishment maintains recall procedures in accordance with the CFDA's *Measure for the Administration of Food Recall (2015)*, as well as records sufficient to conduct traceback activities if adulterated product were exported to the United States. GACC maintains procedures to notify FSIS through the United States Embassy of recalled products.

GACC ensures uniformity in government inspection verification activities performed in establishments certified to export to the United States through *The Manual*. GACC issues updated versions of *The Manual* through its *Internal Administrative Platform* information system to applicable provincial office that further distributes it electronically or issues hard copies to government inspection personnel assigned to establishments certified to export to the United States.
GACC authorizes the China National Accreditation Service for Conformity Assessment (CNAS) to operate the national accreditation system for certifying laboratories that test official

government samples of products destined for the United States. Provincial GACC offices oversee government laboratories within each province. Government inspection personnel and establishments certified to export to the United States send samples to certified government laboratories within their respective province for analysis. Laboratories implement the testing and calibration standards laid out in *Guobiao/Tuījiàn (GB/T) 27025-2008*. Laboratories are audited by CNAS against the standards laid out *in GB/T 27025-2008* to verify conformance with International Organization for Standardization (ISO) 17025 requirements.

During the visit to the 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 managers possess relevant academic credentials and experience as analysts in their specialty areas.

The FSIS auditors concluded that GACC continues to organize and administer its poultry inspection system in a manner that meets the core requirements for this component.

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

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for ante-mortem inspection of poultry; post-mortem inspection of each and every poultry carcass and part; 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.

The FSIS auditors noted that inspection personnel verify that poultry is slaughtered in accordance with good commercial practices, in a manner that will result in thorough bleeding of the poultry carcass and will ensure that breathing has stopped before scalding. Section 5.2 of *GB/T 20094-2006* requires that establishments certified to export to the United States follow the regulations on animal welfare during primary production, transport, and slaughter.

The FSIS auditors' review of ante-mortem inspection indicated that procedures were conducted in accordance with Article 23 of *Order No. 26 (2002)* that requires that government veterinarians conduct ante-mortem inspection at establishments presented for certification to export to the United States of all poultry prior to slaughter. Ante-mortem inspection includes document review, and clinical and animal welfare examinations (Section 3.3.2.2 of *The Handbook*).

The FSIS auditors verified that government inspection personnel were performing on-line post-mortem inspection of each-and-every carcass in accordance with Article 23 of *Order No. 26 (2002)* which requires that government veterinarians conduct post-mortem poultry inspection at establishments certified to export to the United States. The FSIS auditors observed inspection methodologies to verify that proper presentation, examination, and disposition of carcasses and

parts were being implemented. This included verification at the NPIS slaughter establishment that government veterinarians inspect the first 300 carcasses of each flock together, with the viscera uniformly trailing or leading or otherwise identified with the corresponding carcass, to determine whether the flock is affected with leukosis. The FSIS auditors also verified that in-plant inspection personnel enforce requirements equivalent to FSIS's ready-to-cook requirements, and that the establishment has the ability to monitor production to remove protruding pinfeathers, vestigial feathers, head, crop, oil gland, trachea, esophagus, entrails, and lungs from the carcasses before they enter the chilling tanks.

The FSIS auditors observed that government inspectors at the SIS slaughter establishment 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 required for SIS poultry establishments. The FSIS auditors verified through documentation that the establishment was operating under SIS for poultry slaughter. In interviews with the government inspectors and the establishment's management, the FSIS auditors were informed that the establishment was considering transitioning to NPIS for poultry. Therefore, the FSIS auditors identified the following finding:

- At the 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 NPIS.

Currently, the rulemaking pertaining to the eligibility of poultry products originating from birds slaughtered in the PRC for export to the United States is in process (i.e., a proposed rule has issued). Until a final rule is issued all source materials used to produce finished processed poultry products for export to the United States must come from another country that is an approved source. This audit finding is not significant as it does not represent a potential to endanger public health. This finding involves the establishment transitioning from one system to another. The PRC needs to verify that the establishment meets the requirements of the correct, applicable system.

Regarding processed poultry, Article 23 of *Order No. 26 (2002)* requires that government veterinarians conduct inspection at least once per shift when poultry products intended for export to the United States are produced. Additionally, establishments certified to export to the United States are to ensure that source poultry materials and finished processed poultry products are safe, sanitary and meet United States import requirements. Establishments certified to export to the United States may not use source poultry materials that are not derived from an approved source, and that are not accompanied with an original *Entry Goods Inspection and Quarantine Certificate* and other relevant supporting country-of-origin documentation. As per Section 3.4.2.2.1 of *The Handbook*, establishments certified to export to the United States may not use source poultry materials until inspection personnel have verified the supporting documentation.

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. Section 3 of *GB 16548-2006* 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. Procedures for destruction of sick birds and condemned

poultry products are described under Section 3.2. During the audit, the FSIS auditors verified 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 verified that GACC supervisory personnel conduct periodic evaluations of employee performance and provide instructions to address performance deficiencies when necessary. The auditors reviewed supervisory records and interviewed supervisors to assess the procedures used to evaluate employee performance. The auditors concluded that supervisors have the ability to effectively assess the inspectors' knowledge, skills, and ability required to perform their inspection activities. On a quarterly basis, an assigned local GACC tour veterinarian will visit each certified establishment that exports poultry products to the United States. The tour veterinarian verifies the safety and health control systems of the establishments certified to export to the United States, and the inspection personnel activities to ensure continued compliance with export requirements. However, as indicated previously, the supervisory reviews need to be strengthened to ensure that inspection methodologies (such as those used for post-mortem inspection) used in conjunction with exports reflect agreed-upon protocols submitted in the SRT and reviewed by FSIS.

The current audit indicates that the CCA has legal authority to establish regulatory controls over poultry establishments certified to export to the United States. However, a deficiency related to implementing proper post-mortem inspection procedures were noted at the SIS poultry slaughter establishment. During the exit meeting, GACC committed to immediately address the preliminary finding as presented by providing the necessary clarifications to government inspection personnel and establishments.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

Establishments certified to export to the United States are required to meet hygiene requirements of Articles 6, 7, and 8 under *Order No. 23 (2011)* and Sections 6, 7, 8, 9 and 10 of *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. Per Article 5 of *Bulletin No. 3 (2002)* and Sections 11.5 through 11.12 of *GB 12694-2016*, establishments certified to export to the United States are required to develop, maintain and implement a sanitation SOP program.

The FSIS auditors verified the adequacy of official verification and inspection activities related to sanitation programs at establishments certified to export to the United States by observing official inspection personnel as they assessed the implementation of establishment sanitation procedures. The FSIS auditors assessed the adequacy of pre-operational sanitation by observing

official inspection personnel conducting pre-operational verification of the establishment's sanitation program. The FSIS auditors also reviewed inspection records, assessed the overall sanitary conditions of production areas and storage rooms, and observed the production processes conducted in slaughter and processing areas of the establishments.

The FSIS auditors evaluated official inspection personnel verification of establishment sanitary dressing procedures in slaughter establishments. Official inspection personnel routinely verify establishment sanitary dressing, and they perform daily verification of zero tolerance for fecal material. Sections 8.3 and 8.4 of *GB 12694-201*6 stipulate that establishments certified to export to the United States shall develop and implement measures to ensure sanitary dressing procedures during slaughter, avoid cross-contamination, and prevent carcasses with visible fecal contamination from entering the chilling tank. All contaminated equipment and sites in slaughter and processing operations must be cleaned and sanitized under government inspection supervision. The FSIS auditors noted that both slaughter facilities had developed the necessary protocols and maintained records demonstrating a preventive approach in controlling contamination of poultry carcasses with fecal material.

Isolated findings related to the verification of sanitation requirements are noted on the establishment checklists attached to this report (Appendix A). The analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs and the CCA continues to maintain sanitation requirements.

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

The fourth of six equivalence components that 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.

Per articles six through eight of *Bulletin No. 3 (2002)*, establishments intending to export to the United States are to develop their HACCP system by conducting a hazard analysis and identifying the preventive measures; determining the critical control points (CCPs); establishing critical limits for CCPs and associated monitoring procedures; performing corrective actions and recordkeeping and documentation procedures; and performing verification procedures. The HACCP system is to be developed by a HACCP-trained establishment employee. Article 4 of this *Bulletin* identifies government inspection personnel as responsible for verifying the implementation of each certified establishment's HACCP system.

In accordance with *The Handbook*, 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. In addition, establishments certified to export to the United States operating under NPIS are required to maintain a written program to ensure that septicemia and toxemia carcasses do not enter the chiller. 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.

The FSIS auditors assessed the adequacy of design and implementation of the HACCP programs at two poultry slaughter establishments. Documents evaluated by FSIS at those slaughter establishments showed that the design of the HACCP systems in operation at the audited establishments is acceptable. The review demonstrated that the product process flowcharts included all steps in the slaughter and subsequent cut-up phases. Furthermore, documents reviewed by the auditors showed that establishments and inspection officials maintain records to document the results of daily monitoring of the implementation of HACCP plans. However, the FSIS auditors observed at the NPIS establishment not all the records for the 100% carcass monitoring 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. Therefore, the FSIS auditors identified the following finding:

- 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 and did not identify the cause of the deviation.

The FSIS auditors also verified the design and implementation of the HACCP programs at three processing establishments. The FSIS auditors conducted on-site observations and verified that GACC in-plant inspectors regularly evaluate the food safety programs included in establishments' HACCP systems. Documents evaluated by the FSIS auditors at the processing establishments demonstrated that inspection personnel routinely verify that establishments have developed HACCP systems that address 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 determined that the CCA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP systems. However, the audit finding listed above is not significant. It does not represent a potential to endanger public health because adequate corrective actions were taken to ensure the production of safe, unadulterated product, but corrective action records did not meet recordkeeping requirements and did not identify measures to prevent recurrence or the cause of the deviation.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is required to include a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified as potential contaminants by the exporting country's poultry inspection authorities or by FSIS.

Prior to the on-site visit, FSIS' residue experts reviewed the PRC's national residue program (NRP) results from 2017, associated methods of analysis, and additional SRT responses outlining the structure of the PRC's chemical residue testing program. No violative chemical residue samples were reported.

The *Food Safety Law (2015)* of the PRC provides the framework that agencies must follow to develop regulatory controls for the control of chemical residues, and the CCA has developed regulations requiring that poultry companies prevent the presence of chemical residues in their products. Poultry farmers and slaughter establishments regulated by the CCA are required to implement measures that ensure that products intended for export meet national standards and the standards of importing countries. Poultry companies authorized to export their products are required to participate in programs designed to control the supply and use of veterinary drugs in accordance with protocols designed to meet the requirements of importing countries.

GACC continues to use the *Technology Specifications of Residues Monitoring of Animal & Animal-origin Foodstuffs for Export* issued by AQSIQ in 2012. The PRC's sampling plan is based on the European Commission's *Council Directive 96/23/EC*. Every fourth quarter of each year, the CCA organizes an expert panel to review the test results and determine whether a compound should be included or removed from the sampling program. The implementation of the chemical residue controls program for the poultry slaughter inspection system is managed by the CCA in cooperation with MARA. The government agencies set the maximum residue limits, develop the sampling protocols, and delegate the sampling collection and analysis of samples to in-plant officials and laboratories, respectively. For poultry products, the PRC's NRP includes Beta-agonists, carbadox, olaquindox, bacitracin, chloramphenicol, thiamphenicol, florfenicol, quinolones, tetracyclines, sulfonamides, penicillin, nitroimidazole, hormones, nitrofurans, pesticides, and heavy metals. All methods used by the laboratory for the NRP are under the scope of their accreditation.

The FSIS auditors reviewed inspection records and interviewed the veterinary government inspectors that monitor compliance of farmers with residue control requirements that supply slaughter establishments presented by the CCA as eligible to export their products to the United States, and confirmed that the CCA has regulatory mechanisms in place to assure compliance with residue controls that are implemented by government officials. Additionally, in-plant inspection personnel ensure that live poultry received at the slaughter establishments come from approved farms. The reviewed records demonstrated that government veterinarians conduct sampling of muscle and other tissues in accordance with the PRC's NRP sampling schedule. No violative samples were identified. The NRP for poultry does not require that product be held until sample results are received, which is in keeping with FSIS policy for chemical residue testing of poultry carcasses.

The FSIS auditors also visited two official government laboratories that conduct chemical residue testing as part of PRC's NRP. Both laboratories are ISO 17025 as accredited by the China National Accreditation Service for Conformity Assessment (CNAS). CNAS is a member of International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC), as well as a member of Asian Pacific Laboratory Accreditation (APLAC), and Pacific Accreditation Cooperation (PAC). The FSIS auditors reviewed records, and

interviewed laboratory analysts to assess the staff's competency. The FSIS auditors determined that the laboratory personnel are well trained and qualified to perform these analytical methods.

The result of these on-site audit activities indicate that the PRC continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of chemical residues in poultry products destined for human consumption and specifically intended for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

In accordance with the PRC's *Monitoring Program for Microbes in Exported Poultry Product*s (*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 site, sampling frequency, preserving and handling samples, and reporting samples with non-conformities. Samples are to be collected randomly, pre and 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 *Escherichia coli* (*E. coli*) or aerobic plate count (APC), 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 FSIS auditors noted that the NPIS slaughter establishment's written pre-chill and post-chill microbiological testing program did not clearly define process control criteria. The establishment was using reference values outlined in the *MoPMEPP*, as required by the CCA. The *MoPMEPP* includes an aerobic plate count (APC) maximum value for pre-chill testing of 28,000 colony-forming units per milliliter (CFU/ml). While reviewing the establishment's testing results, the FSIS auditors noted that out of a total of 66 pre-chill tests, the maximum value was exceeded on two occasions (with values of 31,000 CFU/ml, and 30,000 CFU/ml) but did not identify the number of occasions the pre-chill threshold could be exceeded to indicate a loss of process of control. This new establishment was collecting sampling data to establish the process control criteria. Therefore, the FSIS auditors identified the following finding:

- 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.

The *MoPMEPP* also establishes an equivalent program for *Salmonella* and *Campylobacter* testing of chicken carcasses, parts, and comminuted product, with specific instructions to ensure

that sampling is performed randomly by government inspection personnel. Samples are submitted to approved 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. While on-site, the FSIS auditors observed GACC officials collecting carcass samples in accordance with procedures outlined in the *MoPMEPP* at both slaughter establishments audited, noting that selected carcasses were hung for at least 60 seconds prior to sample collection to limit the effect of chlorine or other antimicrobials on final test results. No concerns were identified.

The Handbook contains instructions that specifically require establishments to recognize *Lm* and *Salmonella* as pathogens of concern in RTE products. The CCA requirement stipulates a zero tolerance for the presence of *Lm* and *Salmonella* in RTE 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 products and in the post-lethality 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 GACC officials at the provincial and local offices and personnel to determine the level of knowledge that they possess on the protocols to be followed to conduct 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 RTE products to the United States. The officials demonstrated a sound knowledge of the instructions contained in the microbiological sampling manual and their responsibility to verify that establishments develop and implement verification sampling programs.

All RTE sampling protocols include hold and test measures. If a positive sample were found, either by government testing or by establishment testing, the CCA would initiate additional testing of food contact and environmental surfaces. 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 intensive cleaning and sanitizing of the environment and food contact surfaces. GACC officials would also conduct an in-depth verification assessment of the design and implementation of the food safety programs of the HACCP system and would sample product, product contact surfaces and post lethality environment of any establishment that yielded positive test results.

Records reviewed by the FSIS auditors at the three certified processing establishments demonstrated that the establishments are implementing their sampling and testing programs to verify that *Lm* and *Salmonella* are being effectively controlled in their processes, and that these programs are being administered effectively. Routine product sample testing conducted by the government or the establishment has not yielded any positive *Lm or Salmonella* results from these establishments.

The FSIS auditors visited two government microbiology laboratories that provide technical support to GACC offices responsible for certifying product exported to the United States. Both laboratories are ISO 17025 accredited by CNAS, with all microbiology testing methods for poultry included under the scope of their accreditation. Analysts receive adequate training and

participate in various proficiency testing (PT) programs. A review of laboratory PT results found that the laboratories had successfully passed all the PT tests. Additionally, the FSIS auditors interviewed lab analysts and reviewed the laboratory quality manual, audit reports, and other relevant records, concluding that the laboratories have the competency to perform the requested microbiological methods.

The on-site audit activities indicate 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. However, the audit finding noted above is not significant, as it does not represent a potential to endanger public health because the establishment is collecting the sampling data to establish process control criteria.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on December 13, 2018, in Beijing, PRC, with GACC. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors. The FSIS auditors identified the following findings related to the CCA's implementation of the food safety inspection system for slaughtered poultry:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- At the 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).

Government Hazard Analysis and Critical Control Point (HACCP) System

- 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.

Government Microbiological Testing Programs

- 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 was being collected to establish the process control criteria.

The audit findings related to PRC's poultry slaughter establishments are not significant, as they do not represent a potential to endanger public health because the findings involved recordkeeping and necessary technical clarifications that do not impact product safety. The FSIS audit determined that PRC's poultry slaughter and processed products inspection systems are being implemented as documented in the SRT. Additionally, during the on-site audit exit meeting, the CCA committed to immediately address the audit findings presented by providing the necessary clarifications to the government inspection personnel and establishment

management. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided There were no systemic audit findings identified during the 2015 audit of PRC's poultry slaughter inspection system or the 2016 audit of PRC's processed poultry inspection system, and the audits supported that PRC's poultry inspection systems met equivalence requirements.

Currently, the rulemaking pertaining to the eligibility of poultry products originating from birds slaughtered in the PRC for export to the United States is in process(i.e., a proposed rule has issued). Until a final rule is issued all source materials used to produce fully cooked poultry products for export to the United States must come from an approved source outside the country. As a result, the findings related to PRC poultry slaughter establishments described in this report have no bearing on product currently or previously exported to the United States. Additionally, isolated findings concerning the audited processed poultry facilities are included on the individual establishment checklists within Appendix A of this report.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Cargill Animal Protein Co. Ltd. Chuzhou	12/03/2018	3400/03042	China
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by China's inspection officials during the establishment review:

22/51. Ongoing verification records documenting the calibration of processing instruments (thermometers used in association with monitoring the temperature of carcasses leaving the chill tank for CCP2) did not include the specific time the activity occurred.

In addition, FSIS identified the following findings related to the implementation of China's poultry inspection system:

55. The FSIS auditors observed that government inspectors were not conducting proper post-mortem inspection of poultry carcasses. 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. Observing the inner surfaces of the carcass is important to identify conditions such as inflammatory process; airsacculitis; tumors; enlarged or reddened kidneys (infection or early sepsis); ascites; or extensive contamination. The FSIS auditors also identified deficiencies related to the configuration of the post-mortem inspection stations at this location. The particular configuration of the evisceration line was such that it would be difficult for manual manipulation of the flap to actually occur, i.e. the birds were presented out of reach of the inspector. There was no continuous flow faucet (or other means) to indicate that the inspectors would be able to wash their hands on an as-needed basis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/03/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Cargill Animal Protein Further Processing Co., Ltd. Chuzhou	12/04/2018	3400/03045	China
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/04/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Fujian Sunner Development Co., Ltd. Fourth Place Chicken Processing Plant Nanping City, Guang Ze County, Fujian	12/10/2018	3500/03036	China
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	X
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58. Offline poultry reprocessing	X
59.	

60. Observation of the Establishment

22/51. The establishment records documenting 100% monitoring of critical control point # 1 (zero tolerance for feces, septicemia, and toxemia) did not include the time at which each deviation from the critical limit occurred. Furthermore, documentation of corrective actions did not include measures to prevent recurrence.

28/51. The establishment did not develop clear guidance within the context of its prechill and postchill microbiological testing program for poultry carcasses to indicate when a loss of process control occurred and additional measures would be taken. The establishment was using reference values outlined in China's handbook for poultry products exported to the United States, which included an aerobic plate count (APC) maximum value for prechill testing of 28,000 colony forming units per milliliter (CFU/ml). While reviewing the establishment testing results, the FSIS auditors noted that out of a total of 66 prechill tests, the maximum value was exceeded on two occasions (with values of 31,000 CFU/ml, and 30,000 CFU/ml). Neither of the sample results were accompanied by written documentation indicating that additional actions were taken, or a justification as to how it was determined that process control was maintained.

51/58. The FSIS auditors noted that birds with fecal contamination were being washed with fresh water which did not include an antimicrobial agent at the offline reprocessing area associated with the first sorting station. The use of solely fresh water was not supported within the establishment's hazard analysis at this step. While other offline reprocessing areas within the establishment utilized a carcass dip with concentration of free available chlorine at 20-50 ppm (as per the establishment's written program), some of the barrels containing the chlorinated water were incorrectly identified as containing 50-100 ppm.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/10/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Fujian Sunner Food Co., Ltd. (The sixth factory) Nanping City, Guang Ze Country, Fujian	12/07/2018	3500/03066	China
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	12/07/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hebi Yongda Meiyuan Food Co. Ltd. Hebi	11/28/2018	4100/03078	China
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by China's inspection officials during the establishment review:

10/51. A) Meat scraps from the previous production day's production were identified by the FSIS auditors on a conveyor belt used to transport RTE product during verification of pre-operation inspection activities. B) Rusty and corroded hinges observed on the folding lid of the poultry cooker. This could result in contamination of the product and cooking medium (boiling water) when opening and closing the lid during cooking (fully-cooked RTE poultry product). However, no product adulteration was observed at the time as the cooker was empty at the time this deficiency was identified. This establishment had not yet begun to export product to the United States.

13/51. Establishment records did not routinely document the extent to which product was affected (i.e., disposition of product) in association with deficiencies identified during monitoring of operational SSOPs.

20/51. Written corrective actions in the establishment HACCP plan related to deviations from the critical limit for CCP #2 (cooking) did not include measures to prevent recurrence.

22/51. A) Establishment did not maintain records to document the direct observation of monitoring of critical control points (CCP). B) Ongoing verification records documenting the calibration of processing instruments did not include the specific time the activity occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/28/2018

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

Non-conformance Report

Non-conformance and description :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 transitioning to the new poultry inspection system (NPIS).

Reason analysis:Cargill Animal Protein Co. Ltd. Chuzhou was transitioning SIS to NPIS,MARA official veterinarian 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 Poultry Inspection and Quarantine and Supervision Handbook for Poultry Exported to the United States (hereafter referred to as The Handbook)the handbook required.

Corrective /Preventive measures：

Corrective： **1.**On December 4, 2018, The meeting between Hefei customs and veterinary officials of MARA made it clear that during the transition from SIS inspection system to NPIS inspection system of Chuzhou Cargill animal protein Co., Ltd., veterinary officials of MARA should conduct post-mortem inspection in strict accordance with operating under the inspection system for poultry slaughter(See Appendix) .

Preventive measures： **2.**Hefei customs governmentinspectors and MARA official veterinarian learned the ante-mortem inspection and the post-mortem inspection of Poultry Inspection and Quarantine and Supervision Handbook for Poultry Exported to the United States.

3.Hefei customs governmentinspectors and MARA official veterinarian werepractice on-line post- mortem inspection of carcass in accordance with the Handbook.

4.The tour veterinariancontinue to supervise poultry post-mortem inspection to ensure compliance with the requirements of the Handbook.

附件二：

Meeting minutes of Chuzhou customs and Laian Animal Husbandry Bureau on FSIS audit related issues

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Location: Cargill Meeting Room

Date: December 4, 2018 afternoon

Attendees: Hefei Customs: Mengxu Zhu, Yongmei Wang

Chuzhou Customs: Bing Ding, XinQian, Jianwei Zhang, Yongyang Wang

Lai'an Animal Husbandry Bureau: Xiaochun Li, Shiyou Yang, Daojun Chen, ZhixiangZheng, Lexin Du, Huadong Zeng, Baonian Fu

Recorder：YongyangWang

Conference content

1. Director Mengxu Zhu briefly introduced the results of the US FSIS inspection, expressed gratitude for MOA's support, and asked the customs and MOA to negotiate and solve the problems raised by the inspection team.

2. Section chief Yongmei Wang made a detailed explanation on the problems raised by the inspection team. The successful completion of the US audit is inseparable from the strong support of MOA colleagues. The inspection team put forward that our official veterinarian of MOA did not open the carcass and check the body cavity one by one during the online inspection by the end of inspection. To solve this problem, we will learn the requirements of the manual again, discuss with each other, and then go to the slaughterhouse for field operation practice to ensure that our work meets US requirements.

3. Secretary Xiaochun Li affirmed the problems raised by the inspection team and the solutions proposed by director Zhu and chief Wang, and put forward requirements for veterinarians of Animal Husbandry Bureau. Both sides actively cooperated to complete the

export work.

4. Director Ding Bing once again expressed thanks for MOA's support for this work.

5. learning contents are as follows:

(1) Ante-mortem inspection

The Ante-mortem inspection shall be carried out by the official personnel of the competent department with the assistance of the enterprise's personnel. Official quarantine personnel shall carry out Ante-mortem inspection after arrival of poultry to the plant, and the slaughtering and processing can be approved only after pre-slaughter inspection is qualified.

Ante-mortem inspection mainly includes certificate acceptance, clinical inspection and animal welfare inspection. The specific requirements are as follows:

①Certificate acceptance: for each batch of poultry entering the factory, check the animal quarantine certificate and other relevant certificates, check the attached feeding log or drug use record, and know whether the drug use and immunity of poultry in the feeding process meet the requirements.

②Clinical examination: group examination shall be carried out for poultry entering the factory, and individual examination shall be carried out as the case may be. It mainly inspects the mental state, appearance, respiratory state, movement state, drinking water, eating and excretion state, body temperature, feather, head (natural hole, crown, beard), leg, claw, crop content properties, etc. of the birds to determine the health state of the birds.

③Animal welfare inspection: check the situation of poultry fasting, water suspension, transportation loading and unloading, the sanitation and cleanliness of poultry transportation vehicles and tools, the action of employees catching and hanging chickens, the electric hemp facilities and the effect of electric hemp, etc., to ensure that the implementation of poultry and animal welfare meets the requirements.

(2) Post-mortem inspection

The online inspector is responsible for the inspection of the body surface, internal organs and body cavity of the poultry in the slaughtering production line, and determines the birds that need to be sorted, reworked, discarded, and retained for the veterinarian to judge. The slaughter is suspended according to the inspection and the speed of the production line is adjusted.

The offline veterinarian is responsible for inspecting and supervising the online inspector's inspection work, checking the poultry to determine whether the post-mortem inspection is qualified, judging the condition that the online inspector cannot identify, re-examining the reworked poultry, and suspending the slaughter according to the inspection. Production line speed.

The display staff of the company is responsible for displaying the internal organs, body surface and body cavity to the online inspector on the production line, which is convenient for online inspectors to inspect.

The assistants equipped with the company are responsible for picking up the abandoned tissue from the production line, transferring the reworked and the veterinary body and viscera that are left to the veterinarian to the hanging frame, and responsible for repairing minor lesions or pollution online, and making records.

The company's offline trimmers are responsible for the offline trimming and hangback of the reworked carcass.

The post-mortem inspection is divided into three parts: body surface test, visceral test and body cavity test. One official inspector checks the body surface, internal organs and body cavity on the production line.

1 body surface test

Mainly check the integrity of the body surface, skin color, bloodletting, observe whether there are bleeding, congestion, nodules, abscess, necrosis, inflammation (including cellulitis) and other diseases, observe joints and wounds, blood, whether Contaminated by hair, feces, feed and other contaminants, and pay attention to subcutaneous

pathological changes. Treatment of poorly bleed, diseased and contaminated birds.

2 visceral examination

Mainly check the heart, liver, spleen, stomach, intestines, kidneys, etc., check the appearance, shape, size, color, touch the texture hardness and elasticity, check whether there is swelling, discoloration, bleeding, parasites, nodules, tumors, necrosis, etc. Lesion. When an abnormality is found, appropriate treatment measures are taken in conjunction with the overall condition of the bird.

3 body cavity examination

Check the inner wall of the body cavity for ulcers, congestion, masses, parasites, blood clots, air sacs, fecal contamination, bile, and whether there are swollen or congested kidney

4 Ways of online inspection personnel to carry out post-mortem inspection and disposal

First, it is determined that the carcass for human consumption is qualified;

Second, the inspector cannot make a final decision, and keep the corpse waiting for the veterinarian to conduct further inspections;

The third is to discard the carcass that cannot be eaten by humans.

Sixth, The Customs and Animal Husbandry Bureau will discuss the requirements of the manual, clearly define the requirements, and determine the operation time of the next drill.

Annex 1: Meeting staff check-in form

Annex II: Live Walk Photo

Non- Conformance Corrective Action Report

Establishment Name	Fujian Sunner Development Co., Ltd.- Zhongfang No.4 Chicken Slaughtering and Processing Plant		
Non-compliance Description	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.		
Root-cause analysis	There is deviation in the enterprise's understanding of the record when CCP1(inspection before pre-chilling) deviates,and the reason, time, corrective action and preventive action is not clearly required in the program.		
Responsible Departments	Equipment/QA	Responsible person	何树斌
Corrections & Corrective Actions	1. To revise the HACCP Plan, improving the record table by adding deviation time, corrective actions and preventive measures, and analyze the root-causes of deviation. 2. Train CCP1 operators and record personnel		
Date of Completion	19 December 2018	Validation	宫文强 12.20
See Attachment List	Attachment I HACCP Plan Attachment II Pre-chilling (CCP1) inspection records Attachment III Training record of inspectors before pre-chilling		
Signature	叶茂	Date	2018.12.20

Non-conformities Corrective Report

Establishment Name	Fujian Sunner Development Co., Ltd.-Zhongfang No.4 Chicken Slaughtering and Processing Plant		
Non-compliance Description	In enterprises implementing the New Poultry Inspection System (NPIS), the carcass pre-cooling microbiological testing program does not clearly stipulate the standards of process control (criteria for determining whether a process is under control), for which the reason is that the collected sample data is still a part of the initial confirmation of established process control standards.•		
Root-cause analysis	1. The basedata currently collected from the plant for leachate is insufficient, and the analysts are not proficient in using statistical tools to analyze the microbiological data of leachate. 2. The New Poultry Inspection System (NPIS) program has a short running time, and it is not a familiar standard for the plant.		
Responsible Department	Equipment/QA Department	Responsible Personnel	何树诚
Corrections & Corrective Actions	① To use microbiological SPC to analyze the currently collected data; ② To establish the corresponding "self-inspection and self-control procedures" and clearly stipulating the process control standards.		
Date of Completion	19 December 2018	Validation	唐文强 12.20
See attachment List	Attachment I Statistical analysis of carcass leachate Attachment II Article V "Leachate" in 《Self-inspection and Self-control Procedures JG/SC-033-18》		
Signature	叶蔚	Date	2018.12.20

Non-conformities Corrective Report

Establishment Name	Fujian Sunner Development Co., Ltd.-Zhongfang No.4 Chicken Slaughtering and Processing Plant		
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Corrections & Corrective Actions	① To use microbiological SPC to analyze the currently collected data; ② To establish the corresponding "self-inspection and self-control procedures" and clearly stipulating the process control standards.		
Date of Completion	19 December 2018	Validation	唐文强 12.20
See attachment List	Attachment I Statistical analysis of carcass leachate Attachment II Article V "Leachate" in 《Self-inspection and Self-control Procedures JG/SC-033-18》		
Signature	叶荷	Date	2018.12.20

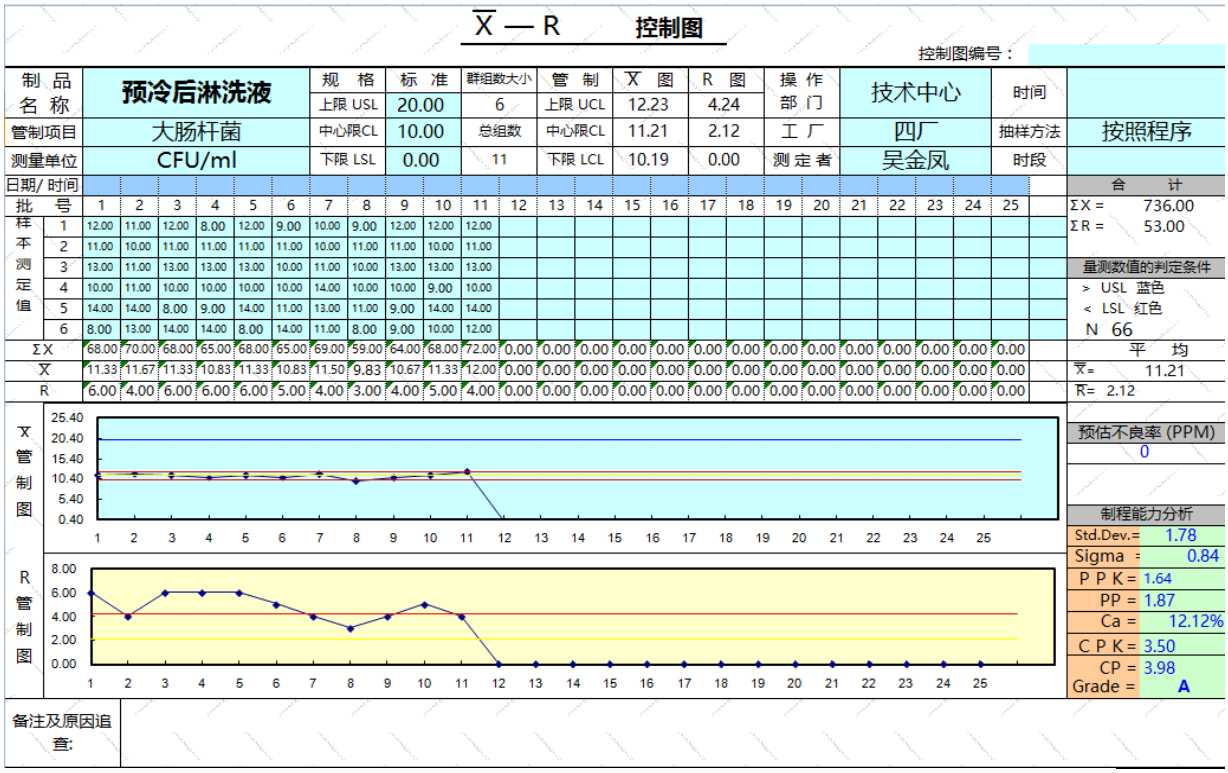
附件一：

淋洗液数据分析

Analysis of leacheate data

1. 利用 SPC 数理统计的方法，分析现有连续 11 天的数据。以预冷后淋洗液为例，如下图

1. Use the method of SPC mathematical statistics to analyze the existing data for 11 consecutive days. Take the pre-chilled leacheate as an example, as shown below



X — R 控制图

控制图编号：

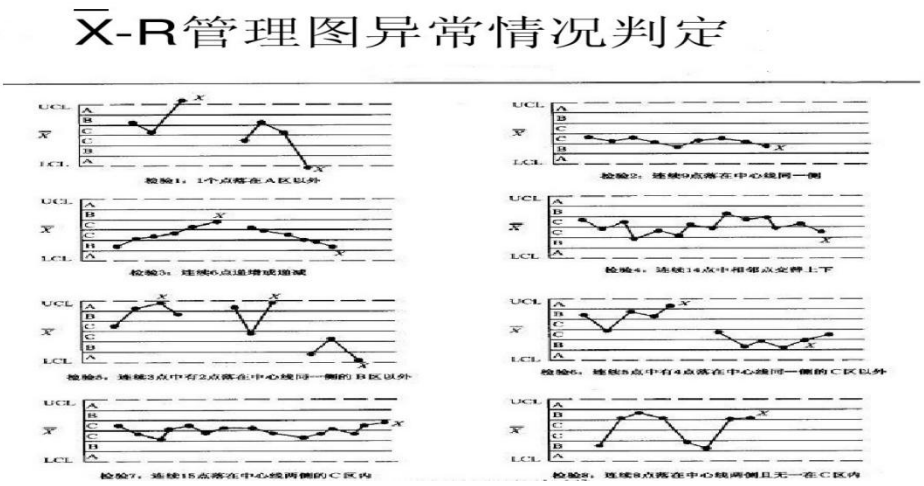
制品名称	预冷后淋洗液	规格	标准	群组数大小	管制	X 图	R 图	操作部门	技术中心	时间	
		上限 USL	20.00	6	上限 UCL	12.23	4.24				
管制项目	大肠杆菌	中心限CL	10.00	总组数	中心限CL	11.21	2.12	工厂	四厂	抽样方法	按照程序
测量单位	CFU/ml	下限 LSL	0.00	11	下限 LCL	10.19	0.00	测定者	吴金凤	时段	

批号	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
样本测定值 1	12.00	11.00	12.00	8.00	12.00	9.00	10.00	9.00	12.00	12.00	12.00														
2	11.00	10.00	11.00	11.00	11.00	11.00	10.00	11.00	11.00	10.00	11.00														
3	13.00	11.00	13.00	13.00	13.00	10.00	11.00	10.00	13.00	13.00	13.00														
4	10.00	11.00	10.00	10.00	10.00	10.00	14.00	10.00	10.00	9.00	10.00														
5	14.00	14.00	8.00	9.00	14.00	11.00	13.00	11.00	9.00	14.00	14.00														
6	8.00	13.00	14.00	14.00	8.00	14.00	11.00	8.00	9.00	10.00	12.00														
ΣX	68.00	70.00	68.00	65.00	68.00	65.00	69.00	59.00	64.00	68.00	72.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
X̄	11.33	11.67	11.33	10.83	11.33	10.83	11.50	9.83	10.67	11.33	12.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R	6.00	4.00	6.00	6.00	6.00	5.00	4.00	3.00	4.00	5.00	4.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

合计	
ΣX =	736.00
ΣR =	53.00
量测数值的判定条件	
> USL	蓝色
< LSL	红色
N	66
平均	
X̄=	11.21
R̄=	2.12
预估不良率 (PPM)	
	0
制程能力分析	
Std.Dev.=	1.78
Sigma =	0.84
PPK =	1.64
PP =	1.87
Ca =	12.12%
CPK =	3.50
CP =	3.98
Grade =	A

备注及原因追查:

2. 对照 SPC 的异常情况对照表（见下图）：2. Compare the abnormal situation of SPC table (see the figure below):



3. 得出预冷后淋洗液（大肠杆菌）的控制情况：

3. Find the control of the pre-chilling leacheate (E. coli):

3.1 目前预冷前淋洗液控制上限为 12.23，控制下限为 10.19 。3.1 At present, the pre-chilling leacheate control upper limit is 12.23, and the lower limit is 10.19.

3.2 连续 11 天数据过程统计分析显示生产过程控制有效（预估不良率为 0PPM)。The statistical analysis of the data process for 11 consecutive days shows that the production process control is effective (estimated defect rate is 0 PPM).

4. 另外，按照 SPC 管理异常对照图，如果出现以上八种情况，工厂将会采取以下措施：4. In addition, according to the SPC management abnormality comparison chart, if the above eight situations occur, the factory will take the following measures:

4.1 定期对设备进行清洁消毒，包括用来去除污染物或切割胴体的工器具。4.1 Regularly clean and disinfect equipment, including tools and equipment used to remove contaminants or cut carcasses.

4.2 对掏膛等设备进行校准和调整，保证设备在参数内正常工作。4.2 Calibrate and adjust equipment such as evisceration to ensure that the equipment works normally within the parameters.

4.3 要求员工加强清洗双手以及与胴体接触的围裙等小工器具。4.3 Employees are required to strengthen washing their hands and small crafts such as aprons that come into contact with carcasses.

4.4 可以选择进一步的控制措施或者干预措施，如胴体新增的冲洗，消毒或者浸泡等措施。4.4 Further control measures or interventions can be selected, such as additional washing, disinfection or soaking of the carcass.

4.5 进一步修理或者更换设备。4.5 Further repair or replacement of equipment.

4.6 员工培训。4.6 Staff training.