



United States Department of Agriculture

Food Safety and
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Dear Dr. Su Jin Kong,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of the Republic of Korea's inspection system from May 13 through May 29, 2019. Enclosed is a copy of the final audit report. The comments received from the Government of the Republic of Korea are included as an attachment to the report.

Sincerely,

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

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN THE
REPUBLIC OF KOREA

MAY 13 - 29, 2019

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

December 9, 2019

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) from May 13 - 29, 2019. The purpose of the audit was to determine whether the Republic of Korea's food safety inspection system governing processed chicken products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The Republic of Korea currently exports thermally processed/commercially sterile; Ready-to-eat (RTE) fully cooked; and RTE, fully cooked without subsequent exposure to the environment, chicken 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.

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

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

- At all three visited chicken slaughter establishments, hand washing sinks were not within easy reach of government inspectors at post-mortem stations. Government inspectors had to leave the inspection stations, not inspecting each and every carcass, in order to reach hand washing stations. Similarly, the re-inspection racks of suspect chickens were not within easy reach of government inspectors at post-mortem stations. Government inspectors had to leave the inspection stations to place suspect chickens on re-inspection racks.
- The Central Competent Authority's (CCA) periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by official inspection personnel.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the Republic of Korea’s food safety system from May 13 through 29, 2019. The audit began with an entrance meeting held on May 13, 2019 in Seoul, Republic of Korea, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – The Ministry of Food and Drug Safety (MFDS) and the Animal and Plant Quarantine Agency (APQA), under the Ministry of Agriculture, Food, and Rural Affairs (MAFRA). Representatives from the CCA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing processed chicken products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The Republic of Korea is currently eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products¹
Thermally Processed/ Commercially Sterile (TPCS)	Thermally processed/ commercially sterile	Chicken, Duck, Goose, Guinea, Squab, Turkey, Emu, Ostrich, and Rhea
Fully Cooked - Not Shelf Stable	Ready-to-eat (RTE) fully - cooked poultry	Chicken, Duck, Goose, Guinea, Squab, Turkey, Emu, Ostrich, and Rhea
Fully Cooked - Not Shelf Stable	RTE, fully cooked without subsequent exposure to the environment	Chicken, Duck, Goose, Guinea, Squab, Turkey, Emu, Ostrich, and Rhea

The USDA’s Animal and Plant Health Inspection Service (APHIS) recognizes the Republic of Korea as a country affected with highly pathogenic avian influenza (HPAI) subtype H5N1 and exotic Newcastle disease as outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §381.196. Due to these disease restrictions, the Republic of Korea is not eligible to export raw chicken products 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 capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

¹ All source poultry used to produce products must originate from eligible countries and establishments certified to export to the United States.

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, two regional offices, and seven local inspection 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. All seven establishments certified to export to the United States were selected. These included three chicken slaughter establishments and four chicken processing establishments.

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, two government laboratories conducting official microbiological and chemical residue analyses 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	<ul style="list-style-type: none"> MFDS and APQA headquarters, Seoul
	Regional Offices	2	<ul style="list-style-type: none"> Honam Regional Office, Honam Jungbu Regional Office, Incheon
Laboratories		2	<ul style="list-style-type: none"> Jeonbuk Veterinary Laboratory Service (government microbiological and chemical residue testing), Jeonbuk-do Chungcheongnam Veterinary Laboratory Service (government microbiological and chemical residue testing), Chungcheongnam-do
Chicken slaughter establishments		3	<ul style="list-style-type: none"> Establishment M01318001, Maniker, Chungcheongnam-do Establishment K01413007, Charmfre, Jeonbuk-do Establishment K01404001, Harim, Jeollabuk-do
Chicken processing establishments		4	<ul style="list-style-type: none"> Establishment GJA14001, Harim, Jeonbuk-do Establishment GIA15001, Maniker Gyeonggi-do Establishment GJA17002, Charmfre, Jeonbuk-do Establishment PSA17001, Ourhome, Gyeongsangnam-do

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

- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.); and
- The Food Safety and Inspection Service Regulations for Imported Poultry (9 CFR Part 381).

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

III. BACKGROUND

From October 1, 2015 to September 30, 2018, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 1,240,716 pounds of TPCS chicken products and 2,291,993 pounds of fully cooked - not shelf stable RTE chicken products exported by the Republic of Korea to the United States. FSIS also performed re-inspection on 368,805 pounds of RTE fully-cooked chicken products and 118,325 pounds of TPCS chicken products at POE for additional types of inspection, including testing for chemical residues and microbiological pathogens including *Listeria monocytogenes (Lm)* and *Salmonella*, for which no products were rejected for issues related to public health.

FSIS previously conducted an on-site equivalence verification audit in FY 2017. The findings from that audit put South Korea in the highest priority category for public health risk. FSIS has instituted a risk-based approach to prioritize and audit the highest priority category countries within 24 months from when FSIS publishes the last audit report.

The previous audit in 2017 identified the following findings:

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS

- The CCA did not have regulatory requirements for maximum line speed allowed in poultry slaughter establishments.

GOVERNMENT HACCP SYSTEM

- The FSIS auditors identified inadequate government verification of HACCP requirements in seven of the eight audited establishments.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The FSIS auditors identified inadequate government verification over implementation of the laboratory quality assurance system in the chemical residue section of the Jeju Veterinary Laboratory Service.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The FSIS auditors identified inadequate government verification over implementation of the laboratory quality assurance system in the microbiological section of the Jeju Veterinary Laboratory Service.

The FSIS auditors verified that the corrective actions for the previously reported findings were implemented and effective, except for that findings under the government chemical residue and microbiological testing programs components were not verified because the Jeju Veterinary Laboratory Service were no longer being provided to a certified establishment. The sole eligible establishment (GJA17001 Agricultural Corporation Cheonghyeon Co.) certified to export chicken products to the United States and receiving technical support from the Jeju Veterinary Laboratory Service had been delisted on April 24, 2019. The Jeju Veterinary Laboratory Service does not provide any technical support to the seven currently eligible plants certified to export chicken to the United States. However, the corrective actions previously proposed by the CCA were determined to be appropriate.

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

The FSIS final audit reports for the Republic of Korea's food safety inspection system are available on the FSIS website at: <https://www.fsis.usda.gov/foreign-audit-reports>.

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

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

The FSIS auditors verified that there have been no changes to the structure of the government since the last FSIS audit in 2017. The Republic of Korea's poultry inspection system is coordinated between the Ministry of Agriculture, Food, and Rural Affairs (MAFRA) and the Ministry of Food and Drug Safety (MFDS). The Animal and Plant Quarantine Agency (APQA),

an agency under MAFRA supervision, is responsible for conducting inspection activities in all chicken slaughter establishments that are certified for export to the United States. The MFDS is responsible for conducting inspection activities in all chicken processing establishments that are certified for export to the United States.

Currently, there are three slaughter and four processing establishments that are certified to export to the United States. The three certified slaughter establishments supply raw chicken products to the four certified processing establishments.

The regional offices of Jungbu and Honam under the APQA oversee slaughter related inspection activities at the three chicken slaughter establishments (K01413007, K01404001, and M01318001) eligible to export to the United States. The regional offices of Busan, Gyeongin, and Gwangju under the MFDS oversee processing related inspection activities at processing establishments (PSA17001, GIA15001, GJA14001, and GJA17002) eligible to export chicken products to the United States. The FSIS auditors met with the MFDS regional offices officials at each corresponding processing establishment and reviewed documents related to trainings, hiring process, method of payment, and supervisory reviews of inspection personnel assigned at processing establishments eligible to export chicken products to the United States. The FSIS auditors examined the operations of the regional offices at the establishment level.

The regulatory authority of the Republic of Korea's poultry inspection system to operate, conduct inspection verification activities, enforce inspection laws, registration of slaughter and processing establishments, and implement the United States export requirements, stem from the *Livestock Products Sanitary Control (LPSC) Act*, *Prevention of Contagious Animal Disease Act*, *Food Sanitation Act*, *Testing and Inspection on Food and Drugs Act*, and the *Quarantine and Inspection Guidelines for the U.S. Export of Poultry Products* (hereinafter referred to as *Guidelines*). The FSIS auditors' review of these Acts indicated that the CCA has the legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported to the United States.

The MAFRA and the MFDS have the legal authority and responsibility to ensure that adulterated chicken products are not exported to the United States in accordance with the *Livestock Products Sanitary Control Act (LPSCA)*. *Article 33* of the LPSCA defines adulterated products as products that are rotten or decayed, contaminated with potential or real toxic or harmful substance, contaminated with potential or real pathogenic microorganisms, pose a potential risk to human health because they are unhygienic or are products with different substances added or infused, or have passed their expiration date. Misbranded products are defined as products with false exaggerated, slanderous labeling, advertising or exaggerating packaging with regard to names, production methods, ingredients, nutritional value, raw materials, use, quality, and packaging.

The *Guidelines* ensure that laws, regulations, and policies are properly implemented and applied consistently to all establishments that are certified to export to the United States. The *Guidelines* provide instructions to the inspection personnel for verification of establishments' prerequisite programs, HACCP systems, product formulation checks, microbiological and chemical residue sampling and testing, sanitary control procedures, and conducting ante-mortem and post-mortem inspection of chicken products intended for export to the United States.

The APQA veterinarians are titled as Quarantine Officers (QOs). The QOs are responsible for conducting slaughter inspection and quarantine duties in chicken slaughter establishments that are certified for export to the United States. The QOs operate in accordance with the provisions of *Article 30* of the *Prevention of Contagious Animal Disease Act* and *Article 13* of the *LPSC Act*. The MFDS veterinarians are titled as Inspection Officers (IOs). The IOs are responsible for conducting processing inspection duties in chicken processing establishments that are certified for export to the United States. The IOs operate in accordance with the provisions of *Article 13* of the *LPSC Act*.

The FSIS auditors verified, through records review and observation that all inspection personnel including the Assistant Inspectors (AIs) of the Livestock Health Control Association (LHCA), are full time government-paid employees of the national and local government. The LHCA is a public institution established to efficiently execute duties related to chicken sanitation management and responsible for training and management of AIs. According to *Article 9* of the *Prevention of Contagious Animal Disease Act*, the AIs provide assistance in the livestock sanitation and slaughter inspection process.

At the CCA headquarters, regional offices, and local inspection offices of all audited establishments, the FSIS auditors verified that the CCA requires the presence of APQA or MFDS inspection personnel during all hours of operation in all chicken slaughter or chicken processing establishments that are certified to export to the United States. Oversight of the entire production process, from ante-mortem inspection to finished product packaging and distribution, of all chicken products intended for export to the United States is performed by government inspectors.

The FSIS auditors reviewed government inspection personnel training records in animal welfare, ante-mortem inspection, post-mortem inspection, sanitation standard operating procedures (sanitation SOPs), HACCP, and United States export requirements. The FSIS auditors verified that the CCA has organized ongoing and annual training programs for inspection personnel and laboratory personnel, in HACCP requirements, sanitation procedures, sampling methodology, and requirements specific to the United States export as stated in the Republic of Korea's *Guidelines Section 8.1*. The FSIS auditors verified documents that the APQA holds periodic trainings specific to the AIs on the *Guidelines* and the United States export requirements. There were no concerns noted with the training materials or the training records.

The FSIS auditors also verified that the CCA has an official website, "Onnara", to disseminate inspection information including updates related to the United States export requirements. While on-site, the FSIS auditors reviewed documentation showing the educational background of the government quarantine and inspection officers, including their veterinary credentials.

At all visited establishments certified to export chicken to the United States, the FSIS auditors verified that chicken products destined for export to the United States are clearly identified and segregated from those that are not designated for the United States, during all stages of production, storage, and shipment. The FSIS auditors verified that the four processing establishments that are certified for export to the United States only receive raw chicken from the

three slaughter establishments that are certified for export to the United States and that none of these processing establishments received raw chicken product from any other country. Additionally, the chicken slaughter establishments receive live chicken only from within the Republic of Korea. The FSIS auditors reviewed documents related to the movement of raw product from slaughter establishments to processing establishments, and associated application or removal of seals by inspection officials.

The FSIS auditors verified records showing that the issuance of export certificates is in accordance with the Republic of Korea's *Guidelines*. These procedures included securing government seals, maintaining required documentation, stamping, and signing the export certificates by two veterinarians each from APQA and MFDS. At the regional offices and local inspection offices, the FSIS auditors verified records supporting that establishments certified to export to the United States are required to maintain a recall plan procedure. The FSIS auditors reviewed written recall plans at each of the seven visited establishments and verified that the CCA has a mechanism (phone call and electronic mail) to notify FSIS through the United States Embassy if adulterated chicken product has been shipped to the United States.

At the regional offices, the FSIS auditors reviewed records and requirements related to the approval and certification process of chicken establishments that intend to export to the United States. These establishments must operate under a HACCP system pursuant to the CCA's *Guidelines, Section 4, Article 9 of the LPSC Act, and Article 42 of the Prevention of Contagious Animal Disease Act*. Following the submission of an establishment's application to the regional office of MFDS (processing establishments) or APQA (slaughter establishments), the head of the regional office reviews the application and conducts an on-site inspection. The review and on-site inspection are in accordance with the CCA's document "*Evaluation Sheet for Designation and Follow-up, Management of the Establishment for Export to the United States*" Annex 1 of the *Guidelines*.

The regional office's approval of the application relies on the results of submitted document review, on-site audits, and implementation of any applicable corrective actions. If there are no impediments for the business applicant to conduct quarantine and inspection duties and it has satisfied the requirements of the importing country, the regional office designates and registers the business. Accordingly, the regional office notifies the CCA headquarters of the newly certified establishment.

The MFDS is responsible for notifying FSIS of newly approved establishments and of delisting a certified establishment, when it does not meet the CCA's regulatory requirements. The FSIS auditors reviewed documents specifically associated with the approval process of an establishment (M01318001) that was newly certified to export to the United States and the new slaughter facility of a previously approved establishment (K01404001). The FSIS auditors' review indicated that the approval process, designation, and registration of those establishments for export was implemented as intended. The FSIS auditors had no issues or concerns with the review process.

The FSIS auditors reviewed a sample of completed noncompliance records and noted results of daily verification activities documented on the government verification diary as directed in the CCA *Guidelines, Section 7*. The QOs or IOs document noncompliance on *Annex 7* and submit to establishments for immediate corrective action and documents the results of daily verification activities in *Annex 8* for submission to the applicable regional office. The FSIS auditors determined from the document review, that the inspection personnel have implemented the *Guidelines*, adequately described noncompliance, and verified the adequacy and effectiveness of the establishment's corrective actions and preventive measures.

During visits to the government laboratories, the FSIS auditors verified the CCA's ability to coordinate evaluations of laboratory performance, including proficiency testing schemes for analysts and evaluations of the quality controls maintained by laboratory managers. The FSIS auditors verified that the CCA maintains administrative and technical support to operate its laboratory system in accordance with the CCA's *Guidelines*. The FSIS auditors verified that the CCA conducts annual audits to ensure that its laboratory network possesses the personnel, facilities, equipment, and methods necessary to fulfill its mission. The FSIS auditors reviewed the CCA's results of the annual audits for those facilities conducting testing of product destined for the United States.

The FSIS auditors verified that laboratories that test chicken products for United States export are operating pursuant to the standards of International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) 17025, *General requirements for the competence of testing and calibration laboratories*. The Korean *Guidelines* adopt recommendations to meet the ISO/IEC 17025 standards. Under the Korean *Testing and Inspection of Food and Drugs Act*, the MFDS has the authority to designate and certify laboratories for testing food and drugs. The MFDS is the designation body for government laboratories and responsible for conducting their annual audits against the standards laid out in the *Guidelines* to verify conformance with the ISO/IEC 17025 standards. However, the laboratories are not ISO-accredited. Government inspection personnel in establishments certified to export to the United States send samples for analysis to the designated government laboratory within the establishment's respective region.

The FSIS auditors concluded that the Republic of Korea's poultry inspection system continues to organize, administer, and enforce 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 good commercial practices (GCPs) of poultry; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift

inspection during processing operations; periodic supervisory visits to official establishments; and requirements for TPCS products.

The FSIS auditors observed that APQA inspection personnel verify that chickens are slaughtered in accordance with GCPs, including the employment of humane practices of slaughter and handling, in a manner that will result in thorough bleeding of the chicken carcasses and will ensure that breathing has stopped before scalding. Per the *Guidelines*, the CCA requires establishments certified to export to the United States to comply with animal welfare regulations during primary production at the farm (live birds), transport, and slaughter.

The FSIS auditors verified government verification ante-mortem inspection procedures through on-site record reviews, interviews with government personnel, and observations of live chicken inspection at the receiving and holding areas of the establishment. The FSIS auditors verified that the QO stationed at the chicken slaughter establishment implemented verification activities as written in the *Enforcement Rule of Livestock Products Processing Act, Article 9.3, Section B*. The QO verifies that chickens are assigned into groups for ante-mortem inspection and ensures that dead or damaged birds are segregated and disposed. Chickens segregated into a suspect group receive an individual inspection by the QO.

At the regional offices and local inspection offices, the FSIS auditors verified through document reviews and interviews that the CCA provided an appropriate number of the inspection personnel to conduct inspection during the entire shift and for all shifts when chicken are slaughtered, and products processed for export to the United States. The regional offices maintained written procedures in order to provide adequate inspection coverage during vacations, illnesses, or other absences.

The FSIS auditors verified post-mortem inspection examinations through on-site record reviews, interviews, and observations of the inspection personnel performing post-mortem examinations. The FSIS auditors verified that the inspection personnel are following the *Guidelines, Section 9.4 (Annex 13)* that contains instructions and procedures on how inspection personnel are to perform post-mortem inspection in chicken slaughter establishments.

The FSIS auditors verified that chicken slaughter establishments that are certified to deliver source material to certified processing establishments operate under a Streamlined Inspection System (SIS) and adhere to the FSIS slaughter line speeds and the *Guidelines, Section 9.5*, with a maximum of 35 birds per minute per inspector. At the visited slaughter establishments, there were three to four post-mortem inspection stations, which are staffed with one QO and two to three assistant inspectors. According to the *Guidelines*, the QO should check and guide the work of the AIs to ensure the proper implementation of the guidelines and the AI should support the QO in conducting slaughter inspections.

The FSIS auditors observed that the post-mortem inspection stations have shadow-free lighting, receptacles for condemned carcasses and parts, hang back racks, and start/stop switches to stop both carcass and viscera lines simultaneously. However, there was no continuous flow faucet (or other means) to show that the inspectors would be able to wash their hands on an as-needed basis. The FSIS auditors observed the following:

- At all three visited chicken slaughter establishments, hand washing sinks were not within easy reach of government inspectors at post-mortem stations. Government inspectors had to leave the inspection stations, not inspecting each and every carcass, in order to reach hand washing stations. Similarly, the re-inspection racks of suspect chickens were not within easy reach of government inspectors at post-mortem stations. Government inspectors had to leave the inspection stations to place suspect chickens on re-inspection racks. FSIS will be issuing a letter to the CCA requesting immediate corrective actions and a written commitment to ensure government inspectors inspect each and every carcass.

The CCA requires official controls over segregation, removal, and destruction of product that is considered inedible or not fit for human consumption as condemned material. The CCA's general requirements for the disposal of condemned materials are outlined in *Article 19* of the *Enforcement Decree of the Livestock Products Sanitary Control Act*; and *Article 18* of the *LPSC Act*. In addition, the CCA has requirements for application of distinctive markings of condemned containers and maintaining appropriate records of disposed materials. The *Guidelines, Sections 6.4* states that the establishment shall dispose of livestock and livestock products that fail slaughter and product inspection in accordance with *Article 44* of the *Prevention of Contagious Animal Disease Act*.

The FSIS auditors verified that QOs performing fecal contamination inspection on 10 randomly selected chickens per slaughter shift, in accordance with the CCA inspection standards for fecal contamination of poultry carcass *Guidelines, Section 9.6 and Annex 14*. The QO visually verifies identifiable excreta contamination of carcasses at specified locations after the final washing process and before carcasses enter the cooling system during slaughter. The process control procedure specified in the *Guidelines* also addresses corrective actions (reprocessing, investigation of cause, additional CCP check by QOs, suspension of slaughter operations) that should be taken in event of noncompliance with the zero-tolerance policy for fecal contamination in poultry.

The *Guidelines, Section 8* gives MFDS and APQA oversight and supervisory authority to provide training to its inspection personnel and conduct HACCP system assessments. This includes the authority to take enforcement action for inadequacies in the establishments' HACCP systems and sanitation SOPs. The FSIS auditors verified that the regional offices' veterinarians are conducting sanitary inspection at establishments eligible for export to the United States prior to and during operations in accordance with the *Guidelines, Section 7.1 and Annex 5*.

The FSIS auditors verified that a follow-up Quarantine Officer from APQA regional office or an Inspection Officer from MFDS regional office conduct supervisory visits on the establishments eligible for export to the United States twice a year according to the *Guidelines, Section 7.3, and Annex 1 (Evaluation Checklist for Designation and Follow-Up Management of the Establishment for Export)*. The APQA has two types of QOs: routine QOs and follow-up QOs. The checklist is designed to assess the establishments' prerequisite programs, facilities, sanitation procedures, HACCP operations, and sampling and testing procedures. During record reviews of the CCA's supervisory reviews checklists at the regional offices, the FSIS auditors noted the following:

- The CCA periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by official inspection personnel.

During on-site visits to the establishments eligible to export to the United States, the FSIS auditors verified that chicken products intended for export to the United States are identified, properly labeled, and separated from that intended for domestic use, complying with the *Guidelines, Section 6.6*. The CCA's requirements for container specifications and product labeling are cited in *Articles 5, 6, and 16* of the *LPSC Act*. This legislation explicitly states that product that does not meet processing standards and ingredient specifications shall not be stored, transported, or displayed for sale. The FSIS auditors confirmed that the CCA had verified the product packaging labels in accordance with these requirements.

As APHIS considers the Republic of Korea to be affected with HPAI and exotic Newcastle disease, the *Guidelines* require inspection officers to verify that source raw materials originate from certified slaughter establishments before the onset of each production shift that is producing products intended for export to the United States. The certified establishments do not receive any source raw materials from other countries. The FSIS auditors verified that the APQA and MFDS veterinarians ensure that source product is only produced in certified slaughter establishments in the Republic of Korea before signing an export certificate. Export certification are always verified and co-signed by the veterinarians of originating slaughter establishment and the veterinarian at the processing establishment where chicken products intended for export to the United States are processed under the TPCS or fully cooked - not shelf stable HACCP process categories.

This audit indicates that the CCA has legal authority to establish regulatory controls over chicken establishments certified to export to the United States and continues to organize and administer its chicken inspection system in a manner that meets the core requirements for this component. However, deficiencies related to the design of post-mortem inspection stations and supervisory review assessments were noted. During the audit, the CCA committed to provide FSIS with corrective action plans for the finding noted.

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 SOPs to prevent direct product contamination or insanitary conditions.

The *Guidelines* supplement the general requirements for establishments to maintain sanitary conditions and construction outlined in *Enforcement Decree on the Livestock Products Sanitary Control Act* and *Food Sanitation Act* by requiring establishments to develop, implement, and maintain daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination of poultry products. The FSIS auditors verified that QOs and IOs conduct daily verification of sanitation requirements in accordance with the APQA's and MFDS' requirements.

The *Guidelines, Section 6* provides instructions and procedures to QOs and IOs on how to verify compliance with sanitation standards and enforce the provision of the Acts regarding sanitation. *Annex 5* of the *Guidelines, Sanitary Control Checkpoints on an Establishment for Export*, describes inspection personnel's daily schedule for pre-operational and operational sanitation. Responsible QOs and IOs are required to record their inspection results onto that form and to document noncompliance on *Annex 7, Non-Compliance Record*, then report it to the headquarters and the supervising regional office.

The FSIS auditors assessed the adequacy of pre-operational sanitation by observing inspection personnel conducting verification of the establishment's sanitation. The inspection personnel conducted this activity in accordance with the established procedures, including a pre-operational record review of the establishment's monitoring results and an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils; as well as an assessment of sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity). The FSIS auditors verified inspection personnel's ability to identify insanitary conditions and exercise regulatory enforcement control to ensure proper sanitary conditions and operations.

The FSIS auditors also observed government personnel performing on-site verification of operational sanitation conditions. The FSIS auditors correlated their observation with that of government inspection verification records and examined additional documentation of sanitation noncompliance records. The FSIS auditors verified that the government personnel took regulatory control actions sufficient to ensure that sanitary conditions were restored, and product was unadulterated.

The FSIS auditors evaluated official inspection personnel verification of establishment sanitary dressing procedures in slaughter establishments. Official inspection personnel routinely verify establishment sanitary dressing procedures and perform daily verification of zero-tolerance for fecal material. *Section 9, Annex 13, and Annex 14* of the *Guidelines* 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. The FSIS auditors observed and verified records that all slaughter facilities had developed the necessary protocols and maintained records demonstrating a preventive approach in controlling contamination of chicken carcasses with fecal material.

The FSIS auditors' on-site observations and record reviews, including the establishment's sanitation monitoring, corrective action records, inspection verification results or periodic supervisory reviews, showed that inspection personnel were implementing inspection activities and ensuring establishments met requirements.

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 SOPs and the CCA continues to maintain the core requirements of this component.

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.

The CCA requires each establishment that is certified for export to the United States to develop, implement, and maintain a HACCP system. All establishments must apply for the registration of their business to operate and submit a HACCP plan to be approved by the MFDS prior to beginning operations. The MFDS or APQA has the authority to take enforcement actions for noncompliance with the requirements. The *Guidelines, Sections 3.1, 3.3, and 3.5* confirm these requirements to prevent the adulteration of poultry products. *Sections 6.1 to 6.8* further provides instructions to certified export establishments on implementation of HACCP requirements. *Sections 7.1 to 7.8* provides procedures for the QOs and IOs to follow about how to verify and enforce sanitation and HACCP requirements, in accordance with the checklist in *Annex 5, Sanitary Control Checkpoints on an Export Establishment*.

The FSIS auditors verified by observing government personnel conducting verification of the establishment's HACCP plans during each shift in accordance with the CCA's *Guidelines*. The government's inspection verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observation of establishment personnel performing monitoring, verification, corrective actions, and recordkeeping activities. The inspection verification activities also include direct observation or record reviews of critical control points (CCPs) with the results of the verifications entered in the associated inspection records. Additionally, the QOs and IOs from regional offices or headquarters are required to verify the adequacy of the establishment's HACCP system at least twice per year. At each visited establishment, the FSIS auditors reviewed the HACCP plan, monitoring and verification records of all CCPs, preshipment, and export records, and observed actual verification activities conducted by the government inspection personnel.

During on-site visits, the FSIS auditors verified establishment sampling procedures of indicator microorganisms (generic *E. coli*) at the pre-chill and post-chill points in the slaughter process, as stated in the establishment's HACCP system. The FSIS auditors also verified that the CCA requires chicken slaughter establishments to include in their HACCP plan procedures preventing carcasses contaminated with visible fecal material from entering the chiller system and that carcasses be chilled immediately after slaughter operations.

In the chicken processing establishments that produce TPCS or fully cooked - not shelf stable RTE products, the establishments have developed and followed their HACCP plans to address all food safety hazards, including microbiological hazards such as *Lm* and *Salmonella* and toxin-forming pathogens associated with TPCS product. Establishments are utilizing process schedules set out by an experienced quality assurance team and a lead process authority. The FSIS auditors did not have any concerns with the TPCS or RTE HACCP plans.

In the chicken slaughter establishments, the FSIS auditors reviewed the fecal zero-tolerance CCP control records, chlorine concentration CCP records (20-50 PPM), and carcass temperature after chilling CCP (2°C). In addition, the FSIS auditors, together with the inspection personnel, observed the establishments' employees conducting hands-on HACCP monitoring and verification activities for the zero-tolerance, chlorine concentration and carcass temperature CCPs.

The FSIS auditors also verified that the CCA requires each slaughter establishment to submit a protocol for water retention rate. The APQA verifies whether it is compliant with the less than 8 percent water retention limit according to the *LPSC Act, Article 4* and clarified in the *Guidelines, Section 9.8 and Annex 33*. The FSIS auditors verified that two out of the three visited chicken slaughter establishments use air-chiller system to chill carcasses.

The FSIS auditors reviewed the HACCP plans and verification activities at all visited establishments, which included interviews with establishment and inspection personnel and review of the establishments' HACCP records. Establishments maintain supporting documents as part of the decision-making process for their HACCP system.

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, auditors observed at two of the three slaughter establishments visited instances of inadequate recordkeeping to confirm the performance of ongoing verification activities and preshipment reviews for product intended for export to the United States.

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 to present 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 by the exporting country's poultry inspection authorities or by FSIS as potential contaminants.

FSIS' residue experts reviewed the Republic of Korea's 2018 residue program, associated methods of analysis, and additional SRT responses outlining the structure of the Republic of Korea's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit in 2017.

Section 10.1.5 of the Quarantine and Inspection Guidelines for the U.S. Export of Poultry Products of Residue Testing for Poultry Meat for Export to the U.S. (Annex 21), outlines random sample collection of chicken product from each farm at the establishment designated for export to the United States during the shipping or slaughtering process. The QO collects the sample and requests the establishment's coordinator to take appropriate actions for any positive sample results. The *Guidelines* also outlines examples of an investigation into a cause of residues in farms with residue violations which are varied from reasons like non-compliance of a withdrawal

period to administration of unauthorized medicines. It also includes a form to document the results of the investigation.

The FSIS auditors verified that the CCA maintains the legal authority and responsibility to develop and implement an annual national residue control plan (NRCP) in accordance with the CCA's requirements and the *Quarantine and Inspection Guidelines for Residue Testing for Poultry Meat for Export to the U.S., Annex 21*, in order to prevent and control the presence of veterinary drugs residues and chemical contaminants in the tissues of poultry slaughtered for human consumption.

The FSIS auditors visited two of the government service laboratories, which are collectively referred to as the Institutes of Livestock Products Sanitation Inspection (LPSI). The Jeonbuk and Chungcheongnam Veterinary Service Laboratories test residue samples originating from the chicken slaughter establishments eligible to export to the United States. Those laboratories conduct testing of chemical residue samples in accordance with the *Act on Testing and Inspection on the Food and Drugs, Article 6*, and *Guidelines in Annex 21*, utilize methods in the *FSIS Chemical Laboratory Guidebook*, and operate pursuant to ISO/IEC 17025 international standards as outlined in the *Guidelines for Residue Testing Laboratory, Annex 27*.

The FSIS auditors verified that the QOs who collect random residue samples at the chicken slaughter establishments have received training in sampling methodology, handling of samples, identification of animals, traceability, and sample security. The FSIS auditors verified by observation and documentation that inspection personnel are following the NRCP sampling protocol and the *Guidelines in Annex 21*. This protocol includes sampling location, sample size, sampling frequency, and secure delivery of residue samples to the designated LPSI laboratory. Residue results are communicated to the CCA headquarters, regional offices, and inspection personnel through a web-based system.

The FSIS auditors verified through document reviews and interviews that the CCA requires LPSI laboratories to implement a laboratory quality assurance system in accordance with the CCA's *Guidelines, Annex 28*. The FSIS auditors also verified that the MFDS ensures that LPSI laboratories were following laboratory operating procedures in terms of maintaining sample identification and integrity and proper chain of custody per the *Guidelines of Residue Testing for Poultry Meat for Export to the U.S., Annex 21* and the *Guidelines for Residue Testing Laboratory, Annex 27* through its on-site annual audits, proficiency testing, and oversight.

The FSIS auditors interviewed laboratory analysts to assess their technical competency, training records, and knowledge of the analytical methods applicable to the laboratory and each analyst. The FSIS auditors verified the laboratory management documentation systems, adequacy of sample handling, sample traceability, chain of custody, tissue matrix for analysis, timely analyses, accuracy of data reporting, equipment operation and calibration, minimum detection level, and percent recovery. The FSIS auditors verified that QOs and IOs are not permitted to issue any export certificate until the government laboratory provides negative results of the sampled lot.

The result of the on-site audit activities indicate that the Republic of Korea continues to meet the core requirements of this component by maintaining the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in poultry products intended for human consumption.

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 to implement certain sampling and testing programs to ensure that processed chicken products prepared for export to the United States are safe and wholesome. There have not been any POE violations related to this component since the last FSIS audit.

The FSIS auditors verified that the MFDS and APQA maintain oversight of its microbiological laboratory system and conduct testing for the establishments exporting product to the United States as documented in the *Guidelines, Section 11.1.1* and managed the laboratories according to the *Guideline for Microbiological Testing Laboratory (Annex 26)*.

Annexes 16, 17, and 19 of the *Guidelines* address pathogen reduction programs including generic *E. coli* and *Salmonella* testing programs, microbiological test methods for slaughterhouses, sampling methods, and sampling records of chicken intended for export to the United States. In general, *Annex 26, The Guideline for Microbiological Testing Laboratory* requires the microbiological testing laboratory to adhere to the ISO/IEC 17025 standards.

The Republic of Korea submitted to FSIS its 2019 microbiological sampling and testing programs including 2018 test results and reactions to detection results of pathogens of public health concern in RTE chicken product. The Republic of Korea did not include *Campylobacter* test results for raw chicken product in its 2018 microbiological sampling; however, testing for *Campylobacter* is included in their 2019 testing programs. The FSIS auditors verified that testing for *Campylobacter* in raw chicken products intended for export to the United States commenced in February 2019. The testing methods employed by the CCA for microbiological analyses of *Campylobacter* is the FSIS Microbiology Laboratory Guideline (MLG) method 41.04. The CCA is currently applying the United States' published performance standards for carcasses for *Campylobacter* testing (*Annex 18* of the *Guidelines*).

The FSIS auditors verified, through document review, that the CCA requires establishments eligible for export to the United States to meet the *Lm* and *Salmonella* sampling requirements for TPCS and RTE chicken products destined for export to the United States. *Annex 17* of the *Guidelines* describes the sample collection procedures and *Annexes 23* and *24* describe test methods for *Salmonella* and *Lm*, respectively. The FSIS auditors reviewed records of recent test results for products exported to the United States at all processing establishments visited and found no concerns. According to the *Guidelines* and interviews of government personnel, the MFDS Inspection Officer collects 325g of sample to be analyzed for *Salmonella* and 25g to be analyzed for *Lm*. The CCA considers RTE products that test positive for *Lm*, and RTE products

that come into contact with food contact surfaces that have tested positive for *Lm* to be adulterated and takes corrective action in response to a positive sample originating from either an establishment test or a government test. *Annex 24* of the *Guidelines* shows that the CCA uses the FSIS MLG analytical method 8.10 for detection of *Lm*.

The FSIS auditors observed QOs at chicken slaughter establishments collecting samples for *Salmonella* and *Campylobacter* testing in accordance with the CCA's requirements (*Annex 23* of the *Guidelines*), and following proper aseptic techniques, testing frequency, labeling, packaging and shipping to applicable government laboratory with appropriate follow up documentation. The CCA is using the FSIS MLG 4.08, "Isolation and Identification of *Salmonella* from Meat, Poultry, and Egg Products" to test for *Salmonella* spp. in poultry carcasses. The FSIS auditors also verified that government personnel were reviewing official testing results for *Salmonella* and verifying that establishments implement corrective measures when test results do not meet the performance standards. The *Guidelines, Section 10.1.2*, addresses generic *E. coli* sampling procedure for raw chicken in accordance with procedure in *Annex 16*. It specifies that the coordinator of establishment for export shall collect samples during the process just before packaging under the supervision of a QO.

The FSIS auditors verified, through observations, record reviews and interviews, that government IOs assigned at TPCS and RTE chicken processing establishments conduct verification activities to ensure that establishments perform the following: check the temperature records of heat-treatment and sterilization (F₀) values, posting of processes, retort traffic control, initial temperature, heat processing equipment, maintenance records, calibration records, repair, and keeping of production records. The FSIS auditors verified that IOs are routinely available on-site whenever establishments are processing chicken products intended for export to the United States, verifying that processes and documents are in line with HACCP plans and prerequisite programs. The FSIS auditors verified that the CCA requires incubation tests on all TPCS products from which the inspection personnel collect and submit the required samples to the government laboratories for incubation testing in accordance with the CCA's *Guidelines*.

The FSIS auditors visited the microbiological section of the Jeonbuk Veterinary Laboratory Service, which conducts analyses of official microbiological testing of inspection verification samples on TPCS and RTE chicken products. The FSIS auditors observed and verified sample receipt and handling procedures, testing methodology, timely analysis of samples, data reporting, equipment operation, technical training, and intra-lab competencies and had no concerns.

The FSIS auditors also reviewed the most recent annual audit report issued by the MFDS dated July 24, 2018 and noted that the laboratory performs its internal audits according to the CCA's Quality Assurance Manual. The FSIS auditors verified that the inspection personnel are not permitted to issue export certificates until the government laboratory provides negative results for sampled lots. The FSIS auditors' observation of the laboratory processes and review of the laboratory documents including the CCA's annual audit reports and corresponding follow-up reports did not raise any concern.

The result of these on-site audit activities indicate that the Republic of Korea 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 chicken products exported to the United States.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on May 29, 2019, in Seoul, Republic of Korea, with the CCA. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

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

- At all three visited chicken slaughter establishments, hand washing sinks were not within easy reach of government inspectors at post-mortem stations. Government inspectors had to leave the inspection stations, not inspecting each and every carcass, in order to reach hand washing stations. Similarly, the re-inspection racks of suspect chickens were not within easy reach of government inspectors at post-mortem stations. Government inspectors had to leave the inspection stations to place suspect chickens on re-inspection racks.
- The CCA periodic supervisory reviews did not include an assessment of ante-mortem and post-mortem inspection procedures performed by official inspection personnel.

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

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 Maniker F&G Co. LTD 36-2, Baegokdaero 144beon-gil, Ildong-myeon Cheoin-gu Yongin-si, mGyeonggi-do Korea	2. AUDIT DATE 05/14/2019	3. ESTABLISHMENT NO. GIA 15001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Chicken Processing Establishment Number GIA 15001 5.14.2019

38. In cold storage room for raw chickens, FSIS auditors observed one dead fly on the side of one empty crate (no direct product contamination).

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

May 14, 2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Maniker Co. 551 Hwabok-ro Dong-myeon Dongnam-gu Cheonan-si Chungcheongnam-do	2. AUDIT DATE 05/16/2019	3. ESTABLISHMENT NO. M01318001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Chicken Slaughter Establishment Number M01318001 5.16.2019

22. Preshipment review of raw chickens intended for thermal processing on 04/08/19 and 04/10/2019 for export to the United States was not signed or dated appropriately. It was documented and expressed by one vertical line of pen stroke from checklist designated for domestic products.

38. During operational sanitation, FSIS auditors observed next to the loading area of live chickens, a massive accumulation of card boards, empty boxes, metal rods, and tires were discarded/ stored directly on the establishment grounds, creating insanitary conditions and potential harborage of pests.

55. At post-Morten inspection station of chicken carcasses for three inspectors of line speed approximately 6,300 birds per hour (35 birds/ minute/ inspector), FSIS auditors observed that few carcasses were not inspected. This is because inspector walked few steps away from his designated spot on the inspection station to place chicken carcass on back rack for further trimming, or condemn barrel, or wash hands on a side sink. Inspectors did not attempt to stop the inspection line or slow line speed.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

May 16, 2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ourhome Co. Ltd. 134 Eogokgongdan 1-gil Yangsansi Gyeongsangnam-do	2. AUDIT DATE 05/17/2019	3. ESTABLISHMENT NO. PSA17001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Chicken Processing Establishment Number PSA17001 5.17.19

19. The HACCP plan of thermally processing commercially sterile chicken products did not include ongoing verification activities (records review, direct observation, and instruments/ equipment calibration) and their frequencies. However, the establishment's daily HACCP records showed that ongoing verification requirements (records review, direct observation, and instruments/ equipment calibration) were performed and documented.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

May 17, 2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Charmfire Co., Ltd. 32-29 Okeyo-gil Haengan-myeon, Buan-gun, Jeonbuk-do	2. AUDIT DATE 05/20/2019	3. ESTABLISHMENT NO. K01413007	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Chicken Slaughter Establishment Number K01413007 5.20.2019

10. During pre-operational sanitation, FSIS auditors observed fat particles, blood and feathers on numerous food-contact and non- food-contact surfaces of equipment and facility (carcass softener, fan guards on overhead cooling units, shackle rail, water pipes, I-beam near scalding tank, walls, above eviscerator, door jamb from air chiller to Post Mortem room) from the previous day's production.

22. In March and April 2019, the establishment did not perform preshipment review of records on the eight exports to the United States.

38. During operation, on the outside premises, FSIS auditors observed tall grass, and a heavy accumulation of used cardboards, white plastic containers, used tires and other electric wires. This could be a breeding ground and harborage of rodents.

45. About seven insulation pipes at the scalding tank were in advanced disrepair.

55. The online hand-rinsing sink was not within easy reach of the Government inspector and inspector helper.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

May 20, 2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Charmfire CO, Ltd. 32-29 Okyeo-gil Haengan-myeon Buan-gun, Jeonbuk-do	2. AUDIT DATE 05/21/2019	3. ESTABLISHMENT NO. GJA17002	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Chicken Processing Establishment Number GJA17002 5.21.2019

16. The ongoing verification activities were not listed in establishment HACCP plan.

19. The FSIS auditors observed that the HACCP records for products intended for export to the United States did not include the time of ongoing verification (direct observation, record review, and calibration of monitoring device) on 4/22 and 4/23/2019.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

May 21, 2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Harim Corporation 14 Mangsung-ro Mangsung-myun Iksan, Jeonbuk	2. AUDIT DATE 05/23/2019	3. ESTABLISHMENT NO. K01404001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.	X	35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Chicken Slaughter Establishment K01404001 5.23.2019

9. The SSOP program was not signed by an establishment official with overall authority.

19. The establishment HACCP plan does not list the ongoing verification activities (direct observation, record review, and instrument calibration) and their frequencies.

22. The FSIS auditors found that the establishment does not generate records showing that preshipment reviews have been performed on product exported to the United States.

55. Start/stop switch and hand-rinsing sink at the post-mortem inspection station was not located within easy reach of government inspectors.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

May 23, 2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Harim Corporation 14 Mangsung-ro Mangsung-myun Iksan, Jeonbuk	2. AUDIT DATE 05/24/2019	3. ESTABLISHMENT NO. GJA14001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
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26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Chicken Processing Establishment Number GJA14001 5.24.2019

38. During operational sanitation, auditors observed dead cockroach at the exit of air shower cabinet leading to the processing department.

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

May 24, 2019

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

To : Michelle Catlin, PhD

International Coordination Executive
Office of International Coordination

Food Safety and Inspection Service
1400 Independence Avenue, SW.
Washington, D.C.20250

Date: Nov. 29. 2019

Dear Dr. Michelle Catlin,

The Korean Ministry of Food and Drug Safety would like to express our gratitude for notifying us dated October 7 with results the audit conducted against Korean export establishments from 13 to 29 May 2019. Referring to the recommendations made by the FSIS auditors in the results, applicable government agencies and export establishments have taken required corrective actions and two competent authorities, APQA and MFDS, have visited the establishments in person and verified their documents with corrective actions. For your reference, the verification report is attached. We believe that it will fully satisfy requirements of the FSIS.

In addition, MFDS has sent on official letter with 4 inquires in regard to the export of Korean poultry meat to the US on 31 May 2019.

The summary of our inquiries are like following:

1. Feasibility of Exporting Sliced Smoked Duck and Sausages to the US
2. Feasibility of Exporting Frozen Products of Charmfre Co. Ltd.
3. Feasibility of Exporting Peeled and Processed Quail Eggs.
4. Regarding the Register for Microbiological Testing of Campylobacter in the Quarantine and Inspection Guidelines for U.S. Export of Poultry Products.

Please kindly review them and provide us with relevant answers.

In the years to come, the Korean government will keep exerting all our efforts for the safety control of livestock products. If you need any cooperation of ours, please feel free to contact us.

Thank you.

Osong Health Technology Administration Complex
187 Osongsaengmyeong2(i)-ro, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, 28159
Republic of Korea



Yours Sincerely,

SHIN YONG JOO

Director

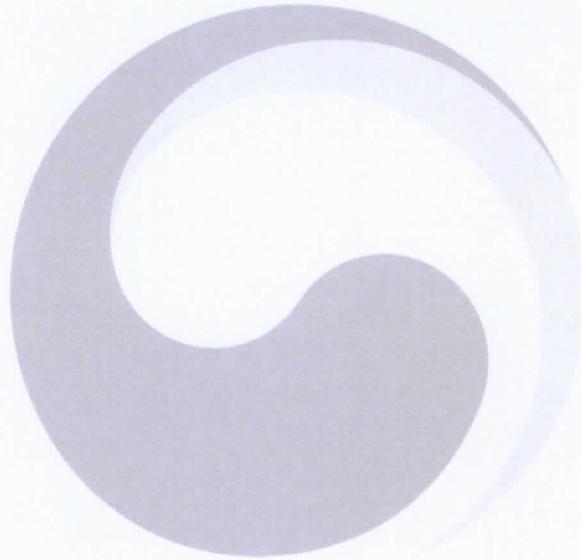
On-site Inspection Division

Imported Food Safety Policy Bureau

Ministry of Food and Drug Safety

Republic of Korea

SHIN Yong Joo



MINISTRY OF FOOD & DRUG SAFETY

To: U.S. Embassy

Subject: Submission of Corrective Action Result for “Onsite Audit of Samgyetang Establishments” for Export to the United States

1. This is related to the letter from the U.S. Food Safety Inspection Service (FSIS), dated October 1, 2019.
2. We hereby provide you the attached result of corrective action for “Onsite Audit of Samgyetang Establishments” for Export to the United States. We request you to convey these documents to the relevant agencies (FSIS/USDA) in the United States.

Attachment:

1. Relevant letter
2. Corrective Action Result /End/

MINISTER OF FOOD & DRUG SAFETY /Sealed/

Approved on December 2, 2019

Assistant Director: Ji Yeon OH / Deputy Director of Int’l Coop. Div.: Hyeon Kyoung KIM

Document: International Cooperation Division-9558 (December 2, 2019)

Tel: 043-719-1570 / Fax: 043-719-1550 / lotus555@korea.kr / Not for public release

Corrective Actions Taken in Response to the FSIS Audit Report

1 Government's supervisory system for ante-mortem and post-mortem inspections personnel

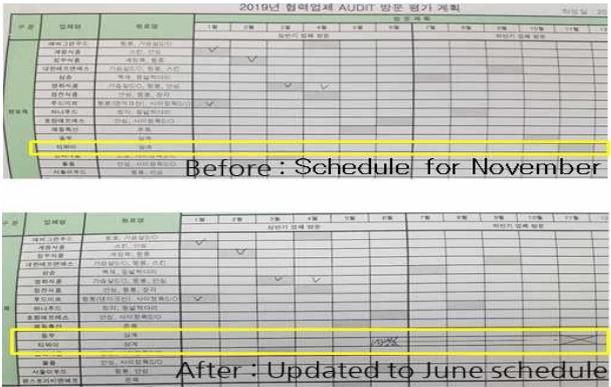
- The periodic supervisory reviews of the Central Competent Authority (CCA) did not include an assessment of ante-mortem and post-mortem inspection procedures performed by official inspection assistants.
- The CCA will newly include the checklist for the assessment of ante-mortem and post-mortem inspection procedures performed in the slaughter establishments for export in the 'Quarantine and Inspection Guidelines for the U.S. Export of Poultry Products'. This regulation has been established by the CCA to provide the sanitary control guidelines on the poultry products for export to the United States. The revised guidelines draft will be provided to the FSIS of the United States.

2 FSIS Comments Made on the Individual Establishments for Export

Maniker F&G Co. LTD (Processing Establishment, GIA15001)

Dead pests (flies) were spotted on the empty crates in the cold storage room for raw chickens.

- Pests monitoring and prevention activities are being thoroughly carried out.

Finding	Corrective Action
	
<p>Dead harmful pests were spotted on the empty crates in the raw material storage. (the dead pests were believed to have been entered in from the slaughterhouse)</p>	<p>Monitoring and prevention activities against pests are being thoroughly carried out.</p>
<p>Preventive Actions against Pests</p>	
	
<p>Inspection for the slaughterhouse concerned (subcontractor) was carried out in July ahead from previously scheduled November.</p>	<p>Air gun is used to remove foreign substances on the surface of each raw material packaging box when raw materials are received.</p>



(Before) There was a air curtain inside the warehousing deck, but very weak.
(wind speed 9.7 m/s)



(After) The special industrial air curtain is installed outside the warehousing deck.
(wind speed ≥ 28 m/s)

□ **Maniker Co. LTD** (Slaughter Establishment, M1318001)

- Pre-shipment document for raw chickens was not signed or dated appropriately. The signature was made inappropriately by inserting one vertical line of pen stroke on the checklist of products for domestic use.
- The log format for pre-shipment review has been now changed and the separation was made between the products for export and domestic use.

Finding		Corrective Action	
		<p>No separation was made between the products for export and domestic use in the pre-shipment review log. The signatures of the responsible persons for each item were not made clearly.</p>	<p>The log format has been changed. (separation is made between the products for export and domestic use) The responsible persons for each item inserted their signatures clearly.</p>

- It was observed that next to the loading area of live chickens, a massive accumulation of the waste (such as card boards, empty boxes, metal rods and tires) was discarded directly on the ground, creating insanitary conditions and a potential harborage of pests.
- The waste is loaded on the palettes to prevent it from directly contacting with the ground.

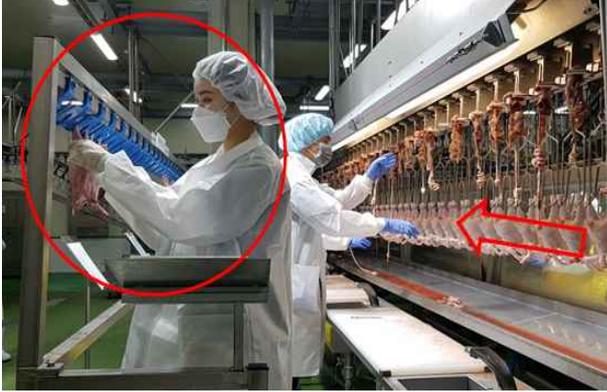
Finding		Corrective Action	
			

The waste was discarded directly on the ground, creating a potential harborage of pests.

The waste must be stored on plastic pallets.

○ It was observed that a few carcasses were not inspected while the inspector was hanging a noncompliant carcass to the shackle rack, discarding a whole carcass to a waste container, or washing his/her hands during the inspection at a post-mortem inspection station. However, the inspector did not attempt to stop the inspection line or slow the line speed.

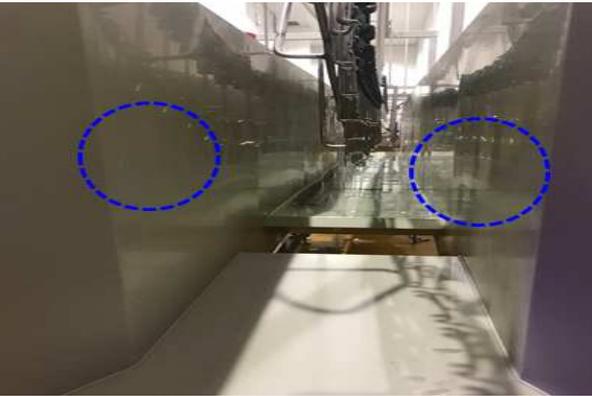
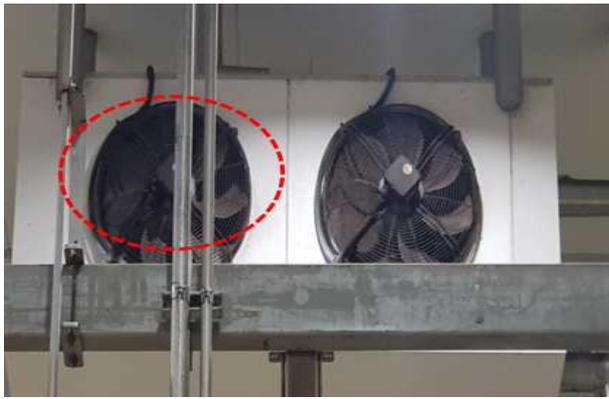
- Inspection assistants are placed and inspection positions are adjusted.

Finding	Corrective Action
	
-	The same number of sub-assistants who can support inspectors and inspection assistants is placed to carry over rejected objects so that no chicken carcasses are missing from inspection. The locations of inspection for the inspectors moved near to the sink.

□ **Charmfre Co. LTD** (Slaughter Establishment, K01413007)

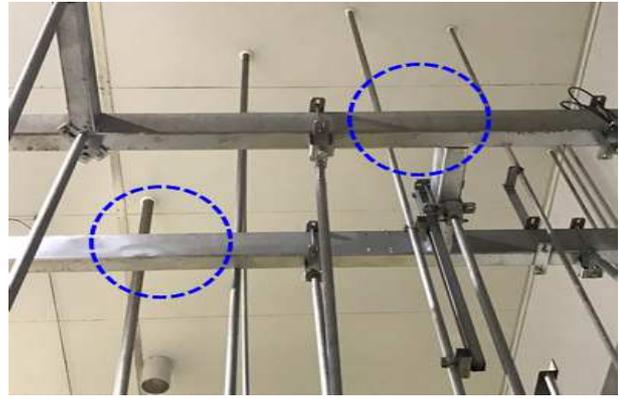
○ During the pre-operational sanitation inspection, the poor sanitary condition was pointed out. Fat particles, blood and feathers were observed on the surfaces of equipment and facility in the establishment.

- Foreign substances in the electric shock water tank were removed.

Finding	Corrective Action
	
<p>Insufficient cleaning on the carcass softener.</p>	<p>The foreign substances on the carcass softener were removed.</p>
	
<p>Insufficient cleaning for the cooling units.</p>	<p>The foreign substances on the cooling units were removed.</p>
	
<p>Insufficient cleaning for the shackle rail in the sorting and packaging room.</p>	<p>The foreign substances on the shackle rail was removed.</p>



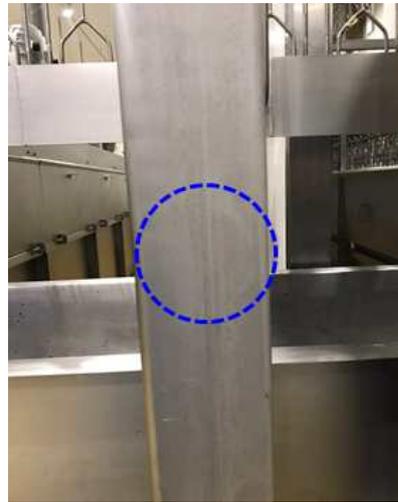
Insufficient cleaning on the water pipes.



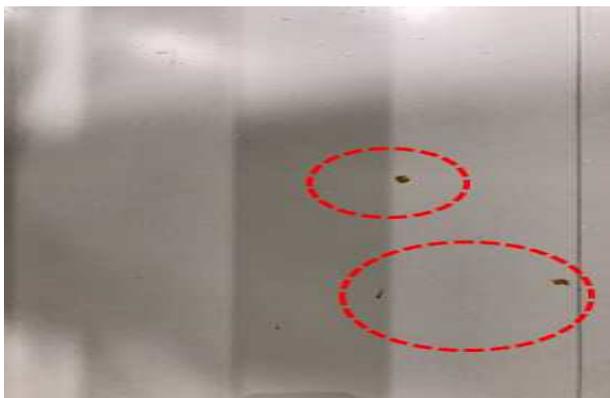
The foreign substances on the water pipes were removed.



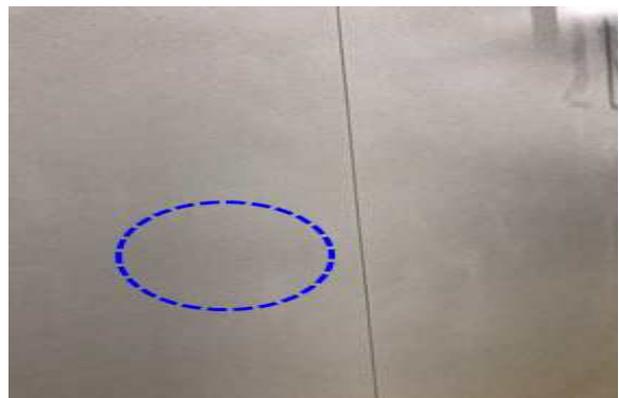
Insufficient cleaning on the I-beam near the scalding machine.



Fat particles, blood and feathers on the I-beam were removed.



Insufficient cleaning on the wall near the machine for evisceration.



The foreign substances on the wall were removed.

<p>Insufficient cleaning for the upper part of the machine for evisceration.</p>	<p>The foreign substances on the upper part of the machine were removed.</p>
<p>Insufficient cleaning for the door jamb between the air chiller and the post-mortem inspection room.</p>	<p>The foreign substances on the door jamb were removed.</p>

- In March and April 2019, the establishment did not have pre-shipment review records on the eight exports to the United States.
- A pre-shipment review checklist sheet was documented and maintained when shipping raw chicken meat for export to the processing establishments. And the form of the test management standard was revised accordingly.

Finding	Corrective Action
-	
<p>It was required to prepare and maintain a pre-shipment review checklist sheet when shipping raw chicken meat for export to the processing establishments.</p>	<p>The pre-shipment review checklist sheet was documented and maintained when shipping raw chicken. The form of the test management standard was revised accordingly.</p>

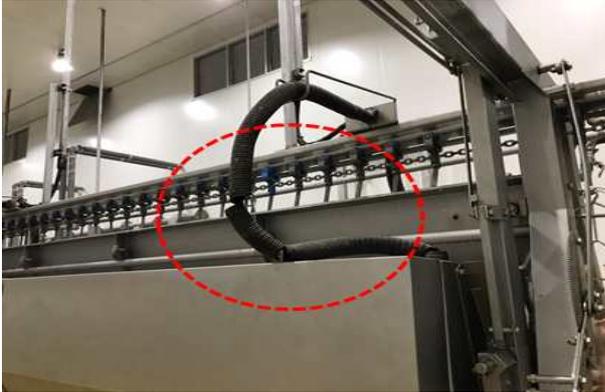
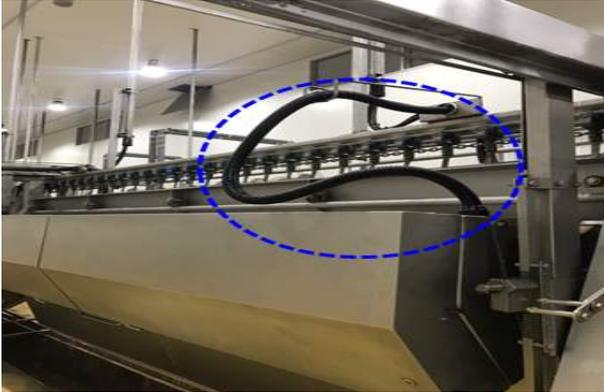
○ It was observed that on the outside of premise, tall grass was abandoned and a large amount of wastes (such as cardboards, white plastic containers, used tires and electric wires) was stored directly on the ground. This could be a habitat or a harborage of rodents.

- The wastes are now stored without direct contact with the ground of the waste disposal station.

Finding	Corrective Action
	
<p>The wastes such as plastic containers and electric wires in the waste disposal station were needed to be stored in a manner without direct contact with the ground surface.</p>	<p>The wastes are now stored without direct contact with the ground.</p>

○ About seven insulation pipes above the feathering machine were damaged.

- The electric line piping of the feathering machine was replaced.

Finding	Corrective Action
	
<p>The electric line piping of the feathering machine was ripped and the cleaning condition of the piping was poor.</p>	<p>The electric line piping of the feathering machine was replaced.</p>

○ The sink and the re-inspection work bench were not within easy reach from the work area of the inspectors.

- The sink was additionally installed near to the post-mortem inspection work bench.

Finding	Corrective Action
	
<p>It was required to change the structure of the sink near to the post-mortem inspection work bench.</p>	<p>The sink was additionally installed near to the post-mortem inspection work bench.</p>

□ Charmfre Co. LTD (Processing Establishment, GJA17002)

- The sanitary control checklist sheet did not include the signature of checker and the time a verifier conducts verification and his/her signature.
- The checklist sheet was revised. And all the relevant signatures of and time the verification is made by responsible persons were inserted before/during the operation.

Finding	Corrective Action																																																																								
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- The ongoing verification activities were not specified in the HACCP plan.
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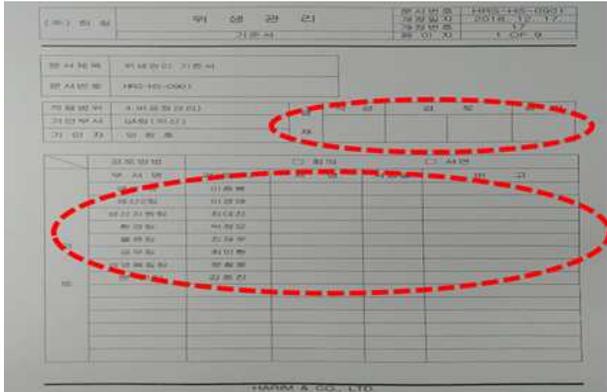
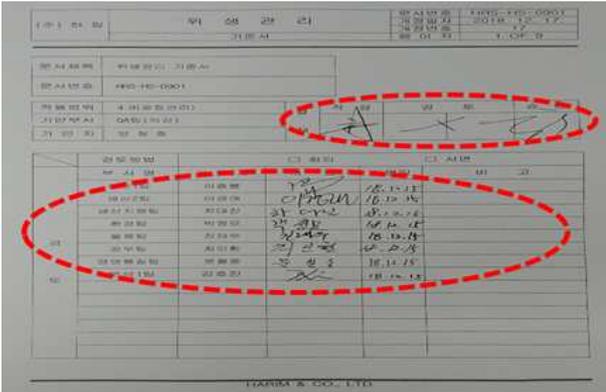
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위험요소	말근세균, 대장균군, 살모넬라																																				
관리요령	말근세균의 102CFU/g 이하로 유지하기 위해																																				
관리기준	1. CCP-03 모니터링 기록 확인 2. 컨트롤리스트 작성/검정 여부 확인																																				
관리방법	1. CCP-03 모니터링 기록 확인(1회/일) 품질관리팀 담당자는 모니터링 기록을 기록하고 있는지 확인. 2. 컨트롤리스트 작성/검정 여부 확인(1회/일) 품질관리팀 담당자는 기록시 해당 컨트롤리스트의 작성/검정 여부를 확인한다. 3. 재검증(1회/일) 재검증에 대한 이상을 감지(1회/일)를 통한 관련 점검을 확인. 4. 말근(1회/일) 확인(1회/일) 품질관리팀 담당자는 1, 2, 3을 통해 100이상 초과하여 컨트롤리스트를 작성한다.																																				
기록 및 보관	CCP-03 모니터링 기록 / 전체를 담겨있는 / 2019년 1월 27일 / 품질관리팀 / 말근세균 기록 / 1년																																				
HACCP PLAN																																					
제조공정	말근 공정																																				
CCP번호	CCP-03																																				
위해요소	세균																																				
위험요소	말근세균, 대장균군, 살모넬라																																				
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관리기준	1. CCP-03 모니터링 기록 확인 2. CCP-03 모니터링 기록의 정확성, 정확성에 대한 검증 확인 3. 컨트롤리스트 작성/검정 여부 확인 및 컨트롤리스트 작성/검정 여부 확인																																				
관리방법	1. CCP-03 모니터링 기록 확인(1회/일) 품질관리팀 담당자는 모니터링 기록을 기록하고 있는지 확인. 2. 컨트롤리스트 작성/검정 여부 확인(1회/일) 품질관리팀 담당자는 기록시 해당 컨트롤리스트의 작성/검정 여부를 확인한다. 3. 재검증(1회/일) 재검증에 대한 이상을 감지(1회/일)를 통한 관련 점검을 확인. 4. 말근(1회/일) 확인(1회/일) 품질관리팀 담당자는 1, 2, 3을 통해 100이상 초과하여 컨트롤리스트를 작성한다. 5. 검증(1회/일) 모니터링 담당자는 ccp성능(기록)에 대한 검증 건 검증결과에 대해 대응 여부를 확인한다. (방법: ccp성능(기록)에 대한 검증 건 검증결과에 대해 대응 여부를 확인한다)																																				
기록 및 보관	CCP-03 모니터링 기록 / 전체를 담겨있는 / 2019년 1월 27일 / 품질관리팀 / 말근세균 기록 / 1년																																				

<p>Implementation of verification, test and calibration was not fully specified in the verification methods of the HACCP plan.</p> <ul style="list-style-type: none"> - The sentence that indicates on-site verification on the implementation conducted by the monitoring personnel was not included. - The sentence that indicates test and calibration to confirm the normal operation of retort machine was not included. 	<p>Verification, test and calibration, and measures taken are added to the verification methods of the HACCP plan.</p> <ul style="list-style-type: none"> - The sentence that indicates on-site verification (once a day) on the implementation conducted by the monitoring personnel was included. - The sentence that indicates test and calibration (once in every six month) to confirm the normal operation of retort machine was included.
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□ **Harim Corporation** (Slaughter Establishment, K01404001)

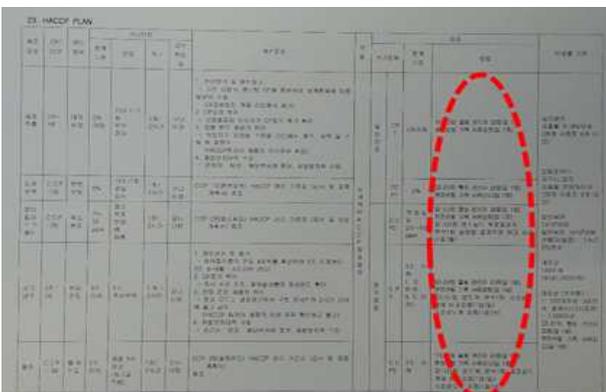
○ The SSOP program was not signed by the quarantine officials with overall authority over the establishment.

- The signatures of the relevant personnel were inserted in the SSOP standard.

Finding	Corrective Action
	
<p>- Improvement of the signature practice on the SSOP standard was needed.</p> <p>- The management of handwriting signatures was required.</p> <p>(HACCP Standard is approved by handwriting signature; SSOP standard is processed with the uniformed electronic approval system)</p>	<p>The signature practice on the SSOP standard was introduced.</p> <p>Handwriting signature approval system for all the standards was enforced.</p>

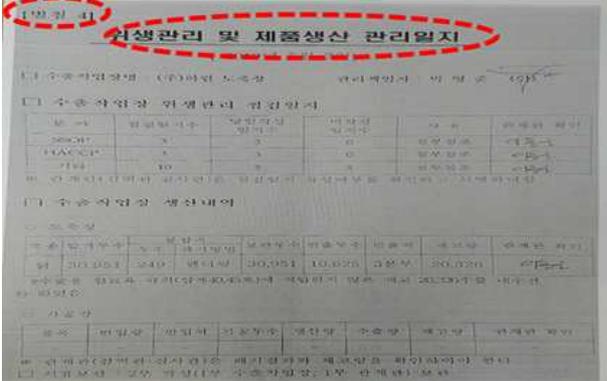
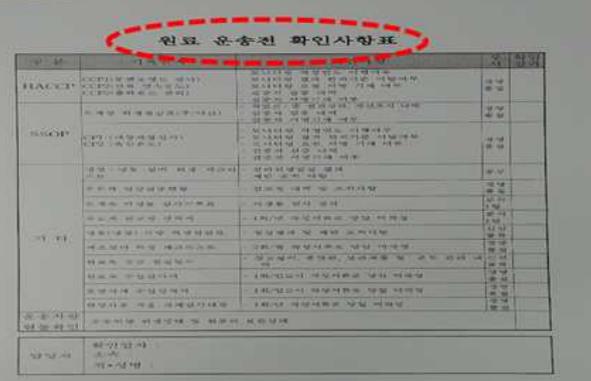
○ The methods of verification (direct observation, record review, and instrument test and calibration) and the frequencies thereof were not included in the HACCP plan.

- The HACCP plan document was updated and applied accordingly.

Finding	Corrective Action
	
<p>The HACCP plan document was needed to be updated.</p> <p>It did not specify the verification methods (monitoring activities and verification),</p>	<p>The HACCP plan document was updated and applied accordingly.</p> <p>It clearly specifies about the verification methods (direct observation, document review, and test</p>

<p>verification frequency, and test and calibration clearly.</p>	<p>calibration); verification frequency and contents of test and calibration (once a day for CCP; once a day for thermometer verification).</p>
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- The establishment did not keep the records related to the pre-shipment reviews on the raw chickens for the products exported to the United States.
- The checklist sheet for the pre-shipment reviews was applied and documented.

Finding	Corrective Action
	
<ul style="list-style-type: none"> - Required to update the pre-shipment checklist sheet for raw chickens shipped to the processing establishments. - Used the government form (log). 	<ul style="list-style-type: none"> - The checklist sheet for the pre-shipment reviews was prepared. - Harim's own checklist sheet was developed. (you should record that no issues occurred when storing and shipping carcasses and products in the sheet)

- Start/stop switch and sink at the post-mortem inspection station were not located within easy reach of the inspectors.
- The facilities for the line 6 post-mortem inspection station were improved to address the above-mentioned issue.

Finding	Corrective Action
	

<ul style="list-style-type: none">- Required to improve the facilities of the line 6 post-mortem inspection station.- The inspector had to move when he/she needs to stop the line or wash his/her hands.	<ul style="list-style-type: none">- Facilities such as start/stop switch and sink for the line 6 post-mortem inspection station were improved to address the issues concerned. (Wire start/stop switch is used so that the inspector can stop the line by pulling it; the sink was moved next to the inspector)
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□ **Harim Corporation** (Processing Establishment, GJA14001)

○ A dead cockroach was observed at the exit of air shower cabinet.

- Cleaning and disinfection was carried out; after identifying the entering-in route, the preventive measures were taken.

Finding	Corrective Action
	
<p>A dead cockroach was spotted on the air shower cabinet.</p>	<p>After cleaning and disinfecting, insect repellent facilities were improved; preventive actions were taken.</p>
Preventive Actions	
	
<p>Cleaning and disinfecting after separating the air shower units.</p>	<p>Check the presence of any gaps in air shower unit. (No gap was identified)</p>
	
<p>Operate the walking pest traps around air shower units. (in front of heat-dissipating door and air shower)</p>	

조치내역 및 향후 서비스 계획	<p>1)5월24일 상계당 일구 에어샤워기 확인된 해충은 일본바퀴벌레 확인되었으며 일본바퀴벌레 육외에서 주로 서식하며 숲속, 토양, 하수관을 선호하는 종으로 공장내부로 연결되는 배수구를 통해 내부로 침입하는 바퀴벌레. 에어샤워기 주변 및 전체 생산라인으로 바퀴 발생유무 점검 실시함.</p> <p>2)에어샤워기 주위 일본바퀴 사제 목적에 따른 공장 내외부 시설점검을 통한 해충 침입을 사전에 파악하여 바퀴 침입이 없도록 관리하겠습니다.</p> <p>3)생산라인 주위 기타보행해충 발생이 목격되고 있는 상황으로 위생, 시설관리가 철저히 이뤄져야하며 차후 이부분에 대해 관심을 가지고 관리하도록 하겠습니다.</p>
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- Entering-in routes were investigated by a pest control company (CESCO)
 - The pest in the picture is Japanese cockroach.
 - Japanese cockroaches inhabit in the forest, soil, and sewer pipes, etc. outside the factory.
 - It was judged that they entered into the factory through the drainage or the external moving passage.

- Measures taken
 - The overall pest control was performed in the internal/external areas of the factory (by CESCO).
 - Cleaning drains once a day and disinfecting once a week → Continued management to catch other walking pests.
 - Disinfection around the outer wall of building and the drainage was perform (once a month).