



United States Department of Agriculture

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Food Safety and
Inspection Service

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Dr. Su Jin Kong
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Dear Dr. Jin Kong,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of the Republic of Korea's inspection system August 16–September 7, 2022. 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 OF THE
REPUBLIC OF KOREA
AUGUST 16 TO SEPTEMBER 7, 2022

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

February 14, 2023

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of the Republic of Korea conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from August 16 to September 7, 2022. The purpose of the audit was to verify whether the Republic of Korea's food safety inspection system governing processed poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. The Republic of Korea currently exports Thermally Processed - Commercially Sterile and Fully Cooked - Not Shelf Stable poultry products to the United States.

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

An analysis of the audit 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 OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The Ministry of Food and Drug Safety (MFDS), the Central Competent Authority (CCA) with oversight of official laboratories, has a provision that allows official samples with violative chemical residue test results to be retested and has not provided written procedures to ensure that products that are retested cannot be exported to the United States.

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

- The Animal and Plant Quarantine Agency (APQA), the CCA with oversight of slaughter establishments, has not provided adequate controls to ensure that chicken feet from corresponding condemned carcasses are excluded from being used in the production of chicken broth as an ingredient used in products intended for export to the United States.

An exit meeting was held September 7, 2022, by videoconference with representatives from MFDS and APQA. During the exit meeting, MFDS and APQA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of MFDS and APQA documentation of proposed corrective actions once received 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 U.S. Department of Agriculture (USDA) conducted an onsite audit of the Republic of Korea’s food safety inspection system from August 16 to September 7, 2022. The audit began with an entrance meeting held August 16, 2022, in Seoul, Korea, to discuss the audit objective, scope, and methodology. The participants included inspection officials from the Ministry of Agriculture, Food, and Rural Affairs (MAFRA), the Ministry of Food and Drug Safety (MFDS), the Animal and Plant Quarantine Agency (APQA), and representatives from the USDA’s Foreign Agricultural Service (FAS). The FSIS auditors were accompanied by representatives from MFDS, APQA, and FAS throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference on September 7, 2022.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products¹
Thermally Processed - Commercially Sterile	Thermally Processed - Commercially Sterile (TPCS)	Chicken and Duck - All Products Eligible
Fully Cooked - Not Shelf Stable	Ready to Eat (RTE) Fully Cooked Poultry	Chicken and Duck - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Poultry Fully Cooked Without Subsequent Exposure to the Environment	Chicken and Duck - All Products Eligible

The USDA’s Animal and Plant Health Inspection Service recognizes the Republic of Korea as affected with highly pathogenic avian influenza and exotic Newcastle disease.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed the Republic of Korea’s Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify whether the Republic of Korea’s food safety inspection system governing processed poultry products is being implemented as documented in the country’s SRT responses and supporting documentation.

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

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

offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a 3-year period, in addition to information obtained directly from APQA and MFDS through the SRT.

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

The FSIS auditors reviewed administrative functions at APQA and MFDS headquarters, three regional offices, and seven local inspection offices within the establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditors visited three poultry slaughter establishments that provide raw source materials to the certified processing establishments and four poultry processing establishments currently certified as eligible to export poultry products to the United States. During the establishment visits, the FSIS auditors paid particular attention to the how industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed APQA and MFDS' ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 381.196.

The FSIS auditors also visited one government microbiological and one government chemical residue laboratory to verify that these laboratories can 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	3	<ul style="list-style-type: none"> Gyeonggi Regional Office, Gwacheon Honam Regional Office, Gunsan Seoul Regional Office, Seoul
Laboratories		2	<ul style="list-style-type: none"> Chungcheongnam Veterinary Laboratory Service, Hongseong North Veterinary Services Laboratory of Gyeonggi Province, Gwacheon
Poultry slaughter establishments		3	<ul style="list-style-type: none"> Establishment K01404001, Harim Corporation, Jeollabuk-do Establishment K01413007, Charmfre Co., Ltd., Jeollabuk-do Establishment M01318001, Maniker Co., Ltd., Chungcheongnam-do

Competent Authority Visits	#	Locations
Poultry processing establishments	4	<ul style="list-style-type: none"> • Establishment GIA15001, Maniker F&G Co. Ltd., Gyeonggi-do • Establishment GJA14001, Harim Corporation, Jeollabuk-do • Establishment GJA17002, Charmfre Co., Ltd., Jeollabuk-do • Establishment SRA200001, Jungdawn Jayeonilga #A Co., Ltd., Gyeonggi-do

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

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

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

III. BACKGROUND

From July 1, 2019, to June 30, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,253,654 pounds of TPCS poultry products and 4,799,726 pounds of Fully Cooked - Not Shelf Stable poultry products exported from the Republic of Korea to the United States. FSIS also performed reinspection on 240,087 pounds of TPCS poultry products and 546,535 pounds of Fully Cooked - Not Shelf Stable poultry products at POE for additional types of inspection, including testing for chemical residues and microbiological pathogens in RTE products (e.g., *Listeria monocytogenes (Lm)* and *Salmonella*), for which no products were rejected for issues related to public health.

The previous audit in May 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of the Republic of Korea
<p data-bbox="201 1572 1386 1673">Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, and Product Standards and Labeling)</p> <ul style="list-style-type: none"> • The Central Competent Authority’s (CCA’s) periodic supervisory review did not include an assessment of ante-mortem and post-mortem inspection procedures performed by government inspectors. • Hand washing sinks were not within easy reach of government inspectors at post-mortem stations.

- FSIS auditors observed some carcasses were not inspected because the inspector was busy hanging back unwholesome carcasses and washing his hands at a distant sink without stopping the line. No inspector helper was assigned to the post-mortem station.
- The start/stop switch at the post-mortem inspection station was not located within easy reach of government inspectors, as required by CCA’s quarantine and inspection guidelines.

During the current audit, the FSIS auditors verified that the corrective actions for the above findings reported in 2019 were implemented and effective in resolving the findings.

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

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

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

The FSIS auditors verified that there had been no major changes to the structure of the Republic of Korea’s poultry inspection system since the previous FSIS audit in 2019. The Republic of Korea’s poultry inspection system is organized by the national government and operates at the national, regional, district and local levels. At the national level, the Republic of Korea’s poultry inspection system is divided between MAFRA and MFDS. APQA, an agency under MAFRA’s supervision, is the CCA responsible for conducting inspection activities in certified poultry slaughter establishments. APQA’s inspection personnel oversee the proper application of legislation, technical guidelines, and instructions for the implementation of poultry slaughter requirements and official controls at its regional, district, and local level offices. MFDS is the CCA responsible for conducting inspection activities in certified poultry processing establishments. MFDS’ inspection personnel oversee the proper application of legislation, technical guidelines, and instructions for the implementation of poultry processing requirements and official controls at its regional and local level offices.

APQA has two regional offices (Honam and Jungbu) and one district office (Cheonan) that oversee poultry slaughter related inspection activities at the three certified slaughter establishments. MFDS has three regional offices (Gwangju, Gyengju, and Seoul,) that oversee poultry processing related inspection activities at the four certified processing establishments.

At the local level, APQA veterinarians are titled as Quarantine Officers (QOs). The QOs are responsible for conducting slaughter inspection and quarantine duties at certified poultry slaughter establishments. The QOs operate in accordance with the provisions of Article 30 of the Prevention of Contagious Animal Disease Act and Article 13 of the Livestock Products Sanitary

Control (LPSC) Act. The QOs are supported by Assistant Inspectors (AIs) of the Livestock Health Control Association (LHCA) who conduct slaughter inspection duties in accordance with the provisions of Article 14 of the LPSC Act. The LHCA is a public institution established to efficiently execute duties related to poultry sanitation management and responsible for training and management of AIs. The MFDS veterinarians are titled as Inspection Officers (IOs). The IOs are responsible for conducting processing inspection duties in certified poultry processing establishments. The IOs operate in accordance with the provisions of Article 13 of the LPSC Act.

The FSIS auditors verified that all inspection personnel including QOs, IOs, and AIs are government-paid employees of the national or local government. The FSIS auditors reviewed government inspection personnel educational credentials and training records concerning good commercial practices (GCPs) and animal welfare, ante-mortem inspection, post-mortem inspection, sanitation standard operating procedures (Sanitation SOPs), HACCP, chemical residue and microbiological sampling methodology, heat treatment and process control, and import requirements specific to the United States. The FSIS auditors verified that APQA and MFDS have organized these ongoing and annual training programs. There were no concerns noted with the training materials or the training records.

The regulatory authority of the Republic of Korea's poultry inspection system to enforce national laws, conduct inspection verification activities, implement importing country's inspection requirements, and certification of poultry slaughter and processing establishments stems from the 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 United States Export of Poultry Products (hereinafter referred to as "Guidelines"). The Guidelines requirements ensure that laws, regulations, and policies are properly implemented and applied consistently at all certified establishments. 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 inspections.

The FSIS auditors verified that APQA and MFDS have the legal authority and ability to take appropriate enforcement measures to implement inspection laws and to ensure that adulterated or misbranded products are not exported to the United States. The FSIS auditors reviewed a sample of completed noncompliance records and noted that the results of inspection verification activities were documented on the government verification diary as prescribed in the Guidelines. At the local level, regulatory control actions include detaining products, rejecting equipment or facilities, or stopping or slowing the line speed. The FSIS auditors confirmed that government inspection personnel had identified, documented, and verified the adequacy of the establishment's preventive measures or corrective actions in response to noncompliance findings. The FSIS auditors noted that the inspection system has not implemented any elevated enforcement actions including closure of an establishment, suspension of inspection, or partial withdrawal of inspection in any of the establishments certified to export to the United States since the previous FSIS audit in 2019.

APQA and MFDS have the legal authority and responsibility to ensure that adulterated or misbranded poultry products are not exported to the United States. Article 33 of the LPSC Act provides regulatory definitions for adulterated and misbranded products that are consistent with FSIS requirements. At the regional and local inspection offices, the FSIS auditors verified that government inspection personnel have legal authority to recall, seize, and destroy hazardous poultry products in accordance with Article 36 of the LPSC Act. The FSIS auditors also verified that each audited establishment had a written recall program meeting the inspection requirement.

MFDS is responsible for notifying FSIS of establishments newly approved or delisted as establishments certified to export to the United States. The FSIS auditors reviewed inspection documents specifically associated with the approval process of a poultry processing establishment that was newly certified as eligible to produce products intended for export to the United States. The FSIS auditors verified that the approval process included evaluation by government inspection personnel of establishment written programs and onsite audits to determine whether the establishment followed the Republic of Korea's export requirements. The FSIS auditors did not identify any concerns.

The FSIS auditors verified that the QOs and IOs are responsible for reviewing and signing export health certificates of poultry products destined for export to the United States. The QOs and IOs conduct a pre-shipment verification task that includes reviewing all associated traceability documents and food safety records for each lot, observing the staged products, and verifying the weight declaration, shipping marks, and labels prior to signing the export health certificate. In addition, the QOs and IOs verify that all official verification samples and establishment monitoring samples are non-violative for microbiological pathogens and chemical residues prior to signing an export health certificate.

MFDS has established the relevant laws and regulations to ensure that the central and local government laboratories can maintain equivalence with international accreditation standards and operate under quality control standards consistent with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Guide 17025 standards. The legal framework of laboratories is captured in the Testing and Inspection on Food and Drug Act (Laboratory Quality Assurance) and the Regulations on Evaluation of Testing and Inspection Agencies in the Food and Drug Industry. The FSIS auditors confirmed that microbiological and chemical residue analytical testing of poultry products intended for export to the United States are carried out in local government laboratories in accordance with the standards, specifications, and testing methods set forth in the Korean Food Code. MFDS has the authority to designate and certify government laboratories to perform analyses for official government sampling and testing programs for poultry products. MFDS is responsible for conducting annual audits of these laboratories against the standards laid out in the Guidelines. The FSIS auditors visited Northern Branch of Gyeonggi-do Veterinary Laboratory Service and Chungcheongnam-do Veterinary Laboratory Service (chemical residue unit). The Gyeonggi-do Veterinary Laboratory Service conducts analyses of official microbiological verification samples on RTE poultry products. The Chungcheongnam-do Veterinary Laboratory Service conducts chemical residue testing on samples originating from the poultry slaughter establishments eligible to export to the United States. These laboratories are accredited by the Korean Laboratory Accreditation Scheme. The FSIS audit's scope in each laboratory included review of sample receipt, timely analysis,

analytical methodologies, analytical controls, analyst qualifications and trainings, proficiency testing, and recording and reporting of results. The FSIS auditors reviewed the most recent accreditation audits, the laboratories' staff training records, and the results of their proficiency testing. The FSIS auditors identified the following finding related to the chemical residue laboratory oversight:

- MFDS has a provision that allows official samples with violative chemical residue test results to be retested and has not provided written procedures to ensure that products that are retested cannot be exported to the United States.

However, the FSIS auditors' review of inspection records indicated that no retesting occurred on product shipped to the United States since the previous FSIS audit in 2019.

FSIS analysis and onsite audit verification activities indicate that the Republic of Korea's poultry inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements. The laboratory finding described above does not indicate an imminent threat to public health.

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

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

Through direct observation, interviews, and record reviews, the FSIS auditors verified that QOs perform ante-mortem inspection of live birds at the receiving and holding areas of the establishment when poultry destined for processing for export to the United States are slaughtered. The QOs perform additional inspection of any birds identified as suspect and verify that condemned birds are properly disposed of.

The FSIS auditors verified through interviews and record reviews that APQA and LHCA provide an appropriate number of QOs and AIs to conduct post-mortem inspection during the entire shift when poultry destined for processing for export to the United States are being slaughtered. The FSIS auditors also verified through interviews and record reviews that the MFDS provides an appropriate number of IOs to conduct inspection at least once per shift in processing establishments when products are being processed for export to the United States.

Through direct observation, interviews, and record reviews, the FSIS auditors verified QOs and AIs are performing post-mortem inspection examinations of every carcass and its parts in accordance with the Guidelines when poultry destined for processing for export to the United

States are slaughtered. The FSIS auditors verified through interviews and record reviews that poultry destined for processing for export to the United States are slaughtered in accordance with maximum line speed requirements as prescribed in the Guidelines.

The FSIS auditors verified that QOs inspect ten randomly selected carcasses per shift for fecal contamination after the final wash and before carcasses enter the cooling system, in accordance with APQA inspection standards. The process control procedure specified in the Guidelines addresses corrective actions that should be taken in event of noncompliance with the zero tolerance policy for fecal contamination in poultry.

The FSIS auditors verified through interviews and record reviews that QOs are performing finished products standards twice per shift at pre-chill and post-chill to determine if the slaughter and dressing process is in control. If the QOs determine the process is out of control, they can request for the establishment to adjust the slaughter line speed as part of the corrective actions.

The FSIS auditors verified through interviews and record reviews that MFDS and APQA conduct supervisory reviews twice a year at establishments eligible to export to the United States. The supervisory reviews are performed by QOs or IOs that are not responsible for performing inspection at the establishments. The supervisory reviews include assessment of the establishment's HACCP system including prerequisite programs, sampling procedures, sanitation, management of facilities, and GCPs. The supervisory reviews also include evaluation of the adequacy of QOs and IOs.

The FSIS auditors verified the processing establishments, producing products for export to the United States, only source materials from certified slaughter establishments within the Republic of Korea. During onsite visits to the establishments, the FSIS auditors verified that products intended for export to the United States are identified, properly labeled, and separated from those intended for domestic use. The FSIS auditors verified that MFDS reviews labels on boxes and individual packages as part of their export certification task to verify compliance with product labeling for export to the United States.

The FSIS auditors verified that each audited establishment has a system in place to identify and segregate poultry products destined for export to the United States from those that are destined for other markets, during all stages of production, storage, and shipment. Currently, there are three certified poultry slaughter establishments that provide raw source materials to four certified processing establishments. The FSIS auditor verified that certified poultry processing establishments only receive raw poultry source materials from the Republic of Korea's certified slaughter establishments and that none of these processing establishments received raw poultry products from any other country. The FSIS auditors reviewed documents related to the movement of raw product from slaughter establishments to processing establishments, and associated application or removal of transport container seals by inspection officials.

The Guidelines require condemned materials to be placed in containers with distinctive markings and require the establishment to maintain appropriate records of disposed materials. The Guidelines require the establishment to dispose of condemned products by incineration, burial, or conversion to uses other than for food in accordance with Article 44 of the Act of the Prevention

of Contagious Diseases and Article 19 of the Enforcement Decree of the Livestock Products Sanitary Control Act. The FSIS auditors verified the use of distinctively marked containers for condemned materials and verified that the QOs reviewed the records associated with disposed materials when poultry destined for processing for export to the United States were being slaughtered. However, FSIS auditors identified the following finding related to the disposition of chicken feet from corresponding condemned carcasses:

- APQA has not provided adequate controls to ensure that chicken feet from corresponding condemned carcasses are excluded from being used in the production of chicken broth used as an ingredient in products intended for export to the United States.

FSIS analysis and onsite audit verification activities indicate that the Republic of Korea's poultry inspection system has the legal authority and responsibility to establish regulatory controls to operate its inspection system. The FSIS auditors identified isolated noncompliances related to traceability and control of condemned materials. These are noted in the individual establishment checklists provided in Appendix A of this report.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component 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, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

The Republic of Korea's food safety inspection system requires slaughter and processing establishments to develop, implement, and maintain written Sanitation SOPs, SPS, and implement sanitary dressing procedures to prevent direct product contamination or the creation of insanitary conditions. The certified establishments must have written procedures to require that food contact surfaces are cleaned prior to the start of operations and to maintain sanitary conditions during operations to prevent product adulteration.

The FSIS auditors verified that each audited establishment maintained a written sanitation program to prevent direct product contamination or creation of insanitary conditions. Each audited establishment's Sanitation SOPs included maintenance and improvement of sanitary conditions through ongoing evaluation of the establishment's hygienic practices. The FSIS auditors confirmed that QOs and IOs conduct daily verification of sanitation requirements in accordance with the Annex 5 of the Guidelines, Sanitary Control Checkpoints on an Establishment for Export. Inspection verification activities consist of a combination of document review, observation, and hands-on inspection verification.

The FSIS auditors observed and assessed the in-plant government inspection personnel conducting pre-operational sanitation verification in one of the audited establishments. The government inspection personnel pre-operational sanitation verification activities included a pre-operational record review of the establishment's monitoring results and a hands-on inspection of food contact surfaces of facilities, equipment, and utensils; as well as an assessment of SPS

requirements (e.g., ventilation, condensation, and structural integrity). The FSIS auditors verified government inspection personnel's ability to identify insanitary conditions and exercise regulatory enforcement controls to ensure proper implementation of sanitary requirements.

The FSIS auditors observed the in-plant government inspection personnel perform hands-on operational sanitation verification in all visited establishments. The FSIS auditors noted that the inspection verification activities included direct observation of the actual operations and review of the establishments' associated records. The FSIS auditors compared their overall observations of the sanitary conditions of the establishments with the in-plant government inspection verification records. The FSIS auditors also examined inspection personnel's documentation of sanitation noncompliance records and verified that government inspection personnel took regulatory enforcement control actions sufficient to ensure that sanitary conditions were restored, and product was protected from contamination. The FSIS auditors' observations and record reviews of establishments' sanitation monitoring, verification, and corrective action records showed no systemic concerns. Similarly, the review of in-plant government inspection personnel records documenting inspection verification results and periodic supervisory reviews showed that inspection personnel were adequately verifying establishments' compliance with sanitation regulatory requirements.

The FSIS auditors evaluated in-plant government inspection personnel verification of establishment sanitary dressing procedures in slaughter establishments. The in-plant government inspection personnel conduct daily verification of the establishment's sanitary dressing procedures including verification of zero tolerance for ingesta and fecal material. Annex 13, Inspection Standards and Detailed Inspection Methods Used for Slaughtered Livestock and Its Meat, and Annex 14, Inspection Standards for the Fecal Contamination of Poultry Carcass, of the Guidelines require certified poultry slaughter establishments to develop, implement, and maintain written procedures to ensure proper application of sanitary dressing procedures and prevent carcasses with visible ingesta or fecal contamination from entering the chiller. The FSIS auditors' observations and record reviews of inspection verification activities did not raise any concerns.

FSIS analysis and onsite audit verification activities indicate that the Republic of Korea's poultry inspection system maintains sanitation programs that are consistent with criteria established for this component. The FSIS auditors identified isolated noncompliances related to the inspection verification of sanitation requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

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

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

The Republic of Korea's poultry inspection system requires certified slaughter and processing establishments to develop, implement, and maintain a HACCP system consistent with FSIS

HACCP requirements in 9 CFR Part 417. MFDS requires certified poultry processing establishments to address the microbiological food safety hazards in their HACCP plan. Establishments must register their business to operate and submit a HACCP plan for approval by MFDS and APQA to become eligible to export to the United States. MFDS and APQA have the authority to take enforcement actions including suspension and withdrawal of inspection for noncompliance with these requirements. The Guidelines provide instructions to certified establishments on implementation of the HACCP requirements and provides procedures for the QOs and IOs for verification and enforcement of the HACCP requirements.

Through direct observation, interviews, and record reviews, the FSIS auditors verified the QOs and IOs are performing HACCP verification tasks according to the Guidelines. The QOs and IOs routinely review HACCP plans; verify annual reassessment of HACCP plans; review critical control point (CCP) monitoring, verification, and corrective action records; observe the establishment performing CCP monitoring and verification; and perform hands-on verification of CCPs. During the biannual supervisory reviews, the QOs and IOs from the regional offices verify the adequacy of the establishment's HACCP system including prerequisite programs. At each visited establishment, the FSIS auditors reviewed the establishment's HACCP plans, CCP monitoring and verification records, records of corrective actions in response to deviations from the critical limit, and pre-shipment reviews. No concerns were identified as a result of these reviews.

FSIS analysis and onsite audit verification activities indicate that the Republic of Korea's poultry inspection system maintains HACCP systems that are consistent with criteria established for this component. The FSIS auditors identified isolated noncompliances related to the inspection verification of HACCP record-keeping requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Provincial and local governments collaboratively work with MAFRA, APQA, MFDS central levels to develop and implement the Republic of Korea National Residue Program (KNRP) to prevent and control the presence of veterinary drugs residues and chemical contaminants in the tissues of poultry slaughtered for human consumption. KNRP determines maximum residue limits allowed in poultry products destined for export to the U.S. The number of poultry samples collected under the KNRP is based on the residue violation rate from the previous year. The allocation of the samples is based on the number of farms and slaughterhouses in the cities and provinces. The FSIS auditors verified the QOs were collecting samples in accordance with the current KNRP schedule. The provincial and local governments report results from the KNRP to

APQA headquarters on a quarterly basis. APQA headquarters analyzes the results and takes appropriate enforcement measures when applicable.

Farms that supply birds that are found to have violative levels of chemical residues are designated as residue violators for six months and incur penalties for violation. MAFRA is responsible for handling the residue violators list. Surveillance testing is conducted on every shipment of animals for slaughter from residue violators. Removal from the residue violator list requires two negative shipments at least ten days apart.

FSIS analysis and onsite audit verification activities indicate that the Republic of Korea's poultry inspection system is implementing its chemical residue sampling and testing as documented through their SRT submission.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The FSIS auditors verified that APQA requires poultry slaughter establishments that produce raw source materials for further processing and export to the United States by certified poultry processing establishments to develop, implement, and maintain a microbiological sampling and testing program. This microbiological sampling program must demonstrate process control to prevent contamination of carcasses by enteric pathogen and fecal material throughout the slaughter and dressing operations in accordance with Annex 16, Microbiological Test Methods for Slaughterhouses for Export to the United States. The FSIS auditors verified that the three audited poultry slaughter establishments have written procedures for pre-chill and post-chill sampling of poultry carcasses for indicator organism testing consistent with FSIS requirements in 9 CFR 381.65. The written procedures provided instructions for random selection of carcasses, aseptic sample collection techniques, sampling frequency, packaging, and delivery of samples to assigned laboratories. The FSIS auditors also observed sample collection by establishment personnel at the pre-chill and post-chill locations. The FSIS auditors review of establishments' monitoring and inspectors' verification records identified no concerns.

The FSIS auditors verified through observations, interviews, and records review that in-plant government inspection personnel conduct official verification sampling for *Salmonella* in raw poultry carcasses in accordance with Annex 16 of the Guidelines. The in-plant government inspector's official verification sampling included the daily collection of one poultry carcass sample until the sample set is completed (set of 51 samples). The FSIS auditors observed QOs sampling collection methodology, labeling, packaging, and shipping of sealed samples to the regional government laboratory with appropriate accompanying documentation. The FSIS auditors also confirmed that the government inspection personnel were reviewing official test results for trend analysis and verifying the establishments' proper implementation of corrective

measures when the establishments do not meet the performance standards. The FSIS auditors' review of inspection records (including *Salmonella* testing results) identified no concerns.

Currently, the Republic of Korea exports TPCS and fully cooked, not shelf stable RTE products to the United States. The latter is hermetically sealed non-post-lethality exposed RTE product. The FSIS auditors verified that MFDS requires certified poultry processing establishments to meet *Lm* and *Salmonella* sampling and testing requirements for RTE poultry products destined for export to the United States. The Korean Food Code mandates zero tolerance of *Lm* and *Salmonella* in RTE poultry products. The FSIS auditors verified that MFDS 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 requires establishments to implement corrective actions in response to a positive sample resulting from either an establishment monitoring test or official government verification test. The FSIS auditors interviewed government inspection personnel at the audited poultry processing establishments to evaluate their level of knowledge regarding control of RTE regulatory requirements and official verification sampling. The government inspection personnel demonstrated a sound knowledge of the Guidelines requirements on how to verify that RTE products destined for export to the United States are not adulterated.

The FSIS auditors reviewed IOs daily verification activities at each certified poultry processing establishment. This included verification of the time and temperature records of heat-treatment and sterilization processes, traceability of the United States eligible products, and retort calibration and maintenance records. The FSIS auditors verified that government inspection personnel conduct official verification sampling including 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 requirements in the Guidelines. The FSIS auditors reviewed inspection verification records and laboratory testing results for products exported to the United States and found no concerns.

FSIS analysis and onsite audit verification activities indicate that the Republic of Korea's poultry inspection system includes microbiological sampling and testing programs implemented as documented through MFDS and APQA's SRT submissions.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held September 7, 2022, by videoconference with representatives from MFDS, MAFRA, APQA, and FAS. At this meeting, the FSIS auditors presented the preliminary findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- MFDS has a provision that allows official samples with violative chemical residue test results to be retested and has not provided written procedures to ensure that products that are retested cannot be exported to the United States.

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

- APQA has not provided adequate controls to ensure that chicken feet from corresponding condemned carcasses are excluded from being used in the production of chicken broth used as an ingredient in products intended for export to the United States.

During the exit meeting, MFDS and APQA committed to address the preliminary audit finding as presented. FSIS will evaluate the adequacy of MFDS and APQA documentation of proposed corrective actions once received 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 Harim Corporation 14, Mangseong-ro, Mangseong-myun, Iksan-si, Jeollabuk-do, Korea/	2. AUDIT DATE 08/25/2022	3. ESTABLISHMENT NO. GJA14001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
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	O
25. General Labeling	X	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Poultry Processing Establishment
Prepared Products:	Thermally Processed Commercially Sterile and Fully Cooked-Not Shelf Stable

60. Observation of the Establishment

22-Retort processing temperature and time in the HACCP plan for pasteurized products eligible to export to the United States is different from the processing temperature and time on the posted retort processing schedule.

22-The establishment's HACCP monitoring records did not include the times of the monitoring activities.

25-Chicken broth, made from source materials produced under APQA inspection, for use in Samgyetang eligible for export to the United States is not separated from chicken broth, made from source materials not produced under APQA inspection, for use in Samgyetang that is non-eligible for export to the United States.

39-The FSIS auditors observed loose and hanging silicone on the overhead structures above exposed products in the production areas. The auditors did not observe any direct product contamination. However, this condition may lead to product adulteration.

41-The FSIS auditors observed beaded condensate on the overhead structures above exposed products in the product storage areas. The auditors did not observe any direct product contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF OIEA International Audit Staff (IAS)	62. DATE OF ESTABLISHMENT AUDIT 08/25/2022
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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, Idong-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do Korea	2. AUDIT DATE 08/29/2022	3. ESTABLISHMENT NO. GIA15001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Poultry Processing Establishment
Prepared Products:	Thermally Processed Commercially Sterile

60. Observation of the Establishment

There were no findings after consideration of extent, degree, and nature of all observations.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/29/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Charmfire Co., Ltd 32-29, Ogyeo-gil, Haengan-myeon, Buan-gun, Jeollabuk-do, Korea/	2. AUDIT DATE 08/26/2022	3. ESTABLISHMENT NO. GJA17002	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
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	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Poultry Processing Establishment
Prepared Products:	Thermally Processed Commercially Sterile

60. Observation of the Establishment

22-The establishment’s HACCP verification records did not include the types (record review or direct observation) of the verification activities.

39-The FSIS auditors observed several holes and gaps between the ceiling and protruding pipes on the ceiling over exposed products in the production areas. The auditors did not observe any direct product contamination. However, this condition may lead to product adulteration.

41-The FSIS auditors observed beaded condensate on the overhead structures above exposed products in the production areas. The auditors did not observe any direct product contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF OIEA International Audit Staff (IAS)	62. DATE OF ESTABLISHMENT AUDIT 08/26/2022
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United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Harim Corporation 14, Mangseong-ro, Mangseong-myun, Iksan-si, Jeollabuk-do, Korea	2. AUDIT DATE 08/25/2022	3. ESTABLISHMENT NO. K01404001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	X
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	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Poultry Slaughter Establishment
Prepared Products:	Raw Intact Chicken

60. Observation of the Establishment

39-The FSIS auditors observed exposed insulation materials on the overhead structures above products in the production area. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.

39-The FSIS auditors observed flaking paints and rusted areas on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.

48/55- APQA’s inspection standard and scope of condemnation requires that carcasses and viscera with systemic disease be condemned; however, this does not include the condemnation of the corresponding feet. The FSIS auditors noted that chicken feet from condemned carcasses may be used to make chicken broth for products destined for export to the United States.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/25/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Maniker Co., Ltd 551, Hwabok-ro, Dong-myeon, Dongnam-gu, Korea	2. AUDIT DATE 08/23/2022	3. ESTABLISHMENT NO. M01318001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	X
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		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	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Poultry Slaughter Establishment
Prepared Products:	Raw Intact Chicken

60. Observation of the Establishment

22-The establishment’s HACCP verification records did not include the results of the verification activities.

39-The FSIS auditors observed deteriorated ceiling surfaces and rusted areas on the overhead structures above exposed products in the production areas. The auditors did not observe any direct product contamination. However, this condition may lead to product adulteration.

40-The establishment met regulatory lighting requirements, minimum of 200-footcandles of shadow-free lighting, to inspect the exterior surfaces of chicken carcass at the post-mortem inspection station. However, the quality and positioning of lighting at the inspector's post-mortem inspection station were not optimum in order to provide sufficient lighting to observe the interior surfaces of chicken carcass.

41-The FSIS auditors observed beaded condensate on the overhead structures above exposed products in the production areas. The auditors did not observe any direct product contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF OIEA International Audit Staff (IAS)	62. DATE OF ESTABLISHMENT AUDIT 08/23/2022
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United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Jungdawn Jayeonilga #A, Co., Ltd 410-8, Jaunseowon-ro, Beobwon-eup, Paju-si, Gyeonggi-do, #10825, Korea	2. AUDIT DATE 08/18/2022	3. ESTABLISHMENT NO. SRA200001	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		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	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Poultry Processing Establishment
Prepared Products:	Thermally Processed Commercially Sterile

60. Observation of the Establishment

22-The establishment's HACCP verification records did not include the times or types of the verification activities.

41-The FSIS auditor observed beaded condensate on the overhead structures above exposed products in the production areas. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/18/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Charmfre Co., Ltd 32-29, Ogyeo-gil, Haengan-myeon, Buan-gun, Jeollabuk-do, Korea	2. AUDIT DATE 08/26/2022	3. ESTABLISHMENT NO. K01413007	4. NAME OF COUNTRY The Republic of Korea
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	X
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	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Poultry Slaughter Establishment
Prepared Products:	Raw Intact Chicken

60. Observation of the Establishment

48- The inspection personnel did not verify establishment controls over condemned or inedible materials until destroyed or otherwise denatured.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/26/2022

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



February 2, 2023

Michelle Catlin, Ph.D.
International Coordination Executive
Office of International Coordination

Subject: Submission of documents elaborating corrective measures taken based on the outcome of an on-site equivalence verification audit of Korea by FSIS

Dear Dr. Michelle Catlin,

This letter is with regards to the FY 2022 draft audit report of Korea that we received on December 16, 2022. After reviewing this report, Korea submits documents (see Annex1) elaborating corrective measures taken for deficiencies observed by FSIS for your review.

By taking this chance, I would also like you to review a revised “Quarantine and Inspection Guidelines for Poultry Products to Be Exported to the United States” (see Annex2) which allows not only government veterinarians but also sanitation inspection officers to carry out works regarding HACCP verification at the export food manufacturing facilities for heat-treated poultry products. MFDS will proceed it as it is and apply this new guidelines starting from March 2023 if there aren't any opinions of your side.

Should you have further questions, please contact us.

Sincerely,

Song Sung-ok
Director of the Imported Food Policy Division
Imported Food Safety Policy Bureau

Submissions of the Corrective Actions for the Results of the U.S. FSIS On-site Audit

□ **Corrective Actions by Government Oversight (Annex 1)**

○ **Government Oversight**

- Revised the related export guideline to prevent the re-test of official samples for residues

Before Revision	After Revision
<p>Appendix 21. Residue Test Method for Poultry Meat Eligible to Export to the United States</p> <p>6. Actions on the results of precise quantitative inspection</p>	<p>Appendix 21. Residue Test Method for Poultry Meat Eligible to Export to the United States</p> <p>6. Actions on the results of precise quantitative inspection</p> <p style="color: blue;">c. If the result of precise quantitative inspection is determined to be non-compliant, the corresponding livestock products for export cannot be requested for re-test and must be excluded from export.</p>

○ **Legal Authority and Regulations for Food Safety and Consumer Protection**

- **Prepare a plan to prevent chicken feet from destroyed carcasses to be used in broth for export**

- ① **With the revision of the Quarantine and Inspection Guidelines for the United States Export of Poultry Products**, it is ensured that chicken feet of destroyed carcasses are not moved to the processing establishment in the slaughter stage for export.

Before Revision	After Revision
<p>Appendix 13. Inspection Standards and Detailed Inspection Methods for Slaughtered Livestock and Their Meat</p> <p>c. Standards for post-mortem inspection of poultry such as chickens, ducks and turkeys</p> <p>(3) Inspection Standards and Destruction Scope If they are determined to be infected with the following diseases as a result of the post-mortem inspection, the carcass and intestines, etc. must be destroyed.</p>	<p>Appendix 13. Inspection Standards and Detailed Inspection Methods for Slaughtered Livestock and Their Meat</p> <p>c. Standards for post-mortem inspection of poultry such as chickens, ducks and turkeys</p> <p>(3) Inspection Standards and Destruction Scope If they are determined to be infected with the following diseases as a result of the post-mortem inspection, the carcass and intestines, chicken feet, etc. must be destroyed.</p>

- ② **Record the quantity (pcs) of chicken feet destroyed due to destroyed carcasses in the post-mortem inspection log**

□ **Corrective Actions by Establishment**

○ **Harim Establishment (GJA14001): Annex 2**

Findings	Details of Corrective Actions
<ul style="list-style-type: none"> The retort processing temperature and time specified in the HACCP plan are different from the processing temperature and time of the indicated retort processing schedule 	<ul style="list-style-type: none"> Match the HACCP plan with the indicated processing temperature and time Modified CCP attachments at site and HACCP plan Refer to Document No. 8 and 9 in Harim corrective actions
<ul style="list-style-type: none"> HACCP monitoring records of the establishment do not include monitoring activity time 	<ul style="list-style-type: none"> Improvements to include activity time in the HACCP monitoring records of the establishment Refer to Document No. 10 in Harim corrective actions
<ul style="list-style-type: none"> Requires separation management between chicken broth for export and chicken broth for domestic use 	<ul style="list-style-type: none"> Separation management of Samgyetang broth for export with yellow identification tags Refer to Document No. 11 in Harim corrective actions
<ul style="list-style-type: none"> Possibility of product cross-contamination due to exposed silicon in the upper structure of the production area 	<ul style="list-style-type: none"> Removed the detached silicone Refer to Document No. 2 to 7 in Harim corrective actions
<ul style="list-style-type: none"> Condensation water generated in the upper structure of the production area 	<ul style="list-style-type: none"> Removed condensation water 4 times a day Refer to Document No. 1 in Harim corrective actions

○ **Charmfre Establishment (GJA15001): Annex 3**

Findings	Details of Corrective Actions
<ul style="list-style-type: none"> The type of verification activities (record review or direct observation) is not included in the HACCP verification record of the establishment 	<ul style="list-style-type: none"> Improvements made to record specific methods in the HACCP inspection record
<ul style="list-style-type: none"> Discovery of holes and gaps between protruding pipes in the establishment 	<ul style="list-style-type: none"> Prevented cross-contamination by attaching caps to gaps between piping in the establishment
<ul style="list-style-type: none"> Condensation water generated in the upper structure of the production area 	<ul style="list-style-type: none"> Actions taken to remove condensation water in case of condensation occurred prior to every operation

○ **Harim Slaughterhouse (K014001): Annex 4**

Findings	Details of Corrective Actions
· Exposed insulation of the upper structure above the product in the production area	· Immediate removal of insulation and cleaning and disinfection around the area
· Peeled paint and rusty areas on the superstructure above the product in the production area	· Repainting after removing all paint · Rework after removing the entire corroded part of the reinforcing bar · Full cleaning and disinfection after work
· Possibility of using destroyed chicken carcass feet when manufacturing chicken broth for export to the United States	· Record the amount (pieces) of destroyed chicken feet in the dismantling inspection record

○ **Maniker Slaughterhouse (M01318001): Annex 5**

Findings	Details of Corrective Actions
· Non-recording of the verification result in the HACCP verification record of the establishment	· Prepared by including the results of verification activities in the export quarantine HACCP verification record to the U.S.
· Aged ceiling surfaces in the production area · Rusty superstructure above the product	· Paint rusty structures · Pre-repair of the establishment through periodic monitoring
· The quality and location of lighting in the post-inspection area are unsuitable for observing the inner surface of chicken carcasses	· Install additional lighting to check illumination over 2,152 lux (11,430 lux) · Illuminance measurement management once a month at the inside surface observation location

○ **Jungdawn Jayeonilga Establishment (SRA 200001): Annex 6**

Findings	Details of Corrective Actions
· Does not include the number or type of the establishment HACCP verification activities	· The recorder in charge of CCP verification record improves it to include activity time and verification type
· Confirmation of condensation water occurred in the upper part of the production area	· Carrying out the gap finishing work leading to the product production area through the ceiling of the establishment

○ **Charmfre Slaughterhouse (K01413007): Annex 7**

Findings	Details of Corrective Actions
· Unconfirmed management of destroyed and non-edible raw material establishment	· Verification of the management of destroyed and non-edible raw material establishment