



United States Department of Agriculture

Food Safety and
Inspection Service

FEB 10 2016

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Dr. Soon Min Oh
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Ministry of Agriculture, Forestry and Rural Affairs
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Dear Dr. Oh,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Korea's poultry inspection system from August 25 through September 11, 2015. Enclosed is a copy of the final audit report. The comments received from the Government of Korea are included as an attachment to the report.

For technical questions regarding the FSIS audit report, please contact Mr. Vincent Fayne, Acting Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at (202) 690-5662, or by electronic mail at international.audit@fsis.usda.gov.

If you have any other questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
THE REPUBLIC OF KOREA
AUGUST 25 TO SEPTEMBER 11, 2015

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

February 2, 2016

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 Food Safety and Inspection Service (FSIS) from August 25 to September 11, 2015. The audit was conducted to determine whether the Republic of Korea's poultry inspection system continues to be equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Korea is eligible to export processed poultry products to the United States.

The audit was designed to assess the equivalence of the Republic of Korea's poultry inspection system and focused on six main system components: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Testing Programs, and (6) Government Microbiological Testing Programs.

The previous FSIS audit of the Republic of Korea's poultry inspection system occurred from November 15-29, 2010. During the course of the 2010 audit, FSIS identified findings within the equivalence components for Sanitation, HACCP, Government Chemical Residue Testing Programs, and Government Microbiological Testing Programs. During the current audit, FSIS verified that the Republic of Korea had implemented the corrective actions proffered to FSIS to remedy the 2010 audit findings.

The 2015 FSIS audit identified some operational (or procedural) weaknesses related to sanitation and HACCP. However, none of these weaknesses was significant enough as to raise a question about the Republic of Korea's on-going equivalence. An exit meeting was held on September 11, 2015, in Osong with the Central Competent Authority (CCA).

Lastly, the CCA must be aware that on August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566). The rule includes (1) a new regulatory program that affects all poultry slaughter establishments and (2) provides for the New Poultry Inspection System (NPIS), an optional post-mortem inspection system. The new regulatory program must be addressed by the CCA. The specific regulatory changes that embody this program can be found in 9 CFR 381.65 and 9 CFR 381.66.

As for NPIS, foreign governments may continue to operate inspection systems that FSIS has determined are equivalent to the United States system. However, if a foreign government decides to implement an NPIS-type system, the CCA must submit documents to explain why the system is equivalent to NPIS. Therefore, all countries exporting slaughtered poultry to the United States must submit as part of their May 2016 SRT update documentation for how the CCA has assessed their inspection system and addressed the across-the-board new regulatory requirements, and, if adopting a NPIS-type system, why the system is equivalent to NPIS, and how it is being implemented. If the materials are not submitted by May 2016, FSIS may take steps to restrict or suspend poultry exports from the country to the United States.

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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 August 25 to September 11, 2015.

The audit began with an entrance meeting held on August 25, in Osong with the participation of representatives from the Central Competent Authority (CCA), Foreign Agriculture Service (FAS), and the FSIS auditor. Representatives from the CCA and FAS accompanied the FSIS auditor throughout the entire audit.

II. OBJECTIVES, SCOPE, AND METHODOLOGY

This was a routine on-going equivalence verification audit. The objective of the audit was to ensure that the food safety system governing processed poultry products maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, results of prior audit-related site visits, Point-of-Entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of information obtained directly from the CCA, through a Self-Reporting Tool (SRT).

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

The auditor reviewed the administrative functions at the CCA headquarters in Osong, two regional offices, four local inspection offices at the audited establishments, one government microbiology laboratory, and one government chemical residue laboratory. During the review, the FSIS auditor evaluated implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement is implemented as intended. This evaluation included on-site verification of the implementation of those corrective actions proffered to FSIS by the Republic of Korea to remedy the 2010 audit findings.

The auditor conducted reviews of the administrative functions of the local inspection offices as part of the establishment review. The FSIS auditor assessed the administrative functions of sampling and testing methodology through a review of records at the regional inspection offices and two government laboratories. The auditor visited two poultry slaughter and two poultry processing establishments certified to export to the United States. During the establishment visits, the auditor paid particular attention to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an

emphasis on the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 381.196.

AUDIT SCOPE SUMMARY			
Competent Authority Visits			Locations
Competent Authority	Central Authority	1	MFDS and MAFRA headquarters, Osong
	Regional Offices	2	Gyeongin Regional Office Honam Regional Office
Microbiology Laboratory		1	Gyeonggi Livestock Products Sanitation Institute
Chemical Residue Laboratory		1	Jeonbuk Livestock Products Sanitation Institute
Poultry Slaughter/Processing Establishments		4	Slaughter: Harim Co., Ltd. and Delicious Meat Food Co., Ltd. Processing: Harim Co., Ltd. and Maniker F & G Co., Ltd.

The audit was undertaken under the specific provisions of United States’ laws and regulations, in particular:

- Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and
- Poultry Products Inspection Regulations (9 CFR Part 381 et seq.).

The audit standards applied during the review of the Republic of Korea’s poultry inspection system included all applicable legislation and procedures submitted to FSIS and determined to be equivalent as part of the initial review process. The Republic of Korea has adopted and implemented HACCP and Sanitation Standard Operating Procedure (SSOP) requirements in accordance with FSIS regulations.

III. BACKGROUND

The Republic of Korea is eligible to export processed poultry products to the United States. Between May 14, 2014 and July 21, 2015, FSIS’ import inspectors performed 100% re-inspection for labeling and certification on 1,172,489 pounds of poultry products exported by the Republic of Korea to the United States. FSIS also performed re-inspection on 894,185 pounds at POE using additional types of inspection, of which a total of 144 pounds were refused entry for missing shipping marks.

Previous FSIS final audit reports for the Republic of Korea's food safety system are available on the FSIS’ website at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>

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

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

The evaluation of this component included an analysis of information provided by the CCA through the SRT, as well as interviews and observations during the on-site portion of the audit. There has been a change in the organizational structures of the CCA since the last FSIS audit conducted in 2010.

At the central level, the Republic of Korea's poultry inspection system is divided between two ministries: Ministry of Agriculture, Food and Rural Affairs (MAFRA) and Ministry of Food and Drug Safety (MFDS). The Animal and Plant Quarantine Agency (QIA), an Agency under MAFRA supervision, is responsible for conducting inspection activities in all of the United States-certified poultry slaughter establishments while MFDS is responsible for conducting inspection activities in all of the United States-certified poultry processing establishments. Currently, there are two slaughter and two processing establishments that are certified to export to the United States.

At the regional level, four regional offices are overseeing inspection activities in the United States-certified establishments. The regional offices of Jungbu and Honam under MAFRA oversee slaughter related inspection activities at Delicious Meet Food and Harim slaughter establishments while the regional offices of Gyeongin and Gwangju under MFDS oversee processing related inspection activities at Maniker F & G and Harim processing establishments.

At the establishment level, the Quarantine Officers (QO) are the veterinarians of QIA/MAFRA, who are responsible for conducting slaughter inspection and quarantine duties in the two United States-certified poultry slaughter establishments in accordance with the provisions of Article 30 of the *Prevention of Contagious Animal Disease Act (PCAD)* and Article 13 of the *Livestock Products Sanitary Control Act (LPSC)*. The Inspection Officers (IO) are the veterinarians of MFDS, who are responsible for conducting processing inspection duties in the two United States-certified poultry processing establishments in accordance with the provisions of Article 13 of the *LPSC*.

The primary laws for regulating poultry inspection in the Republic of Korea are the *LPSC*, *PCAD*, *Food Sanitation Act*, and *Testing and Inspection on Food and Drugs Act*. These Acts provide the operational and regulatory authority to carry out the Republic of Korea's poultry inspection system. FSIS' review of specific regulations based on these Acts concerning the registration of slaughter and processing establishments, inspection verification activities, and implementation of the United States export requirements indicated that the CCA has legal

authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported to the United States.

The FSIS auditor reviewed the approval process for poultry establishments that intend to be designated as United States-certified establishments. These establishments must operate under a HACCP system pursuant to Article 9 of the LPSC and Article 42 of the PCAD. Following the submission of an establishment application to the regional office of MFDS (processing establishments) or QIA (slaughter establishments), the head of the regional office would review the application document and conduct an on-site inspection in accordance with the CCA's document "*Evaluation Sheet for Designation and Audit of the Establishment for Export to the United States*" that has a design similar to FSIS' *Foreign Establishment Audit Checklist* (FSIS Form 5000-6). The regional office may approve the application based on the results of the document review, on-site audits, and implementation of any applicable corrective action. The MFDS is responsible for notifying FSIS concerning approval of any new establishment or delisting of a certified establishment when they do not meet the CCA's regulatory requirements.

The FSIS auditor reviewed non-compliance reports (NRs) that were generated by the in-plant inspection personnel at all four audited establishments. FSIS noted that the inspection personnel had identified and documented deficiencies in NRs using a similar format as FSIS' NRs. The inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The FSIS auditor reviewed a sample of all open and closed NRs and determined that the inspection personnel have adequately described non-compliances and verified the effectiveness of the establishment's corrective actions.

The FSIS auditor verified that the inspection personnel assigned to the United States-certified establishments are full-time employees of the national government and perform activities under administration of the CCA. Since the last FSIS audit in 2010, the CCA has organized ongoing training programs for inspection personnel assigned in the United States-certified establishments. Trainings have covered such subjects as Pathogen Reduction/HACCP, sanitation, sampling methodology, and specific export requirements concerning United States equivalence requirements. The FSIS auditor interviewed a number of the inspection personnel to assess their knowledge, skills, and abilities and reviewed their training records from 2014 to 2015. The auditor confirmed that inspection personnel have attended the ongoing trainings and have sufficient training in performing inspection activities.

The FSIS auditor interviews of inspection personnel and reviews of official inspection records during the on-site audit confirm that the CCA has administrative controls to support its inspection system, and that the CCA is enforcing applicable regulatory requirements.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for ante-mortem inspection of

animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; and periodic supervisory reviews to the official establishments certified to export to the United States. The evaluation of this component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit.

FSIS has determined that Korea's poultry laws, regulations, and inspection system are equivalent to the Poultry Products Inspection Act, the FSIS regulations implementing this statute, and the United States food safety system for poultry. The CCA has issued a guideline "*Quarantine and Inspection Guidelines for the Poultry Products to be Exported to the United States.*" This guideline provides detailed instructions to the CCA's inspection personnel for proper implementation of inspection procedures, pre-requisite programs, HACCP, sanitation, product formulation, and microbiological or chemical residue sampling and testing in accordance with PCAD, LPSC, and the relevant notifications concerning FSIS requirements.

During the audit of the two slaughter and two processing establishments, the FSIS auditor accompanied the CCA's representatives and observed the implementation of inspection verification activities of in-plant inspection personnel. The verification activities that the FSIS auditor observed included ante-mortem inspection, post-mortem inspection, *Salmonella* and generic *Escherichia coli* (*E. coli*) sample collection, verification of pre-operational and operational sanitation monitoring procedures, and HACCP verification activities.

The FSIS auditor assessed ante-mortem and post-mortem inspection examinations through on-site record reviews, interviews, and observations of the in-plant inspection personnel performing ante-mortem and post-mortem examinations in audited poultry slaughter establishments. The FSIS auditor observed and verified that the in-plant inspection personnel are following ante-mortem and post-mortem inspection procedures in accordance with the CCA's guidelines. The FSIS auditor also noted that the audited slaughter establishments meet post-mortem facility requirements including such equipment as a distortion-free mirror, sufficient shadow-free lighting, online hand rinsing facilities, hang back racks, a receptacle for condemned carcasses and parts, and start/stop switches.

During the on-site audit of the establishments, the FSIS auditor verified that daily inspection is provided when establishments are producing product for export to the United States. The FSIS auditor interviewed the inspection personnel; reviewed in-plant inspection generated verification records; and observed the functions of the in-plant inspectors while conducting their daily inspection verification activities. These daily verification activities included direct observation of the production process and review of the establishment records, including HACCP (monitoring, verification, and corrective actions), SSOP, Sanitation Performance Standards (SPS), and microbiological sampling techniques and records.

The FSIS auditor also accompanied and observed the functions of the regional veterinarians who are responsible for conducting the periodic supervisory reviews with a minimum frequency of two supervisory reviews per year in accordance with the CCA's guidelines. During the supervisory reviews, the regional veterinarians verify the CCA's implementation of requirements for ante-mortem inspection, post-mortem inspection, microbiological sampling including

Salmonella sample collection in raw product (slaughter establishment), microbiological verification sampling including *Listeria monocytogenes* and *Salmonella* sample collections in ready-to-eat (RTE) product (processing establishments), verification of pre-operational and operational sanitation monitoring procedures, sanitation, and HACCP verification activities including the review of Critical Control Points (CCPs). The FSIS auditor verified that the regional veterinarians are conducting this task in accordance with the CCA's guidelines that are equivalent to the United States requirements.

FSIS's observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirm that the CCA's poultry inspection system continues to have both legal authority and a regulatory framework to implement requirements equivalent to those governing the United States' system of poultry inspection, and that the regulatory framework is being implemented as written.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that FSIS reviewed is Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of SSOP. The evaluation of the sanitation component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit.

The CCA has adopted FSIS regulatory requirements for sanitation (9 CFR Part 416 et seq.). FSIS audited the CCA headquarters, two regional, and four local inspection offices in order to assess the CCA's ability to effectively communicate and enforce the sanitation requirements throughout the inspection system to prevent direct product contamination or the creation of insanitary conditions.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at the audited establishments. The FSIS auditor assessed the adequacy of the pre-operational inspection verification by shadowing and observing the in-plant inspection personnel conducting pre-operational sanitation verification inspection in one of the audited establishments. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification inspection. The in-plant inspection personnel conducted this activity in accordance with the CCA's established procedures.

The FSIS auditor also observed the in-plant inspection personnel perform actual operational sanitation verification in all of the audited establishments. The auditor noted that the inspection verification activities included direct observation of the actual operations and review of the establishments associated records. The auditor compared his overall observation of the sanitary conditions of the establishments with the in-plant inspection verification records. The FSIS auditor's record review included both the establishment's sanitation monitoring and corrective action records and the inspection records documenting inspection verification results, non-compliances, and supervisory reviews of establishments. The auditor noted that the inspection

and establishment records for the most part mirrored the actual sanitary conditions of the establishments. The auditor noted that establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date. The SSOP conditions in the audited establishments met the CCA regulatory requirements, and the audit did not observe any SSOP deficiencies on the day of the audit.

The auditor found, based on his analysis and on-site observations, that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs, and that the CCA inspection program personnel are effectively verifying that they are doing so.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

The fourth of six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system requires that each official establishment develop, implement, and maintain a HACCP plan. The evaluation of the HACCP component included an analysis of information provided by the CCA through the SRT, interviews, and observations made during the on-site portion of the audit.

The CCA has adopted FSIS regulatory requirements for HACCP (9 CFR Part 417 et seq.). The CCA headquarters, two regional, and four local inspection offices were audited in order to assess the CCA's ability to maintain adequate government oversight throughout the inspection system for the implementation of HACCP requirements.

The FSIS auditor reviewed the HACCP plans and records, observed the actual verification activities conducted by the in-plant inspection personnel, and reviewed the associated verification records generated by the in-plant inspection personnel. The auditor noted that the in-plant inspection personnel at the audited establishments conduct daily verification of the establishment's HACCP plans in accordance with the instructions described in the CCA's guidelines. The in-plant inspection verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The in-plant inspection verification activities also include direct observation or record review of Critical Control Points (CCPs) with results of the verifications entered in the associated inspection records.

The FSIS auditor conducted an on-site observation and document review of CCPs in all the audited establishments. In the poultry processing establishments that produce thermally processed/commercially sterile (03D) products, the establishments have developed and followed their HACCP plans to address all food safety hazards including the microbiological hazards. The auditor's review of the plans, CCPs, critical limits, monitoring procedures, and verification procedures did not raise any concerns. In the poultry slaughter establishments, the auditor reviewed the zero tolerance (fecal material) CCP control records. In addition, the FSIS auditor, together with the in-plant inspection personnel, observed the establishment's employee

conducting hands-on HACCP monitoring and verification activities for the zero-tolerance CCP. Neither the FSIS auditor nor the inspection personnel observed any deviations from the critical limits. The FSIS auditor also reviewed the establishment and the in-plant inspections' zero tolerance records. These reviews identified no concerns.

The analysis and on-site activities of the FSIS auditor show that the CCA verifies that operators of official establishments implement the CCA's requirement to develop, implement, and maintain HACCP programs for each processing category. The FSIS auditor's analysis determined that the CCA continues to demonstrate the ability to effectively implement and verify the core equivalence requirements for this component as articulated by the FSIS import regulations (9 CFR 327.2).

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of the six equivalence components that the FSIS auditor reviewed was Government Chemical Residue Control Programs. To be equivalent to FSIS's inspection system, the inspection system must have a chemical residue control program designed and administered by the national government that functions to prevent chemical residue contamination of food products. In addition, the program must include random sampling of the internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The CCA must provide a description of its residue sampling and testing plan and the process used to design the plan. The CCA must verify that the laboratories are producing valid and reliable test data.

The evaluation of the government chemical residue testing programs component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit. The CCA headquarters, two regional offices, and one chemical residue laboratory were audited to assess the CCA's regulatory authority to enforce requirements of the Chemical Residue Testing Programs equivalence component. FSIS analysis and on-site audit verification of the CCA's chemical residue testing program, as designed and implemented, show that the CCA is effectively using its authority to ensure that safe product is produced. The CCA continues to demonstrate the ability to meet the equivalence requirements for this component that are articulated in FSIS import regulations (9 CFR 327.2).

Based on the CCA's guidelines and in accordance with the CCA's "*Rules for Inspecting the Residue of the Poultry Meat for Export*," the QO collects random residue samples at the poultry slaughter establishments. The QO who collects the residue samples receives periodical training that includes such subjects as sampling methodology, identification of animals, traceability, and sample security. The FSIS auditor verified that the inspection personnel are following the Republic of Korea's National Residue Program sampling protocol. This protocol includes sampling location, sample size, sampling frequency, and secure delivery of residue samples to designated government residue laboratories.

The FSIS auditor visited the Jeonbuk Livestock Products Sanitation Institute that is a government residue laboratory under Gwangju regional office. The residue laboratory audit focused on sample handling, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, percent recoveries, intra-laboratory check samples, and quality-assurance programs, including standards books and corrective actions. These reviews identified no concerns.

The auditor verified that the implementation of the current year's sampling plan at the headquarters, regional, and in-plant inspection levels was proceeding in the manner outlined in the CCA's national plan, and that sampling was occurring on time, analyses were completed in a timely manner, and results were distributed as directed. In addition, analytical testing conducted by FSIS at United States POE has not detected any violative level of chemical residues in poultry products exported to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system is to organize and implement certain sampling and testing programs to ensure that poultry products produced for export to the United States are safe, wholesome, unadulterated, and meet all relevant equivalence criteria.

The evaluation of the government microbiological testing programs component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit. The CCA headquarters, two regional offices, and one microbiological laboratory were audited to assess the CCA's regulatory authority to enforce microbiological sampling plans and criteria, which contains regulatory requirements for certified establishments exporting eligible products to the United States.

The CCA requires that the United States-certified slaughter establishments that produce raw materials for the United States-certified processing establishments have a microbiological sampling and testing program to show process control for poultry carcasses for generic *E. coli*. The FSIS auditor reviewed the CCA's document "*microbiological inspection of a HACCP applied slaughter house*" and verified that the system was properly implementing this requirement. The inspection personnel verify that each establishment maintains written procedures for sample collection; that the establishment's employees collect samples under the supervision of a QO; that the written plan addresses the location of sampling, randomness, and sample integrity; that appropriate sampling methodology is used; that the lab is using an appropriate method for analysis; that results are correctly evaluated and reported; and that establishments take appropriate corrective action when they exceed the acceptable levels. The auditor's review of the establishment's sampling records and inspection verification records identified no concerns.

The CCA also requires testing for *Salmonella* species (spp) in raw products. FSIS has determined that the Korean *Salmonella* sampling and testing program is equivalent to that of FSIS. In accordance with the CCA's document "*microbiological inspection of a HACCP*

applied slaughter house),” the QO collects samples, documents the sample collection on the standard form “*sampling record of poultry exporting to the United States*,” requests sample analysis at a government laboratory, and takes appropriate actions based on the test results. The FSIS auditor verified that the inspection personnel are following the CCA’s sampling protocol, which includes testing frequency, sample collection, and the delivery of samples to government laboratories.

The CCA requires that the United States-certified establishments meet *Listeria monocytogenes* and *Salmonella* sampling requirements for thermally processed/commercially sterile RTE poultry products destined for export to the United States. In addition to the establishment’s sampling protocol, the CCA has established verification testing programs that include test and hold by inspection personnel. FSIS has determined that the Korean RTE program is equivalent to that of FSIS. The FSIS auditor review of the implementation of the CCA’s requirements did not raise any concern.

The FSIS auditor visited the Gyeonggi Livestock Products Sanitation Institute that is a government microbiology laboratory under Gyeonggi regional office. During the laboratory visit, the FSIS auditor reviewed documents pertaining to the sample receipt, timely analysis, analytical methodologies, analytical controls, and reporting of results. In addition, the auditor reviewed training records and the results of proficiency testing. There were no deficiencies identified during the review of documents.

The analysis and on-site verification activities indicate that the CCA poultry inspection system has a microbiological testing program, organized, and administered by the national government. Analytical testing conducted by FSIS at United States POE has not reported any violations.

X. CONCLUSIONS AND NEXT STEPS

The previous FSIS audit of the Republic of Korea’s poultry inspection occurred from November 15-29, 2010. During the course of the 2010 audit, FSIS identified findings within the equivalence components for Sanitation, HACCP, Government Chemical Residue Testing Programs, and Government Microbiological Testing Programs. During the current audit, FSIS verified that the corrective actions proffered to FSIS by the Republic of Korea to remedy the 2010 findings were implemented. The 2015 FSIS audit identified some operational (or procedural) weaknesses related to sanitation and HACCP.

An exit meeting was held on September 11, 2015, in Osong with the CCA. FSIS will evaluate any information provided by the Republic of Korea, including the CCA’s proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions. FSIS requests that the CCA provide a detailed response within 60 calendar days of receipt of this draft report.

Lastly, the CCA must be aware that on August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566). The rule includes (1) a new regulatory program that affects all poultry slaughter establishments and (2) provides for the New Poultry Inspection System (NPIS), an optional post-mortem inspection system. The new regulatory

program must be addressed by the CCA. The specific regulatory changes that embody this program can be found in 9 CFR 381.65 and 9 CFR 381.66.

As for NPIS, foreign governments may continue to operate inspection systems that FSIS has determined are equivalent to the United States system. However, if a foreign government decides to implement an NPIS-type system, the CCA must submit documents to explain why the system is equivalent to NPIS. Therefore, all countries exporting slaughtered poultry to the United States must submit as part of their May 2016 SRT update documentation for how the CCA has assessed their inspection system and addressed the across-the-board new regulatory requirements, and, if adopting a NPIS-type system, why the system is equivalent to NPIS, and how it is being implemented. If the materials are not submitted by May 2016, FSIS may take steps to restrict or suspend poultry exports from the country to the United States.

XI. ATTACHMENTS TO THE AUDIT REPORT

Attachment A: Individual Foreign Establishment Audit Checklist

Attachment B: Foreign Country Response to Draft Final Audit Report

Attachment A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Harim Corporation 14, Mangsung-ro, Mangsung-myun Iksan-City, Jeonbuk	2. AUDIT DATE 08/31/2015	3. ESTABLISHMENT NO. K 0140441	4. NAME OF COUNTRY Korea
5. NAME OF AUDITOR(S) Nader Memarian, DVM			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)	Audit Results	Part D - Continued Economic Sampling	Audit Results
Basic Requirements			
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	
Ongoing 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.			
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			
Part C - Economic / Wholesomeness		Part F - Inspection Requirements	
23. Labeling - Product Standards		49. Government Staffing	
24. Labeling - Net Weights		50. Daily Inspection Coverage	
25. General Labeling		51. Enforcement	X
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		52. Humane Handling	
Part D - Sampling Generic E. coli Testing		53. Animal Identification	
27. Written Procedures		54. Ante Mortem Inspection	
28. Sample Collection/Analysis		55. Post Mortem Inspection	
29. Records			
Salmonella Performance Standards - Basic Requirements		Part G - Other Regulatory Oversight Requirements	
30. Corrective Actions		56. European Community Directives	
31. Reassessment		57. Monthly Review	
32. Written Assurance		58.	
		59.	

60. Observation of the Establishment Harim Corporation – Poultry Slaughter Establishment (K 0140441) – 08/31/2015 - Korea

41/51: Other Requirements – Ventilation

Beaded condensation and rusted areas were observed on the overhead structures above a poultry carcass chiller. No direct product contamination observed by the FSIS auditor at this time.

61. NAME OF AUDITOR
Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE
Nader M. Memarian 8-31-15

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-City, Jeonbuk	2. AUDIT DATE 09/01/2015	3. ESTABLISHMENT NO. GJA14001	4. NAME OF COUNTRY Korea
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		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. Enforcement	
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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Harim Corporation – Poultry Processing Establishment (GJA14001) – 09/01/2015 - Korea

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

61. NAME OF AUDITOR
Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE
Nader Memarian 9-1-15

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, 144 Beon-gil, Idong-myeon. Cheoin-gu, Yongin-si, Gyeonggi-do	2. AUDIT DATE 09/04/2015	3. ESTABLISHMENT NO. GIA15001	4. NAME OF COUNTRY Korea
	5. NAME OF AUDITOR(S) Dr. Nader Memarian		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. Enforcement	
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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Comments	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Maniker F & G Co., Ltd. – Poultry Processing Establishment (GIA15001) – 09/04/2015 - Korea

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

61. NAME OF AUDITOR
Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

Nader Memarian 9-4-15

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Delicious Meet Food Co., Ltd. 73, Hayondu3-gil Chungju City, Chungbuk-do	2. AUDIT DATE 09/07/2015	3. ESTABLISHMENT NO. SB1406001	4. NAME OF COUNTRY Korea
	5. NAME OF AUDITOR(S) Dr. Nader Memarian		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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Delicious Meet Food Co., Ltd. – Poultry Processing Establishment (SB1406001) 09/07/2015 - Korea

38/51: Other Requirements – Establishment Grounds and Pest Control

Seal around a shipping door did not provide a tight seal when door was closed, which would allow for the entrance of pests into this area.

39/51: Other Requirements – Establishment Construction/Maintenance

Small holes and rusted areas were observed on the overhead structures above exposed products in the production areas. No direct product contamination observed by the FSIS auditor at this time.

22/51: HACCP – Ongoing Requirements

The establishment's HACCP verification records for calibration of monitoring instruments did not document the time of the calibration activities conducted by the establishment's personnel.

61. NAME OF AUDITOR
Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

 9-7-15

Attachment B: Foreign Country Response to Draft Final Audit Report



식품의약품안전처

Ministry of Food and Drug Safety

Osong Health Technology Administration Complex, 187 Osongsaengmyeong2(i)-ro,
Osong-eup, Heungduk-gu Cheongju-si, Chungbuk-do, Rep. of Korea, 363-700

Tel : +82-43-719-3241 FAX: +82-43-719-3240, email: csgg@korea.kr

To: Dr. Jane H. Doherty
International Coordination Executive
Office of International Coordination, FSIS

cc: Mr. Stephen L. Wixom
Agricultural Attaché
Office of Agricultural Affairs, U.S. EMBASSY

Date: January 12, 2015

Subject: 2016 Annual Certification of Establishments Eligible to Export Meat, Poultry, or Egg products to the United States and the response to Draft Final Report of an Audit in Korea, 2015

Dear Dr. Jane H. Doherty

With regard to FSIS's letters dated December 14, 2015 concerning 2016 annual certification of establishments and December 7, 2015 concerning the draft final audit report, responses to these letters are provided in attachments as follows:

- ✓ Attachment 1: Foreign Official Poultry Establishment Certificate
- ✓ Attachment 2: Response to Draft Final Audit Report (2015 Korea)

Thank you for your cooperation in advance.

Sincerely,

Choi Soongom

Choi Soon Gon
Director of Livestock Products Sanitation Division
Agro-Livestock and Fishery Products Safety Bureau
Ministry of Food and Drug Safety

Attachment 1

FOREIGN OFFICIAL POULTRY ESTABLISHMENT CERTIFICATE

I hereby certify that the establishments listed below fully comply with the requirements of the Republic of Korea equivalent to all the provisions of the Poultry Products Inspection Act and regulations issued thereunder, which apply to official establishments in the United States, and their poultry products, as provided in 381.196(a)(2)(i) and (ii) of the Code of Federal Regulations governing poultry inspection of the United States Department of Agriculture.

Establishment Number	Establishment NAME	Establishment ADDRESS and Telephone Number	Eligibility Status (new, relisted, or changed)	TYPE OF OPERATION (Slaughter, Processing, or Cold Storage)	PROCESS CATEGORY	SPECIES
GJA14001	Harim Corporation	14, Mangsung-ro, Mangsung-myun, Iksan-city, Jeonbuk, Republic of Korea / +82-31-264-3323	relisted	Processing	Thermally Processed-Commercial sterile, Fully Cooked-not shelf stable	Chicken
K01404001	Harim Corporation	14, Mangseong-ro, Mangseong-myeon, Iksan-si, Jeollabuk-do, Korea / +82-63-860-2448	relisted	Slaughter		Chicken
SB1406001	Delicious Meet Food Co., Ltd	73, Hayongdu3-gil, Chungju-si, Chungbuk-do, Korea / +82-43-856-0111	relisted	Slaughter		Chicken
GIA15001	Maniker F&G Co., Ltd	36-2, Baegokdaero 144Beon-gil, Idong-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Korea / +82-31-338	relisted	Processing	Thermally Processed-Commercial sterile	Chicken

DATE: January 12, 2015

Choi Siomgon

SIGNATURE:

OFFICIAL TITLE: Director of Livestock Products Sanitation Division, Agro-Livestock and Fishery Products Safety Bureau, Ministry of Food and Drug Safety

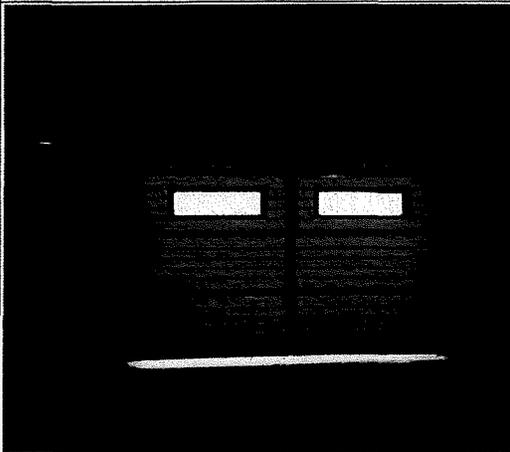
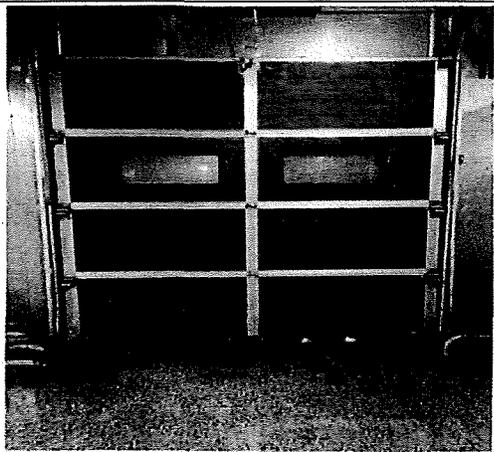
Response to Draft Final Audit Report (2015 Korea)

FSIS's Observations

- Delicious Meet Food Co., Ltd. (Est No.: SB1406001)**
 - Seal around a shipping door did not provide a tight seal when door was closed, causing potential introduction of insects or rodents.
 - Small holes and rusted areas were observed on the overhead structures above exposed products in the production areas.
 - The establishment's HACCP verification records for calibration of monitoring instruments did not document the time of the calibration activities conducted by the establishment's personnel
- Harim Corporation (Est No.: K0140441)**
 - Beaded condensation and rusted areas were observed on the overhead structures above a poultry carcass chiller

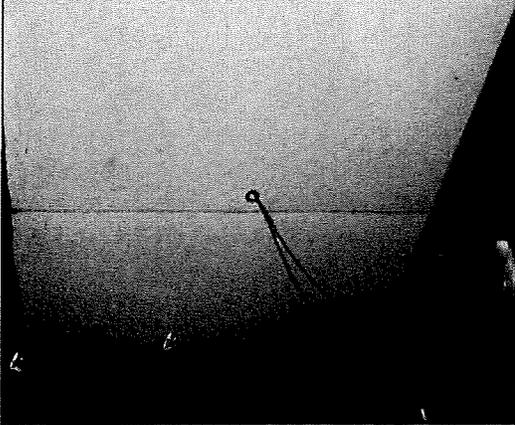
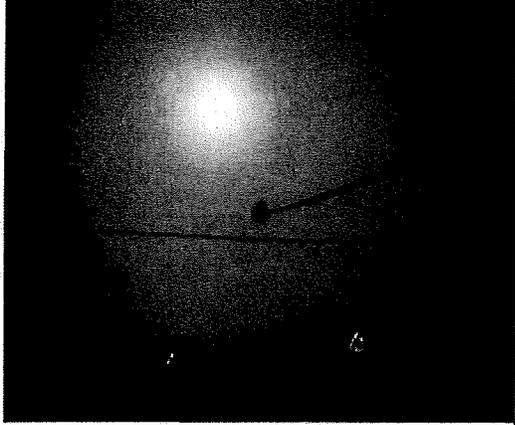
< Delicious Meet Food Co., Ltd. (Est No.: SB1406001) >

- Seal around a shipping door did not provide a tight seal when door was closed, causing potential introduction of insects or rodents.
 - The establishment reinforced the sealing by installing an additional rubber guide.

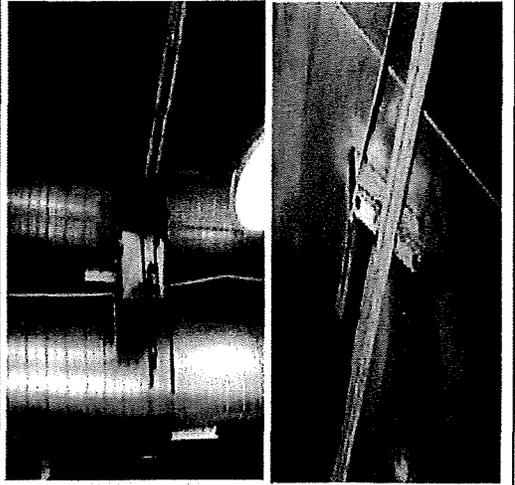
Deficiency	Corrective Action
	
◦ Gap between door and floor	◦ Installing an additional rubber guide

Small holes and rusted areas on the overhead structures

Filling the holes on the ceiling

Deficiency	Corrective Action
	
◦ Small holes on the ceiling	◦ Filling the holes

Removal of rusted areas and painting on the overhead structures

Deficiency	Corrective Action
	
◦ Rusted areas on the ceiling	◦ Removal of rust and painting

Inappropriate documentation of HACCP verification records

○ Recording the time of calibration activities

Deficiency		Corrective Action																																																																																																																																																																																																																																																			
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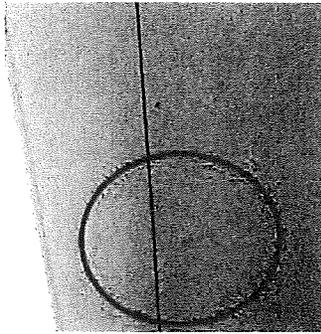
< Harim Corporation (Est No. : K0140441) >

Beaded condensation and rusted areas on the overhead structures

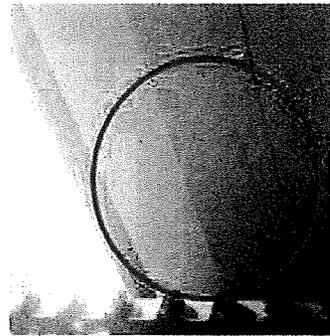
Deficiency



Corrective Action



Preventive Action



* In addition to 5 mobile fans for the chiller room, such mobile fans are installed at areas where condensation may occur, such as evisceration room.