United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

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Dear Dr. Chang:

The Food Safety and Inspection Service (FSIS) has received your May 4, 2011, letter in which you submitted the Republic of Korea's comments to the Draft Final Audit Report and proposed corrective actions that address the findings of FSIS' initial equivalence on-site audit conducted November 15-29, 2010. The purpose of this letter is to provide Korea with a copy of the Final Audit Report and an update of our review of the corrective actions. In addition, we want to respond to your proposal to hold a digital video conference (DVC) to discuss the corrective actions and the timeline for FSIS to determine Korea's eligibility to export poultry products to the United States.

FSIS has reviewed your comments and included them as an attachment to the enclosed Final Audit Report dated June 22, 2011. This report will be posted on the FSIS website: http://www.fsis.usda.gov/regulations_&_policies/Foreign_Audit_Reports/index.asp

In regard to the corrective actions submitted by Korea, FSIS has completed its initial review and will provide a thorough explanation of FSIS' evaluation in a separate letter. Once Korea has had the opportunity to review our letter, we are agreeable to hold a DVC to further discuss the corrective actions and any other matter you would like to discuss.

Concerning the timeline and process for obtaining U.S. eligibility to export poultry products to the United States, there are several remaining steps that must take place before shipments can begin. First, FSIS must resolve any outstanding issues and concerns identified during the audit and addressed in your corrective action plan, so that an equivalence determination can be made. As we move forward with this step, FSIS will confirm whether an on-site verification audit will be needed. Second, FSIS must proceed with the U.S. rulemaking process to add Korea to the list of countries in the U.S. Code of Federal Regulations that are eligible to export poultry products to the United States. As you may know, this involves FSIS publishing a proposed rule in the U.S. *Federal Register*. This proposal will include a 60-day comment period, at which time FSIS will review and respond to all the comments that are received prior to publication of a final rule.

Once a final rule is published in the *Federal Register*, Korea can then certify to FSIS the establishments that have been determined to be in compliance with FSIS inspection requirements or equivalent inspection requirements and, therefore, eligible to export poultry products to the United States. As for a timeline when a final rule will be published, FSIS is unable to provide a specific date at this time. However, we want to assure you that FSIS is

committed to continue working closely with Korea to address any outstanding equivalence issues and to expedite the rulemaking process to the best of its ability.

If you have any questions, please contact me by telephone at 202-720-6400, by facsimile at 202-720-6050, or by electronic mail at internationalequivalence@fsis.usda.gov

Sincerely,

for P. C. Kadam

Andreas Keller, Director
International Equivalence Staff
Office of International Affairs

Enclosure

FINAL REPORT OF AN INITIAL EQUIVALENCE ON-SITE AUDIT

CONDUCTED IN

THE REPUBLIC OF KOREA

NOVEMBER 15 - 29, 2010

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
THE PRODUCTION OF POULTRY
PRODUCTS INTENDED FOR EXPORT TO THE
UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This audit report describes the outcome of an on-site audit of the Republic of Korea's (Korea) poultry inspection system conducted by the Food Safety and Inspection Service (FSIS) from November 15 - 29, 2010.

This was an initial equivalence verification audit with emphasis on process controls exercised by the Central Competent Authority (CCA) over Korea's poultry inspection system and corrective actions proffered and implemented by the CCA in response to the previous FSIS initial equivalence on-site audit conducted in 2008. The audit objective was to ensure that Korea has an inspection system for slaughtering and processing poultry products equivalent to the United States' (U.S.) inspection system with the resultant capacity to produce poultry products that are safe, unadulterated, and properly labeled.

The auditors confirmed that all prior systemic findings related to the 2008 audit were appropriately addressed. Furthermore, the auditors concluded that the CCA was able to meet the FSIS requirements for the following equivalence components: (1) Government Oversight, (3) Sanitation, and (4) HACCP.

However, the current audit resulted in the identification of systemic findings within the equivalence components of: (2) Statutory Authority and Food Safety Regulations, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs.

- The CCA did not provide adequate control of establishment facilities for post-mortem inspection.
- The CCA did not provide adequate control over the implementation of laboratory quality systems within its National Residue Program.
- The CCA did not provide adequate controls over the implementation of laboratory quality systems associated with microbiological testing of product which is intended for export to the U.S.

In order to demonstrate that Korea's poultry inspection system meets the FSIS import requirements, the CCA is to submit a comprehensive corrective action plan addressing the specific audit findings outlined in the report for each component. FSIS will evaluate the extent to which the proffered corrective actions sufficiently address the systemic findings identified. Provided the corrective actions are sufficient, FSIS will make the recommendation to move forward with the rulemaking process for system equivalence. However, FSIS may conclude that an additional on-site audit is necessary to verify the adequacy of the corrective actions provided.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority
CCP	Critical Control Point
CVO	Chief Veterinary Officer
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
Lm	*Listeria monocytogenes*
MIFAFF	Ministry for Food, Agriculture, Forestry and Fisheries
MLG	Microbiology Laboratory Guidebook
NVRQS	National Veterinary Research and Quarantine Service
OIA	Office of International Affairs
NRP	National Residue Program
QVO	Quarantine Veterinary Officer
RTE	Ready-to-Eat
Salmonella spp.	*Salmonella* species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an initial equivalence on-site audit of the Republic of Korea's poultry food safety system from November 15 - 29, 2010.

The audit began with an entrance meeting held on November 15, 2010, in Seoul with the participation of representatives from the Central Competent Authority (CCA) – the Ministry of Food, Agriculture, Forestry and Fisheries (MIFAFF), the National Veterinary Research and Quarantine Service (NVRQS), representatives from the United States Embassy in Korea, and the FSIS audit team.

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was an initial equivalence verification audit with emphasis on process controls exercised by the CCA over Korea's poultry inspection system, and corrective actions proffered and implemented by the CCA in response to the previous initial equivalence on-site audit conducted by FSIS in 2008.

The audit objective was to verify Korea has implemented an inspection system for poultry slaughter and poultry processing equivalent to the U.S. inspection system with the resultant capacity to produce poultry products that are safe, unadulterated, and properly labeled.

In pursuit of this objective, FSIS conducted a comprehensive document review which included an analysis of the inspection documents submitted by Korea in response to the 2008 on-site audit findings, in advance of its second initial equivalence on-site audit of Korea.

FSIS auditors were accompanied throughout the entire audit by representatives from the CCA and representatives from the regional, branch, and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems (HACCP), (5) Chemical Residue Programs, (6) Microbiological Testing Programs.

Administrative functions were reviewed at the CCA headquarters in Seoul, three regional, and two branch offices, during which the auditors evaluated the implementation of those management control systems which ensure that the national inspection system, verification, and enforcement strategies are implemented as intended.

All three establishments intending to export poultry products to the United States were audited. During the establishment audits, particular attention was paid 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. Additionally, five residue and five microbiology laboratories were audited to verify the CCA's ability to provide adequate technical support to its inspection system.

AUDIT SCOPE SUMMARY

Competent Authority Visits			Locations
Competent Authority	Central Authority	1	Seoul
	Regional Offices	3	Jungbu Regional Office, Honam Regional Office, Youngnam Regional Office
	Branch Offices	2	Cheongju Branch, Daegu Branch
Microbiology Laboratories		5	NVRQS Headquarter Laboratory –Anyang, Institute of Livestock and Veterinary Research (Iksan Branch), Gyeongsangbuk-do Veterinary Service Laboratory (Headquarter) Chungcheonbuk-do Institute of Livestock and Veterinary Research (North Branch) Jeollabuk-do Institute of livestock and Veterinary Research
Residue Laboratories		5	National Veterinary Research & Quarantine Service, Toxic Chemical Division, Headquarter (HQ) Chungcheonbuk-do Institute of Livestock and Veterinary Research (North Branch and HQ) Jeollabuk-do Institute of Livestock and Veterinary Research (Iksan Branch and HQ) North Chungcheong AHL HQ IKsan Branch
Poultry Slaughter/Processing Establishments		3	Iksan City, Chungju City, Kyeongsan City

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
- Poultry Products Inspection Regulations (9 CFR Part 381 et seq.)
- HACCP Regulations (9 CFR Part 417 et seq.)
- Sanitation Regulations (9 CFR Part 416 et seq.)

The audit standards applied during the review 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. Korea has adopted both HACCP and Sanitation Standard Operating Procedures (SSOP) requirements in accordance with the FSIS regulations.

4. BACKGROUND

In December 2005, Korea submitted an initial equivalence determination and requested that FSIS conduct a review of Korea's poultry slaughter and processing system, to establish eligibility to export ginseng chicken soup (Samgyetang [*pronunciation*: säm-gae-täng]) and, possibly, frozen ready-to-eat (RTE) poultry products.

Following the document review process, FSIS conducted the first initial equivalence on-site audit of Korea's poultry inspection system in October 2008. This audit identified findings in the following equivalence components:

- *Government Oversight:* The CCA did not have adequate government oversight and administrative controls over the inspection system. Inspection activities were being conducted by non-government employees who were paid by the establishment. The CCA did not provide evidence to demonstrate direct and continuous official supervision of processing activities for poultry products by the assigned inspectors to assure that adulterated or misbranded poultry products are not prepared for export to the U.S.
- *Sanitation*: Failure to implement and verify sanitation programs within the system.
- *HACCP:* Failure to implement and verify HACCP requirements within the system.
- *Microbiological Testing and Chemical Residue Programs:* FSIS auditors were unable to visit any of NVRQS' laboratories conducting chemical or microbiological analyses of poultry products.

5. GOVERNMENT OVERSIGHT

FSIS import eligibility requirements oblige that the foreign inspection system be organized and administered by the national government and provide standards equivalent to those of the U.S. system. The audit focused on the CCA's performance within six equivalence components upon which system equivalence is based. The first of the six equivalence components that the auditors reviewed was Government Oversight.

Korea's inspection system is divided into two program areas, one overseeing domestic production, and the other for export. The inspection of poultry products proposed for export to the U.S. is under the authority of the Ministry of Food, Agriculture, Forestry and Fisheries (MIFAFF) and the National Veterinary Research and Quarantine Service (NVRQS). NVRQS works in conjunction with the Korean Food and Drug Administration and provincial authorities to ensure products eligible for export meet the requirements of the importing country.

The primary laws for regulating poultry inspection in Korea are the *Livestock Sanitary Control Act* and the *Prevention of Contagious Animal Disease Act*, the *Livestock Products Sanitary Control Act*, and the *Livestock Products Processing Act.* These Acts provide the operational and regulatory authority to carry out Korea's poultry inspection system. FSIS' review of specific regulations based on these Acts concerning the registration of slaughter and processing establishments, inspection activities, and import/export requirements, indicated that the CCA has a clear legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported.

The auditors confirmed that NVRQS maintains ultimate control and supervision for establishments eligible to export poultry and poultry products: enforcement strategies were in place which are similar to those outlined in 9 CFR 500 (Rules of Practice), internal audits were conducted and documented on a form similar to *FSIS' Foreign Establishment Audit Checklist* (FSIS Form 5000-6), and controls were in place to prevent fraud or misuse of export certificates. Export documents are maintained electronically and are password protected. The NVRQS Quarantine Veterinary Officers (QVO) at the Regional Office are in charge of the export certificates, stamps, and the sealing of poultry trucks, thereby maintaining the security and integrity of poultry products during transportation between establishments and port facilities.

The audit indicated that inspection personnel assigned to export facilities were competent and qualified to perform their duties. The NVRQS is responsible for hiring and assigning QVOs who perform inspection oversight and enforcement activities at the export establishments. All QVOs are veterinarians graduated from a college of veterinary medicine with a Doctor of Veterinary Medicine degree. QVOs must pass the National Veterinary Board Exam and obtain a license of Doctor of Veterinary Medicine in accordance with the Article 4 of the Veterinary Law. The QVOs have attended various training programs to gain an understanding of FSIS' inspection requirements: (1) FSIS International Meat and Poultry Inspection Seminar, (2) NVRQS headquarters training course on USDA regulatory requirements (once a month), and (3) Introduction of the Livestock Product Safety Management and the Equivalence Assessment with Practical Case Analysis of the U.S., provided by a consulting firm.

The audit included an assessment of the oversight provided by the CCA to ensure that procedures for laboratories were established and followed as intended. The microbiological staffs at NVRQS headquarters are responsible for formulating microbiological test plans, conducting the test, evaluating microbiological hazards, training analyst, and resolving any microbiological issues. The laboratory testing methods employed by NVRQS for its microbiological testing program are the same as the FSIS Microbiological Guidebook. The MIFAFF and NVRQS are responsible for developing and implementing the National Residue Program (NRP) to ensure safety and wholesomeness of poultry products from poultry farm to poultry slaughter house. The NRP consists of training of analysts, monitoring residues, sampling, laboratory analysis, and an enforcement strategy. NVRQS has the authority to approve and accredit private laboratories. The private laboratories must meet the requirements specified by NVRQS before they are permitted to conduct any analyses for official establishments.

Based on review of official inspection and laboratory documents maintained at headquarters, regional, branch, and local inspection offices, the auditors concluded that Korea's legislation, guidance documents, and instructions were properly disseminated from the CCA headquarters to all inspection and laboratory personnel by e-mail, Intranet, or SharePoint®.

This audit indicated that the CCA has well developed administrative controls in place to support the inspection system; therefore, FSIS concluded that Korea's inspection system meets the requirements for this component.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS team reviewed was Statutory Authority and Food Safety Regulations.

The inspection system must be organized and administered by the national government of the foreign country. The system must provide for ante-mortem inspection of birds, post-mortem inspection of carcasses and parts, controls over condemned materials, controls over establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to official establishments.

The headquarters in Seoul, three regional, and two branch offices were audited in order to review the legislation associated with this component, as well as assess the CCA's ability to effectively communicate these requirements throughout the inspection system.

Korea's requirements for ante-mortem and post-mortem inspection are outlined in the document entitled *Inspection Standards and Detailed Inspection Guidelines Used for Slaughter Livestock and its Meat*. A review of this document indicated that it provides detailed instruction on how inspection officials are to perform post-mortem inspection of poultry carcasses. Korea's *Inspection and Quarantine Guidelines for the Poultry Products to be Exported to the United States, January 2009, Section 6 (Slaughter Inspection)* stipulates the requirements for establishment construction, facilities, and equipment. Inspection personnel are required to condemn livestock or livestock products that fail to meet inspection standards according to Korea's *Enforcement Decree of the Livestock Product Processing Act, Article 19*. Korea's *Livestock Products Processing Act, Article 11 and 12, and* Korea's official letter, January 30, 2009, to the U.S. Ambassador indicated that the CCA would provide daily inspection to establishments that intend to export poultry products to the U.S.

In keeping with FSIS import requirements, *Korea's Inspection and Quarantine Guidelines for the Poultry Products to be Exported to the United States, January 2009, Section 2* requires the CCA perform periodic supervisory visits. These reviews serve as a fundamental layer of oversight to ensure that standards are being met on a routine basis. The auditors observed that supervisory reviews were being conducted bi-monthly by the senior veterinary officer as intended.

As indicated previously, three establishments intending to export to the U.S. were audited. During the audit FSIS reviewed relevant procedures and records maintained by the local inspection offices, and observed how inspection personnel carried out their responsibilities related to verification and enforcement. This review resulted in the identification of the following systemic findings affecting this component:

- One slaughter facility did not have conveniently located controls (e.g., start-stop switches) which would permit government inspectors to regulate line-speeds in order to conduct a protracted post-mortem inspection of carcasses when necessary, or preclude adulterated product from entering the chill tank. Furthermore, a review of Korea's requirements for construction, facilities, and equipment for slaughter operations, contained in *the Inspection and Quarantine Guidelines for the Poultry Products to be Exported to the United States, January 2009, Section 6 (Slaughter Inspection)*, did not address control mechanisms of this type. The absence of this requirement poses a difficulty for the CCA to uniformly implement the enforcement strategies outlined in Korea's *Enforcement Decree of Livestock Products Processing Act*, which grants authority for inspection personnel to slow line speeds as appropriate, and ultimately demonstrate consistent control over non-conforming product.
- Korea's legislation and guidelines do not have a provision requiring inspection stations to have online hand rinsing facilities with a continuous flow of water within easy access to prevent incidental cross-contamination of carcasses associated with post-mortem inspection procedures.

- Korean legislation requires 52-footcandle (540 Lux) lighting at post-mortem inspection stations, while U.S. requirements for a similar system configuration (Streamlined Inspection System [SIS]) and line speed calls for a minimum of 200-footcandles of shadow free lighting, with a minimum color rendering index value of 85. Inadequate lighting at post-mortem inspection stations could result in the failure to perform accurate dispositions. At the time of the audit, Korean officials were unable to provide additional documentation (e.g., performance studies) to demonstrate that a thorough post-mortem inspection of poultry carcasses could be accomplished based on the current lighting requirements.

In addition, while Korean legislation allows up to 8% retained water in poultry carcasses and parts, one establishment audited did not maintain documentation indicating that this standard was being met. The lack of establishment records is an indication that inspection officials were not routinely conducting the appropriate verification activities associated with this requirement.

This audit identified systemic findings regarding controls over facilities for post-mortem inspection. The lack of sufficient controls over post-mortem inspection facilities poses a significant concern, as this could lead to inadequate post-mortem inspection and product contamination. Therefore, FSIS concluded that Korea's inspection system does not meet the requirements for this component.

7. SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and development and implementation of sanitation standard operating procedures.

The CCA has adopted FSIS regulatory requirements for sanitation (9 CFR Part 416 et seq.). The headquarters in Seoul, three regional, and two branch offices were audited in order to assess the CCA's ability to effectively communicate and enforce these requirements throughout the inspection system. The auditor reviewed Korea's strategies including verification procedures to implement sanitation requirements. The following documents were reviewed: K*orea's Inspection and Quarantine Guidelines for the Poultry Products to be Exported to the United States*, *January 2009, Section 4 (Sanitary Control of Establishments for Export), Sanitation Manual for Export Establishments,* Korea's *Livestock Products Processing Act, Chapter 3,* and *Standards for Hazard Analysis Critical Control Point System of Livestock Products, Notification No. 2005-2.* This review concluded that the CCA's strategies in place to disseminate FSIS sanitation requirements were effective.

Three establishments intending to export poultry products to the U.S. were audited to assess the CCA's ability to implement the inspection system's requirements for sanitation. The auditor reviewed the CCA's inspection instructions and inspection records maintained by local inspection offices overseeing these establishments. In addition, the FSIS auditor observed how inspection personnel verified establishment compliance, and assessed the ability to take enforcement action when appropriate. This review resulted in the following finding:

- At one establishment, inspection personnel did not demonstrate the ability to effectively enforce sanitation performance standards requirements for employee hygiene. The auditor observed establishment employees exiting the restroom and returning to the production line

without first sanitizing their plastic sleeves. A parallel review of the establishment's production practices indicated that these sleeves routinely came into contact with product. Additionally, production line employees were observed wearing product contact clothing in the establishment's cafeteria. In both cases, the CCA failed to address these deficiencies in a manner which would indicate that appropriate enforcement controls would be applied on a routine basis.

The CCA has demonstrated process control for the Sanitation equivalence component with the exception of one isolated employee hygiene non-compliance. FSIS concluded that Korea's inspection system meets the requirements for this component.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS

The forth of the six equivalence components the FSIS auditors reviewed was HACCP. The inspection system must require that all official establishments develop, implement, and maintain HACCP plans.

The CCA has adopted FSIS regulatory requirements for HACCP (9 CFR Part 417 et seq.). The headquarters in Seoul, three regional, and two branch offices were audited in order to review the legislation associated with this component, as well as assessing the CCA's ability to effectively communicate these requirements throughout the inspection system. The auditor reviewed Korea's strategies including verification procedures to implement HACCP requirements. The auditor reviewed the following documents: *Standards for Hazard Analysis Critical Control Point System of Livestock Products, Notification No. 2005-2* and *Livestock Products Act.* This review concluded that the CCA has adequate strategies to implement FSIS HACCP requirements.

Three establishments intending to export poultry products to the U.S. were audited to assess the CCA's ability to implement the inspection system's HACCP requirements. The auditor reviewed Korea's inspection instructions and inspection records maintained by local inspection offices having regulatory oversight of the audited establishments. The auditor also observed how inspection personnel applied 9 CFR 417 and other official instructions to verify establishment compliance with the HACCP equivalence component.

This review resulted in the identification of one finding for this component:

- In one establishment's HACCP plan, the CCP monitoring frequency was once per hour. However, the auditors observed that the actual monitoring frequency was every two hours. Additionally, the HACCP plan required daily verification, yet the auditors observed that the actual verification frequency was once per -week. The failure of inspection personnel to identify this non-compliance is most likely related to the frequency which HACCP verification activities were conducted, rather than a lack of knowledge. Interviews with inspection personnel indicated that they were familiar with HACCP requirements, but verification activities had only been conducted bi-monthly, as the establishment was not yet exporting to the U.S.

The CCA has demonstrated process control for the HACCP equivalence component with the exception of one isolated HACCP finding. FSIS concluded that Korea's inspection system meets the requirements for this component.

9. CHEMICAL RESIDUE PROGRAMS

The fifth of the six equivalence components the FSIS auditors reviewed was Chemical Residues. The inspection system must have a chemical residue control program, organized and administered by the national government, which includes random sampling of internal organs and fat of carcasses for chemical residues identified by either the exporting country's poultry inspection authorities or by FSIS as potential contaminants.

The CCA headquarters in Seoul, three regional, and two branch offices were audited to determine if Korea has regulatory authority to enforce requirements of the Chemical Residue Control Program equivalence component.

The auditors interviewed the CCA and reviewed the NRP, laboratory testing methods, enforcement strategies, and communication tools. The auditor concluded that Korea's residue plan was properly designed to include all compounds of concern to both Korea and the U.S.

Two slaughter establishments were audited to determine Korea's regulatory authority to implement and enforce the requirements of the Chemical Residue Control Program equivalence component at the establishment level. The auditor reviewed Korea's legislation, inspection instructions, and inspection records maintained by local inspection offices, which had regulatory oversight over these establishments. Also, the auditor observed how inspection personnel applied Korea's legislation and official instructions to verify establishment compliance with the requirements of the Chemical Residue Control Program. The auditor observed inspection personnel were following Korea's NRP sampling protocol. This included sampling location, sampling size and site, and the delivery of residue samples to laboratories. Animal Health Laboratories report test results to NVRQS. In case of a violative sample result, NVRQS implements an enforcement strategy, which includes investigating the cause of the violation and collecting additional samples. The investigation will determine the type of enforcement action taken against the violator in accordance with Article 32 (Procedures for Imposition and Collection of Fines for Negligence) of Korea's *Enforcement Decree of Livestock Products Processing Act*.

In addition, five government laboratories were audited. The auditor reviewed the following: sample handling, sampling frequency, timely analysis, date reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, percent recoveries, intra-laboratories check samples, and quality assurance programs, including standards books and corrective actions. This review identified several systemic deficiencies in laboratory practices.

The laboratory did not consistently maintain the proper identification of analytical reagents (dates opened, expiration dates, and inventory control numbers), and standard solutions did not consistently identify the preparer's name, date of preparation, standard identity, concentration, and expiration date. Additionally, they did not document Upper Control Limits, Upper Warning Limits, Lower Control Limits, and Lower Warning Limits on control charts, and laboratory supervisors failed to include routine recoveries and intra-laboratory checks for each analyst in the control charts.

Other findings included the fact that they did not have a consistent procedure among establishments on the type of samples collected for the NRP, such as one government inspector would send the whole bird as a sample, while another would send the tissue. They also did not demonstrate consistent policies and procedures for temperatures and calibration records; did not consistently conduct intra-laboratory sample checks for analysts; and did not consistently implement the Limit of Detection and Limit of Quantification methods among laboratories conducting the same analyses.

The NVRQS headquarters laboratory is ISO 17025 accredited, however this laboratory did not have an effective quality control system and it did not require standardized testing procedures amongst its laboratories. Other laboratories performing NVRQS chemical residue testing were not ISO 17025 accredited.

This audit detected significant systemic findings in laboratory practices for this equivalence component. The CCA did not have consistent controls over the implementation of laboratory quality systems. Lack of controls in NVRQS' laboratory oversight could lead to inadequate detection of chemical residues, potentially resulting in adulterated products being exported to the U.S. Therefore, FSIS concluded that Korea's inspection system does not meet the requirements for this component.

10. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components the FSIS auditors reviewed was the CCA Microbiological Testing Program. The system must implement sampling and testing programs to ensure that poultry products produced for export to the U.S. are safe, wholesome and unadulterated.

The CCA headquarters in Seoul, three regional, and two branch offices were audited to determine if Korea has regulatory authority to maintain and enforce adequate government oversight for the implementation of the CCA's microbiological program.

The auditor's interviewed the CCA and reviewed relevant records including analyst qualifications, sampling protocols, testing methods, test reporting, enforcement strategies, and communication tools. This review concluded that the CCA's microbiological program was properly designed.

Three establishments were audited to determine Korea's regulatory authority to enforce the requirements of the Microbiological Testing Programs equivalence component. The auditor reviewed Korea's legislation, inspection instructions, and inspection records maintained at local inspection offices, which had regulatory oversight over the audited establishments. Also, the auditor observed how inspection personnel applied Korea's legislation and official instructions to verify establishment compliance with the requirements for Microbiological Testing Programs.

The CCA has regulatory requirements including sampling and enforcement strategies for testing programs related to *Salmonella* species, which mirror FSIS testing requirements. The inspection personnel followed FSIS' sampling protocol, which includes testing frequency, sample collection, and the delivery of samples to laboratories. The Animal Health laboratories report the test results to the NVRQS.

The CCA conducts verification activities monitoring establishment's generic *Escherichia coli* requirements for poultry products. The CCA has implemented generic *Escherichia coli* requirements in accordance with FSIS regulations. The auditor concluded that the CCA's testing program is compliant with FSIS requirements.

Korea requires that establishments intending to export to the U.S. meet FSIS requirements for *Listeria monocytogenes* and *Salmonella spp.* for both post-lethality and non post-lethality exposed ready-to-eat (RTE) poultry products, and have verification testing programs. The RTE programs include specific provisions for government sampling of product, government oversight of establishment sampling, and the verification of control measures in every establishment certified for export to the United States. Korea's RTE program meets FSIS requirements.

Five government laboratories were audited. This review resulted in the identification of systemic findings in laboratory practices.

While testing methods for *Salmonella spp.* and *Listeria monocytogenes* were successfully implemented, the CCA did not demonstrate adequate oversight for quality control and assurance programs for the laboratories in their system. While the headquarters laboratory in Anyang was ISO 17025 accredited, other laboratories in the program were not accredited, and recordkeeping for quality systems were inconsistent and incomplete regardless of accreditation status. As an example, the frequency and the documentation of equipment verification, calibration and maintenance related to relevant testing methods was variable among laboratories and not entirely consistent with international standards (ALACC and EA 04/10 guidance for microbiological testing laboratories). Verification records related to culture media preparation, testing procedures and use of controls were not consistent or complete from one laboratory to the next. Sample reports did not include information on testing methods used for the analysis.

This audit detected significant systemic findings in laboratory practices for this equivalence component. The CCA did not have adequate controls over the implementation of laboratory quality systems. The lack of proper implementation of laboratory quality systems could compromise effective detection and identification of pathogens, potentially resulting in adulterated products being exported to the U.S. Therefore, FSIS concluded that Korea's inspection system does not meet the requirements for this component.

11. EXIT MEETING

An exit meeting was held on November 29, 2010, in Seoul with the CCA, NVRQS, and representatives of the Foreign Agricultural Service. At this meeting the preliminary findings from the audit were presented by the FSIS team leader.

The CCA understood and accepted the audit findings.

12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The auditors confirmed that all prior systemic findings were appropriately addressed. Furthermore, the auditors concluded that the CCA was able to meet the FSIS requirements for the following equivalence components: (1) Government Oversight, (3) Sanitation, and (4) HACCP.

However, the current audit resulted in the identification of systemic findings within the equivalence components of: (2) Statutory Authority and Food Safety Regulations, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs.

- The CCA did not provide adequate control of establishment facilities for post-mortem inspection.
- The CCA did not provide adequate control over the implementation of laboratory quality systems within its National Residue Program.
- The CCA did not provide adequate controls over the implementation of laboratory quality systems associated with microbiological testing of product, which is intended for export to the U.S.

In order to demonstrate that Korea's poultry inspection system meets the FSIS import requirements, the CCA is to submit a comprehensive corrective action plan addressing the specific audit findings outlined in the report for each component. FSIS will evaluate the extent to which the proffered corrective actions sufficiently address the systemic findings identified. Provided the corrective actions are sufficient, FSIS will make the recommendation to move forward with the rulemaking process for system equivalence. However, FSIS may conclude that an additional on-site audit is necessary to verify the adequacy of the corrective actions provided.

AJ Ogundipe
Senior Equivalence Officer

13. ATTACHMENTS TO THE AUDIT REPORT

Foreign Country Response to Audit Report

MINISTRY FOR FOOD, AGRICULTURE, FORESTRY & FISHERIES

To: See recipients listed below.

Subject: Notification of Comments on U.S. Draft Audit Report for Equivalence Related to the Export of Ginseng Chicken Soup (*Samgyetang*)

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1. This is related to the document from the U.S. Embassy, dated March 7, 2011.

2. The U.S. Government, in the above referenced document, provided the audit report (draft) based on the onsite audit (November 15~29, 2010) conducted in relation to the export of ginseng chicken soup to the United States. The U.S. Government asked the Korean government to provide comments if we had any comments regarding the audit report (draft).

3. In relation to this, we hereby provide you with the attached Korean government's comments on the audit report (draft). We ask the U.S. Embassy in Korea provide assistance in allowing for these comments to be conveyed back to the U.S. government.

4. In addition, we propose that we hold a DVC among the experts from both countries, as we judge that we need to provide you with a thorough explanation about the comments being sent to your government. We would like to receive your thoughts about such proposal. We would also appreciate it if you could provide us with your government's opinion and the future time schedule within the U.S. government regarding the export of chicken ginseng soup to the United States.

Attachment: Copy of Korea's comments (sent separately) /End/

MINISTER FOR FOOD, AGRICULTURE, FORESTRY & FISHERIES /Sealed/

Recipients: U.S. Ambassador to Korea (Agricultural Attaché), Ministry of Foreign Affairs & Trade (Director of North America and EU Trade Division), Director of International Cooperation Coordination Division, Director of Safety & Sanitation Division, Director General of National Veterinary Research & Quarantine Service (Director of Livestock Products Safety Division)

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