



United States Department of Agriculture

Food Safety and
Inspection Service

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OCT 20 2014

Dear Dr. Galon,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Israel's poultry inspection system from June 23 through July 4, 2013. FSIS received your comments to the report, and has included them as an attachment to the enclosed copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-0676, or electronic mail at international.audit@fsis.usda.gov.

Sincerely,

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit

Enclosure

ISRAEL
FINAL AUDIT REPORT

October 20, 2014

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an ongoing equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from June 23 - July 4, 2013, to determine whether Israel's food safety inspection system governing the production of poultry continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled. Currently, Israel has 12 establishments certified eligible to export processed poultry product to the United States.

The audit focused on six equivalence components: (1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. Within each of these components, the FSIS auditor reviewed available information, including verification of the proffered corrective actions by the Central Competent Authority (CCA) to findings from FSIS' July/August 2009 audit.

The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters in Tel Aviv, Haifa regional office, and two poultry slaughter and processing establishments and one poultry processing-only establishment to verify that the national system of inspection, verification, and enforcement is being implemented as described by the CCA.

The on-site audit findings are summarized below and further described in the respective sections of the report.

- In the two of seven slaughter establishments certified to produce raw poultry product audited, evisceration lines exceeded the "24 birds per minute" line speed required by Israel for poultry products exported to the United States. The CCA did not provide documented support for the higher speed or for why higher speed would not result in public health concerns.
- Poultry carcasses were entering the chillers in both slaughter establishments with an abnormal number of feathers attached.
- In one slaughter establishment, during the pre-operational verification, the auditor noted that in the feather-picking room, there was organic matter build-up behind the washers that supported rubberized picker. These washers were thus not maintained in a sanitary manner. The sanitation of these areas is not included in SSOP or any other sanitation program. In addition, the auditor observed that chiller tanks had pieces of fat of varying sizes floating in multiple sections of two chillers.
- In the second slaughter establishment, during the operational sanitation verification, the auditor noted that the overflow mechanism was faulty, which allowed scum and extraneous material to form on the surface of the water, creating insanitary conditions and allowing for potential contamination of the product.
- A review of the microbiological results for *Salmonella* performance standards for the slaughter establishments revealed that the percentage of positive results was trending higher than the Israel inspection system permits.

The audit results indicate that Israel's food safety inspection system continues to maintain equivalence with the United States' system and is operating at an "adequate" level of performance. However, the audit findings and post-audit POE violations raise concerns about the CCA's government oversight and food safety program implementation. FSIS needs a response from Israel within 60 days to support Israel's ability to effectively verify that establishment will conduct a hazard analysis, implement controls, and oversee controls to prevent future *Salmonella* violations. During the exit meeting, the CCA noted that it will verify that corrective actions have been taken to address the above audit findings.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an equivalence verification audit of Israel's poultry inspection system from June 13-July 4, 2013. Israel is eligible to export processed poultry product to the United States and has certified 12 establishments to export product.

During calendar years 2012 and 2013, Israel cumulatively exported 2,620,857 pounds of processed poultry products to the United States, of which 449,301 pounds were re-inspected by FSIS' import inspectors at point-of-entry (POE). During 2012, no product exported to the United States was rejected for food safety reasons. Following completion of the FSIS audit, FSIS identified *Salmonella* in two separate lots of fully-cooked, not shelf stable RTE poultry products from the same Israeli establishment. The first violation was identified in September 2013 and involved RTE chicken nuggets, while the second was identified during intensified sampling in October 2013 in grilled chicken breast. Both lots were refused entry, and Israel was notified of the findings. FSIS received the investigative report and corrective measures provided in response to the finding. The proffered corrective actions are under review by FSIS.

This audit was conducted pursuant to the specific provisions of United States laws and regulations, in particular:

- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.); and
- The Poultry Products Inspection Regulations (9 CFR Part 381 et seq.), which includes the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations.

In addition, the standards applied during this audit of Israel's poultry inspection system included all applicable legislation originally determined by FSIS as equivalent as part of the initial equivalence process, and any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement.

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Israel's food safety inspection system governing poultry products continues to be equivalent to that of the United States, with the ability to produce and export products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six program components with the objectives of determining whether each component is and can maintain its system equivalence. The six equivalence components are the following: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the July/August 2009 FSIS audit's finding were being implemented.

III. AUDIT METHODOLOGY

For this equivalence verification audit, FSIS utilized its established four-phase process: planning, execution (on-site), evaluation, and feedback. Each phase is described below.

The planning phase involved document and data analysis of previous audit observations and other available information. FSIS examined the CCA's performance within six equivalence components, data on exported product types and volumes, POE testing results, and other data collected since the last FSIS audit in 2009. The 2009 audit findings concerned mainly sanitation and HACCP components. These findings are further detailed in the corresponding sections of this report. The 2013 audit confirmed that the corrective actions are in place and effective. In addition, the FSIS auditor reviewed information obtained directly from the CCA, through the Self-Reporting Tool (SRT), outlining the structure of the inspection system, and identifying any significant changes that have occurred since the last FSIS audit. This comprehensive analysis served as the basis for planning the on-site audit itinerary.

The second phase was the onsite verification. FSIS verified the CCA's oversight activities through onsite document reviews, interviews, and observations and site visits. The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA, Ministry of Agriculture, Veterinary Services and Animal Health (VSAH), including members from the regions or establishment inspection offices.

The second phase was the onsite verification. The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters, Haifa Regional Office, three establishments (two poultry slaughter/processing and one processing) eligible to export to the United States, and one of three private laboratories. This review verified that the national system of inspection, verification, and enforcement was being implemented in an equivalent manner. There are twelve certified establishments approved for export of product to the United States— seven slaughter/processing and five processing. Three of these twelve were selected for the audit based on the volume of exports to the United States and POE results. During the establishment visits, particular attention was paid to the extent to which government ensures control of hazards and prevents non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with the Title 9 Code of Federal Regulations (CFR) (9 CFR 381.196).

The third phase was evaluation. FSIS conducted an evaluation of all data collected on-site to determine whether the CCA's performance design and execution were consistent with the information provided to FSIS via the SRT and other submitted documents. An extensive analysis of all data was used to make the equivalence decision.

The final phase of the audit is feedback, which begins with this draft audit report providing the CCA with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report. Then, FSIS and the CCA mutually develop an action plan to address any issues raised by the audit. These issues will be tracked by FSIS until resolution and will be automatically included as areas of special emphasis in the next onsite verification audit.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import eligibility requirements state that the foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the system of poultry inspection in the United States. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices, audited establishments and a private laboratory.

Israel's administration of food safety is vertically organized into national, regional, and local government levels. At the national level, the Israeli Veterinary Services and Animal Health (IVSAH) is a subdivision of the Ministry of Agriculture and Rural Development (MARD) and is considered the Central Competent Authority (CCA). The director of IVSAH provides leadership to a variety of programs, including products of animal poultry origin and the import/export of these products. Among the offices overseen by the director of IVSAH related to FSIS import requirements include Control of Animal Products and Kimron Veterinary Institute located in Beit Dagan. The Office of Control of Animal Products, which is headed by the Chief Veterinarian, is responsible for supervising inspection offices directly below the national level.

For the purpose of export, Israel is comprised of two regions, located in Haifa and Beit Dagan respectively. Each of the regions is headed by a regional veterinary officer (RVO) who is a second-level inspection official and is responsible to provide oversight to the poultry slaughter and processing establishments eligible to export to the United States in his/her respective region. The RVOs are also responsible for conducting periodic supervisory reviews at the United States-eligible establishments and recommending the approval or withdrawal of these establishments.

The local level of inspection within the IVSAH consists of a team of inspectors. A large percentage of this workforce includes veterinarians. The other members are trained and skilled inspectors, who work under the supervision of the veterinarians. Each United States-eligible establishment within Israel is overseen by a Veterinarian In-Charge (VIC). The VIC oversees a staff of inspection personnel, whose size varies based on the size and complexity of the operation. Under the supervision of the VIC, the inspection staff at each United States-eligible establishment performs daily inspection tasks within slaughter and processing establishments to ensure that products exported to the United States are safe, wholesome, and properly labeled. All RVOs, VICs, and line inspectors in the slaughter establishments are full-time employees of the Israeli Egg and Poultry Board (EPB), which is co-owned by the government and the poultry farmers, and whose chairman is an official nominated by the government. The EPB collects fees from the establishments for the inspection services rendered. The previous audits of the Israeli inspection system provided information on the EPB, the nature and extent of farmers' involvement as a co-owner of the board and its ultimate impact on inspection system policies including matters related to conflict of interest. FSIS will evaluate this information in conjunction with the response provided in the CCA-SRT to determine if the pertinent criteria in the government oversight are satisfied.

The FSIS auditor found that, in the further-processing facilities, the non-veterinary inspection personnel are employed by the local municipal councils and are paid from fees collected by these government agencies from the establishments for inspection services rendered. Under the specific provisions of "The Animal Diseases Regulations (Poultry Slaughterhouses), 5720-1960," the CCA is entrusted with the authority to certify or decertify the slaughter establishment and appoint the inspection staff to perform specific inspection duties in these facilities. Additionally, the aforesaid authorities empower the head of the inspection system to independently render decisions pertaining to disciplinary actions, including removal from employment of any employee determined to be in violation of employment terms or performing his/her duties at a marginal level.

The CCA's authority to enforce inspection laws is outlined in the Animal Diseases Regulations (Poultry Slaughterhouses), 5720-1960, the Business Licensing Regulations (Sanitary Conditions for Food Production Businesses), 5732-1972, and Regulations for the Control of the Manufacture of Poultry Products for Export and their Export, 1976. These regulations grant the authority to the inspection system to enforce food safety regulations and require that establishments implement sanitary measures when preparing food for domestic and foreign markets. In addition, a supplemental document entitled "*Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*" is implemented and enforced for those establishments certified to export to the United States. Based on these regulations, the CCA has developed documents known as "procedures and procedure instructions" to facilitate implementation of its inspection policies. These procedures include a range of documents, which include staff assignments, exporting establishments, qualifications and hiring procedures, and training programs, among others.

The CCA has the legal authority and responsibility to enforce requirements equivalent to those governing the system of poultry inspection organized and maintained in the United States. A direct authority of inspection staff assigned to the exporting establishments to enforce Israeli laws regulations and FSIS import requirements is drawn from the aforesaid regulations. All processed poultry products exported to the United States, in all three audited establishments, were segregated from domestic production. The FSIS auditor identified several findings related to oversight within four of the six equivalence components.

Below are examples of findings related to system requirements outlined in 9 CFR 381.196.

- In two audited slaughter establishments, concerns related to line speed were identified.
- The on-site audit identified issues with Sanitation Performance Standard (SPS) and Standard Sanitation Operating Procedures (SSOP) in all three establishments.
- During the review of microbiological testing results in two slaughter establishments, the auditor noted a higher percentage of positive results for *Salmonella* performance standards sets than the Israel inspection system permits.

The twelve United States-eligible establishments are located in two regions. Each region is overseen by an RVO who conducts periodic supervisory reviews in the establishments located in his/her respective region. During the audit of the Haifa regional office, the FSIS auditor interviewed the RVO and reviewed inspection-related documents maintained in either electronic format or hard copy. The FSIS auditor confirmed that the frequency of periodic supervisory reviews conducted at the United States-certified establishments is every 30 - 90 days regardless of the type and size of operation. The criteria for these varying frequencies are derived from the establishment's compliance history and performance of the VIC.

The procedure sheet 0.2.2 “Regional Veterinary Officers – Monthly Report” lays out instructions for RVOs on how to complete the reviews and consists of two sections: The first section of the review is plant-specific, while the second section is the portion of the report where RVO provides details of his/her observation on the performance of the inspection staff. A copy of the plant portion is provided to the plant management. The portion pertinent to the VIC performance is discussed separately with the VIC. Serious issues with the performance of the VIC or other staff are immediately addressed. During the Haifa regional office audit, the auditor verified an example of a recent disciplinary action taken against inspection personnel and determined that the RVO follows the governmental standards and policies when handling performance-related issues.

The auditor examined a sample of supervisory reviews for the last 90 days (March-May 2013) and verified that the reviews were conducted in a manner that conforms to the procedures specified in the procedure instructions 0.2.2 “Regional Veterinary Officers – Monthly Report.” The auditor further verified that the frequency of these reviews was in accordance with the specified schedule. The FSIS auditor noted that the supervisory review was somewhat lacking in its ability identify weaknesses in verification methodology pertaining to pre-operational SSOP and SPS which were not being followed in accordance with procedural documents 1.2.1 “SSOP- IIC Verification of Sanitary Standard Operating Procedures (SSOP) in Poultry Establishments Authorized for Export” and 1.3.1 “SPS-Veterinary inspection of Sanitation Performance Standards (SPS) in Production areas of Poultry Establishments Approved for Export”, respectively.

The FSIS auditor assessed the CCA’s oversight of the food microbiology section of the Kimron Veterinary Institute (KVI) a part of IVSAH during both the planning and execution phases; however, no on-site visit to this laboratory was made during this audit. The microbiology laboratory was last reviewed during the 2009 FSIS audit, while the chemical residue laboratory of KVI was last audited in 2008. Neither audit noted any significant findings as a result of FSIS’ reviews of these laboratories. The FSIS auditor reviewed laboratory-related data collected prior to the 2013 audit by analyzing documents in the SRT. The FSIS auditor interviewed inspection personnel RVO on-site and reviewed the CCA’s verification activities with respect to these laboratories. The auditor confirmed CCA’s verification of the fact that the government-owned laboratories have developed a Quality System Manual and Standard Operating Procedures for conducting analytical methods on the product for export to the United States.

The audited slaughter and processing establishments use private laboratories for analysis of products and the processing environment as part of their food safety verification program. The private laboratories conduct generic *E. coli* testing on raw products, test products, and the environment in which these RTE products are processed and held. Private laboratories do not conduct analysis on official government samples. Two of such laboratories were audited in the last FSIS audit with no significant findings. The current audit included an on-site visit to one of seven private laboratories that analyzes samples submitted by establishments certified to export to the United States.

The FSIS auditor reviewed the following:

- Receipt of samples, the security of samples and the traceability of samples
- Electronic entry of information into the laboratory electronic information system
- Processing of samples by the analyst assigned to the sample
- Laboratory practices and review of application of methods

- Calibration of equipment, both annual certifications of calibration and daily verification calibration
- the procedures and records of calibration
- Media preparation
- Traceability and preparation of media
- Sterility and selectivity checks for media
- Control and documentation of standards used to conduct sterility and selectivity checks for media
- Sample storage prior to analysis and after analysis
- Recording and distribution of results

Any concerns that arose as result of the review are noted in the relevant section of the microbiological component of this report. The CCA relies on the requirement that each private laboratory serving exporting establishments be accredited by the Israel official accreditation body known as National Certification Agency (ISRAC) for the standards specified in ISO 17025. In addition to accreditation of laboratories, the ISRAC provides approval of analytical methods used by the laboratories in Israel.

During the on-site visit to the Haifa regional office, slaughter establishments, and one processing establishment, the FSIS auditor reviewed inspector-generated records and interviewed in-plant inspection personnel as well as regional auditors conducting supervisory reviews. At all establishments, the auditor identified concerns pertaining to the sanitation component. At the two slaughter establishments, the FSIS auditor noted that the line speed was greater than stated in the Veterinary Service procedure sheet 3.1.5 "Slaughter and 'Evisceration' Line Speed in an Abattoir," which contains instructions to industry and the inspection personnel. Further details regarding these findings are discussed in the appropriate section of the Statutory Authority and Food Safety Regulations Component.

The FSIS auditor reviewed the last 12 months of periodic supervisory reviews conducted at the two slaughter and one processing establishments and determined that some of the concerns identified above were not detected in the reviews conducted by the RVOs.

Lastly, the auditor verified that the CCA had corrected all the findings from the 2009 audit of Israel's inspection system. These findings were mainly related to SSOP, SPS, and HACCP.

FSIS' onsite audit, including observations, document reviews, and interviews, in combination with FSIS' review of the SRT and document analysis of the CCA's control measures, establish that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection and periodic supervisory visits to United States-eligible establishments.

FSIS' evaluation of this component included an analysis of information that CCA provided in the SRT and information gathered during the on-site verification phase of the audit. The FSIS auditor confirmed that official inspection and verification activities were in accordance with the responses in the SRT and supporting documentation.

During the CCA's headquarters audit, the FSIS auditor verified that the CCA derives its regulatory authority to organize the inspection system and regulate national ordinance, laws, and regulations governing poultry inspection system from the following:

- Animal Disease Regulations (Poultry Abattoirs), 5720-1960
- Business Licensing Regulations (Sanitary Conditions for Food Production Businesses), 5732-1972 and,
- Animal Diseases Regulations (Import and Export of Animal Products) 5748-19881

The auditor confirmed that the CCA has developed instructions to implement the aforesaid regulations governing the poultry inspection system, including FSIS import requirements. The instructions give regulatory authority to enforce requirements for HACCP, sanitation, chemical residue and microbiological sampling, ante-mortem inspection, post-mortem inspection of carcasses and parts, controls over condemned materials, controls over establishment construction, facilities, equipment, and daily inspection.

During the on-site visit to the Haifa regional office, the FSIS auditor conducted a thorough examination of regional oversight activities, including periodic supervisory reviews of United States-eligible establishments, monthly microbiology laboratory reviews, inspection enforcement activities, and on-going training for inspection personnel by interviewing the regional auditors and reviewing numerous inspection documents.

As a part of the evaluation of information contained in the CCA-SRT and the associated supporting documents, the auditor verified that the CCA exercises its authority to conduct ante-mortem and post-mortem inspection grounded in accordance with articles 9c and 11 of Poultry Abattoirs Regulations 1960 and Article 50 of the Inspection of Animals and Animal Products for Export Regulations (Poultry Products) 1976. The inspection system has developed procedural instructions for establishments to meet the requirements of aforesaid regulatory requirements. The FSIS auditor verified that in-plant personnel conduct ante-mortem inspection in accordance with the standards established in the following procedure sheets:

- PS 3.1.2 "Ante-Mortem Poultry Inspection in an Abattoir"
- PS 6.1.9 "Poultry Cruelty Prevention in an Abattoir"

Ante-mortem inspection is conducted on the day of slaughter. In the event that in-plant inspection personnel detect during ante-mortem inspection the clinical signs suggestive of conditions listed below, the slaughter of poultry is delayed, and RVO is notified. The VIC is required to document the finding using the appropriate appendix of the PS 3.1.2 "Ante-Mortem Poultry Inspection in an Abattoir" for the final disposition of the affected flock. The disposition of a suspected flock is rendered either by an RVO or the chief of the animal product inspection. When warranted, the RVO will seek laboratory

confirmation for a definitive diagnosis of the condition of the flock. The following conditions require delayed slaughter and a decision from the RVO on final disposition of the flock:

- Symptoms of Newcastle disease
- Respiratory diseases
- Poultry showing diseased conditions because of parasitic infestation, neoplasm, injuries and bruises, dead on arrival, or contamination by chemical or toxic substances

A number of instruction sheets pertaining to the implementation of post-mortem inspection of poultry are available to inspection personnel. The auditor's assessment of post-mortem inspection included the reviews of information contained in CCA-SRT and associated supporting documents. The on-site portion of the auditor's assessment of post-mortem inspection included record review, interviews, and observation of inspection activities in all audited slaughter establishments. The auditor confirmed that the VIC and other inspection staff assigned to the slaughter establishments conduct post-mortem examination on each poultry carcass. While verifying the implementation of standards specified in PS 3.1.5 "Slaughter and Evisceration Line Speed in an Abattoir" regarding slaughter line speed, the auditor noted that:

- In the two of seven chicken slaughter/processing United States -eligible establishments audited, lines were running past the inspectors at the rate greater than 24 birds/minute which is contrary to the standards stated in aforesaid procedure instructions. In one slaughter establishment, the evisceration line was running 7.7% higher than allowed speed, while in the second slaughter establishment the observed speed was 9.6% greater than CCA-mandated speed. The relevant section of the PS 3.1.5 "Slaughter and Evisceration Line Speed in an Abattoir" states, "According to the Veterinary Services' instructions, slaughter line speed in abattoirs authorized for poultry meat export to the United States, must not exceed 24 fowls per minute per inspector."
- In the two slaughter establishments, an abnormal number of feathers remained attached to the poultry carcasses entering the chillers. The presence of feather on the carcass and parts was also observed but to a significantly lesser extent in the cut-up areas.

The FSIS auditor verified that the CCA exercises its legal authority to require that the United States -eligible establishments develop, implement, and maintain sanitation programs that sufficiently prevent direct product contamination or insanitary conditions. The in-plant inspection personnel at three audited slaughter/processing establishments verify sanitary conditions in accordance with the methodology described in the procedure sheet, which include the evaluation of written sanitation programs and the verification inspection of both pre-operational and operational procedures. Sanitation verification further requires in-plant personnel to observe the establishments' verification of monitoring, to review records, and to conduct hands-on activities that prove the effectiveness of sanitary measures.

The observations made during FSIS' on-site audit, document reviews, and interviews in combination with FSIS' pre-audit SRT document analysis of the CCA's statutory authorities all sufficiently demonstrate that the CCA continues to meet the core equivalence requirements for this component. Israel's meat inspection system has legal authority and a regulatory framework to implement requirements equivalent to those governing the FSIS system of meat inspection in the United States. The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA must provide requirements for all areas of sanitation, sanitary handling of products, and SSOP. Prior to the on-site portion of the audit, the auditor reviewed and analyzed the information provided in the CCA component of the SRT and the supporting documents pertaining to implementation and verification of sanitation requirements. The analysis indicates that the Israeli inspection system draws its legal authority to require food businesses to implement and maintain sanitation through the following legal instruments:

- Animal Diseases Regulations (Poultry Abattoirs), 1960
- Business Licensing Regulations (Sanitary Conditions for Food Manufacture Business), 1972
- Regulations for the Control of the Manufacture of Poultry Products for Export and their Export, 1976

The CCA delivers instructions to United States- eligible establishments through a series of written implementation documents referred to as Procedure Sheets (PS). Additionally, these PS also provide guidance to the inspection personnel on how to verify the implementation of sanitation requirements by the establishments. Relevant to the sanitation component, the auditor reviewed and analyzed the following PS:

- PS 3.0.0 – Cleaning and Disinfection of Poultry Transport Cages
- PS 2.0.2 – Level of Cleanliness in Abattoirs and Factories for the Processing of Poultry Meat for Export – Microbial Monitoring
- PS 3.0.7 – Handling and Reporting Procedure in Animal Products Processing Factories which Endure Recurring Sanitary Deficiencies
- PS 1.2.1 – IIC Verification of Sanitary Standard Operating Procedures (SSOP) in Poultry Establishments Authorized for Export
- PS 1.3.1 – Veterinary Inspection of Sanitation Performance Standards (SPS) in Production Areas of Poultry Establishments Approved for Export

The Procedure Sheets 1.2.1 "IIC Verification of Sanitary Standard Operating Procedures (SSOP) in Poultry Establishments Authorized for Export" and 1.3.1 "Veterinary Inspection of Sanitation Performance Standards (SPS) in Production Areas of Poultry Establishments Approved for Export" provide the instructions to the in-plant inspection personnel on how to verify the establishment's compliance with the requirements of SSOP and SPS respectively in United States-certified establishments. In each procedure sheet, inspectors verify the following, which ensures that each United States-eligible establishment has the following:

- Written SSOP and SPS plans that are approved and signed by the establishment management, and identification of the person responsible for implementation.
- Implementation and monitoring of the SSOP and SPS as written.

- Procedures to maintain and routinely evaluate the effectiveness of the Sanitation SOPs and the elements identified in SPS in preventing direct contamination or adulteration of products and revise them as necessary.
- Corrective actions implemented as required.
- Record of the SSOP and SPS plans to document that each procedure in the plans is carried out as intended.

The SSOP verification activities are clearly defined into pre-operational and operational components. In a two-shift operation, only operational sanitation is verified for the second shift as such establishments continue the operation into second shift without an intervening pre-operational sanitation.

The PS 1.2.1 “IIC Verification of Sanitary Standard Operating Procedures (SSOP) in Poultry Establishments Authorized for Export” contains six appendices, most of which are daily inspection verification forms completed by the VIC or inspection personnel during the operation. Other appendices are guidance and decision trees to assist inspection personnel in making critical inspection assessments. The product retention or condemnation and/or equipment rejection are identified by applying official retain/reject tags.

The PS 1.3.1 “Veterinary Inspection of Sanitation Performance Standards (SPS) in Production Areas of Poultry Establishments Approved for Export” is also supplemented with three appendices. Appendix A identifies the areas that need to be verified by inspection personnel for establishments’ compliance with the SPS requirements. Appendix A mirrors FSIS’ regulatory requirements as described in 9 CFR 416.2-6. The appendix B of the remaining two appendices is the daily inspection verification form. Appendix C is used by inspection personnel to document noncompliance.

The FSIS auditor gathered information at government offices and three of the United States-eligible establishments. The FSIS auditor observed, at one slaughter/processing and one processing establishment the inspection personnel conducting pre-operational sanitation verification. The verification activities include reviewing daily pre-op document and corrective action when applicable.

During the VIC-led verification review of facilities:

- In an establishment that processes RTE products, the auditor observed multiple brown totes that receive raw poultry that had visible pieces of meat and fat from the previous day, cracks, and other damage.
- During the pre-operational verification at one slaughter establishment, the auditor noted that in the feather picking room, there was organic build-up behind washers supporting rubberized pickers with organic matter and was not maintained in sanitary manner. The sanitation of these areas is not included in SSOP or any other sanitation program.
- In the same slaughter establishment, the auditor observed that chiller tanks had pieces of fat of varying sizes floating in multiple sections of two chillers.
- In the slaughter establishment, the auditor noted that the overflow mechanism was faulty, which allowed scum and the extraneous material to form on the surface of the water, creating insanitary condition and potential for contamination of the product.

The VIC at each establishment took immediate corrective action that included rejecting defective equipment followed by issuance of noncompliance document to the establishment.

The FSIS auditor observed inspection personnel conducting inspection verification of operational sanitation procedures at three of twelve United States-eligible establishments. Verification activities consist of two components: a direct observation of operations and review of the establishment's records relevant to the SSOP. In addition, FSIS reviewed each establishment's sanitation monitoring and correlated its inspection verification records and supervisory reviews for the same time period. The auditor noted that some of the observations made during the pre-operational verification should have been detected either by the in-plant personnel or by supervisory reviews. The establishments did maintain sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken.

This audit confirmed that the CCA had implemented corrective actions pertaining to Sanitation component in response to the audit of 2009 for the following deficiencies:

- One establishment did not maintain the spice room in a sanitary condition
- One establishment did not maintain the room utilized for the storage of product labels in a manner to prevent the creation of insanitary conditions.
- One establishment did not provide written procedures for the cleaning of the ice storage room and also failed to include the ice storage room in their pre-operational and operational sanitation monitoring program. In addition, condensation was observed around refrigeration unit; however, no direct product contamination was observed.

FSIS did not note any instances of direct product contamination. However, the audit findings indicated a weakness in the CCA's enforcement of sanitation requirements. The results of the overall assessment of the sanitation programs demonstrated that the inspection system provides requirements equivalent to that of the United States for sanitary handling of products and for the development and implementation of sanitation standard operating procedures. The CCA has implemented immediate corrective actions in response to those observations.

FSIS determined that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as development and implementation of SSOP. In-plant veterinary officials and departmental supervisors enforce the regulatory requirements and monitor the ability of the establishments to maintain sanitary conditions. The enforcement by the CCA of the corrective actions to the deficiencies above is being addressed. The audit findings support that the CCA continues to maintain equivalence and is operating at an "adequate" level of performance for this component

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

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require that each official establishment develop, implement, and maintain an equivalent HACCP plan for each operation.

The analysis of the component consisted of a review of information contained in CCA-SRT and the associated supporting documents along with an on-site audit of the inspection system. The auditor

reviewed the following procedure sheets (PS) pertaining to meeting HACCP requirements in the United States certified establishments:

- PS 0.2.1 “Food Safety Arrangement in a Plant Approved for Exporting Poultry Product”
- PS 1.1.1 “Yearly Reevaluation of HACCP Program Verification of Implementation by Inspecting Veterinarian”
- PS 1.1.3 “HACCP- Veterinary Inspection of HACCP Programs in Poultry Slaughterhouses and Processing Establishments Approved for Export”

The procedure sheet 0.2.1 “Food Safety Arrangement in a Plant Approved for Exporting Poultry Product” provides instructions on how to conduct audits of establishments certified for exporting poultry product to foreign countries including the United States. These audits evaluate the design and implementation of an establishment’s food safety programs, including risk analysis, HACCP plan, SSOP program, prerequisite programs, and the Microbiological Monitoring Program (MMP). The MMP’s review determines the efficacy of the verification program in raw products and in ready-to-eat (RTE) products. The HACCP project manager who directly reports to the Chief Veterinarian (CV) conducts HACCP audits of establishments certified to export to the United States at least one time per year. The HACCP project manager provides written reports with findings and recommendations. The extent of recommendations may range from no action required to suspension of eligibility to export. These audit reports are presented to the HACCP committee, which consists of the CV, HACCP Project Manager, and two Regional Veterinary Officers.

The committee disapproves of those proposed HACCP programs that could negatively impact the establishment’s ability to export to the United States. An analytical review of the procedure sheet 0.2.1 “Food Safety Arrangement in a Plant Approved for Exporting Poultry Product” shows an extensive similarity to FSIS’ Food Safety Assessments conducted by Enforcement, Investigation, and Assessment Officers in official establishments in the United States. The instruction in procedure sheet 1.1.1 “Yearly Reevaluation of HACCP Program Verification of Implementation by Inspecting Veterinarian” requires the United States certified establishments to conduct an annual reassessment of their HACCP Program identical to the requirements contained in 9 CFR 417.4(a) (3). In addition to the requirements, the procedure provides guidance on how to verify that establishments have conducted the reassessment in accordance with the instructions outlined in the procedure.

The PS 1.1.3 “HACCP- Veterinary Inspection of HACCP Programs in Poultry Slaughterhouses and Processing Establishments Approved for Export” is a document that provides instructions to inspection personnel on how to verify the design and execution of HACCP system requirements. The elements that a VIC needs to verify to find that the HACCP plan of a United States-certified establishment meets the requirements are those listed in 9 CFR 417.3. The document contains three appendices, and these appendices are identified as VIC- HACCP verification form, weekly summary of the HACCP system’s verification data by the establishment’s VIC, and announcement regarding non-compliance in the establishment’s activities, respectively. This audit confirmed that the CCA had implemented corrective actions pertaining to HACCP component during the FSIS 2009 audit for the following deficiencies:

- One establishment did not identify all the hazards reasonably likely to occur in the hazard analysis.
- One establishment did not maintain the minus 26 degree Celsius finished product freezer in good repair.

- One establishment did not have supporting documentation for the lack of Certificate of Analysis (COA) lot identification that would link ingredients to specific RTE products.

The analysis of the information in the above-cited documents led to the conclusion that the inspection system requires all United States -eligible slaughter and processing establishments to meet HACCP requirements equivalent to 9 CFR 417.

The FSIS auditor visited one regional office and two poultry slaughter and cut-up establishments and one processing establishment producing RTE product for the United States export to determine whether the CCA ensures that inspectors verify that establishments meet HACCP requirements. The FSIS auditor also assessed the adequacy of HACCP program verification activities conducted by inspection personnel at the three audited establishments. The auditor observed inspection verification activities and reviewed the monitoring and verification records generated by the establishment's operators and inspection personnel. The auditor noted that the inspection personnel at the three audited United States-eligible establishments conduct daily verification of the establishment's HACCP plans, which includes such activities as the evaluation of written HACCP programs, monitoring, verification, corrective actions, and recordkeeping.

The FSIS auditor's review of the establishment's corrective actions in response to deviations from critical control point (CCP) limits found that all four parts of the corrective actions are addressed in accordance with Israel's requirements meeting equivalence criteria. The auditor verified that negative findings pertaining to the HACCP system component identified during the 2009 audit of Israel's inspection system had been corrected.

The document analysis and on-site audit verification, including observations and interviews, demonstrate that the CCA meets FSIS equivalence core criteria at an "adequate" level of performance for this component.

VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAM

As the fifth of the six equivalence components, the FSIS auditor reviewed Chemical Residues Control Programs and assessed the implementation of the laboratory's policies and procedures based on information obtained from interviews with the CCA and regional auditors. The FSIS criteria include the design and implementation of a program managed by the CCA that carries out effective regulatory activities to prevent chemical residue contamination of food products. The program must include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of its residue plan and the supporting documentation. The CCA must also provide a description of the actions taken to identify and remove unsafe residues from products as they occur. In addition, the CCA must provide oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

As part of the SRT review, the auditor analyzed procedure sheets 2.2.2-"Biological Residues in Poultry Meat - Treating Irregular Findings" and 2.2.3 "Chemical Residues in Poultry Meat and its Products -

Inspection and Follow-up” received by FSIS with CCA-SRT. The PS 2.2.2 -“Biological Residues in Poultry Meat – Treating Irregular Findings” provides a regulatory definition of biological residue as: “pesticide, organic substance, non-organic substance, metal material, hormones, antibiotics, other antimicrobial substances, anti-worm substances, sedatives, or any other substance or its derivatives, which leaves traces in the animal’s tissues, organs or produce, at the time of death or after it.” The second document groups all chemicals identified above into three main classes, namely, Pesticides, Medicinal Compound, and Environmental Pollutants. The other notable attributes of the PS 2.2.2 -“Biological Residues in Poultry Meat – Treating Irregular Findings” are:

- The document differentiates sampling into National Surveillance and VIC’s discretionary sampling.
- VIC must take a sample when there are reasons to believe that the flock presented for slaughter may have been medicated. When there are reasonable doubts that the flock may have been medicated with chemicals, the product sampled by VIC is always retained until the results of analysis are obtained. The deterrents discussed below are applied to the growers of chicken or turkey whose product tested positive for the presence of any identified chemical residues.
- The document is a guide for the steps to be taken when VIC is notified that a flock tested positive for the presence of certain residue category in the poultry carcasses or parts. Certain deterrents have been established to producers whose flocks are tested and found to contain chemical residues above Maximum Permitted Level (MPL) for any known residues. These deterrents have been further discussed in the relevant paragraphs below. The PS 2.2.2 -“Biological Residues in Poultry Meat – Treating Irregular Findings” provides two appendices. One is the notification to the VIC about the positive results, and the other one is the letter to the farmer notifying the latter about the positive results and action to be taken under the regulation. The PS 2.2.3 “Chemical Residues in Poultry Meat and its Products – Inspection and Follow-up” is essentially guidance to inspection personnel on collecting and submitting samples to the residue laboratory.

The instructions contained in the above-referenced procedure sheets in conjunction with Animal Diseases Regulations pertinent to Biological Residues Prevention clearly prohibit the marketing of animal carcasses or animal products containing biological residues above MPL. The MPLs of various known compounds have been compiled into a notebook by the IVSAH. The IVSAH conducts annual surveys for likely sources of chemical contamination of poultry meat and its products. The information gathered in the survey is utilized by a central steering committee to prepare the list of compounds to be included in the residue program. The IVSAH administers the sampling plan, which is designed to provide each sample an equal chance of being analyzed for any residue. This equal chance is achieved through a random selection of a sample for a particular chemical residue upon receipt of a sample at the residue laboratory.

The sample request for residue testing comes through the regional veterinary office, usually via telephone for the subsequent month. By accessing the IVSAH intranet portal, the VIC obtains complete information on the type of residue, matrices to be collected, and the appropriate form that must accompany the sample submission. The same portal can also be accessed to obtain results of analysis. The IVSAH intranet has a capability to filter the results, by plant, by regions, by chemical substances, and by farms. The flocks whose carcasses or parts tested positive for MPL are subjected to a series of “delayed slaughter” for five consecutive shipments of poultry as a deterrent until subsequent testing proves that the farmer or breeder guarantees that future flocks will be free of chemical residue.

Oversight of the government-owned and -operated residue and microbiology laboratories is performed by the Israel Laboratory Accreditation Authority (ISRAC), an autonomous member of the Ministry of Industry and Trade. The CCA provides a table to the laboratory management, which contains all FSIS-approved methodologies; and the SOPs ensure that they are used for United States-eligible products.

The FSIS auditor assessed the implementation of the laboratory's policies and procedures based on information obtained from interviews of CCA's and regional auditors.

FSIS determined that the Chemical Residue Control Programs component includes a national program managed by the CCA. The inspection system has appropriate laws and implementation documents that serve as the legal authority for the implementation of this program. The CCA achieves its oversight obligation over the government owned and operated chemical laboratory KVI through ISRAC and supervises the activities of analytical laboratories to ensure the validity and reliability of analytical test data. The CCA receives copies of the ISRAC reports and reviews the corrective action proffered by the laboratory in response to the audit findings. The laboratories post the results of analytical testing on CCA's intra-site web application for IVSAH to access the results. The document analysis and on-site verification including observations, document reviews, and interviews demonstrate that the CCA meets FSIS equivalence core criteria at an "average" level of performance for this component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

To assess the CCA's program for RTE products, *Listeria* control, and microbiological testing programs, the auditor evaluated the supporting documents submitted in the CCA-SRT under both component one and this component. In addition, additional assessment was conducted during the on-site involving the verification of inspection and establishment records and audit of microbiological laboratory activities.

The auditor conducted an analysis of the PS 5.1.6 "*Escherichia coli* – follow up and inspection in the slaughterhouse" and an on-site verification, including a review of inspection and establishment-generated records, interviews with inspection personnel and supervisors, and observations of whether the requirements of the previously mentioned Procedure Sheet are being implemented. All results support that the inspection system meets the FSIS criteria established for *E. coli* testing.

The PS 5.1.4 "*Salmonella* – Monitoring and Inspection in the Slaughterhouse" and 5.4.3 "*Campylobacter* – Monitoring and Inspection in the Slaughterhouse" establish standards for the regulatory requirements pertaining to enforcing *Salmonella* and *Campylobacter* performance standards under HACCP/Pathogen Reduction requirements, respectively. The testing for *Campylobacter* follows the sampling frequencies for *Salmonella* testing. The FSIS auditor accompanied and observed the inspection personnel conducting verification activities for sample collection as well as their methodology for *Salmonella* and *Campylobacter* testing on chicken and turkey carcasses in two audited slaughter establishments. The demonstrated methodology was in compliance with Israel's United

States-export requirements. Except as noted below, the auditor concludes that the Inspection system meets the FSIS criteria established for *Salmonella* and *Campylobacter* performance standards.

- The review of the microbiological results for *Salmonella* performance standards for the slaughter establishments revealed that there had been a trend of a higher percentage of positives set than the Israel inspection system permits.

To assess the CCA's program for the RTE products, *Listeria* control, and microbiological testing programs, the auditor evaluated the implementation documents submitted in conjunction with CCA component of SRT. The on-site audit included the review of records maintained at the inspection office, establishments' records, and supervisory reviews. The data gathering process also led to interviews with the VIC, RVO, and the establishments' person responsible for managing the RTE program.

The IVSAH requires that each establishment processing and preparing RTE poultry products must develop and implement the *Listeria* control program within the framework of its HACCP plan or Sanitation SOP. An RTE product regarded as contaminated in accordance with the procedure instructions 6.2.5 "*Listeria monocytogenes* in "Ready to Eat" Poultry Products" (i.e., *Listeria monocytogenes* is detected on surface of or within the product) may not be put into commerce for human consumption. The PS 2.3.1 "Microbial Indices for the Export of Poultry Meat to the Countries of the European Union (E.U) and the United States of America" mandates zero tolerance of *Listeria monocytogenes* and *Salmonella* in the RTE product. An RTE product is also regarded as contaminated when the product either comes in direct contact with equipment or food contact surface contaminated with *Listeria monocytogenes*, *Listeria spp.*, or any *Listeria* like organism.

The PS 5.2.2 "*Listeria monocytogenes* in ready-to-eat poultry products monitoring and control – verification" is one of the principal documents that survey the public health risk involved in processing RTE product and the type and the frequencies of verification testing to be conducted based on the identified risks. This document compares the sources of contamination from *Listeria* and *Salmonella* in RTE product. The document attributes the presence of *Salmonella* in the processed product (including RTE products) to a host of reasons related to processing, including insanitary manufacturing practices, deviation from critical operational parameter, or employee hygiene.

With respect to *Listeria monocytogenes*, on the other hand, contamination is most likely to occur in the post-lethality environment. The document outlines the CCA's verification testing for *Listeria* and the frequencies thereof. This procedure sheet also provides instructions to inspection personnel on how to collect, store, and ship samples of RTE products intended for microbiological testing, which is equivalent to the United States requirements. Additionally, this procedure sheet outlines procedures and frequencies for sampling of food contact surfaces and environment where RTE product is processed.

The CCA requires establishments that process and prepare RTE product that is exposed to a post-lethality environment to control the *Listeria* hazard by adopting one of the three alternatives that are equivalent to the alternatives specified in 9 CFR 430.4(b). The establishment choosing Alternative 3 needs to evaluate the effectiveness of its SSOP in preventing the contamination of the product with *Listeria monocytogenes* in the post-lethality environment. The establishments operating under Alternative 3 must evaluate the effectiveness of sanitation through microbiological testing of food contact surfaces and products in accordance with the standards specified in the RTE program.

The intent of PSs 6.2.5 "*Listeria monocytogenes* in Ready to Eat Poultry Products" and 6.2.6 "Clarifications to Procedure Sheet about *Listeria monocytogenes* in 'Ready to Eat' Poultry Products" is to outline the monitoring and control measures that may be implemented by an establishment producing RTE products. The requirements of PS 6.2.6 "Clarifications to Procedure Sheet about *Listeria monocytogenes* in 'Ready to Eat' Poultry Products" mirror FSIS' "Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products." When the results of the bacteriological examinations of RTE product indicate the presence of the bacteria such as *Salmonella* or *Listeria*, the Regional Supervisor and HACCP Project Manager must conduct an evaluation of the implementation and enforcement of the veterinary requirements in accordance with PSs 5.2.3 "*Listeria monocytogenes* – Evaluation of Implementation and Enforcement of Veterinary Requirements by the Area Supervisor Inspection" and 0.2.1. "Food Safety Arrangement in a Plant Approved for Exporting Poultry Products." In addition to daily inspection verification and periodic supervisory reviews, the establishments producing RTE products receive a third type of periodic evaluation in accordance with the standards established in PS 0.2.1 "Food Safety Arrangement in a Plant Approved for Exporting Poultry Products."

Each United States-eligible establishment producing RTE product receives such an assessment once every 2 years. When RTE assessments and the comprehensive food safety assessments of an establishment occur at the same time, the two activities are conducted simultaneously as a comprehensive evaluation of the overall food safety program. Nevertheless, the RTE assessment portion remains the responsibility of RVOs. One unique feature of the assessment that makes it effective is random sampling of product for the presence of *Lm* and *Salmonella*. The sampling regimen also includes testing of food contact surfaces, equipment, and the processing environment. It is important to note that the product testing conducted under RVO assessment is independent of other testing that is equivalent to FSIS' ALLRTE and RTERISK1 testing. While establishments are not obligated to hold the product for sampling results, they are highly encouraged to do so, as any positive results will invoke a recall in accordance with the establishment-maintained recall program.

The PS 2.3.1 "Microbial Indices for the Export of Poultry Meat to the Countries of the European Union (E.U) and the United States of America" provides instruction to inspection personnel on how to verify that shipments destined for the United States meet requirements for export. One of the requirements in the previously mentioned procedural sheet is that inspection personnel must sample RTE product that is destined for the United States in accordance with microbiological testing criteria which guarantee that shipments tested positive for either *Lm* or *Salmonella* are not eligible for export.

The auditor reviewed the results of the microbiological testing on raw and RTE products sampled by the inspection personnel and analyzed at government laboratories for a period of 6 months, January thru June 2013. The auditor confirmed that the CCA utilizes the analytical method listed in FSIS' Microbiological Laboratory Guide (MLG) testing raw and RTE products destined for the United States. These methods are kept up-to-date with revisions to the methods in MLGs.

The FSIS auditor reviewed Bactochem Laboratory, a private laboratory. The laboratory conducts microbiological testing for establishments certified to export to the United States. The audit of the laboratory examined the analyst qualifications, sample receipt, timely analysis, analytical

methodologies, analytical controls, recording and reporting of results, and check samples. The auditor noted that the CCA does not approve or disapprove the private laboratories. A review of laboratory documents identified the following concerns:

- During the tour of the laboratory, a number of samples stored in the receiving refrigerator were found to not have any identification. The failure to identify them is contrary to the standards applied to the receiving samples by the laboratory.
- According to the SOP, any receiving sample should immediately get an electronic identification.
- The laboratory's SOP for the receiving samples did not specify measures for sample security.
- The samples were being received in a variety of ways, for example, some samples received were boxed, and some were simply enclosed in thin plastic bags with information written using ballpoints.

The CCA relies on the requirement that each private laboratory serving United States -eligible establishments must be accredited from the Israel official accreditation body ISRAC for the standards specified in ISO17025.

The results of the overall microbiological component assessment show that the Israel's poultry inspection system has regulatory requirements for a microbiological testing program that are designed and administered in accordance with requirements and standards determined to be equivalent by FSIS. At this time, the CCA's microbiology testing program operates at an "adequate" level of performance.

X. CONCLUSIONS AND NEXT STEPS

This audit found that the CCA was performing at an "adequate" level in terms of maintaining its equivalence. The inspection program met most of the established core criteria for all six equivalence components; however, the CCA's government oversight within the different equivalence components showed a need for improvement. These preliminary audit findings were conveyed by the FSIS auditor to the CCA inspection officials at an exit meeting on July 4, 2013, in Tel Aviv. The CCA understood and accepted the need to address the following audit findings in order to maintain its equivalence status:

- In the two of seven slaughter establishments certified to produce raw poultry product audited, evisceration lines exceeded the "24 birds per minute" line speed required by Israel for poultry products exported to the United States. The CCA did not provide documented support for the higher speed or for why higher speed would not result in public health concerns.
- Poultry carcasses were entering the chillers in both slaughter establishments with an abnormal number of feathers attached.
- In one slaughter establishment, during the pre-operational verification, the auditor noted that in the feather-picking room, there was organic matter build-up behind the washers that supported rubberized picker. These washers were thus not maintained in a sanitary manner. The sanitation of these areas is not included in SSOP or any other sanitation program. In addition, the auditor observed that chiller tanks had pieces of fat of varying sizes floating in multiple sections of two chillers.
- In the second slaughter establishment, during the operational sanitation verification, the auditor noted that the overflow mechanism was faulty, which allowed scum and extraneous material to form

on the surface of the water, creating insanitary conditions and allowing for potential contamination of the product.

- A review of the microbiological results for *Salmonella* performance standards for the slaughter establishments revealed that the percentage of positive results was trending higher than the Israel inspection system permits.

Following completion of the FSIS audit, FSIS identified *Salmonella* in two separate lots of fully-cooked, not shelf stable RTE poultry products from the same Israeli establishment. The first violation was identified in September 2013 and involved RTE chicken nuggets, while the second was identified during intensified sampling in October 2013 in grilled chicken breast. Both lots were refused entry, and Israel was notified of the findings. These post-audit POE violations illustrate FSIS concerns about Israel's government oversight and food safety program implementation. FSIS needs a response from Israel within 60 days to support Israel's ability to effectively verify that establishment will conduct a hazard analysis, implement controls, and oversee controls to prevent future *Salmonella* violations. FSIS received an investigative report and corrective measures provided in response to the POE violations. The proffered corrective actions are currently under review by FSIS.

APPENDICES

APPENDIX 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 Cornish Chen, Ofaquim, Israel	2. AUDIT DATE 07-01-2013	3. ESTABLISHMENT NO. 020	4. NAME OF COUNTRY Israel
	5. NAME OF AUDITOR(S) Alam Khan, 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 SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
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	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	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	X	59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

July 01, 13 Est. 020 (Slaughter/cut-p) , Ofaquim

30/51 The review of the microbiological results for Salmonella performance Standards reveals Israel uses the FSIS's criteria for set pass/fail which is designed after calculating national prevalence of Salmonella on the chicken. There has been a trend of higher percentage of positives set for the carcasses used to supply to the RTE establishments certified to export the processed poultry product to the US.

46/51 a) During the operational sanitation verification the auditor observed that the innumerable chicken carcasses with varying length of feathers attached to various part of the carcass were entering into the chiller.

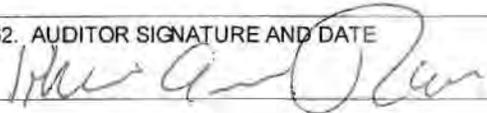
b) The auditor noted that the overflow mechanism was faulty which allowed formation of scum and the extraneous material on the surface of the water creating insanitary condition and potential for contamination of the product.

55/51 The evisceration lines were running at the speed greater than 24 birds per minute required by Israel for poultry products exported to the United States.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE

 10/20/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Tiv-Tirat-Zvi 2000, Meat Specialities Travel Beit Shean Valley, Israel	2. AUDIT DATE 06-27-2013	3. ESTABLISHMENT NO. 022	4. NAME OF COUNTRY Israel
	5. NAME OF AUDITOR(S) Alam Khan, 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.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
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	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

June 27, 13 Est. 022 (processing/RTE) Tiv-Tirat-Zvi, Beit Shean

The auditor made following observations during the on-site audit of the establishments led by the Veterinarian Incharge (VIC):

10/51 During pre-operational sanitation verification, multiple brown totes to receive raw poultry had visible pieces of meat and fat from the previous day.

45/51 Several brown totes had cracks and were broken in different place.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE

 10/20/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Off Oz Marketing Ltd, POB 865, Shegev Shlom, 85740, Israel	2. AUDIT DATE 06-30-2013	3. ESTABLISHMENT NO. 035	4. NAME OF COUNTRY Israel
5. NAME OF AUDITOR(S) Alam Khan, 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.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
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	X
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	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	X	59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

June 30, 13 Est. 035 (Slaughter/cut-p), Segev Shalom

10/51 a) During the pre-operational verification of the feather plucking room, hard to reach spaces between metal washer to support rubberized projections and the frame of the feather picker was filled with organic matter that was not cleaned for days as the sanitation of these areas was not included in either SSOP or any other sanitation program. Organic build up behind hard to clean surfaces over a period is insanitary and is potential for harborage of biological contaminants. The establishment committed to implement the sanitation program for washers and the mounts with some frequencies

b) During the pre-operational verification of Chillers tanks the pieces of fat of varying sizes were observed floating in multiple sections of two chillers. The VIC retained the noncompliant chillers which was immediately cleaned and sanitized and filled with new chilled water.

30/51 The review of the microbiological results for Salmonella performance Standards reveals Israel uses the FSIS's criteria for set pass/fail which is designed after calculating national prevalence of Salmonella on the chicken. There has been a trend of higher percentage of positives set for the chicken in the US. The last set of Salmonella completed on March 03, 2013 had a 74.5 percentage positive.

46/51 During the operational sanitation verification the auditor observed that the innumerable chicken carcasses with varying length of feathers attached to various part of the carcass were entering into the chiller. The presence of feather on the carcass and parts were also observed but to a significantly lesser extent in the other process and cut areas.

55/51 The evisceration lines were running at the speed greater than 24 birds per minute required by Israel for poultry products exported to the United States.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE

 10/20/2014

APPENDIX B: Foreign Country Response to Draft Final Audit Report



STATE OF ISRAEL

Ministry of Agriculture and Rural Development
Veterinary Services and Animal Health, Control of Animal Products' department.
P.O.B 12, Beit -Dagan, 50250

October 06, 2014

Dear Dr Shaukat H. Syed

Director International Audit Staff

Office of International Affairs

Subject: Comments From the Government of Israel to the "Israel draft final audit report"

We read the letter carefully and we accept all your comments, we plan to correct the deficiencies that were received by you after you accept our corrective actions.

First I would like to refer to the NC we received by you:

- 1. In the two of seven slaughter establishments certified to produce raw poultry product audited, evisceration lines exceeded the "24 birds per minute" line speed required by Israel for poultry products exported to the United States. The CCA did not provide documented support for the higher speed or for why higher speed would not result in public health concerns.*

Procedure sheet 2/2007 (3.1.5) you are referring to has been canceled and replaced by a new procedure sheet in 2009 (3.1.0), which was lately updated resulting uniformity and eliminating the double standard that has been in the country.

In the updated procedure sheet there is no difference between production to the United States, Europe or Israel regarding the velocity of the slaughtering line (inspection line). According to the new procedure sheet, the velocity should be not more than 35 birds per one inspector.

In to the same procedure sheet, the VIC should check the inspector work and the sanitary and health status for each flock of birds and according to that the VIC has the opportunity to reduce the line velocity.

- 2. Findings can be seen when counting the number of birds that are... with an abnormal number of feathers removed.*



STATE OF ISRAEL

Ministry of Agriculture and Rural Development
Veterinary Services and Animal Health, Control of Animal Products' department,
P.O.B 12, Beit –Dagan, 50250

We accept the comment above despite the fact that all slaughter houses in Israel that export to the United States and to Europe are producing kosher poultry meat and according the Jewish religion it is forbidden to use the scalded machine before the picking. To try and overcome this obstacle, all picking machines in the kosher slaughter houses are very long respective to non-kosher slaughterhouses, which can cause mangled carcasses, and we must find the balance between good picking and preventing damage to the carcasses.

In any case of high quantity of feathers attached to the carcasses, the VIC should reduce the line speed and the establishment is required to use also manual piking as well and products are checked for feathers before entering the chiller and at the cutting room.

In addition, the VIC controls the presence of feathers according the procedure sheet no. 5.1.7 (Checking by the veterinary officer the slaughterhouse processes, Hygiene and control of the chicken carcass treatment).

3+4. • In one slaughter establishment, during the pre-operational verification, the auditor noted that in the feather-picking room, there was organic matter build-up behind the washers that supported rubberized picker. These washers were thus not maintained in a sanitary manner. The sanitation of these areas is not included in SSOP or any other sanitation program. In addition, the auditor observed that chiller tanks had pieces of fat of varying sizes floating in multiple sections of two chillers.

• In the second slaughter establishment, during the operational sanitation verification, the auditor noted that the overflow mechanism was faulty, which allowed scum and extraneous material to form on the surface of the water, creating insanitary conditions and allowing for potential contamination of the product.

Immediate corrective actions were carried out during the audit by the establishments and by the veterinary inspection to correct the above deficiencies.

All those point were added to the SSOP program in order to be monitored daily.

5. A review of the microbiological results for Salmonella performance standards for the slaughter establishments revealed that the percentage of positive results was trending higher than the Israel inspection system permits.

We accept this comment and we are working on finding a solution for this problem that we have.



STATE OF ISRAEL

Ministry of Agriculture and Rural Development
Veterinary Services and Animal Health, Control of Animal Products' department,
P.O.B 12, Beit –Dagan, 50250

In addition, there were some inaccuracies in the report and these are:

1. Page no. 3 paragraph 4: All RVOs, VICs, and line inspectors in the slaughter establishments are full-time employees of the Israeli Egg and Poultry Board (EPB), which is co-owned by the government and the poultry farmers

The RVOs are full-time employees of the veterinary services, Ministry of Agriculture.

2. Page no. 4 paragraph 1: The FSIS auditor found that, in the further-processing facilities, the non-veterinary inspection personnel are employed by the local municipal councils and are paid from fees collected by these government agencies from the establishments for inspection services rendered

The veterinary and the non-veterinary inspection personnel are employed by the local municipal councils

For the time, we send you this brief reference to your draft. Once we receive the final report, you will get more detailed reply, with specific reference for each establishment.

A handwritten signature in black ink, appearing to be 'Sergio Dolev', written in a cursive style.

Sincerely,

Dr. Sergio Dolev

Head of the Department for Control of Animal Products

CC:

Dr Nadav Galon – Director of the IVSAH