



United States Department of Agriculture

Food Safety and
Inspection Service

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Dr. Nadav Galon
Director, Israeli Veterinary Services and Animal Health
Ministry of Agriculture and Rural Development
Post Office Box 12, Beit Dagan, 50250, Israel

Dear Dr. Galon,

The USDA, Food Safety and Inspection Service (FSIS) conducted an on-site audit of Israel's poultry inspection system from November 11 through December 1, 2015. Enclosed is a copy of the final audit report. The comments received from the Government of Israel are included as an attachment to the report.

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

Sincerely,

A handwritten signature in blue ink that reads "Jane H. Doherty".

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
ISRAEL

NOVEMBER 11 TO DECEMBER 1, 2015

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

April 19, 2016

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from November 11 to December 1, 2015. The audit was conducted to determine whether Israel's poultry inspection system continues to be equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Israel is eligible to export processed poultry products to the United States.

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

The previous FSIS audit of Israel's poultry inspection occurred from June 23 to July 4, 2013. During the course of the 2013 audit, FSIS identified findings within the equivalence components for Government Oversight, Sanitation, and Government Microbiological Testing Programs. During the current audit, FSIS verified that the corrective actions proffered to FSIS by Israel to remedy the 2013 findings were effectively implemented.

The 2015 FSIS audit showed that the Central Competent Authority (CCA) provides sufficient oversight over its inspection personnel and meets its regulatory requirements. The on-site audit did not identify any significant findings. An exit meeting was held on December 1, 2015, in Beit Dagan, Israel with the CCA.

On August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566). The rule includes (1) a new regulatory program that affects all poultry slaughter establishments and that involves sampling at two points on the line to demonstrate process control and treating enteric pathogens as hazards reasonably likely to occur; and (2) an optional post-mortem inspection system known as the New Poultry Inspection System (NPIS). The FSIS auditor did not assess implementation of these new provisions in the 2015 audit. The specific regulatory changes that were made by this final rule can be found in 9 Code of Federal Regulations (CFR) 381.65 and 381.66.

Foreign governments may continue to operate inspection systems that FSIS has determined are equivalent to the United States system. However, if a foreign government decides to implement an NPIS-type system, the CCA must submit documents to explain why the system is equivalent to FSIS' regulations. Therefore, all countries exporting slaughtered poultry to the United States must submit as part of their May 2016 Self Reporting Tool (SRT) update, documentation that the CCA has addressed the new food safety regulatory requirements, and how the CCA has assessed their inspection system. The CCA must specifically show the implementation of new Salmonella and Campylobacter standards. FSIS will now verify whether the CCA is now testing to these new standards.

Countries that are in the process of changing their inspection system in order to address any of the new provisions of the FSIS final rule should submit their plans for when the changes will be fully implemented. If adopting a NPIS-type system, the CCA should provide documentation as to why the system is equivalent to NPIS, and how it is being or will be implemented. If the materials are not submitted through the May 2016 SRT submission, FSIS may take steps to restrict or suspend poultry exports from the country to the United States.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Israel's food safety system from November 11 to December 1, 2015. The audit began with an entrance meeting held on November 11, in Beit Dagan, Israel with the participation of representatives from the Central Competent Authority (CCA), USDA's Foreign Agriculture Service (FAS), and the FSIS auditor. Representatives from the CCA accompanied the FSIS auditor throughout the entire audit.

II. OBJECTIVES, SCOPE, AND METHODOLOGY

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

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

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

The FSIS auditor reviewed the administrative functions at the CCA headquarters in Beit Dagan, two regional offices, six local inspection offices at the audited establishments, one private microbiology laboratory, and one government chemical residue laboratory. During the review, the FSIS auditor evaluated implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement is implemented as intended. This evaluation included on-site verification of the implementation of those corrective actions proffered to FSIS by Israel to remedy the 2013 audit findings.

The FSIS auditor also reviewed the administrative functions of the local inspection offices as part of the establishment review. The FSIS auditor assessed the CCA's sampling and testing methodology through a review of records at the regional inspection offices and two audited laboratories. The auditor visited two poultry slaughter and four poultry processing establishments certified to export to the United States.

During the establishment visits, the auditor paid particular attention to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten

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

AUDIT SCOPE SUMMARY			
Central Competent Authority Visits		Locations	
Central Competent Authority	Central Competent Authority	1	Israeli Veterinary Services and Animal Health (Beit Dagan)
	Regional Offices	2	North Regional Veterinary Office (Haifa) South Regional Veterinary Office (Beit Dagan)
Microbiology Laboratory		1	Institute for Food Microbiology (Haifa)
Chemical Residue Laboratory		1	National Residue Control Laboratory (Beit Dagan)
Poultry Slaughter/Processing Establishments		6	2 - Slaughter: Of-Tov (Beit Shean) and Kornish Chen (Beit Harishonim) 4 - Processing: Tnuva Galil (Kiryat Shmona), Maadaney Yehiam (Kibutz Yehiam), Of-Tov Products (Beit-Shean Valley), and Tiv-Tirat-Zvi (Kibutz Tirat)

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

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

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

III. BACKGROUND

Israel is eligible to export processed poultry products to the United States. Between October 1, 2012 to July 31, 2015, FSIS import inspectors performed 100% re-inspection for labeling and certification on 6,777,514 pounds of poultry products exported by Israel to the United States. FSIS also performed re-inspection on 1,232,291 pounds at POE using additional types of inspection, of which a total of 21,149 pounds were rejected due to presence of Hazardous Material (Smoked Turkey Meat-May 2015), *Listeria monocytogenes* (Chicken Breast-August 2014), Sulfadimethoxine (Turkey Kabanos Sausage-April 2014), Mold (Turkey Kabanos Sausage-April 2014), and *Salmonella* (Grilled Chicken Breast-October 2013) in the exported processed poultry products.

Previous FSIS final audit reports for Israel's food safety system are available on the FSIS website at:

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

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

The first of six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import regulations require that the foreign inspection system be organized by the national government in such manner to provide ultimate control and supervision over all official inspection activities. The system must also ensure that there is uniform enforcement of requisite laws; provide sufficient administrative and technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States. The verification of this component was based on information previously submitted in the SRT, in addition to on-site record reviews, interviews, and observations.

Israel's administration of the poultry inspection system is vertically organized into national, regional, and establishment levels. At the national level, the Israeli Veterinary Services and Animal Health (IVSAH), a subdivision of the Ministry of Agriculture and Rural Development (MARD), is the CCA. The director of IVSAH, the Chief Veterinary Officer (CVO), is in charge of issuing laws, guidelines, and instructions for implementation of official controls over production of poultry origin products. The Department of Control of Animal Products, within IVSAH, is headed by the Chief Veterinarian, who is responsible for providing technical guidance and supervising the functions of official inspection personnel at regional and local levels.

At the regional level, two regional offices, North Region (Haifa) and South Region (Beit Dagan), are overseeing inspection activities in the United States-certified establishments. The Regional Veterinary Officers (RVO) who supervise the overall inspection activities of the inspection personnel at the local level head each region. The RVO is also responsible for conducting periodic supervisory reviews at the United States-certified establishments.

At the establishment level, the inspection personnel consist of a Veterinarian in-Charge (VIC) and a number of non-veterinary inspectors. At the United States-certified establishments, the non-veterinary inspectors perform daily official controls and inspection activities within poultry slaughter or processing establishments under direct supervision of the VIC.

The FSIS auditor noted that the inspection personnel located at the CCA headquarters and regional levels are full-time employees of the national government, while the inspection personnel located at the local level (VIC and non-veterinary inspectors at establishment level) are full-time employees of the local government. The local government is a public body under Ministry of Interior. The CCA is responsible for hiring, firing, training, and supervising the inspection personnel in all United States-certified poultry establishments.

In the poultry Ready-to-Eat (RTE) processing establishments, the VICs and non-veterinary inspectors are salaried employees of the local government according to the geographical location of the processing establishments. Local government collects inspection related fees from the processing poultry establishments for the payment of inspection services rendered by VICs and non-veterinary inspectors in the processing establishments.

In the poultry slaughter establishments, the VICs and non-veterinary inspectors are salaried employees of a government statutory body, known as the Egg and Poultry Board (EPB). The chairperson of the EPB is appointed by the MARD. The EPB collects inspection related fees from the poultry slaughter establishments for the payment of inspection services rendered by VICs and non-veterinary inspectors in the slaughter establishments. The EPB has no role in hiring, firing, or supervising the inspection personnel assigned in the United States-certified establishments.

Since the last FSIS audit in 2013, the CCA has organized ongoing training programs for inspection personnel assigned in the United States-certified establishments. Training courses have covered such subjects as Pathogen Reduction/HACCP, sanitation, sampling methodology, and specific export requirements concerning United States equivalence requirements. The FSIS auditor interviewed a number of the inspection personnel to assess their knowledge, skills, and abilities and reviewed their training records from 2013 to 2015. The auditor confirmed that inspection personnel have attended the ongoing trainings and have sufficient training in performing inspection activities.

The FSIS auditor's interviews of inspection personnel and reviews of official inspection records during the on-site audit confirm that the CCA officials enforce laws and regulations governing production and export of poultry at certified establishments.

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

The second of six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; and periodic supervisory reviews to the official establishments certified to export to the United States. The evaluation of this component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit.

The primary laws for regulating poultry inspection in Israel are *Animal Diseases Regulations* (Poultry Slaughterhouses), 1960, *the Business Licensing Regulations* (Sanitary Conditions for Food Production Businesses), 1972, and *Regulations for the Control of the Manufacture of Poultry Products for Export and their Export*, 1976. These regulations provide the operational and regulatory authority to carry out Israel's poultry inspection system. FSIS' review of these regulations concerning the registration of slaughter or processing establishments, inspection verification activities, and implementation of the United States export requirements indicated

that the CCA has legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported to the United States. In addition to these regulations, the CCA has developed written procedural documents known as "Procedures Sheet (PS)" in order to provide clear instructions to its inspection personnel regarding implementation of national laws and proper inspection verification procedures. For example, the PS No. 0.0.3 outlines the CCA's requirements for export of processed poultry products to the United States. These PSs are available for review on the CCA's website. The FSIS auditor verified the proper implementation of several PSs including those related to ante-mortem, post-mortem, HACCP, sanitation, and periodic supervisory reviews. FSIS' review of national laws and implementation of inspection verification procedures in accordance with associated PSs indicated that the CCA has clear legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported to the United States.

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

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

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

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

described non-compliances and verified the effectiveness of the establishment's corrective actions.

The FSIS auditor accompanied and observed the functions of the CCA's Regional Veterinary Officers (RVO) who are responsible for conducting the periodic supervisory reviews with a minimum frequency of one supervisory review per quarter in accordance with the CCA's instructions. During the supervisory reviews, RVOs verify the proper implementation of requirements for ante-mortem inspection, post-mortem inspection, microbiological sampling including *Salmonella* and *Campylobacter* sample collection in raw product (poultry slaughter establishments), microbiological verification sampling including *Listeria monocytogenes (Lm)* and *Salmonella* sample collections in RTE product (poultry processing establishments), and verification of pre-operational and operational sanitation monitoring procedures, sanitation, and HACCP verification activities including the review of Critical Control Points (CCPs).

In addition, RVOs observe and conduct the performance appraisal of the in-plant VICs during the periodic supervisory reviews. Based on the satisfactory results of these performance appraisals, the CCA issues annual veterinary accreditation certificate for VICs assigned in slaughter and processing establishments. Furthermore, the Food Safety System and Training Management Unit of the Department of Control of Animal Products conducts a comprehensive audit of the United States-certified establishments at a frequency of once per year. The FSIS auditor reviewed a number of the annual and periodic supervisory review reports generated by the responsible inspection personnel. These reviews identified no concerns.

On August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566). The rule includes (1) a new regulatory program that affects all poultry slaughter establishments that involves sampling at two points on the line to demonstrate process control and treating enteric pathogens as hazards reasonably likely to occur; and (2) an optional post-mortem inspection system known as the New Poultry Inspection System (NPIS). Implementation of these new provisions was not assessed by FSIS in the 2015 audit. The specific regulatory changes that were made by this final rule can be found in 9 Code of Federal Regulations (CFR) 381.65 and 9 CFR 381.66.

Foreign governments may continue to operate inspection systems that FSIS has determined are equivalent to the United States system. However, if a foreign government decides to implement an NPIS-type system, the CCA must submit documents to explain why the system is equivalent to NPIS. Therefore, all countries exporting slaughtered poultry to the United States must submit as part of their May 2016 Self Reporting Tool (SRT) update, documentation that the CCA has addressed the new food safety regulatory requirements, and how the CCA has assessed their inspection system. The CCA must show that it is requiring establishments to treat enteric pathogens (*Salmonella* and *Campylobacter*) as hazards reasonably likely to occur in their slaughter process. FSIS will now verify that the CCA has addressed these new requirements.

The new regulatory changes are not optional and must be addressed by the CCA. These specific regulatory changes can be found in 9 CFR 381.65 that relate to operations and procedures and include the development, implementation and maintenance of written procedures to ensure that carcasses with visible fecal contamination do not enter the chiller and to prevent contamination

of carcasses by enteric pathogens and fecal material throughout slaughter and dressing operation.

Countries that are in the process of changing their inspection system in order to address any of the new provisions of the FSIS final rule should submit their plans for when the changes will be fully implemented. If adopting a NPIS-type system, the CCA should provide documentation as to why the system is equivalent to NPIS, and how it is being or will be implemented. If the materials are not submitted through the May 2016 SRT submission, FSIS may take steps to restrict or suspend poultry exports from the country to the United States.

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

VI. COMPONENT THREE: SANITATION

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

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

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

The FSIS auditor also observed the in-plant inspection personnel perform actual operational sanitation verification in all of the audited establishments. The auditor noted that the inspection verification activities included direct observation of the actual operations and review of the establishments associated records. The auditor compared his overall observation of the sanitary conditions of the establishments with the in-plant inspection verification records.

The FSIS auditor's record review included both the establishment's sanitation monitoring and corrective action records and the inspection records documenting inspection verification results, non-compliances, and supervisory reviews of establishments. The FSIS auditor's review of records generated by inspection personnel (including non-compliance and verification records) showed that the inspection personnel have identified and documented sanitation findings in their daily verification or periodic supervisory review records.

The FSIS auditor noted that the inspection and establishment records for the most part mirrored the actual sanitary conditions of the establishments. The auditor noted that establishments maintained sanitation records sufficient to document the implementation and monitoring of sanitation and any corrective actions taken. The inspection personnel provided additional verification records addressing the establishment's proposed maintenance schedule and any applicable enforcement actions taken by the inspection personnel. The establishment employees responsible for the implementation and monitoring of the sanitation procedures correctly authenticated these records with initials or signatures and the date. The sanitation conditions in the audited establishments met the CCA's regulatory requirements and mirrored the FSIS auditor's observations on the day of the audit. The FSIS auditor did not identify any significant sanitation findings to report during the audit.

The FSIS auditor found, based on analysis and on-site verification activities, that the CCA requires operators of the United States-certified establishments to develop, implement, and maintain sanitation programs sufficient for sanitary handling of products in order to prevent direct product contamination, and that the CCA inspection program personnel are effectively verifying that they do so.

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

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

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

The FSIS auditor reviewed the HACCP plans and records, observed the actual verification activities conducted by the in-plant inspection personnel, and reviewed the associated verification records generated by the in-plant inspection personnel. The auditor noted that the in-plant inspection personnel at the audited establishments conduct daily verification of the establishment's HACCP plans in accordance with the CCA's requirement. The in-plant inspection verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel perform

monitoring, verification, corrective actions, and recordkeeping activities. The in-plant inspection verification activities also include direct observation or record review of the CCPs with results of the verifications entered in the associated inspection records.

The FSIS auditor conducted an on-site observation and document review of CCPs in all the audited establishments. The auditor's review of the plans, CCPs, critical limits, monitoring procedures, verification procedures, and implemented corrective actions did not raise any concerns. In the poultry slaughter establishments, the auditor reviewed the zero tolerance (fecal material) CCP control records. In addition, the FSIS auditor, together with the in-plant inspection personnel, observed the establishment's employee conducting hands-on HACCP monitoring and verification activities for the zero-tolerance CCP. Neither the FSIS auditor nor the inspection personnel observed any deviations from the critical limits. The FSIS auditor also reviewed the establishment and the in-plant inspections' zero tolerance records. These reviews identified no concerns.

The analysis and on-site activities of the FSIS auditor show that the CCA verifies that operators of official establishments implement the CCA's requirement to develop, implement, and maintain HACCP programs for each processing category. The FSIS auditor's analysis determined that the CCA continues to demonstrate the ability to effectively implement and verify its regulatory requirements.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

The evaluation of the government chemical residue testing programs component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit. The CCA headquarters, two regional offices, and one chemical residue laboratory were audited to assess the CCA's regulatory authority to enforce requirements of the Government Chemical Residue Testing Programs equivalence component. FSIS analysis and on-site audit verification of the CCA's chemical residue testing program, as designed and implemented, show that the CCA is effectively using its authority to ensure that safe product is produced.

In November 2015, the CCA implemented five (5) new PSs concerning the national residue policy, monitoring, and supervision of the prevention of chemical residues in products of animal-origin. These included the following:

- Procedure 0.2.8 "The advisory inter-ministerial (the steering committee) and the branch sub-committees" describes the manner in which the committees decide upon the annual national residue program.
- Procedure 0.2.9 "The annual plan for monitoring chemical residues: organization, implementation, surveillance" provides the framework for the actual implementation of the national residue program, including monitoring, and delegates responsibilities.
- Procedure 2.2.1 "The sampling process for monitoring chemical residues" describes the actual sampling, provides the workflow from the initial notification to sample, sampling, shipping, receiving results, to the actions that need to be done in accordance to the results.
- Procedure 2.2.2 "Handling above Maximum Residues Limit (MRL) findings and declaring of farm under surveillance" describes the workflow, notification process, increased residue testing and additional sampling, and other actions, as well as the responsibilities of each section in the production chain and in the inspection chain in a case of deviation from the MRLs.
- Procedure 0.2.7 "The inquiry and investigation after receiving an above MRL result" that details the workflow and the responsibilities after an above MRL result, as well as the reference to further enforcement actions.

The CCA's instructions contained in the above procedures in conjunction with the Animal Diseases Regulations pertinent to Biological Residues Prevention prohibit the marketing of poultry products containing biological residues above Maximum Permitted Level (MPL). The IVSAH conducts annual surveys to identify the potential sources of chemical residue 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 national residue program.

The RVOs initiate the CCA's chemical residue sampling request through the CCA's web-application "food inspection" a few days before the actual sampling date as described in PS 2.2.1. The in-plant inspection personnel review the "food inspection" application and obtain required residue sampling information including the type of residue, matrices to be collected, and the appropriate forms that must accompany the sample submission. The RVOs and other inspection personnel have access to the laboratory results through the "food inspection" application. The "food inspection" application has a capability of filtering the results by establishments, CCA's regions, chemical substances, and poultry farms.

The inspection personnel who collect the residue samples receive periodic training that includes such subjects as sampling methodology, identification of animals, traceability, and sample security. The FSIS auditor verified that the inspection personnel are following the CCA's National Residue Program sampling protocol. This protocol includes sampling location, sample size, sampling frequency, and secure delivery of residue samples to designated government residue laboratories.

The FSIS auditor visited the Kimron Veterinary Institute (KVI). KVI is the National Residue Control Laboratory that is accredited to International Organization for Standardization (ISO) 17025 by the Israeli Laboratory Accreditation Authority (ISRAC). KVI is the government laboratory used for analysis of official samples taken from products destined for export to the

United States. The KVI residue laboratory audit focused on sample handling, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, percent recoveries, intra-laboratory check samples, and quality-assurance programs, including standards books and corrective actions. These reviews identified no concerns.

The FSIS auditor verified that the implementation of the current year's sampling plan at the headquarters, regional, and in-plant inspection levels was proceeding in the manner outlined in the CCA's national plan. Sampling is occurring on time, analyses are completed in a timely manner, and results are distributed as directed.

The poultry inspection system of Israel has the regulatory requirements that are necessary for a chemical residue control program that is organized and administered by the national government. The program includes random sampling of the internal organs, muscle, and fat of carcasses for chemical residues, and the program is adjusted on a yearly basis to address emerging concerns. The program also contains provisions that, in accordance with the CCA's requirements, impose penalties on those that supply poultry with violative residue levels to establishments.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

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

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

The inspection personnel conduct verification sampling for *Salmonella* species (spp) and *Campylobacter* in raw poultry products. 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. The inspection verification sampling for *Campylobacter* (weekly) follows the inspection sampling for *Salmonella* (daily) at audited slaughter establishments. The FSIS auditor accompanied and observed the inspection personnel sample collection methodology for *Salmonella* and *Campylobacter* in two audited slaughter establishments. The demonstrated methodology met the CCA's requirements.

The CCA requires RTE processing establishments that produce post-lethality exposed product to control *Listeria monocytogenes* (*Lm*) by adopting one of the three alternatives in accordance with 9 CFR 430.4(b). The CCA's 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" outline the monitoring and control measures that may be implemented by an establishment producing RTE products. The requirements of PS 6.2.6 mirror FSIS' "Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products." In accordance with these procedures, an RTE product is considered to be 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.

In addition, PS 2.3.1 "Microbial Standards for the Export of Poultry Meat to the Countries of the European Union (EU) and the United States of America" mandates zero tolerance of *Listeria monocytogenes* and *Salmonella* in the RTE product. This PS provides instruction to inspection personnel on how to verify that RTE products destined for export to the United States meet equivalence requirements. One of the requirements is that the inspection personnel must collect RTE product samples prior to shipment of RTE product to the United States. Establishments are required to hold the product for sampling results. If the RTE product tests positive for either *Lm* or *Salmonella*, it is not eligible for export to the United States.

In order to verify the effectiveness of establishments' RTE control measures, the CCA has implemented on-going verification sampling of post-lethality exposed RTE products. The RVOs are responsible to conduct the CCA's on-going verification sampling program at each United States-certified RTE producing establishments. The official verification sampling consists of sampling RTE products (six samples from two processing lines), food contact surfaces (10 samples), and non-food contact surfaces or the environment (five samples). The FSIS auditor noted that the RVO's verification samples are analyzed at a government microbiology laboratory using the analytical methods listed in FSIS' Microbiological Laboratory Guide (MLG). When the results of the bacteriological examinations of RTE product find the presence of *Salmonella* or *Listeria*, the RVO and Food Safety Program Manager conduct an evaluation of the implementation and enforcement of the CCA's requirements in accordance with PS 5.2.3 "*Listeria monocytogenes* – Evaluation of Implementation and Enforcement of Veterinary Requirements by the RVO."

PS 2.3.2 “Meat composition and Identity Testing” requires monthly species verification sampling by the VICs in United States-certified establishments. KVI is responsible for analyzing species verification samples in accordance with the CCA’s requirements. The FSIS auditor’s review of this program and related records did not identify any concerns.

The FSIS auditor visited the Institute for Food Microbiology located in Haifa, Israel. This private microbiology laboratory conducts microbiological testing for establishments certified to export to the United States. The CCA relies on the requirement that each private laboratory be accredited by ISRAC for the standards specified in ISO17025. In addition to the ISRAC audit, the CCA conducts annual audits of private microbiology laboratories. The CCA’s audit verifies the implementation of specific testing methodology based on importing country requirements (e.g., United States or EU requirements). During the laboratory visit, the FSIS auditor reviewed documents pertaining to the sample receipt, timely analysis, analytical methodologies, analytical controls, and reporting of results. In addition, the auditor reviewed training records and the results of proficiency testing. The auditor did not identify any deficiencies during the review of documents.

The audit found that the CCA’s poultry inspection system has a microbiological testing program that is organized and administered by the national government, and that the CCA has implemented sampling and testing programs to verify its system. FSIS’ analysis of the CCA’s control measures and its on-site audit verification activities found that Israel’s microbiological testing program as designed and implemented meets the requirements for equivalence with the United States’ system.

X. CONCLUSIONS AND NEXT STEPS

The previous FSIS audit of Israel’s poultry inspection occurred from June 23 to July 4, 2013. During the course of the 2013 audit, FSIS identified findings within the equivalence components for Government Oversight, Sanitation, and Government Microbiological Testing Programs. During the current audit, FSIS verified that Israel had implemented the corrective actions that it had proffered to FSIS to remedy the 2013 findings. The 2015 FSIS audit did not identify any significant findings to report. An exit meeting was held on December 1, 2015, in Beit Dagan, Israel with the CCA.

On August 21, 2014, FSIS published a final rule to modernize poultry slaughter inspection (79 FR 49566). The rule includes (1) a new regulatory program that affects all poultry slaughter establishments that involves sampling to demonstrate process control at two points on the line and treating enteric pathogens as hazards reasonably likely to occur; and (2) an optional post-mortem inspection system known as the New Poultry Inspection System (NPIS). Implementation of these new provisions was not assessed by FSIS in the 2015 audit. The specific regulatory changes that were made by this final rule can be found in 9 Code of Federal Regulations (CFR) 381.65 and 381.66.

Foreign governments may continue to operate inspection systems that FSIS has determined are equivalent to the United States system. However, if a foreign government decides to implement an NPIS-type system, the CCA must submit documents to explain why the system is equivalent

to NPIS. All countries exporting slaughtered poultry to the United States must submit as part of their May 2016 Self Reporting Tool (SRT) update documentation that the CCA has addressed the new food safety regulatory requirements, and how the CCA has assessed their inspection system. FSIS will verify that countries have addressed these new requirements.

Countries that are in the process of changing their inspection system in order to address any of the new provisions of the FSIS final rule should submit their plans for when the changes will be fully implemented. If adopting a NPIS-type system, the CCA should provide documentation as to why the system is equivalent to NPIS, and how it is being or will be implemented. If the materials are not submitted through the May 2016 SRT submission, FSIS may take steps to restrict or suspend poultry exports from the country to the United States.

XI. ATTACHMENTS TO THE AUDIT REPORT

Attachment A: Foreign Establishment Audit Checklist

Attachment B: Israel's Response to Draft Final Audit Report (when available)

Attachment A: Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Of-Tov (Beit Shean), Kornish Chen (Beit Harishonim) Tnuva Galil (Kiryat Shmona), Maadaney Yehiam (Kibutz Yehiam), Of-Tov Products (Beit-Shean Valley), Tiv-Tirat-Zvi (Kibutz Tirat)	2. AUDIT DATE 11/11/2015 12/01/2015	3. ESTABLISHMENT NO. 008,018,022,104,108,209	4. NAME OF COUNTRY Israel
5. NAME OF AUDITOR(S) MNM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

The FSIS audited the following six poultry establishments:

11/22/2015 Establishment No. 008 Of-Tov (Beit Shean)
11/25/2015 Establishment No. 018 Kornish Chen (Beit Harishonim)
11/17/2015 Establishment No. 209 Tnuva Galil (Kiryat Shmona)
11/18/2015 Establishment No. 104 Maadaney Yehiam (Kibutz Yehiam)
11/19/2015 Establishment No. 108 Of-Tov Products (Beit-Shean Valley)
11/23/2015 Establishment No. 022 Tiv-Tirat-Zvi (Kibutz Tirat)

The FSIS audit did not report any significant findings after consideration of the nature, extent, and degree of all observations made during the onsite audit of the above six poultry establishments.

61. NAME OF AUDITOR
MNM

62. AUDITOR SIGNATURE AND DATE

MNM 2-10-2016

Attachment B: Israel's Response to Draft Final Audit Report



STATE OF ISRAEL

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

April 7 2016

Mr. Vincent Fayne
Acting Director of the International Audit Staff
with the Office of Investigation
Enforcement and audit
International.audit@fsis.usda.gov

Dear Mr. Vincent Fayne,

I would like to thank FSIS for performing the audit of the Israeli inspection services for poultry products.

We have received the FSIS audit draft report and reviewed it thoroughly and have no comments to the report.

Sincerely,

Dr. Sergio Dolev
Chief veterinarian, control of animal products
Israeli Veterinary Services and Animal Health

C.C:

Dr. Nadav Galon, Director of the IVSAH
Dr. Shimon Perk, chief poultry veterinarian IVSAH
Dr. Shlomo Garazi, chief veterinarian for import-export IVSAH
Dr. Michal Hanovice Ziyoni, control of animal products IVSAH