



United States Department of Agriculture

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Food Safety and
Inspection Service

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Washington, D.C.
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Dr. Tamir Goshen
Acting Director, Israeli Veterinary Services and Animal Health
Ministry of Agriculture and Rural Development
Post Office Box 12, Beit Dagan, 50250, Israel

Dear Dr. Goshen,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Israel's poultry inspection system from November 3 through November 20, 2019. Enclosed is a copy of the final audit report. The comments received from the Israeli Veterinary Services and Animal Health (IVSAH) are included as an attachment to the report.

If you have any questions regarding the audit report, please contact the Office of International Coordination by electronic mail at internationalcoordination@usda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Michelle Catlin".

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN ISRAEL

NOVEMBER 3–20, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

POULTRY PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

May 1, 2020

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) November 3–20, 2019. The purpose of the audit was to determine whether Israel's food safety inspection system governing poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Israel currently exports ready-to-eat (RTE), fully cooked not shelf stable poultry products to the United States.

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

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following findings:

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

- Not all results of official microbiological samples tested at the government laboratory are reported directly to the Central Competent Authority (CCA). Only positive results are reported but not the negative results.
- All refrigeration units in the sample receiving area of one microbiological laboratory were not identified and labeled with a calibration certification and an expiration date.

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

- The CCA periodic supervisory review documentation does not address the topic of official control over condemned material until destroyed or removed from the establishment.
- The Israeli poultry inspection system relies on traceability labeling to identify poultry products eligible for export to the United States rather than by separation through means of sanitation, physical barriers, or production during different shifts.

GOVERNMENT SANITATION

- The FSIS auditor observed feather shafts embedded in turkey skins for further processing at two slaughter establishments and one RTE processing establishment.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Israel’s food safety inspection system from November 3–20, 2019. The audit began with an entrance meeting held on November 3, 2019, with representatives of the Israeli Veterinary Services and Animal Health (IVSAH) in Beit Dagan, Israel, during which the FSIS auditor explained the audit objective, scope, and methodology. IVSAH is the Central Competent Authority (CCA) of Israel’s food safety inspection system. During the audit exit meeting on November 20, 2019, IVSAH committed to address the preliminary findings. Representatives from IVSAH accompanied the FSIS auditor throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products¹
Fully Cooked – Not Shelf Stable	RTE fully-cooked poultry	Diced/shredded; hot dog products; other fully cooked not sliced product; other fully cooked sliced product; parts; patties/nuggets; poultry and nonpoultry components; salad/spread/pate; and sausage products.
Fully Cooked – Not Shelf Stable	RTE poultry fully-cooked without subsequent exposure to the environment	Diced/shredded; hot dog products; other fully cooked not sliced product; other fully cooked sliced product; parts; patties/nuggets; poultry and nonpoultry components; salad/spread/pate; and sausage products.

The USDA’s Animal and Plant Health Inspection Service (APHIS) recognizes Israel as affected with highly pathogenic avian influenza and not free from Newcastle disease.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Israel’s self-reporting tool (SRT) responses and supporting documentation. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to determine whether Israel’s food safety inspection system governing poultry products is being implemented as documented in the country’s SRT responses and supporting documentation.

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

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the SRT.

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

The FSIS auditor reviewed administrative functions at CCA headquarters, two regional offices, and five local inspection offices within the establishments. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditor visited all five poultry establishments (two poultry slaughter and raw processing, three poultry processing) certified as eligible to export poultry to the United States during this audit. These establishments produce and export to the United States fully cooked – not shelf stable chicken and turkey products. During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threaten food safety. The FSIS auditor assessed the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 381.196.

The FSIS auditor also visited one government microbiological and chemical residue laboratory and one private microbiological laboratory to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	National	1	<ul style="list-style-type: none"> • IVSAH, Beit Dagan
	Regional Offices	2	<ul style="list-style-type: none"> • North Regional Veterinary Office, Haifa • South Regional Veterinary Office, Beit Dagan
Laboratories		2	<ul style="list-style-type: none"> • Kimron Veterinary Institute, Beit Dagan (government microbiological and chemical residue laboratory) • Institute for Food Microbiology, Haifa (private microbiological laboratory)
Poultry slaughter and processing establishments		2	<ul style="list-style-type: none"> • Establishment No. 008, Off-Tov (Shan) Hodu Tov (Shan) Ltd., Beit Shean Valley

Competent Authority Visits	#	Locations
		<ul style="list-style-type: none"> • Establishment No. 018, Kornish Chen (1987) Ltd.-Hod Hefer, Beit Harishonim St.
Poultry processing establishments	3	<ul style="list-style-type: none"> • Establishment No. 022, Tiv-Tirat-Zvi (2000), Meat Specialties, Beit Shean Valley • Establishment No. 104, Maadaney Yehiam, Kibutz Yehiam • Establishment No. 108, Of-Tov Products (2001) Ltd., Beit Shean Valley

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

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

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

III. BACKGROUND

From July 1, 2016 to June 30, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 8,656,539 pounds of poultry from Israel. This included 66,380 pounds of ready-to-eat (RTE) chicken fully-cooked without subsequent exposure to the environment; 3,731,565 pounds of RTE fully-cooked chicken; 70,786 pounds of RTE turkey fully-cooked without subsequent exposure to the environment; and 4,787,808 pounds of RTE fully-cooked turkey exported by Israel to the United States. Of these amounts, additional types of inspection were performed on 1,421,478 pounds of poultry (2,064 pounds of RTE chicken fully-cooked without subsequent exposure to the environment; 591,092 pounds of RTE fully-cooked chicken; 18,537 pounds of RTE turkey fully-cooked without subsequent exposure to the environment; and 809,785 pounds of RTE fully-cooked turkey). These additional types of inspection included product examination and testing for chemical residues and microbiological pathogens; *Listeria monocytogenes (Lm)* and *Salmonella* in RTE products. As a result of these additional inspections, 16,081 pounds of turkey were rejected for issues related to public health, including positive tests for *Lm* and the presence of physical hazards.

In the past three years, the primary exporters of RTE poultry have been Establishments 022, Tiv-Tirat-Zvi (2000), Meat Specialties; 104, Maadaney Yehiam (1993) Ltd.; 108, Of-Tov Products (2001) Ltd.; and 209, Tnuva Galil Inc. However, on October 10, 2019, upon request by the Israeli industry, IVSAH delisted Establishment 209, citing the lack of eligible source materials. Similarly, in September 2019, IVSAH delisted three additional source suppliers: Establishment 005, Milouof Poultry Integration; Establishment 020, Kornish Chen (1987) Ltd. Off Hanegev;

and Establishment 035, Off Oz Marketing Ltd. Establishment 035 had been implicated in POE violations as a source supplier of turkey skins contaminated with feather shafts.

From the last FSIS audit in January 2018 to the closing date of this audit on November 20, 2019, there have been 14 POE violations originating from Establishments 104 and 108, which continue to be eligible to export to the United States. These POE violations primarily resulted from failure of the product examination type of inspection due to the presence of inedible physical hazards (hard white material) in fully cooked poultry sausage. The description of the violations and subsequent investigation by the IVSAH identified the contamination as turkey feather shafts. These violations raise concerns regarding the establishments' compliance with Israel's regulation *The Business Licensing Regulations-Sanitary Conditions for Food Production Businesses, 5732-1972*, which prohibits the presence of feathers in poultry meat. The FSIS auditor visited both processing establishments that produced product identified in the POE violations.

The last audit in January 2018 identified the following findings:

Component One: Government Oversight (e.g., Organization and Administration)
<ul style="list-style-type: none">• Israel uses in-plant inspection personnel hired and assigned by the Egg and Poultry Board (EPB) to perform all aspects of carcass inspection, including final carcass disposition during post-mortem inspection of the poultry product destined for export to the United States. This practice does not meet FSIS' requirements that a government inspector or contract employee under the supervision of a government inspector perform these inspection activities.• There is a conflict of interest between some of the EPB's members and the EPB's hired in-plant inspection personnel who conduct inspection activities in the poultry slaughter establishments eligible to produce poultry products for export to the United States.

During the November 2019 audit, the FSIS auditor verified that IVSAH continues to address the corrective actions for the January 2018 findings and anticipates complete implementation by March 1, 2020. Further clarification is discussed under component one.

The FSIS final audit reports for Israel's food safety inspection system are available on the FSIS website at: <https://www.fsis.usda.gov/foreign-audit-reports>.

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

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

The Israeli inspection system is organized and administered by the national government, where the inspection system operates at three distinct levels – the national, regional, and local levels. At the national level, IVSAH is a subdivision of the Ministry of Agriculture and Rural Development and is considered the CCA. The director of IVSAH, the Chief Veterinary Officer, is in charge of issuing legislations, guidelines, and instructions for implementation of official controls over production of poultry products. Under IVSAH are the Department of Control of Animal Products and the Kimron Veterinary Institute (KVI). The Chief Veterinarian heads this department, which is responsible for supervising inspection offices. Additionally, the Chief Veterinarian is responsible for providing technical guidance and supervising the functions of official inspectors at the regional and local levels.

At the regional level, the poultry inspection system is divided into two regions, the North Regional Veterinary Office and the South Regional Veterinary Office, located in Haifa and Beit Dagan, respectively. Each region is headed by a Regional Veterinary Officer (RVO), and this position is responsible for oversight at the establishments and for conducting periodic supervisory reviews. The local level, or in-plant inspection, is comprised of a team made up of an in-plant Veterinarian in Charge (VIC) and non-veterinary inspection personnel. This is the front-line force that implements inspection and enforces national food inspection safety laws. The laws of Israel require kashrut or kosher certification of poultry; therefore, all processes and ingredients must meet kosher standards.

The FSIS auditor verified that IVSAH has the authority and responsibility to certify the eligibility of establishments to export poultry products to the United States and to enforce compliance with the inspection laws relevant to establishments certified as eligible to export poultry products to the United States. The FSIS auditor also verified that the government inspectors ensure products destined for export to the United States are wholesome, unadulterated, and prepared and labeled in accordance with *The Control of the Export of Animals and Animal Products (Poultry Products) Regulations, 5737-1976*. The *Regulations for the Control of the Manufacture of Poultry Products for Export and their Export, 1976* addresses the export of poultry products standards, defines “adulteration”, and includes provisions for labeling.

At the national, regional, and local levels, the FSIS auditor verified that IVSAH and its subordinates have the authority and ability to require corrective actions and to take enforcement measures as appropriate in establishments certified as eligible to export processed poultry to the United States, per the *Regulations for the Control of the Manufacture of Poultry Products for Export and their Export, 1976*. The *IVSAH Procedure Sheet 0.2.5 (Regulatory Actions when an Establishment is not in Compliance with IVSAH Requirements)* outlines the sanctions that can be taken against an establishment for failure to correct noncompliance, which include delistment for export or closure.

The FSIS auditor performed onsite observations and reviewed records maintained by inspection personnel at headquarters and inspection offices within establishments certified as eligible to export to the United States. Officials used the authority of the laws of Israel to enforce the rules of the poultry inspection system, identify and document noncompliance, and verify the adequacy of corrective actions and preventive measures in accordance with *P.S. 3.0.7 (Noncompliance –*

Handling and Reporting by the VIC) or P.S. 0.2.5 (Regulatory Actions when an Establishment is not in Compliance with IVSAH Requirements).

The FSIS auditor also verified that IVSAH has a published recall process as defined in *Procedure Sheet (P.S.) 1.0.1 (Recall of Food Products from Retail to the Establishment)* and *P.S. 1.0.3 (Veterinary Verification of the Recall of Food Products from Retail to the Establishment)*. *P.S. 1.0.1* requires the establishment to develop a written recall procedure and the establishment must immediately notify IVSAH and the Ministry of Health regarding potential recalls. The FSIS auditor verified that each certified establishment eligible to export poultry products to the United States has written procedures for effective recalls.

The FSIS auditor verified at each visited establishment that the VICs keep adequate documentation of all export certificates issued to export poultry products to the United States in accordance with IVSAH's instructions in *P.S. 0.0.2 (Health Certificates for Export of Animal Products)*. These instructions include ensuring the facility is eligible to export to the United States, that products subject to sampling are not released until the inspection personnel receives acceptable results, and that exported product labeling is correct. The FSIS auditor verified that each export certificate is accurately signed, dated, stamped, and properly correlated with a signed preshipment review. The FSIS auditor also verified that export certificates and export stamps are properly secured in the VIC government office.

The FSIS auditor verified that the chicken and turkey used in processing operations originate from Israeli slaughter establishments, which are certified by IVSAH for export to the United States in accordance with *P.S. 6.0.5 (Receiving Raw Material from a Source Approved for Export)*. This procedure requires establishments to use source materials that are approved by the importing country and instructs the VIC to verify the eligibility of the raw source material once per week.

At the IVSAH headquarters, the FSIS auditor reviewed the approval process for poultry establishments that apply for certification to export to the United States according to *P.S. 0.0.3*. The Chief Veterinarian and his staff review the written application from the poultry operator seeking to export to the United States, which includes plans of the facility and equipment as stipulated in *The Zoonosis Regulations (Poultry Slaughterhouses) 5720 –1960*. Following the submission of an establishment's application, the IVSAH lead inspection personnel and the RVO review the application package and conduct an onsite inspection. IVSAH has the authority to approve the application and issue the export permit after considering the results of the document review, onsite audits, and implementation of any applicable corrective actions.

The FSIS auditor verified that IVSAH maintains a single standard of laws and regulations applicable to all establishments certified as eligible to export poultry products to the United States. In addition, IVSAH provides instructions to government inspectors in the field by procedure sheets or by an internal website called "foodsafety". IVSAH posts inspection assignments and tasks to be performed by government inspectors through an additional website called "foodinspection". IVSAH requires certified establishments to maintain HACCP programs. IVSAH receives automatic updates from the FSIS website on new policy issuances

and subsequently notifies certified establishments on any updates that affect the export requirements through the procedure sheets.

The FSIS auditor verified that in-plant VICs and non-veterinary inspectors in all poultry slaughter establishments are salaried employees of a government statutory body, the Egg and Poultry Board (EPB). 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 these establishments. The legal basis for the formation of the EPB is established by the law *Egg and Poultry Board—Production and Marketing of 1963*. The main purpose of the EPB is to promote the poultry sector and its products.

The FSIS auditor also verified that IVSAH plays a key role in the selection and hiring process of all qualified veterinarians and non-veterinary inspectors as detailed in *P.S. 0.1.1 (The Procedure for Inspection Personnel to be Employed by the Egg and Poultry Board)*. The *Egg and Poultry Board -Production and Marketing of 1963* law prohibits the EPB from interfering with the inspection activities conducted in the poultry slaughter establishments. Therefore, the EPB only acts as a platform for the employment of the VICs and non-veterinary inspectors in the poultry slaughter establishments.

In 2018, IVSAH initiated an organizational structure change by amending the *Veterinarians Law-1991* and the *Public Health (Food) Protection Law, 5755-2015* in order to create the Agency for Veterinary Inspection of Food (AVIF). IVSAH's Chief Veterinarian informed FSIS that AVIF functions will be fully implemented by March 1, 2020. The AVIF functions include employing veterinarians, advising on veterinary oversight, and collecting fees and payments in accordance with Section 32 of the *Public Health (Food) Protection Law, 5755-2015*. As discussed above, after the implementation of this reorganization, the EPB will no longer be involved in the hiring and payment of VICs and non-veterinary inspectors at poultry slaughter establishments.

In the beginning of this year, the Directorate for the AVIF was created, consisting of 12 members; eight are government officials, two are public representatives, one is a representative of all veterinarians, and one is a representative of the local governments. The Directorate appointed two project managers who began to perform the preliminary steps necessary for the AVIF to start functioning by the beginning of March 2020. On November 15, 2019, a Chief Executive Officer (CEO) of the AVIF was chosen. The CEO will begin working with the project managers to complete the final tasks in order that the AVIF will be operational in the first half of 2020.

Additionally, this organizational structure change results in creation of two CCAs in Israel: one for unprocessed (raw) poultry, which will be supervised by IVSAH, and the second for processed poultry, which will be supervised by the Ministry of Health. Effective March 2, 2020, both CCAs will be responsible for defining functions of the official VICs and non-veterinary inspectors and assigning inspection personnel to establishments. IVSAH will continue to oversee and supervise the veterinarians and inspectors in both poultry slaughter and processing establishments until the Ministry of Health is ready to take over these functions. Therefore,

IVSAH will continue to be the point of contact CCA for all establishments certified for export to the United States for at least one additional year.

The FSIS auditor verified that VIC and non-veterinary inspectors in processing establishments are employees of the local government (municipalities), which is a public body under the Ministry of Interior. The Ministry of Interior is responsible for overseeing and financing (in part) the local government, city councils, local councils, and associations. The legal basis for the work of the local municipalities can be found in the *Municipalities' Ordinance [new version]*, and in the *Local Municipalities' Ordinance [new version]*, both of which are signed by the Minister of Interior. The declaration of a new municipality, whether it is a city or a local municipality which includes a number of villages is made by the Minister of Interior and therefore the municipality has to report back to the Ministry of Interior. Moreover, the Ministry of Interior finances in part the activities of the cities and the local municipalities.

The FSIS auditor verified that IVSAH's Chief Veterinarian or Deputy is responsible for issuing annual accreditation for both VICs and non-veterinary inspectors in all certified establishments eligible to export to the United States in accordance with *P.S. 0.1.4 (The Veterinary Inspector in Slaughterhouse)*. IVSAH's accreditation authorizes the assignments of these personnel to poultry slaughter and processing establishments. The accreditation of an inspector or veterinarian can be revoked by IVSAH based on recommendation by the RVO. Further, *P.S. 0.1.1* stipulates that the official veterinarian and non-veterinary inspector are public servants and must adhere to all administrative requirements. The VICs assigned to poultry slaughter or processing establishments must possess a veterinary degree and a professional license issued by the Director of IVSAH to be considered qualified for annual accreditation. The FSIS auditor verified that the inspection personnel located at the IVSAH headquarters and regional level offices are full-time veterinarians employed by the national government.

The Control of the Export of Animals and Animal Products (Poultry Products) Regulations, 5737-1976 and *P.S. 6.0.1 (Work Shifts in Slaughterhouses and Establishments Processing Poultry Products for Export)* require the presence of government inspection personnel for an establishment to operate. The FSIS auditor verified through onsite observations and records review that each visited certified establishment had enough qualified government inspectors to provide inspection coverage continuously during slaughter operations, and at least once per production shift during processing operations when producing poultry products for export to the United States. The RVO maintains a roster of replacement veterinarians to ensure coverage for planned and unplanned absences. The RVO manages vacations and other absences via the "foodsafety" website.

The FSIS auditor verified that a government inspector (the VIC or trained official inspector) performs both ante-mortem and carcass-by-carcass post-mortem inspections. Post-mortem inspection includes visual and manual examination of each carcass and corresponding viscera and manually reflecting the skin flap to inspect the body cavity. The FSIS auditor verified that inspection occurs at least once per shift when establishments process RTE poultry products for export to the United States.

The FSIS auditor verified that IVSAH ensures that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to perform their inspection tasks. In accordance with *The Veterinary Physician's Act-1991* and *P.S. 0.1.3*, a veterinarian must possess a Doctor of Veterinary Medicine degree recognized by the Higher Education Council. The VICs receive periodic training and inspection updates from both IVSAH and the RVO twice a year at the CCA office and at monthly meetings with their respective RVO. The non-veterinary inspectors must have a high school diploma and receive theoretical and practical training in poultry inspection, export requirements, and general sanitation prior to starting an assignment. The non-veterinarian inspectors receive training and inspection updates from both IVSAH and the VIC once a year at the CCA office and at ongoing training at the establishment level with their respective VIC.

The FSIS auditor verified that IVSAH ensures adequate oversight of government laboratories that perform analyses for official government sampling and testing programs for poultry products exported to the United States. Additionally, IVSAH has the authority and responsibility to approve the laboratories used by the Israeli poultry inspection system to conduct testing of official government samples of product destined for the United States. The government Food Hygiene Microbiology Laboratory and the National Residue Control Laboratory are in Beit Dagan at the KVI and these laboratories conduct analyses of all official government sampling and testing programs.

IVSAH relies on the requirement that the government laboratories of the KVI and the laboratories of the non-governmental Institute for Food Microbiology (IFM) are accredited by the Israel Laboratory Accreditation Authority (ISRAC) for the standards specified in International Organization for Standardization (ISO) 17025, *General requirements for the competence of testing and calibration laboratories*. During the laboratory visits, the FSIS auditor reviewed documents pertaining to the sample receipt, timely analysis, analytical methodologies, analytical controls, and reporting of results. The FSIS auditor verified that IVSAH relies on ISRAC to conduct accreditation audits of laboratories in accordance with ISO 17025. In addition to the ISRAC audit, IVSAH conducts annual audits of private laboratories.

The FSIS auditor verified that IVSAH is using FSIS' Microbiology Laboratory Guidebook (MLG) for isolation and identification of *Salmonella* (MLG 4.09), *Campylobacter* (MLG 41.04), and *Lm* (MLG 8.10). In addition, the FSIS auditor reviewed the most recent accreditation audit, the laboratories' staff training records, and the results of their proficiency testing and found no concerns. However, at the IFM laboratory (private), the FSIS auditor observed the following:

- All refrigeration units in the sample receiving area of one microbiological laboratory were not identified and labeled with a calibration certification and an expiration date.

The FSIS auditor verified that IVSAH ensured that all microbiological and chemical residue sample results are reported directly to the RVOs and VICs, however only positive sample results were reported to the Chief Veterinary Officer of the Department of Control of Animal Products. The FSIS auditor identified the following:

- Not all results of official microbiological samples tested at the government laboratory are reported directly to the CCA. Only positive results are reported but not the negative results.

IVSAH provided FSIS with a list of four private laboratories authorized for use by poultry establishments. The FSIS auditor verified through records review, that none of these private laboratories are used to analyze official government samples for either chemical residue or microbiological analyses. However, VICs routinely oversee sampling procedure of poultry products collected by the establishment (non-official) before establishment ship to some of these private laboratories and receive test results.

The FSIS analysis and on-site verification activities indicated that Israel's poultry inspection system has an organizational structure that provides ultimate control, supervision, and enforcement of regulatory requirements. The audit findings associated with this component do not raise concerns regarding food safety and ongoing equivalence. Prior to the exit meeting on November 20, 2019, the FSIS auditor verified that IVSAH took corrective action to ensure that all microbiological and chemical residue sample results including the negatives are reported directly to the Chief Veterinary Officer of the Department of Control of Animal Products.

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

The second of six equivalence components that the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for Good Commercial Practices in poultry; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and all parts; controls over condemned materials; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

IVSAH implements the *Animal Welfare Law of 1994*, which prohibits cruelty to animals and the *Animal Welfare Regulations (Transport of Poultry)-2011*, which includes requirements regarding the transportation and holding/storage of poultry prior to slaughter. The FSIS auditor verified that poultry destined for slaughter are transported, unloaded, and slaughtered in accordance with IVSAH ritual slaughter requirements. The VIC is responsible to verify the proper implementation of animal welfare laws once per day and to complete a checklist to assess the condition of live poultry at receiving and handling during slaughter in accordance with *P.S. 6.1.9 ((Prevention of Animal Suffering During Transport of Poultry and Official Controls in the Slaughterhouse))*. This verification is recorded electronically on the "foodsafety" website. *P.S. 6.1.9* also requires the establishment to assign a trained employee to monitor animal welfare twice per day.

The FSIS auditor verified at each visited poultry slaughter establishment that ante-mortem inspection is performed prior to slaughter on every truck load by the VIC or trained official inspector in accordance with *The Control of the Export of Animals and Animal Products (Poultry Products) Regulations, 5737-1976*. Poultry presented for slaughter are accompanied by health

certificates that declare the health condition of the flock as required by the *Animal Disease Regulations (Poultry Slaughterhouses)-1960* and *P.S. 3.1.2 (Antemortem Examination of Poultry in Slaughterhouses Approved for Export and Local Production)*. Poultry that exhibit signs of illness are prohibited from slaughter and results from ante-mortem inspection are documented electronically on the “foodsafety” website.

At the two visited poultry slaughter establishments, the FSIS auditor also verified that government inspection personnel were performing carcass-by-carcass post-mortem inspection as required in *The Control of the Export of Animals and Animal Products (Poultry Products) Regulations, 5737-1976*. The government inspectors examine each-and-every carcass and viscera visually and manually, reflecting the flap away from the opening cut and observing the inner surface of the carcass as required in *P.S. 3.1.1 (Post-mortem Veterinary Examination of Poultry)*.

The FSIS auditor verified that the poultry slaughter establishments visited followed the IVSAH requirements in *P.S. 3.1.0 (Post-Mortem Examination and Slaughter Line Speed)* which stipulates that line speed in slaughter establishments approved for United States export must not exceed 24 chickens or 15 turkeys per minute per inspector. IVSAH informed the FSIS auditor that they are in the process of updating *P.S. 3.1.0* as it lists an incorrect line speed for turkey slaughter. The FSIS auditor verified that each of these slaughter establishments meet post-mortem inspection facility requirements in *P.S. 5. (Inspection Station on the Slaughter Line)*, including sufficient shadow-free lighting of at least 2000 lux, on-line hand rinsing facilities, hang back racks, a receptacle for condemned carcasses and parts, and line stop switches.

The FSIS auditor verified that government inspectors performed zero-tolerance checks for ingesta and feces twice per evisceration line per shift, as stipulated in *P.S. 5.1.5 (Fecal Contamination – the Examination by the Official Veterinary Inspector in the Exporting Slaughterhouse)*. The FSIS auditor observed that the VIC physically examines ten randomly selected carcasses prior to entering the chiller at the same location as the establishment’s zero-tolerance checks. The results of the zero-tolerance verification checks are documented on a form and entered electronically on the “foodsafety” website.

At the IVSAH headquarters and regional office, the FSIS auditor verified that the RVO conducts periodic supervisory reviews at certified establishments eligible to export the United States. The frequency of these reviews is based on the establishment’s size and risk profile of the establishment. In accordance with *P.S. 0.2.2 (Official Controls as Performed by the RVO and CVO)*, the RVO must visit each establishment in the region at least once every quarter. The FSIS auditor reviewed supervisory review reports generated by the RVOs. These reports encompass several topics to verify the proper implementation of IVSAH’s requirements by the in-plant inspection personnel. This includes verification of ante-mortem and post-mortem inspection; microbiological sampling of *Salmonella* and *Campylobacter* in raw product; microbiological verification sampling of *Lm* and *Salmonella* sample collections in RTE product; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities that include the review of critical control points (CCPs). However, the FSIS auditor identified the following finding:

- The CCA periodic supervisory review documentation does not address the topic of official control over condemned material until destroyed or removed from the establishment.

The FSIS auditor verified that processing establishments only receive raw poultry source materials from Israel's eligible slaughter establishments and the eligible poultry slaughter establishments receive live poultry only from within Israel. However, the FSIS auditor could not confirm that IVSAH has measures in place to ensure the segregation of domestic product from product destined for export to the United States. Hence, the following finding is reported:

- The Israeli poultry inspection system relies on traceability to identify poultry products eligible for export to the United States rather than by separation through means of sanitation, physical barriers, or production during different shifts.

The FSIS auditor verified that IVSAH ensures that poultry products intended for export to the United States meet FSIS labeling requirements as required in *P.S. 4.0.5 (Poultry and Poultry Products Labeling Approval)*. Labels for exported products must meet target country requirements and regulations and comply with the requirements in *The Control of the Export of Animals and Animal Products (Poultry Products) Regulations, 5737-1976*. The FSIS auditor verified that the labeling verification requirements is an ongoing topic that the RVOs verify during their quarterly supervisory reviews and it is included in the VIC's checklist whenever issuing an export certification as required in *P.S. 0.0.2 (Health Certificate for Exporting Products of Animal Origin)*.

As Israel is affected with highly pathogenic avian influenza and not free from Newcastle disease, APHIS-restricted products (raw poultry) are not eligible for export to the United States. The FSIS auditor verified that only eligible poultry product is exported from processing establishments via the export certification process and the VIC signing and stamping the Veterinary Health Certificate for export. IVSAH communicates with World Organization for Animal Health and APHIS representatives in Europe to maintain awareness of animal disease restrictions. IVSAH conveys APHIS disease restrictions to government personnel in certified establishments by the "foodsafety" website, during monthly meetings with VICs, and during periodic supervisory reviews.

The FSIS auditor verified that IVSAH has control over condemned poultry and inedible materials until destroyed. Dead birds are removed and incinerated, and inedible materials are destroyed within the establishment or denatured prior to removal from the establishment. The VIC issues an inedible waste removal veterinary certificate per *Procedure Sheet 3.1.4 (Removal of Inedible Products from Approved Establishments)*, which includes the total weight of inedible materials before transporting to the rendering plant.

FSIS concluded that Israel's poultry safety inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component; however, the documented IVSAH periodic supervisory reviews lacked verification of official control over condemned materials and the IVSAH procedures did not ensure separation of poultry products eligible for export to the United States from other products. The FSIS auditor verified through traceability and records review that only eligible product was exported to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (SOPs) to prevent direct product contamination or insanitary conditions; to include requirements for sanitation performance standards (SPS); and sanitary dressing.

The FSIS auditor verified that whenever the VIC identifies insanitary conditions or contaminated products, the incident is reported to the establishment management, taking regulatory action as needed, and initiation of appropriate corrective actions by the establishment.

At the two visited poultry slaughter establishments, the FSIS auditor observed implementation of IVSAH requirements for sanitary procedures in accordance with the *Business Licensing Regulations (Sanitary Conditions for Food Production Businesses)*, 5732-1972. *P.S. 5.1.5 (Fecal Contamination – The Examination by the Official Veterinary Inspector in the Exporting Slaughterhouse)* requires slaughter establishments to develop, implement, and maintain written procedures to ensure that carcasses with visible fecal contamination or ingesta do not enter the chiller. This requirement includes sampling and analysis for microbial organisms to monitor the efficacy of the establishment's process control, which are further discussed in Component Six. *P.S. 5.1.5* requires that the VIC randomly examines ten carcasses per evisceration line, twice per day, at the location where the slaughterhouse has designated the zero-tolerance CCP to ensure carcasses contaminated with fecal matter or ingesta do not enter the chiller. The FSIS auditor observed the VICs performing routine zero-tolerance checks after the final wash and before carcasses enter the chiller. This verification showed no contamination with feces or ingesta; however, at one establishment the FSIS auditor observed insanitary handling of the selected carcasses. This observation is listed in Appendix A of this report (individual foreign establishment audit checklists).

The FSIS auditor verified that IVSAH ensures that certified establishments maintain construction, facilities, and equipment in a sanitary manner to prevent the contamination or adulteration of poultry products designated for export to the United States. The *Business Licensing Regulations (Sanitary Conditions for Food Production Businesses)*, 5732-1972 contains Israeli requirements for operators of poultry slaughter and processing establishments to maintain sanitary conditions and adequate construction. These requirements are comprehensive and equivalent to the FSIS sanitation requirements cited in 9 CFR 416.

The FSIS auditor verified that IVSAH requires certified establishments to develop and implement written sanitation SOPs that address cleaning and sanitizing of food contact surfaces prior to and during operations. *P.S. 1.2.1 (IIC Verification of Sanitary Standard Operating Procedures (SSOP) in Poultry Establishments Authorized for Export)* enables sanitation requirements in Israeli regulations. *P.S. 1.2.1* requires that the VIC verify implementation of the sanitation SOPs once per day per shift, either before or during operations, using a checklist containing areas for verification. Additionally, this procedure sheet indicates that the establishment must reassess the sanitation SOPs twice per year, at minimum.

The FSIS auditor reviewed sanitation SOPs and records related to the design and implementation of sanitation programs at each of the five visited establishments. The FSIS auditor assessed the adequacy of the pre-operational inspection verification at one establishment by shadowing and observing the in-plant inspection personnel conducting pre-operational sanitation verification inspection. 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 FSIS auditor observed the in-plant inspection personnel perform actual operational sanitation verification in all visited establishments. The FSIS auditor noted that the inspection verification activities included direct observation of the actual operations and review of the establishments' associated records. The FSIS auditor compared his overall observations of the sanitary conditions of the establishments with the in-plant inspection verification records. The FSIS auditor also examined the inspection personnel's documentation of sanitation noncompliance records and verified that the inspection personnel took regulatory enforcement control actions sufficient to ensure that sanitary conditions were restored, and product was protected from contamination. The FSIS auditor's observations and record reviews of establishments' sanitation monitoring, verification, and corrective action records showed no systemic concerns. Similarly, review of government inspection personnel records documenting inspection verification results and periodic supervisory reviews showed that inspection personnel were adequately verifying establishments' compliance with sanitation regulatory requirements.

Additionally, the FSIS auditor verified that establishment records represented the actual sanitary conditions. The FSIS auditor verified that establishments maintained sanitation records sufficient to demonstrate the implementation and monitoring of sanitation procedures and appropriate corrective actions taken. The establishment employees responsible for the implementation and monitoring of the sanitation procedures correctly authenticated these records. However, the FSIS auditor identified several isolated insanitary conditions that are noted in their respective establishment checklists provided in Appendix A of this report.

From the last FSIS audit in January 2018 to the closing date of this audit on November 20, 2019, there have been 14 POE violations originating from two processing establishments eligible to export RTE products to the United States. These POE violations are primarily a failure of the product examination type of inspection due to the presence of inedible physical hazards (hard white material) in fully cooked poultry sausage. The descriptions of these violations are indicative of contamination with turkey feather shafts, which have been confirmed by the subsequent IVSAH investigations. These violations are not consistent with Israel's regulation *The Business Licensing Regulations (Sanitary Conditions for Food Production Businesses)*, 5732-1972 that prohibits the presence of feathers in poultry product.

During onsite visit of slaughter establishments, the FSIS auditor observed the process of removing the remaining feathers on turkey carcasses after the de-feathering process. The establishment's workers were not fully removing the remaining feather shafts embedded in the skin layer; they were shaving the surface feathers with scissors or knives. At one of the visited poultry processing establishments, the FSIS auditor also observed a box of semi-frozen turkey skins that had numerous feather shafts embedded in turkey skins. Consistent with the POE

violations discussed above, the FSIS auditor observed noncompliance with Israel's regulation *The Business Licensing Regulations (Sanitary Conditions for Food Production Businesses)*, 5732-1972 that prohibits the presence of feathers in poultry product.

- The FSIS auditor observed feather shafts embedded in turkey skins for further processing at two slaughter establishments and one RTE processing establishment.

During this audit, the FSIS auditor verified that no product that might be contaminated with feather shafts were shipped to the United States because the establishments were not producing poultry product destined for export to the United States. Also, before the onset of this audit and as a corrective action to the repeated POE violations of similar root cause, IVSAH prohibited all certified poultry processing establishments from producing product for export to the United States that contains turkey skin as an ingredient.

FSIS concluded that Israel's poultry inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component. However, the FSIS auditor's observation of feather shafts remaining in turkey skins and the repeated POE violations of similar root cause raises concerns about the sanitary dressing procedure and compliance with Israeli regulations. IVSAH has committed to address these sanitation findings.

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

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

The FSIS auditor verified that IVSAH requires each certified establishment to develop, implement, and maintain a HACCP system to ensure that food safety hazards are identified, and prevented or controlled when producing poultry products for export to the United States.

IVSAH requires certified establishments to adopt and implement the FSIS HACCP requirements per 9 CFR 417 as published in the FSIS *2009 HACCP Guidelines – Control of Animal Products*. The initial certification of an establishment to export poultry product to the United States is contingent upon the approval of a validated HACCP program. Once an establishment is certified, it is subject to a yearly audit by IVSAH for evaluation of the HACCP program and for continued approval as certified establishment for export, as stipulated in *P.S. 0.2.1 (Food Safety Arrangement in a Plant Approved for Exporting Poultry Product)*. The FSIS auditor verified that IVSAH's Chief Veterinarian (or deputy) at the Department of Control of Animal Products conducts an annual audit of each certified establishment for HACCP plan compliance and implementation.

The FSIS auditor verified that the VIC verifies different sections of the HACCP system daily such as monitoring, verification, validation, product sampling and testing, ongoing verification (direct observation, records review, and instrument calibration), recordkeeping, supporting documentation, corrective actions, and preshipment review as required in *P.S. 1.1.3 (Veterinary*

Controls of HACCP Activities in Slaughterhouses and Poultry Processing Plants for Export). This procedure sheet requires the VIC to verify at least two CCPs daily either by document review, direct observation, or in-person examination. *P.S. 1.1.1 (Yearly Reevaluation of HACCP Program Verification of Implementation by Inspecting Veterinarian)* requires certified establishments to assess their HACCP program annually.

For certified poultry slaughter establishments, the FSIS auditor verified that IVSAH requires a CCP for zero tolerance of fecal matter and ingesta per *P.S. 5.1.5*, as previously discussed in Component Two of this report. For certified RTE poultry processing establishments, the FSIS auditor verified that IVSAH requires a post-lethality treatment to be addressed by a CCP per *P.S. 5.2.1 (CCA Requirements for Monitoring LM in RTE Poultry Products)* and requires compliance with chilling and stabilization requirements in accordance with *P.S. 1.1.2 (RTE Poultry Products – Chilling and Stabilization Requirements)*. Also, IVSAH requires that certified establishments abide by the FSIS Compliance Guidelines Appendix A (for lethality) and Appendix B (for stabilization).

At each visited establishment, the FSIS auditor reviewed the HACCP plan and verified that the design and implementation comply with HACCP requirements. The FSIS auditor put special emphasis on reviewing records associated with the production of product for export to the United States to ensure that all HACCP requirements were met, including all critical limits at all CCPs were met, all required corrective actions were taken prior to shipping the product to the United States, and that preshipment reviews were verified by the VIC as being completed by the establishment prior to signing an export certificate. The review of the establishments' HACCP plans, CCPs, critical limits, monitoring procedures, verification procedures, and implemented corrective actions did not raise any systemic concerns.

The FSIS auditor verified that the visited poultry slaughter establishments have developed, implemented, and incorporated into their HACCP plan a microbiological sampling program for detection of indicator organisms at pre-chill and post-chill stations. The establishments sampling program contains written procedures in place to ensure that poultry carcasses contaminated with visible fecal material would not enter the carcass chiller. The FSIS auditor also verified that the visited poultry slaughter establishments have implemented procedures to ensure that poultry carcasses are chilled immediately after evisceration in accordance with the IVSAH requirements.

The FSIS auditor reviewed the zero-tolerance CCP monitoring and related corrective action records of the establishments and the verification records of the VIC in two visited poultry slaughter establishments. In addition, the FSIS auditor, together with the in-plant inspection personnel, observed an establishment employee conducting hands-on HACCP monitoring and verification activities for the zero-tolerance CCP. Although, this verification showed no contamination with feces or ingesta, at one establishment the FSIS auditor observed insanitary handling of the selected carcasses due to inadequacy in the inspection station design and lighting, which raise concerns about the ability of personnel to adequately monitor and verify the CCP.

The FSIS auditor also verified that pre-chill and post-chill sampling for enteric pathogens was implemented in the HACCP systems of the poultry slaughter establishments, and that inspection personnel reviewed and verified the accuracy of the results of such programs. The FSIS auditor

observed establishment personnel collecting chicken wash samples and turkey sponge samples at pre-chill stations in two different slaughter establishments and noted no concerns. The FSIS auditor's review of the HACCP requirements and government verification activities indicates that IVSAH continues to maintain a system equivalent to that of FSIS.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed the National Residue Program (NRP) results from 2018, a portion of the 2019 results, associated methods of analysis, and additional SRT responses outlining the structure of Israel's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit in 2018.

Israel conducts residue monitoring according to European Union (EU) and United States standards. Israel's Ministry of Health regulates the use of pesticides and heavy metals and determines maximum residue limits (MRLs) allowed in foods according to toxicological findings and the agricultural need. The marketing of poultry products containing chemical residues above the MRL is prohibited.

P.S. 0.2.8 (Activities of the Interministerial Advisory Committee (Steering Committee) and Subcommittees in Determining MRLs) provides information on how the residue monitoring program is developed and planned for upcoming years. IVSAH conducts an annual survey to identify the potential sources of chemical residue contamination of poultry meat and its products. A central steering committee uses the information gathered in the survey to determine which compounds to be included in the NRP of the following year. The sampling program is designed proportionally by each slaughter establishment's production volume. Samples are not requested for specific testing; all samples have an equal chance of being analyzed for any residue.

The FSIS auditor visited the Chemical Residue Laboratory of the KVI, which is an ISO-accredited National Residue Control Laboratory. The KVI is the government laboratory used for analysis of official samples taken from products destined for export to the United States. At the KVI, the FSIS auditor focused on sample handling, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, intra-laboratory check samples, quality assurance programs, and corrective actions. Israel does not use private laboratories to conduct analyses for chemical residue samples.

The FSIS auditor reviewed the implementation of the 2019 chemical residue sampling plan at the IVSAH headquarters, regional offices, and in-plant inspection offices. The FSIS auditor verified that the inspection personnel who collect the residue samples receive periodic training in

accordance with the NRP sampling protocol. This protocol includes sampling methodology, identification of animals, sampling location, sample size, sampling frequency, traceability, and secure delivery of residue samples to the KVI.

The VIC collects random residue samples based on instructions from the RVO each month. The VIC accesses sampling instructions, matrices to be collected, and forms from the “food inspection” website. Results from residue sampling analyses by the KVI are reported to the VIC through the “food inspection” website. IVSAH and the RVOs have direct access to the laboratory results through this electronic system.

The NRP for poultry does not require that product be held until sample results are received. The FSIS auditor verified that IVSAH does not require holding of product from routine chemical residue testing; however, in-plant government inspection personnel are required to hold products from farms at risk that have histories of violative results above the MRL, until the receipt of a specified number of consecutive negative residue testing results, according to the type of chemical residue detected. *P.S. 2.2.2 (Follow-up of a Farm at Risk and the Treatment of Noncompliant Results)* outlines the process when a violative result is found. Products found to have noncompliant residue levels, or the presence of prohibited compounds are not fit for human consumption and must be rejected and destroyed.

The results of this onsite audit indicate that IVSAH continues to ensure the implementation and maintenance of an official government chemical residue control program that prevents and controls all specific compounds of concern in Israel and in the United States. FSIS analysis and verification of IVSAH’s chemical residue testing program, as designed and implemented, show that IVSAH is effectively using its authority to ensure the production of safe product.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that poultry products prepared for export to the United States are safe and wholesome.

IVSAH ensures that poultry slaughter establishments verify process control using microbiological analyses for indicator organisms of intestinal and fecal contamination. IVSAH requires that eligible poultry slaughter establishments that produce raw materials for export by certified poultry processing establishments to develop, implement, and maintain a microbiological sampling and testing program to demonstrate process control to prevent contamination of carcasses by enteric pathogen and fecal material throughout the slaughter and dressing operations in accordance with *P.S. 5.1.6 (Microbiological Monitoring in Slaughterhouses Approved for Export to the United States)*. At the two visited slaughter establishments, the FSIS auditor verified that establishment personnel sample for microbiological indicators (generic *E. coli*) of intestinal and fecal contamination as required by IVSAH.

The FSIS auditor verified that establishments have written procedures for pre-chill and post-chill sampling of poultry carcasses for indicator organism testing and applied statistical process control to assess results. Carcasses are selected randomly, and samples are tested at an accredited laboratory (private or government) that conforms to FSIS MLG methods. The sampling frequencies per *P.S. 5.1.6* are one broiler carcass for every 22,000 broilers slaughtered and one turkey carcass for every 3,000 turkeys slaughtered. The FSIS auditor observed establishment personnel sampling one broiler carcass at the pre-chill location, collecting carcass-wash aseptically, packaging, and shipping according to written procedures.

P.S. 5.1.6 appears to indicate that it is acceptable to sample parts such as wings or thighs in lieu of carcasses for indicator organisms. At the IVSAH office, the FSIS auditor verified that no certified poultry slaughter establishments sample poultry parts in lieu of carcass for indicator organisms.

The FSIS auditor observed that government inspection personnel conduct verification sampling for *Salmonella* and *Campylobacter* in raw poultry carcasses in accordance with *P.S. 5.1.9 (Salmonella and Campylobacter-Monitoring and Inspection in the Slaughterhouse)*. This procedure establishes standards for the regulatory requirements pertaining to enforcing *Salmonella* and *Campylobacter* performance standards that are consistent with FSIS HACCP/pathogen reduction requirements. IVSAH's sampling included the daily collection of one chicken rinse sample (set of 51 samples) and one turkey swab sample (set of 56 samples) until the sample set is completed.

The FSIS auditor observed the in-plant government inspection personnel sample collection methodology for *Salmonella* and *Campylobacter* in the two visited slaughter establishments. Sample collection methodology was in accordance with IVSAH's requirements and consistent with FSIS Directive 10,250.1 *Salmonella and Campylobacter Verification Program For Raw Meat And Poultry Products*. Sampling of broilers is conducted by rinsate using 400 milliliters of buffered peptone water (60 milliliters are collected for analysis). Sampling of turkeys is conducted by swabbing the back and thigh of the carcass (5 centimeters by 10 centimeters each). The samples are collected aseptically and sent to the KVI for *Salmonella* analysis using FSIS MLG 4.09, and for *Campylobacter* analysis using FSIS MLG 41.04.

The FSIS auditor also verified that the government inspection personnel were reviewing official test results for trend analysis and verifying the establishments implement corrective measures when the establishments do not meet the performance standards. The results of the government *Salmonella* and *Campylobacter* sample sets are reported to the VIC only at the end of the set; however, the RVO receives individual test results of each carcass-wash sample for chicken and each swab sample for turkey.

The FSIS auditor verified that IVSAH considers an RTE product containing *Lm* or *Salmonella*, and an RTE product that comes into direct contact with a food contact surface (FCS) contaminated with *Lm* or *Salmonella*, to be adulterated per *P.S. 6.2.5 (Lm in Ready-to-Eat Poultry Products)* and *P.S. 6.2.6 (Clarifications to Procedure Sheet 6.2.5 About Lm in Ready-to-Eat Poultry Products)*. IVSAH ensures through sampling and other verification activities that RTE poultry products are not contaminated with microbiological pathogens or their toxins,

including *Lm* and *Salmonella*. *P.S. 2.3.1 (Microbial Standards for the Export of Poultry Meat to the Countries of the European Union and the United States of America)* mandates zero tolerance of *Lm* and *Salmonella* in RTE product.

Additionally, *P.S. 2.3.1* provides instructions 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, 325 grams for *Salmonella* and 25 grams for *Lm*, prior to shipment of every lot of RTE product to the United States. IVSAH's prescribed verification sampling protocol mandates hold and test practices. If the RTE product tests positive for either *Lm* or *Salmonella*, it is not eligible for export to the United States.

The FSIS auditor observed the RVO collecting samples of food contact surfaces (FCS) and environment in processing establishments producing RTE product for export to the United States. Once every 18 months, the RVO collects from each processing establishment certified as eligible to export to the United States 10 FCS swabs and five non-food contact surface swabs for *Lm* testing, (per *P.S. 5.2.3*) and five FCS swabs and eight non-food contact surface swabs for *Salmonella* testing (per *P.S. 5.2.2*). The sampling site size is at least 900 centimeters square. *P.S. 2.3.0 (Microbiological Monitoring in Exported Food Products)* requires establishments to sample products and the production environment for *Lm*.

The FSIS auditor verified that the VIC collects the required verification samples in establishments certified as eligible to export to the United States. The VIC conducts random sampling of RTE poultry products that are packaged, labeled, and ready for shipping. The sampling occurs on the production day at the completion of the production process. Per *P.S. 5.2.2* the frequency of official sampling for post-lethality exposed product is two products per month; one product sample is selected based on risk analysis and the second product sample is selected randomly. IVSAH also conducts species verification testing on a monthly basis.

Official government samples of *Lm* and *Salmonella* for products exported to the United States are sent to the KVI. The KVI tests for *Lm* using FSIS MLG 8.10 (test portion of 25 grams) and *Salmonella* using FSIS MLG 4.09 (test portion of 325 grams). If the RTE product tests positive for either *Lm* or *Salmonella*, that product is not eligible for export to the United States. The FSIS auditor visited the microbiology laboratory of the KVI and the Institute for Food Microbiology (IFM), a private microbiological laboratory. The KVI conducts microbiological testing on the official verification samples and the IFM conducts microbiological testing for establishments certified as eligible to export to the United States. The FSIS auditor's review of this program and related records did not identify any concerns, except for the findings listed under Component One.

The results of this onsite audit indicate that IVSAH's poultry inspection system has a microbiological testing program that is organized and administered by the national government, and that IVSAH has implemented sampling and testing programs to verify its system. FSIS analysis and verification indicate that IVSAH's microbiological testing program as designed and implemented meets the requirements for equivalence with the United States' system. Further, there have not been any POE violations related to this component since the last FSIS audit.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on November 20, 2019, in Beit Dagan, Israel, with representatives from IVSAH. At this meeting, the FSIS auditor presented the preliminary findings from the audit.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following findings:

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

- Not all results of official microbiological samples tested at the government laboratory are reported directly to the CCA. Only positive results are reported but not the negative results.
- All refrigeration units in the sample receiving area of one microbiological laboratory were not identified and labeled with a calibration certification and an expiration date.

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

- The CCA periodic supervisory review documentation does not address the topic of official control over condemned material until destroyed or removed from the establishment.
- The Israeli poultry inspection system relies on traceability labeling to identify poultry products eligible for export to the United States rather than by separation through means of sanitation, physical barriers, or production during different shifts.

GOVERNMENT SANITATION

- The FSIS auditor observed feather shafts embedded in turkey skins for further processing at two slaughter establishments and one RTE processing establishment.

During the audit exit meeting, the IVSAH committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the IVSAH's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Off-Tov (Shan) Hodu-Tov Ltd. M.P. Beit Shean Valley 10.900	2. AUDIT DATE 11/14/2019	3. ESTABLISHMENT NO. 008	4. NAME OF COUNTRY Israel
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

10. Operational Sanitation (SSOP):

The FSIS auditor observed the process of removing the remaining feathers on turkey carcasses after the de-feathering process. The establishment's workers were not fully removing the remaining feather shafts embedded in the skin layer; they were shaving the surface feathers with scissors or knives. Like the POE violations, the FSIS auditor's on-site observation is not consistent with Israel's regulation *The Business Licensing Regulations (Sanitary Conditions for Food Production Businesses)*, 5732-1972 that prohibits the presence of feathers in poultry product.

18. Monitoring of the HACCP plan:

In the HACCP plan, the monitoring procedure of CCP#4 (cpc antimicrobial concentration) is not recorded or referenced to in a prerequisite program).

39. Establishment Construction/ Maintenance:

a) In two out of the six post-mortem inspection station of chicken slaughter line, the on/off switch of hand washing sink is too far from the inspector to use; this does not meet the CCA and FSIS requirements. b) In cold processing room, there were structural gap between the walls and metal frame and the metal frames have rusty spots. In another area of framed ceiling, there were excessive gray sealant or concrete bulging outside the surface level creating insanitary condition and possibility of sloughing off.

51. Periodic Supervisory Reviews:

The CCA periodic supervisory review documentation does not address the topic official control over condemned material until destroyed or removed from the establishment as required in 9 CFR 381.196(a)(2)(ii)(G).

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

11/14/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Komish Chen (1987) Ltd. - Hod Refer Beit Harishonim st. Zip code 38800 Emek Refer	2. AUDIT DATE 11/07/2019	3. ESTABLISHMENT NO. 018	4. NAME OF COUNTRY Israel
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	X
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

10. Operational Sanitation (SSOP)

a) The zero-tolerance inspection station designated for Turkey carcasses is inadequate to prevent cross contamination between carcasses (insufficient space); inspector frequently touched the carcasses with his flashlight or sleeves. b) The FSIS auditor observed the process of removing the remaining feathers on turkey carcasses after the de-feathering process. The establishment's workers were not fully removing the remaining feather shafts embedded in the skin layer; they were shaving the surface feathers with scissors or knives. Like the POE violations, the FSIS auditor's on-site observation is not consistent with Israel's regulation *The Business Licensing Regulations (Sanitary Conditions for Food Production Businesses)*, 5732-1972 that prohibits the presence of feathers in poultry product.

40. light:

Absence of light source specifically designated for ZT check and carcass rework stations. The CCA requires lighting at the inspection station(s) must be 2000 lux.

51. Periodic Supervisory Reviews

The CCA periodic supervisory review documentation does not address the topic official control over condemned material until destroyed or removed from the establishment as required in 9 CFR 381.196(a)(2)(ii)(G).

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

11/07/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Tiv-Tirat-Zvi 2000,Meat Specialties Kibutz Tirat Tsvi M.P. Beith Shean Valley 10815	2. AUDIT DATE 11/13/2019	3. ESTABLISHMENT NO. 022	4. NAME OF COUNTRY Israel
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

13. Daily Record Document:

On June 11, 2019, a noncompliance was identified by company personnel, however no corrective actions was documented.

51. Periodic Supervisory Reviews:

The CCA periodic supervisory review documentation does not address the topic official control over condemned material until destroyed or removed from the establishment as required in 9 CFR 381.196(a)(2)(ii)(G).

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT

11/13/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Maadaney Yehiam (I 993) Ltd. Kibutz Yehiam 22125	2. AUDIT DATE 11/11/2019	3. ESTABLISHMENT NO. 104	4. NAME OF COUNTRY Israel
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	
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.	X	Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

10. Implementation of SSOPs.

During per-operational sanitation the following was observed: dried meat on product contact surface of product injection machine. Rusty spots on product contact surface (blades) of slicers. Rusty ceiling localized in front of a cooling unit in processing area and rusty spots on two motors attached to the cooling unit. In the peeling room, long steam pipe and an elbow are covered with aluminum foils creating an unstable structure to wash and sanitize. At one loading and unloading door, one roach entered a gap between the wall and door frame.

21. Adequacy of the HACCP plan.

During a tour of the processing department cold storage area, the FSIS auditor observed a box of semi-frozen turkey skins that had numerous long feather shafts embedded on the skins. This product originated from a certified poultry slaughter establishment eligible to export to the United States. Establishment 104 considers receiving edible turkey skins with inedible material (feather shafts) embedded as an acceptable practice because they have a pre-requist program (PRP) to separate or extract the feathers from the skin during the preparation and production of RTE poultry product. In the last six months there have been six point-of-entry violations originated from establishment 104 due to the presence of physical hazard (whitish hard foreign material/ feathers ranged from 3mm-8mm in size). First, the presence of feathers in raw edible product on the receiving step is not consistent with Israel law, *The Business Licensing Regulations (Sanitary Conditions for Food Production Businesses)*, 5732-1972 prohibits the presence of feathers in poultry meat. Second, the PRP does not seem to be effective or adequate to prevent the presence of feathers in RTE product. During this audit, no product that might be contaminated with feathers were shipped to the United States because the establishment was not producing for the United States that day. Additionally, the CCA recently forbid all certified poultry processing establishment from producing or shipping product made with turkey shins to the United States.

51. Periodic Supervisory Reviews

The CCA periodic supervisory review documentation does not address the topic official control over condemned material until destroyed or removed from the establishment as required in 9 CFR 381.196(a)(2)(ii)(G).

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Of-Tov Products, (2001) Ltd. Beit Shean Valley 10900	2. AUDIT DATE 11/17/2019	3. ESTABLISHMENT NO. 108	4. NAME OF COUNTRY Israel
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	X	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.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment**12. SSOP Corrective Actions:**

In the processing room at the injection machine exit, there were black grease smear on overhead hose/wire and foreign string hanging from that hose/ wire. The establishment's SSOP and SPS monitoring records do not show that product contact surfaces have been sanitized before starting operations and do not state corrective actions taken to prevent recurrence.

15. Contents of the HACCP list of hazards:

Establishment's hazard analysis and decision that physical hazards in processing, cooking, cooling, and packaging of ready to products is not reasonably likely to occur because of pre-request program is not supported by an adequately written program. However, the establishment has documentations of metal detector hourly checks at the end of each production line.

51. Periodic Supervisory Reviews:

The CCA periodic supervisory review documentation does not address the topic official control over condemned material until destroyed or removed from the establishment as required in 9 CFR 381.196(a)(2)(ii)(G).

61. AUDIT STAFF

OIEA International Audit Branch (IAB)

62. DATE OF ESTABLISHMENT AUDIT11/17/2019

Appendix B: Foreign Country Response to the 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 26, 2020

Michelle Caitlin, PhD
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue, SW
Washington, D.C. 20250, United States

Dear Dr. Caitlin,

In reference to your letter of February 27, 2020, regarding the draft final audit report, below please find our response:

We would like to thank Dr. Nader Ismail for his professionalism, courtesy, and thoroughness during the audit. We view his comments during the audit and the report as a way to improve ourselves and appreciate his insights.

Attached please find an appendix with responses to the noncompliances listed in the report. Please note that in light of the persistent coronavirus outbreak, not every corrective action has been implemented in the establishments.

We remain at your disposal for any further questions or clarifications.

Sincerely,

Dr. Sergio Dolev
Chief Veterinarian, Control of Animal Products
Israeli Veterinary Services and Animal Health

cc:

Dr. Tamir Goshen – Acting Director, Israeli Veterinary Services and Animal Health
Dr. Riva Ben-Ezra – Deputy Chief Veterinarian, Control of Animal Products
Mr. Oren Shaked – Senior Agricultural Specialist- US Embassy, Tel Aviv, USDA-FAS



STATE OF ISRAEL

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

APPENDIX

Noncompliance	Corrective Action
<p>Not all results of official microbiological samples tested at the government laboratory are reported directly to the Central Competent Authority (CCA). Only positive results are reported but not the negative results.</p>	<p>The STARLIMS system has been updated so that all positive and negative results of official microbiological samples tested at the government laboratory are sent to the CCA.</p>
<p>All refrigeration units in the sample receiving area of one microbiological laboratory were not identified and labeled with a calibration certification and an expiration date.</p>	<p>Labels identifying calibration certification and an expiration date were adhered to the refrigeration units that were lacking labels.</p>
<p>The CCA periodic supervisory review documentation does not address the topic of official control over condemned material until destroyed or removed from the establishment.</p>	<p>A Procedure Sheet and associated CCA periodic supervisory review documentation has been updated to more specifically address the topic of official control over condemned material.</p>
<p>The Israeli poultry inspection system relies on traceability labeling to identify poultry products eligible for export to the United States rather than by separation through means of sanitation, physical barriers, or production during different shifts.</p>	<p>A Procedure Sheet has been written to address the separation of poultry products eligible for export to the United States from other products.</p>
<p>The FSIS auditor observed feather shafts embedded in turkey skins for further processing at two slaughter establishments and one RTE processing establishment.</p>	<p>Establishments exporting RTE poultry products were notified that they are unable to use turkey skins as raw material for products exported to the United States.</p>