United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
20250

JAN 0 5 2023

Dr. Tamir Goshen
Chief Veterinary Officer
Israeli Veterinary Services and Animal Health (IVSAH)
Ministry of Agriculture & Rural Development
Hamakkabim Road, Rishon LeZion, P.O. Box 30 Beit Dagan 50200
Israel

Dear Dr. Goshen,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Israel's poultry food safety and inspection system June 27–July 19, 2022. Enclosed is a copy of the final audit report. The comments received from the Government of Israel are included as an attachment to the report.

For any questions regarding this audit report, please contact the Office of International Coordination at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF ISRAEL

JUNE 27 TO JULY 19, 2022

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

PROCESSED POULTRY PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

October 6, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Israel conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from June 27 to July 12, 2022. The purpose of the audit was to verify whether Israel's food safety system governing processed poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly 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, and Product Standards and Labeling); (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 audit findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following findings related to laboratory oversight:

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

- The Central Competent Authority (CCA) has a provision that allows official samples with violative chemical residue test results to be retested at the laboratory's discretion and has not provided written procedures to ensure that these products cannot be exported to the United States.
- The CCA does not ensure that the government microbiological laboratory conducting official testing for *Salmonella* and *Listeria monocytogenes* (*Lm*) in RTE poultry products fully complies with certain criteria for traceability of test results provided in the International Organization for Standardization/International Electrotechnical Commission 17025 (ISO/IEC 17025) standards. Specifically, the FSIS auditor identified that laboratory technicians did not record start and stop times for incubation steps in the *Salmonella* and *Lm* methods.

An exit meeting was held July 19, 2022, by videoconference with representatives from the CCA. During the 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 once received and base future equivalence verification activities on the information provided.

TABLE OF CONTENTS

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 system from June 27 to July 12, 2022. The audit began with an entrance meeting held June 27, 2022, in Beit Dagan, Israel, to discuss the audit objective, scope, and methodology. The participants included inspection officials from Israel's Veterinary Services and Animal Health (IVSAH) and Food Control Service (FCS). IVSAH is Israel's Central Competent Authority (CCA) for poultry slaughter, and FCS is Israel's CCA for poultry processing operations. Representatives from IVSAH and FCS accompanied the FSIS auditor throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference on July 19, 2022.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety system for processed 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 properly labeled and packaged. Israel is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Fully Cooked - Not Shelf Stable	Ready-to-Eat (RTE) Fully-Cooked Poultry	Chicken and Turkey - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Poultry Fully-Cooked Without Subsequent Exposure to the Environment	Chicken and Turkey - All Products Eligible

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, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to verify whether Israel's food safety system governing processed poultry products is being implemented as documented in the country's SRT responses and supporting documentation.

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 IVSAH and FCS through the SRT.

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

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, and Product Standards and Labeling); (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 IVSAH and FCS headquarters, two regional offices, and six 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 three poultry slaughter establishments that provide raw source materials to the certified processing establishments, and three poultry processing establishments currently certified as eligible to export poultry products to the United States. 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 threatens food safety. The FSIS auditor assessed IVSAH and FCS' ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) Part 381.196.

The FSIS auditor also visited one government microbiological and chemical residue laboratory and one private microbiological laboratory to verify that these laboratories can provide adequate technical support to the food safety system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• IVSAH and FCS, Beit Dagan and Tel Aviv
	Regional Offices	2	• IVSAH's North Regional Veterinary Office, Haifa • FCS' North Regional Veterinary Office, Haifa
Laboratories		2	• Kimron Veterinary Institute, Beit Dagan (government microbiological and chemical residue laboratory) • Institute for Food Microbiology, Haifa (private microbiological laboratory)
Poultry slaughter establishments		3	• Establishment No. 8, Off-Tov (Shan) Hodu-Tov (Shan) Ltd., Beit Shean Valley • Establishment No. 18, Kornish Chen (1987) Ltd., Hod Hefer, Beit Harishonim St. • Establishment No. 37, Tari and Chalak 2, Shlomi
Poultry processing establishments		3	• Establishment No. 22, Tiv-Tirat-Zvi (2000), Meat Specialties, Beit Shean Valley • Establishment No. 104, Maadaney Yehiam (1993) Ltd., Kibutz Yehiam • Establishment No. 108, Of-Tov Products (2001) Ltd., Beit Shean Valley

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

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

The audit standards applied during the review of Israel's food safety 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 May 1, 2019, to April 30, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 9,282,457 pounds of poultry from Israel. This included 98,060 pounds of RTE chicken fully-cooked without subsequent exposure to the environment; 4,481,339 pounds of RTE, fully-cooked chicken; 40,419 pounds of RTE turkey fully-cooked without subsequent exposure to the environment; and 4,662,639 pounds of RTE, fully-cooked turkey. Of these amounts, additional types of inspection were performed on 1,334,029 pounds of poultry (13,068 pounds of RTE chicken fully-cooked without subsequent exposure to the environment; 615,454 pounds of RTE, fully-cooked chicken; 3,988 pounds of RTE turkey fully-cooked without subsequent exposure to the environment; and 701,519 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, 41,593 pounds of chicken and 7,322 pounds of turkey were refused entry due to product exam failures (i.e., foreign material or off-condition). FSIS evaluated FCS' corrective action responses, found them sufficient, and closed the respective POE violation cases.

The last audit in November 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of Israel
Component 1: Government Oversight (e.g., Organization and Administration)
• Not all results of official microbiological samples tested at the government laboratory were reported directly to the CCA. Only positive results were reported but not the negative results. • All refrigeration units in the sample receiving area of one microbiological laboratory were not labeled with a calibration certification and an expiration date.
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, and Product Standards and Labeling)
• 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.
Component 3: 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 current audit, the FSIS auditor verified that the corrective actions for the above findings reported in 2019 were implemented and effective in resolving the findings.

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

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

The first equivalence component the FSIS auditor reviewed was Government Oversight. FSIS import regulations require the foreign food safety 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.

Israel's poultry inspection system is organized by the national government and operates at the national, regional, and local levels. At the national level, Israel's poultry inspection system is divided between two ministries: the Ministry of Agriculture and Rural Development (MOAG) and the Ministry of Health (MOH). IVSAH, an agency under MOAG supervision, is the CCA responsible for conducting inspection activities in certified poultry slaughter establishments. IVSAH's director, the chief veterinary officer, oversees the issuance of legislations, technical guidelines, and instructions for implementation of poultry slaughtering requirements and official controls at its regional and local level offices. Since September 1, 2020, FCS, an agency under MOH supervision, is the CCA responsible for conducting inspection activities in certified poultry processing establishments. FCS' veterinarian director oversees the issuance of legislation, technical guidelines, and instructions for implementation of poultry processing requirements and official controls at its regional and local level offices.

At the regional level, three regional offices oversee poultry inspection activities in certified establishments. The North Regional Veterinary Office and the South Regional Veterinary Office, located in Haifa and Beit Dagan, respectively, and both under MOAG, oversee poultry slaughter related inspection activities, while the North Regional Veterinary Office, located in Haifa, under MOH, oversees poultry processing related inspection activities. Each region is headed by a regional veterinary officer (RVO) who is responsible for oversight at the certified establishments and for conducting periodic supervisory reviews.

At the local level, in-plant government inspection personnel are comprised of a veterinary inspector in charge (VIC) and non-veterinary inspectors (auxiliary inspectors (AI)). The FSIS

auditor verified that in-plant VICs and AIs in certified poultry slaughter and processing establishments are salaried government employees of an entity called the Agency for Veterinary Inspection of Food (AVIF). The AVIF collects inspection-related fees from the poultry slaughter and processing establishments as payment for the inspection services rendered by VICs and AIs at these establishments. IVSAH and FCS maintain legal authority and responsibility for assigning in-plant inspection related activities, conducting performance evaluations, and providing inspection related trainings.

The FSIS auditor verified that IVSAH and FCS conduct, at a minimum, two performance appraisals for each in-plant government inspector per year to assess their knowledge, skills, and abilities. Each performance appraisal includes interviews, review of inspection-generated records, and direct observation of the government inspection personnel while conducting their assigned inspection activities in the following areas, where applicable: ante-mortem inspection; post-mortem inspection; verification of Sanitation Standard Operating Procedures (Sanitation SOP) and Sanitation Performance Standards (SPS); HACCP verification; labeling verification; sampling methodology; export certificates; complete separation of authorized establishments; and official control over the condemned materials. The FSIS auditor reviewed in-plant government inspection personnel educational credentials, performance evaluations, and training records in Good Commercial Practices (GCP), ante-mortem inspection, post-mortem inspection, sanitation procedures, HACCP, sampling methodology, and FSIS import requirements. The FSIS auditor verified that IVSAH and FCS have organized ongoing and annual training programs for both inspection and laboratory personnel. No concerns arose regarding these reviews.

The regulatory authority of Israel's poultry inspection system to enforce national laws, conduct inspection verification activities, implement importing country's inspection requirements, and certification of poultry slaughter and processing establishments, stems from the Control of the Export of Animals and Animal Products (Poultry Products) Regulations, 5737-1976. Israel has adopted and incorporated requirements consistent with FSIS' regulations into its inspection system via the Procedure Sheets (PS). The PSs provide instructions and standard verification activities to government inspection personnel to ensure that the same set of laws, regulations, and policies are applied consistently to all establishments certified to export poultry products to the United States.

IVSAH has provided regulatory definitions for adulterated and misbranded products that are consistent with FSIS requirements. IVSAH and FCS have the legal authority and responsibility to ensure that adulterated poultry products are not exported to the United States in accordance with Regulations 5737-1976. The recall procedures are defined in the PS 1.0.1 (Recall of Food Products from Retail to the Establishment) and PS 1.0.3 (Veterinary Verification of the Recall of Food Products from Retail to the Establishment). These procedures and related inspection verification activities are equivalent and consistent to those in 9 CFR Part 418.3. The FSIS auditor verified that each audited establishment has a written recall program meeting the inspection requirement.

The FSIS auditor verified that IVSAH and FCS have the legal authority and ability to take appropriate enforcement measures in accordance with the Regulations for the Control of the Manufacture of Poultry Products for Export and their Export, 1976. At the local level, regulatory

control actions include detaining products, rejecting equipment or facilities, or stopping or slowing the line speed. The FSIS auditor confirmed that government inspection personnel had identified, documented, and verified the adequacy of the establishment's preventive measures or corrective actions in response to noncompliance findings in accordance with PS 0.2.5 (Regulatory Actions when an Establishment is not in Compliance with IVSAH Requirements) and PS 3.0.7 (Noncompliance – Handling and Reporting by the VIC). The FSIS auditor noted that the inspection system has not implemented any elevated enforcement actions including closure of an establishment, suspension of inspection, or partial withdrawal of inspection in any of the establishments certified to export to the United States since the last FSIS audit in 2019.

The FSIS auditor verified that each audited establishment has a system in place to identify and segregate poultry products destined for export to the United States from those that are destined for other markets, during all stages of production, storage, and shipment. Currently, there are three slaughter establishments that provide raw source materials to the certified processing establishments and three poultry processing establishments that are certified to export to the United States. The FSIS auditor verified that certified poultry processing establishments only receive raw poultry source materials from Israel's certified slaughter establishments and these establishments receive live poultry only from poultry farms within Israel.

IVSAH is responsible for notifying FSIS of newly approved establishments and of delistments of certified establishments when they do not meet the applicable regulatory requirements. The FSIS auditor reviewed inspection documents specifically associated with the approval process of a poultry slaughter establishment that was newly certified as eligible to produce raw source materials to certified establishments for the production of processed products intended for export to the United States. The FSIS auditor verified that the approval process included government inspection personnel's evaluation of establishment written programs and their onsite audits to determine whether the establishment followed Israel's export requirements.

The FSIS auditor verified that the VICs are responsible for reviewing and signing export health certificates of poultry products destined for export to the United States. The VICs conduct a pre-shipment verification task that includes reviewing all associated traceability documents and food safety records for each lot, observing the staged products, and verifying the weight declaration, shipping marks, and labels prior to applying the official export stamp and signature on the export health certificate. In addition, the VICs also verify that all official verification samples and establishment monitoring samples are negative for microbiological pathogens and chemical residues prior to signing an export health certificate. The FSIS auditor confirmed that VICs maintain the pertinent verification documents for each production lot intended for export to the United States.

IVSAH has the legal authority and responsibility to approve or disapprove laboratories conducting analytical testing of poultry products intended for export to the United States. The FSIS auditor visited Kimron Veterinary Institute (KVI) and Institute for Food Microbiology (IFM). KVI is a government laboratory that is comprised of the Food Hygiene Microbiology Laboratory and the National Residue Control Laboratory. These laboratories conduct analyses of all official verification sampling and testing programs. IFM is a private laboratory which conducts analytical testing on samples collected by certified establishments as part of their

microbiological sampling program. These laboratories are accredited by the Israel Laboratory Accreditation Authority in accordance with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025 standards. The FSIS auditor's scope in each laboratory included review of sample receipt, timely analysis, analytical methodologies, analytical controls, analyst qualifications and trainings, proficiency testing, and recording and reporting of results.

The FSIS auditor verified that KVI conducts microbiological testing on official verification samples. The FSIS auditor reviewed the most recent accreditation audits, the laboratories' staff training records, and the results of their proficiency testing. The FSIS auditor's review of this laboratory identified two findings related to laboratory oversight:

- IVSAH has a provision that allows official samples with violative chemical residue test results to be retested at the laboratory's discretion and has not provided written procedures to ensure that these products cannot be exported to the United States.
- IVSAH does not ensure that the government microbiological laboratory conducting official testing for *Salmonella* and *Lm* in RTE poultry products fully complies with certain criteria for traceability of test results provided in the ISO/IEC 17025 standards. The FSIS auditor identified that laboratory technicians did not record start and stop times for incubation steps in the *Salmonella* and *Lm* methods.

Although IVSAH allows official samples to be retested at the laboratory's discretion, the FSIS auditors reviewed recent records and did not identify any circumstances where product intended for export to the United States had been retested.

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. Results from residue sampling analyses by KVI are reported to the VIC via an electronic system. IVSAH and the RVOs have direct access to the laboratory results through this electronic system.

FSIS analysis and onsite audit verification activities indicate that Israel's poultry inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements. The laboratory findings described above regarding implementation of internal quality control parameters and traceability of results do not indicate an imminent threat to public health.

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

The second equivalence component the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for GCP in poultry; ante-mortem inspection of animals; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditor verified that IVSAH requires poultry slaughter establishments to comply with the Animal Welfare Law of 1994 and the Animal Welfare Regulations (Transport of Poultry) 2011, which include requirements regarding proper loading and unloading of live birds, maintenance of coops, transportation methods, and holding or storage of poultry prior to slaughter. The FSIS auditor's review of poultry transfer certificates indicated that poultry destined for slaughter are transported, unloaded, and slaughtered in accordance with IVSAH ritual (Kosher) 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 PS 6.1.9 (Prevention of Animal Suffering During Transport of Poultry and Official Controls in the Slaughterhouse).

The FSIS auditor verified that in-plant government inspection personnel conduct ante-mortem inspection of all poultry in accordance with Regulations 5737-1976. The Animal Disease Regulations (Poultry Slaughterhouses) requires poultry presented for slaughter to arrive in the slaughter establishment with a health certificate issued by the veterinarian on the poultry farm. This certificate must be provided to in-plant government inspection personnel prior to slaughter. The in-plant ante-mortem inspection includes examination of the birds for flock health status, physical condition, and appearance. Poultry that exhibit signs of illness are prohibited from slaughter in accordance with the Animal Disease Regulations (Poultry Slaughterhouses)-1960 and PS 3.1.2 (Antemortem Examination of Poultry in Slaughterhouses Approved for Export and Local Production).

The FSIS auditor noted that Regulations 5737-1976 and PS 6.0.1 (Work Shifts in Slaughterhouses and Establishments Processing Poultry Products for Export) require the presence of in-plant 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 in-plant government inspectors to provide inspection coverage continuously (of all carcasses and parts) 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 FSIS auditor observed in-plant government inspection personnel when conducting post-mortem inspection activities. This included inspection verification of proper presentation of poultry carcasses and parts and examination of every carcass, viscera and all parts visually and manually as required by IVSAH. The FSIS auditor noted that PS 3.1.0 (Post-Mortem Examination and Slaughter Line Speed) sets the maximum line speeds at certified poultry slaughter establishments of 35 chickens per minute per inspector, and 25 (hens) and 15 (toms) turkeys per minute per inspector. The FSIS auditor verified that post-mortem inspection stations

at the audited slaughter establishments were equipped with shadow-free lighting of at least 2000 lux, receptacles for condemned carcasses and parts, hang back racks, and start/stop switches to stop both carcass and viscera lines simultaneously in accordance with IVSAH requirements.

The FSIS auditor verified that in-plant government inspection personnel perform poultry zero tolerance verification tasks at least twice per evisceration line per shift to verify that the establishment is preventing carcasses with fecal material from entering the chiller in accordance with PS 5.1.5 (Fecal Contamination – the Examination by the Official Veterinary Inspector in the Exporting Slaughterhouse). The FSIS auditor observed that the VICs physically examine randomly selected 10-bird sample sets at the pre-chill re-inspection station. The results of the zero tolerance verification checks are documented in accordance with IVSAH requirements.

The FSIS auditor verified that IVSAH and FCS require that poultry products intended for export to the United States meet FSIS labeling requirements cited in PS 4.0.5 (Poultry and Poultry Products Labeling Approval) and comply with the requirements in Regulations 5737-1976. The FSIS auditor noted that government inspection personnel have an ongoing labeling verification activity. The VICs routinely verify labeling requirements and, in particular, prior to issuing an export health certification as required in PS 0.0.2 (Health Certificate for Exporting Products of Animal Origin). In addition, the RVOs verify product labeling requirements during their quarterly supervisory reviews.

FCS requires monthly species verification sampling by in-plant government inspection personnel in certified poultry processing establishments. These samples are analyzed in the KVI laboratory. Government inspection personnel review of species verification sampling results is part of inspection labeling verification activities.

The FSIS auditor verified that IVSAH and FCS ensure 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 equivalent to the FSIS sanitation requirements cited in 9 CFR Part 416.

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. IVSAH conveys APHIS disease restrictions to in-plant government inspection personnel in certified establishments through its website and during RVOs' periodic supervisory reviews.

The FSIS auditor verified that IVSAH and FCS maintain official controls over segregation, removal, and destruction of product that is condemned and considered inedible or not fit for human consumption. 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 PS 3.1.4 (Removal of Inedible

Products from Approved Establishments), which includes the total weight of inedible materials before transport to the rendering plant.

At the IVSAH and FCS headquarters and two regional veterinary offices, the FSIS auditor verified that the RVOs conduct periodic supervisory reviews at poultry slaughter and processing establishments certified to export the United States. The frequency of these reviews is based on the establishment's size and risk profile. In accordance with PS 0.2.2 (Official Controls as Performed by the RVO and CVO), the RVO must visit each certified establishment 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 poultry inspection requirements by in-plant government inspection personnel. This includes verification of ante-mortem and post-mortem inspection; microbiological sampling of *Salmonella* and *Campylobacter* in raw products; microbiological sampling of *Lm* and *Salmonella* in RTE products; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities that include the review of critical control points (CCP). In addition, the RVOs evaluate the VICs' performance concerning proper implementation and verification of regulatory requirements in the certified slaughter and processing establishments. The FSIS auditor reviewed several periodic supervisory review records for each audited establishment and noted that these reviews are being conducted as intended. The FSIS auditor also reviewed VICs' performance evaluations of subordinate government inspection personnel with a minimum frequency of two performance evaluations per year. These evaluations consist of record reviews and onsite observations of in-plant government inspection personnel to assess their knowledge, skills, and abilities in conducting their assigned inspection verification activities. The FSIS auditor's review of periodic supervisory reviews and performance evaluation reports did not identify any concerns.

FSIS analysis and onsite audit verification activities indicate that Israel's poultry inspection system has the legal authority and responsibility to establish regulatory controls to operate its inspection system. The FSIS auditor identified isolated noncompliances related to labeling and species verification sampling requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component 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 SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPSs and sanitary dressing.

Israel's food safety system requires slaughter and processing establishments to develop, implement, and maintain written Sanitation SOPs, SPSs, and implement sanitary dressing procedures to prevent direct product contamination or the creation of insanitary conditions. The certified establishments must have written procedures to require that food contact surfaces are cleaned prior to the start of operations and to maintain sanitary conditions during operations to prevent product adulteration.

The FSIS auditor verified that each audited establishment maintained a written sanitation program to prevent direct product contamination or creation of insanitary conditions. Each audited establishment's Sanitation SOPs included maintenance and improvement of sanitary conditions through ongoing evaluation of the establishment's hygienic practices. The FSIS auditor confirmed that in-plant government inspection personnel conduct daily verification procedures in accordance with the Business Licensing Regulations (Sanitary Conditions for Food Production Businesses), 5732-1972. Inspection verification activities consist of a combination of document reviews, observations, and hands-on inspection verification.

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. PS 1.2.1 (IIC Verification of Sanitary Standard Operating Procedures (SSOP) in Poultry Establishments Authorized for Export) enables sanitation requirements in Israeli regulations. PS 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 observed in-plant government inspection personnel conduct pre-operational sanitation verification inspection in one of the audited establishments. The verification inspection was performed after the establishment had conducted its pre-operational sanitation procedures and determined that the facility was ready for production. The FSIS auditor observed the in-plant government inspection personnel perform hands-on 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 government inspection verification records. The FSIS auditor also examined government inspection personnel's documentation of sanitation noncompliance records and verified that government 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 in-plant 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.

The FSIS auditor evaluated in-plant government inspection personnel verification of establishment sanitary dressing procedures in slaughter establishments. The in-plant government inspection personnel routinely verify establishment sanitary dressing, and they perform daily verification of zero tolerance for ingesta and fecal material. PS 5.1.5 (Fecal Contamination – The Examination by the Official Veterinary Inspector in the Exporting Slaughterhouse) requires certified slaughter establishments to develop, implement, and maintain written procedures to ensure that carcasses with visible fecal contamination or ingesta do not enter the chiller. PS 5.1.5 requires that the VIC randomly examine ten carcasses per evisceration line, twice per day, at the location where the slaughter establishment has designated to conduct the zero tolerance CCP. The FSIS auditor observed the VICs performing zero tolerance verification checks at the designated areas and prior to carcasses entering the chiller.

FSIS analysis and onsite audit verification activities indicate that Israel's poultry inspection system maintains sanitation programs that are consistent with criteria established for this component. The FSIS auditor identified isolated noncompliances related to the inspection verification of sanitation requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

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

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

Israel's poultry inspection system requires certified slaughter and processing establishments to develop, implement, and maintain a HACCP system consistent with FSIS HACCP requirements cited in 9 CFR Part 417. The initial certification of an establishment to export poultry products to the United States is contingent upon the approval of a validated HACCP plan. Once an establishment is certified, it is subject to a yearly audit by IVSAH and FCS for evaluation of the HACCP plan and for continued approval as a certified establishment for export, as stipulated in PS 0.2.1 (Food Safety Arrangement in a Plant Approved for Exporting Poultry Product).

The FSIS auditor verified that each audited establishment's HACCP plan includes written hazard analysis, flow charts, and HACCP plans to identify, evaluate, and prevent or control food safety hazards in their production processes. The HACCP plans included activities designed to validate the adequacy of controls, to conduct monitoring and verification procedures, and to document the results of monitoring and verification activities, as well as implementation of corrective actions in response to deviations from CCP critical limits. The FSIS auditor verified that IVSAH and FCS have the legal authority and responsibility to take enforcement actions for noncompliance with the requirements.

The in-plant government inspection personnel conduct daily HACCP verification activities in accordance with PS 1.1.3 (Veterinary Controls of HACCP Activities in Slaughterhouses and Poultry Processing Plants for Export). Inspection verification methodology includes such activities as evaluating the establishment's written HACCP programs and observing establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. Inspection verification activities also include direct observation of monitoring of establishment employees, hands-on verification, and review of establishment records, with the results of verification being entered in the associated inspection records.

The FSIS auditor verified that IVSAH requires certified poultry slaughter establishments to have a zero tolerance CCP for fecal material and ingesta per PS 5.1.5*,* as previously discussed in components two and three of this report. The FSIS auditor also verified that FCS requires certified poultry processing establishments to comply with chilling and stabilization requirements in accordance with PS 1.1.2 (RTE Poultry Products – Chilling and Stabilization Requirements). PS 1.1.2 requires that certified poultry processing establishments abide by the FSIS Compliance Guidelines Appendix A (for lethality) and Appendix B (for stabilization).

The FSIS auditor observed in-plant government inspection personnel conducting inspection verification of the establishment's HACCP plans. The government's inspection verification methodology includes the evaluation of the establishment's written HACCP plans and observation of establishment personnel performing monitoring, verification, corrective actions, and recordkeeping activities. The inspection verification activities also include direct observation or record reviews of CCPs with the results of the verifications entered in the associated inspection records. At each visited establishment, the FSIS auditor reviewed the HACCP plan, monitoring, and verification records of all CCPs, pre-shipment reviews, and export certificates. The FSIS auditor verified that audited establishments took appropriate corrective actions in response to any critical limit deviations. The FSIS auditor's observations and review of records (including in-plant inspection verification records and periodic supervisory review records) did not identify any systemic concerns.

The FSIS auditor verified that the audited poultry slaughter establishments have developed, implemented, and incorporated into their HACCP plan a microbiological sampling program for detection of indicator microorganisms at the pre-chill and post-chill stations in accordance with IVSAH requirements. The establishments' microbiological sampling programs included written procedures in place to prevent poultry carcasses contaminated with visible fecal material from entering the chiller system and carcasses are chilled immediately after evisceration in accordance with the IVSAH requirements.

FSIS analysis and onsite audit verification activities indicate that Israel's poultry inspection system maintains HACCP systems that are consistent with criteria established for this component. The FSIS auditor identified isolated noncompliances related to the inspection verification of HACCP record-keeping requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Israel conducts its National Residue Program (NRP) in accordance with the European Union and United States standards. The MOH regulates the use of pesticides and heavy metals and determines maximum residue limits (MRL) allowed in foods according to toxicological findings and the agricultural need. The marketing of poultry products containing chemical residues above the MRL established by the MOH is prohibited.
PS 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 include in the NRP the following year. The allotted samples are assigned proportionally based on each slaughter establishment's production volume.

The FSIS auditor reviewed the implementation of the 2021 chemical residue sampling plan at the IVSAH headquarters, North Regional Veterinary Office, and in-plant inspection offices. The FSIS auditor verified that government 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 in-plant government inspection personnel at certified poultry slaughter establishments are required to hold products from poultry farms that have histories of violative results above established MRLs. PS 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. The FSIS auditor's review of Israel's NRP identified no concerns.

FSIS analysis and onsite audit verification activities indicate that Israel's poultry inspection system is implementing its chemical residue sampling and testing as documented through their SRT submission.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The FSIS auditor verified that IVSAH requires poultry slaughter establishments that produce raw source materials for further processing and export by certified poultry processing establishments to develop, implement, and maintain a microbiological sampling and testing program that includes microbiological sampling at pre-chill and post-chill locations. This microbiological sampling program must demonstrate process control to prevent contamination of carcasses by enteric pathogens and fecal material throughout the slaughter and dressing operations in accordance with PS 5.1.6 (Microbiological Monitoring in Slaughterhouses Approved for Export to the United States). The FSIS auditor verified that the three audited poultry slaughter establishments have written procedures for pre-chill and post-chill sampling of poultry carcasses for indicator organism testing consistent with FSIS requirements in 9 CFR Part 381.65. These establishments applied statistical process control criteria to assess sampling results. The written procedures provided instructions for random selection of carcasses, aseptic sample collection techniques, sampling frequency, packaging, and delivery of samples to assigned laboratories. The sampling frequencies are one chicken carcass for every 22,000 broilers slaughtered and one turkey carcass for every 3,000 turkeys slaughtered. The FSIS auditor confirmed that VICs (daily) and RVOs (during quarterly supervisory reviews) verify that certified slaughter establishments comply with PS 5.1.6 requirements. The FSIS auditor also observed sample collection by establishment personnel at the pre-chill and post-chill locations. The FSIS auditor's review of establishments' monitoring and inspectors' verification records identified no concerns.

The FSIS auditor verified through observations, interviews, and records review that in-plant government inspection personnel conduct official verification sampling for *Salmonella* and *Campylobacter* in raw poultry carcasses in accordance with PS 5.1.9 (Pathogenic Bacteria in Poultry (*Salmonella* and *Campylobacter*) – Follow-up and Controls in the Slaughterhouse). This procedure establishes standards for the regulatory requirements pertaining to enforcing *Salmonella* performance standards that are consistent with FSIS HACCP/pathogen reduction requirements. IVSAH's official verification sampling included the daily collection of one chicken carcass sample (set of 51 samples) and one turkey carcass sample (set of 56 samples) until the sample set is completed. The FSIS auditor observed carcass sample collection technique by government inspection personnel in the audited slaughter establishments. The FSIS auditor noted that official verification sampling is conducted 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. The official verification samples are sealed by government inspection personnel prior to submission to the government laboratory. KVI is using FSIS' Microbiology Laboratory Guidebook (MLG) methods for *Salmonella* and *Campylobacter* analysis. The FSIS auditor also confirmed that government inspection personnel were reviewing official test results for trend analysis and verifying the establishments' proper implementation of corrective measures when the establishments do not meet the performance standards. The FSIS auditor's review of inspection records (including *Salmonella* testing results) identified no concerns.

The FSIS auditor verified that PS 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 poultry products. In addition, PS 6.2.5 (*Lm* in Ready-to-Eat Poultry Products) and PS 6.2.6 (Clarifications to Procedure Sheet 6.2.5 About *Lm* in Ready-to-Eat Poultry Products) consider RTE product as adulterated when it comes in direct contact with equipment or surfaces contaminated with *Lm*, *Listeria* species, or any *Listeria*-like organisms. Additionally, RTE product that directly contacts a surface contaminated with *Salmonella* is adulterated. The requirements of PS 6.2.6 are consistent with content included in 9 CFR 430.1 and 9 CFR 430.4. FCS mandates that all certified RTE poultry processing establishments implement controls for *Lm* in post-lethality exposed products and in the post-lethality processing environment. The FSIS auditor interviewed government inspection personnel assigned to the audited poultry processing establishment to evaluate their level of knowledge regarding control of RTE regulatory requirements and official verification sampling to detect *Lm* and *Salmonella* in product, as well as *Lm* on food contact surfaces and the environment at certified establishments eligible to export post-lethality exposed, RTE products to the United States. The government inspection personnel demonstrated a sound knowledge of PS 2.3.1, which provides instructions to government inspection personnel on how to verify that RTE products destined for export to the United States are not adulterated.

The FSIS auditor verified that government inspection personnel conduct official verification sampling of RTE poultry products that are packaged, labeled, and ready to ship into commerce. The RTE product sample collection occurs on the production day at the completion of the production process. The official verification samples are sealed by government inspection personnel prior to submission to the government laboratory. KVI uses FSIS' MLG methods for isolation and identification of *Salmonella* and *Lm* in RTE products intended for export to the

United States. The official sampling protocol requires that RTE products subject to official verification sampling be held until results are available. If the RTE product tests positive for either *Lm* or *Salmonella*, that product is not eligible for export to the United States. PS 5.2.20 (Central Competent Authority's Heightened Sampling Plan for *Listeria* and *Salmonella*) outlines the verification activity of conducting follow-up sampling after obtaining positive results during routine sampling by either establishment monitoring or official verification sampling. The follow-up sampling for *Lm* consists of 10 food contact surface swabs, 5 environmental swabs, and 3 RTE product samples. The follow-up sampling for *Salmonella* consists of five food contact surface swabs, eight environmental swabs, and five RTE product samples. The FSIS auditor's review of inspection verification records including follow-up sampling identified no concerns.

FSIS analysis and onsite audit verification activities indicate that Israel's poultry inspection system implements its microbiological sampling and testing programs as documented in its SRT submission.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held July 19, 2022, by videoconference with representatives from IVSAH and FCS. At this meeting, the FSIS auditor presented the preliminary findings from the audit including the following findings related to laboratory oversight:

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

- IVSAH has a provision that allows official samples with violative chemical residue test results to be re-tested at the laboratory's discretion and has not provided written procedures to ensure that these products cannot be exported to the United States.
- IVSAH does not ensure that the government microbiological laboratory conducting official testing for *Salmonella* and *Lm* in RTE poultry products fully complies with certain criteria for traceability of test results provided in ISO/IEC 17025 standards. The FSIS auditor identified that laboratory technicians did not record start and stop times for incubation steps in the *Salmonella* and *Lm* methods.

During the exit meeting, IVSAH and FCS committed to address the preliminary audit findings as presented. FSIS will evaluate the adequacy of the IVSAH and FCS documentation of proposed corrective actions once received 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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Of-Tov (Shan) Hodu-Tov (Shan) Ltd., Beit Shean Valley	07/03/2022	8	Israel
	5. AUDIT STAFF: OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT: [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	X
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Poultry slaughter establishment
Prepared Products:	Raw products

60. Observation of the Establishment

25-The indicator and titration solutions used to measure the concentration of an antimicrobial food processing aid for poultry carcasses and parts were not properly labeled to show the expiration dates of each solution.

38-The FSIS auditor observed a deteriorated seal under an exterior shipping door that did not provide a tight seal when the door was closed. This could create insanitary condition and facilitate the entrance of vermin to the production areas.

40-The establishment met regulatory lighting requirements, minimum of 200-footcandles of shadow-free lighting, to inspect the exterior surfaces of turkey carcass at the post-mortem inspection station. However, the quality and positioning of lighting at the inspector's post-mortem inspection station were not optimum in order to provide sufficient lighting to observe the interior surfaces of turkey carcass.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/03/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Kornish Chen (1987) Ltd., Hod Hefer, Beit Harishonim St.	06/29/2022	18	Israel
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	X
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Poultry slaughter establishment
Prepared Products:	Raw products

60. Observation of the Establishment

39-The FSIS auditor observed exposed insulation materials on the overhead structures above products in the production area. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.

39-The FSIS auditor observed several holes and rusted areas on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.

40-The establishment's zero tolerance CCP monitoring and verification station was not equipped with adequate lighting to conduct either establishment or inspection zero tolerance CCP checks. The establishment could not provide a light meter to have an accurate reading of light intensity. The FSIS auditor and inspection officials mutually agreed that the lighting intensity was insufficient and below lighting requirement (200 footcandles).

41-The FSIS auditor observed beaded condensate on the overhead structures above poultry carcass chiller. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/29/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tiv-Tirat-Zvi (2000), Meat Specialties, Beit Shean Valley	07/11/2022	22	Israel
	5. AUDIT STAFF: OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT: [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	X
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Poultry processing establishment
Prepared Products:	Ready-to-eat (RTE) fully-cooked products

60. Observation of the Establishment

16-The establishment's HACCP verification record for cooking CCP did not include the results of verification activities.

39-The FSIS auditor observed exposed insulation materials on the overhead structures above products in the production areas. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.

41-The FSIS auditor observed beaded condensate on the overhead structures above exposed products in the production areas. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/11/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tari and Chalak 2, Shlomi	07/04/2022	37	Israel
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	X
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Poultry slaughter establishment
Prepared Products:	Raw products

60. Observation of the Establishment

16-The establishment's HACCP verification records, calibration of process monitoring equipment, did not include the times or types of the verification activities.

39- The FSIS auditor observed several rusted areas on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.

41- The FSIS auditor observed beaded condensate on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/04/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Maadaney Yehiam (1993) Ltd., Kibutz Yehiam	07/05/2022	104	Israel
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

Establishment Operations:	Poultry processing establishment
Prepared Products:	Ready-to-eat (RTE) fully-cooked products

60. Observation of the Establishment

38-The FSIS auditor observed a deteriorated seal under an exterior shipping door that did not provide a tight seal when the door was closed. This could create insanitary condition and facilitate the entrance of vermin to the production areas.

46-The Israeli's regulation requires a minimum of 20 cm space between stored containers and walls. The FSIS auditor observed that ingredients containers used for product formulation were stored too close to walls in the establishments' spice room. This condition may interfere with inspection verification activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/05/2022

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Of-Tov Products (2001) Ltd., Beit Shean Valley	07/06/2022	108	Israel
	5. NAME OF AUDITOR(S) OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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	X
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	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.	X	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	
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		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Poultry processing establishment
Prepared Products:	Ready-to-eat (RTE) fully-cooked products

60. Observation of the Establishment

16- The establishment's HACCP verification record for calibration of monitoring instruments did not include the times of verification activities.

16-The establishment's HACCP verification record for CCP2 (cooking) and CCP5 (chilling) did not include the results of verification activities.

34-The in-plant inspection personnel has not collected all required species verification samples on a monthly basis as prescribed by the CCA.

39-The FSIS auditor observed holes (processing areas) and loose silicon type sealant (post lethality exposed chilling room) on the overhead structures over exposed products. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.

39-The FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditors did not observe any direct product contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/06/2022

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

December 19, 2022

Dr. Michelle Catlin
International Coordination Executive, Office of International Coordination
United States Department of Agriculture
Food Safety and Inspection Service
Independence Avenue, SW 1400
Washington, DC 20250
USA

SUBJECT: Israel's Response to the USDA-FSIS Draft Audit Report

Dear Dr. Michelle Catlin,

On behalf of Dr. Tamir Goshen, I would like to provide you with Israel's response to the draft report of the USDA-FSIS onsite equivalence verification audit in Israel conducted from June 27 to July 19, 2022.

Our response is comprised of two tables as listed below:

- Annex I: Response of the IVSAH to the draft audit report
- Annex II: Response of the establishments to the draft audit report

On behalf of the Israeli team who participated in this audit, I would like to express my gratitude for the positive approach your auditor brought to this process and we look forward to the continued collaboration between the USDA and Israel.

Best regards,

Dr. Riva Ben-Ezra
Acting Director, Food Control Department

cc: Dr. Tamir Goshen – CVO, Israeli Veterinary Services and Animal Health
Ms. Pnina Oren Shneydor – Chief, Food Control Services, Ministry of Health

P.O.B. 12, Beit-Dagan 50250 TEL: +972-3-9681612/606 FAX: +972-3-9681641

Annex I: Response of the IVSAH to the draft audit report

USDA-FSIS Draft Report Reference	USDA- FSIS draft report text	IVSAH response
GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)	IVSAH has a provision that allows official samples with violative chemical residue test results to be re-tested at the laboratory's discretion and has not provided written procedures to ensure that these products cannot be exported to the United States.	Corrective action: Violative result will be reported as is. Samples may be retested only for internal quality control evaluations. Attachment: SOP 02-03.2.01, paragraph 4.5.5.
GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)	IVSAH does not ensure that the government microbiological laboratory conducting official testing for Salmonella and Lm in RTE poultry products fully complies with certain criteria for traceability of test results provided in ISO/IEC 17025 standards. The FSIS auditor identified that laboratory technicians did not record start and stop times for incubation steps in the Salmonella and Lm methods.	Root cause analysis: The work patterns in the laboratory are carried out at fixed times. The laboratory works in one shift, so the defined incubation times of 22-24 hours are maintained. The laboratory accepts that no documentation was kept for the required incubation times. Corrective action: Updating the test procedure "Preparation of samples for Listeria and Salmonella testing" number 02-03.4.07 (edition 15), adding section 8.7 regarding documentation of incubation times and adding a form for documentation of incubation times (02.03.4-07). The laboratory staff was instructed. Attachments: Incubation times form 02-03.4-07-T-01 Example of a completed form Training documentation

Annex II: Response of the establishments to the draft audit report

Establishment name (number)	USDA-FSIS comments	Establishment response
Of-Tov (Shan) Hodu-Tov (Shan) Ltd. (8)	25-The indicator and titration solutions used to measure the concentration of an antimicrobial food processing aid for poultry carcasses and parts were not properly labeled to show the expiration dates of each solution.	The indicator and titration solutions were replaced with the original bottles with the right expiration dates.
	38-The FSIS auditor observed a deteriorated seal under an exterior shipping door that did not provide a tight seal when the door was closed. This could create insanitary condition and facilitate the entrance of vermin to the production areas.	The seal under an exterior shipping door was fixed. The rest of the other exterior doors in the plant were checked and found to be sealed.
	40-The establishment met regulatory lighting requirements, minimum of 200-footcandles of shadow-free lighting, to inspect the exterior surfaces of turkey carcass at the post-mortem inspection station. However, the quality and positioning of lighting at the inspector's postmortem inspection station were not optimum in order to provide sufficient lighting to observe the interior surfaces of turkey carcass.	A proper lighting was installed above the post mortem inspection station. No other places with improper lighting were found.
Kornish Chen (1987) Ltd., Hod Hefer (18)	39-The FSIS auditor observed exposed insulation materials on the overhead structures above products in the production area. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.	The exposed insulation materials were sealed off. Attachment: Pictures of corrective actions
	39-The FSIS auditor observed several holes and rusted areas on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.	All defects were repaired. Attachment: Pictures of corrective actions
	40-The establishment's zero tolerance CCP monitoring and verification station was not equipped with adequate lighting to	Additional lighting was added – projector

Annex II: Response of the establishments to the draft audit report

	conduct either establishment or inspection zero tolerance CCP checks. The establishment could not provide a light meter to have an accurate reading of light intensity. The FSIS auditor and inspection officials mutually agreed that the lighting intensity was insufficient and below lighting requirement (200 footcandles).	Attachment: Pictures of corrective actions
	41-The FSIS auditor observed beaded condensate on the overhead structures above poultry carcass chiller. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.	All defects were repaired. Attachment: Pictures of corrective actions
Tari and Chalak 2 (37)	16-The establishment's HACCP verification records, calibration of process monitoring equipment, did not include the times or types of the verification activities.	The hazard analysis for the entire HACCP plan (in addition to those sections that were not mentioned by USDA-FSIS) were reviewed and updated as needed to include the times and types of verification activities.
	39 -The FSIS auditor observed several rusted areas on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.	The walls were thoroughly sealed, including the hole in the ceiling with the rust. General sealing of the structure was carried out, sealing by a new casting. Quality control workers were instructed that these points must be paid attention to, including external openings in all departments, and updated immediately on the factory SPS form for immediate treatment of these defects.
	41 -The FSIS auditor observed beaded condensate on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products	Corrective action was immediately carried out according to the establishment's condensation treatment procedure.

Annex II: Response of the establishments to the draft audit report

	contamination. However, this condition may lead to product adulteration.	About 50 birds that were nearby were taken to a rescue station for treatment according to the procedure. The head of the department was instructed that this issue should be checked often and corrective action should be taken immediately according to the procedure. At the same time, the head of the department was instructed that the doors of the departments must be closed at all times to prevent condensation due to temperature differences. Quality control workers were instructed that this issue should be checked frequently including taking corrective action when necessary. Updated the SSOP department form at the start of work and during work regarding the inspection of this section by quality control.
Tiv-Tirat-Zvi (2000), Meat Specialties (22)	16-The establishment's HACCP verification record for cooking CCP did not include the results of verification activities.	For every batch of cooked product, a form is filled out by hand by the oven operator, recording the time-temperature values measured for each batch. The results for each oven are checked opposite the HACCP requirements , and verified by the shift manager. These forms , together with similar forms for each of the other

Annex II: Response of the establishments to the draft audit report

		HACCP requirements for each product, are passed on for review by the chief food technologist. He in turn, fills out a form -summing up and verifying the time temperature values of all cooking and cooling procedures carried out per day. For example: Form X001: COOKING AND COOLING OPERATIONS FOR OVENS 1- Date .7… Any non-compliances regarding HACCP requirements should be identified at this stage. This form includes a column for stating necessary corrective action in case of non-compliance, and another column for performance of said corrective action. It is the responsibility of the chief technologist to fill in this column and .verify performance of corrective action Upon identification any non- compliant variable will be recorded on the .verification form The Chief Technonlogist is responsible for recording all such variables. He has undergone instruction regarding this .responsibility
	39-The FSIS auditor observed exposed insulation materials on the overhead structures above products in the production areas. The	All damaged and/or exposed insulation materials above production areas

Annex II: Response of the establishments to the draft audit report

	auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.	were repaired or replaced. Quality Control inspectors were instructed to visually inspect integrity of overhead insulation in production and packaging areas as part of daily inspection tour.
	41-The FSIS auditor observed beaded condensate on the overhead structures above exposed products in the production areas. The auditor did not observe any direct product contamination. However, this condition may lead to product adulteration.	The condensate was observed on an ingoing vent of the air conditioning system. Large volumes of air pass through these vents, and they must be kept clean to prevent accumulation of dirt which provides a substrate for condensate. All ingoing vents of the air conditioning system were repainted, and some, whose paint had peeled, were replaced. These vents in the various departments, and their state of cleanliness, were added to the routine maintenance check list of the Quality Control inspectors in order to improve monitoring of the system.
Maadaney Yehiam (1993) Ltd. (104)	38-The FSIS auditor observed a deteriorated seal under an exterior shipping door that did not provide a tight seal when the door was closed. This could create insanitary condition and facilitate the entrance of vermin to the production areas.	The door of the delivery ramp was sealed. The QA personnel were guided to pay attention to this kind of discrepancy.
	46-The Israeli's regulation requires a minimum of 20 cm space between stored containers and walls. The FSIS auditor observed that ingredients containers used for product formulation were stored too close to walls in the establishments' spice room. This condition may interfere with inspection verification activities.	The regulation requires a minimum of 30 cm. The pallets were moved from the wall and the floor was marked at 30 cm, so the

Annex II: Response of the establishments to the draft audit report

		employees will know not to store the pallets after the mark. The QA personnel were guided to pay attention to this kind of discrepancy.
Of-Tov Products (2001) Ltd. (108)	16 -The establishment's HACCP verification record for calibration of monitoring instruments did not include the times of verification activities.	Guidance for performing calibration verification is required to make sure to .record an hour in all verification records Use a uniform signature.
	16-The establishment's HACCP verification record for CCP2 (cooking) and CCP5 (chilling) did not include the results of verification activities.	The correct / incorrect registration was made on the stamp of the .reviewer of the forms In any case training for all verifiers in reviewing forms is .required
	34-The in-plant inspection personnel has not collected all required species verification samples on a monthly basis as prescribed by the CCA.	Due to in-plant inspection personnel changes, not all the samples were collected. The training procedures were reviewed in order to prevent reccurence of such cases, and the CCA had a training regarding the sampling protocols with the in-plant inspection personnel.
	39-The FSIS auditor observed holes (processing areas) and loose silicon type sealant (post lethality exposed chilling room) on the overhead structures over exposed products. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.	,Returning the thermocapel to its place sealing the thermocaple to the ceiling. Training for strict adherence to monitoring ceilings on a daily level in SSOP forms. The monitoring includes holes, flying silicones, open piping .Update SSOP forms
	39-The FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditors did not observe any direct product	The open holes and exposed pipes were sealed. Training for strict adherence to monitoring ceilings on a daily level in SSOP forms.

Annex II: Response of the establishments to the draft audit report

	contamination. However, this condition may lead to product adulteration.	The monitoring includes holes, flying silicones, open piping .Update SSOP forms