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

OCT 2 7 2009

Dr. Moshe Chaimovitz
Director, Veterinary Services and Animal Health
Ministry of Agriculture and Rural Development
50 Post Office Box 12 Beit Dagan 50250, Israel

Dear Dr. Chaimovitz:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Israel's poultry inspection system July 13 to August 6, 2009. You were invited to provide comments regarding the information in the draft final audit report. No comments were received from the government of Israel within 60 days. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

for Manzoor H. Chaudry

James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

OCT 2 7 2009

FINAL REPORT OF AN AUDIT CARRIED OUT IN ISRAEL COVERING ISRAEL'S POULTRY INSPECTION SYSTEM

July 13 THROUGH August 6, 2009

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Veterinary Services and Animal Health)
CV	Chief Veterinarian, Control of Animal Products
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
HACCP/PR	Hazard Analysis and Critical Control Point/Pathogen Reduction Systems
RVO	Regional Veterinary Officer
Salmonella species	*Salmonella*
SSOP	Sanitation Standard Operating Procedure(s)
VIC	Veterinarian in Charge
VSAH	Veterinary Services and Animal Health

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Israel from July 13 through August 6, 2009. This was a routine audit. Israel is eligible to export cooked poultry meat and cooked poultry meat products to the United States (U.S.). At the time of the audit, seven establishments were eligible to export to the U.S. Between January 1, 2008 and December 31, 2008, Israel exported 1,957,215 pounds of poultry products to the U.S. and between January 1 and June 30, 2009 Israel exported 1,204,008 pounds of poultry products to the U.S.; there were no rejections for any food-safety concerns. Activities of the current audit appear in the table below.

The findings of the previous audit conducted May 11 through June 4, 2008 resulted in no restrictions of any Israeli establishment's ability to export poultry products to the U.S.

1.2 Comparison of the Current Audit and the Previous Audit

		07/13-08/06, 2009	05/11-06/04, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	2	1
	Establishment Level	7	8
Laboratories Audited			
	Microbiology	3	2
	Residue	0	1
Establishments Audited			
	Slaughter/processing	2	3
	Processing	5	5
Enforcement Actions Initiated			
	NOID	0	0
	Delistment	0	0
Risk Area Findings			
	Sanitation Controls (SSOP, SPS)	5	1
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	2	0
	Residue Controls	0	0
	Microbiology Controls	0	1
	Inspection/Enforcement Controls	4	2

1.3 Summary Comments for the Current Audit

The results of this audit reflected an increase in the total number of audit non-compliances over the previous audit. The increase in non-compliances noted were Sanitation Performance Standards (SPS), non-product based, and the design and implementation of some sections of the establishment's food safety programs. No

adulterated product was produced or shipped. Although some FSIS requirements were not enforced in four of the seven establishments audited, the review of the government oversight of Israel's poultry inspection system at the central, regional and local (establishment) offices demonstrated that inspection system controls were in place. Findings from the previous audit were determined to be corrected.

2. INTRODUCTION

An entrance meeting was held on July 13, 2009 in Beit Dagan with the Central Competent Authority (CCA), Veterinary Services and Animal Health (VSAH). In this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Israel's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA and/or representatives from the regional and local inspection offices.

3. OBJECTIVES OF THE AUDIT

The objectives of the audit were to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States and to verify corrective actions for findings from the previous audit.

4. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the Israel's inspection headquarters and in two regional offices. The third part involved on-site visits to 7 establishments: two slaughter establishments and five processing establishments. The fourth part involved visits to two private microbiology laboratories and one government-owned and –operated microbiology laboratory.

Program effectiveness determinations of Israel's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of HACCP programs and the testing program for generic *Escherichia coli (E. coli)*, (4) residue controls, and (5) enforcement controls, including the testing programs for *Listeria* and *Salmonella*. Israel's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Israel and also determined if establishment and inspection system controls were in place to ensure the production of poultry meat products that are safe, unadulterated and properly labeled.

During the entrance meeting, the auditor explained to the CCA that foreign inspection systems are audited in accordance with two areas of focus. First, FSIS auditors audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification, and FSIS' requirements for HACCP, SSOP, and testing for *E. coli* and *Salmonella*.

Second, FSIS auditors audit against any equivalence determinations that have been made by FSIS for an exporting country under provisions of the Sanitary/Phytosanitary Agreement. Israel was granted an equivalence determination for samples of generic *E. coli* to be analyzed in government laboratories. During this current audit generic *E. coli* samples were being analyzed in private laboratories.

5. LEGAL BASIS FOR THE AUDIT

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

- The Code of Federal Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations

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

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

October-November 2006

Seven of the eight certified establishments and one government microbiology laboratory were audited; there were no delistments or Notices of Intent to Delist (NOID). The following deficiencies were reported:

- Neglected maintenance of over-product structures in two establishments
- Numerous combo bins that were in need of repair in two establishments
- Illegible corrections in the monitoring documentation in two establishments
- Failure to document the times when the verifications were performed in one establishment

May-June 2008

Eight of the eight certified establishments, one government microbiology laboratory, one government residue laboratory, and one private microbiology laboratory were audited; there were no delistments or NOIDs. The following non-compliances were reported:

- Neglected maintenance of over-product structures in one establishment
- There was no intra-laboratory check-sample program for generic *E. coli* in the private microbiology laboratory
- No internal reviews had been conducted since March 2007 for the private laboratory

7. MAIN FINDINGS

7.1 Government Oversight

7.1.1 CCA Control Systems

The CCA is Veterinary Services and Animal Health (VSAH), which is a subdivision of the Ministry of Agriculture and Rural Development. There have been no changes in the organization or structure of VSAH since the last FSIS audit of Israel in May-June, 2008.

There are three levels of inspection: VSAH Headquarters, two VSAH Regional Veterinary Offices, and in-plant inspection, which consist of an in-plant Veterinarian-In-Charge (VIC) and inspection staff.

The headquarters office of VSAH is located in Beit Dagan. All activities that concern the export of poultry product to the United States are coordinated by the Chief Veterinarian, Control of Animal Products (CV). The CV is supported within the office by a HACCP Project Manager and the Head of Updating and Training.

At the second level, Israel has been divided into two regions, Beit Dagan and Haifa. At the time of this audit, the Haifa office provides oversight over six of the seven establishments and the Beit Dagan office provides oversight over the one. The two Regional Veterinary Officers (RVOs) are responsible for the oversight of the field veterinarians and inspection personnel, perform the required periodic internal reviews of the establishments, and ensure that the FSIS requirements forwarded to them by the Beit Dagan headquarters office are implemented appropriately.

The third level of inspection within VSAH consists of the in-plant personnel. Each establishment within Israel is headed by a VIC. Each VIC has been given his/her authority to perform oversight inspection by VSAH headquarters in Beit Dagan. The VIC oversees a staff of inspection personnel, whose size varies according to the size and complexity of each establishment's operations.

7.1.2 Ultimate Control and Supervision

The VSAH maintains ultimate control and supervision over the establishments certified by VSAH as eligible to export to the United States. New requirements are received in VSAH headquarters and are reviewed and signed by the Chief Veterinarian. They are placed on the VSAH website and are also sent by e-mail or fax to the Regional Supervisors, who are responsible for ensuring their implementation and enforcement in the establishments by the VICs during their (the Regional Supervisors') periodic

(monthly) internal supervisory reviews. Each RVO must provide a monthly report to the Chief Veterinarian, covering his/her supervisory procedures regarding the activities of the establishments and the performance of the in-plant inspection personnel. The CV reviews these reports and evaluates the performance of the Area Supervisors. The VICs also provide monthly reports to the RVOs documenting the work performed in the establishments by themselves and by the inspectors who report to their offices. At least once per year, all Area Supervisors and Veterinarians in Charge are brought to VSAH-HQ for special instruction regarding all FSIS requirements.

In processing and slaughter establishments, the health certificates for export to the U.S. are generated by the VICs with a government computer program. The RVOs verify the completeness and correctness of the health certificates during their internal reviews.

All seven certified establishments' HACCP systems are reviewed at least annually by the HACCP Project Manager, whose findings are brought before a special certification committee in the office of the CV; the committee discusses the findings and, in case of recurrent problems, decides on a course of action.

7.1.3 Assignment of Competent, Qualified Inspectors

Each CCA veterinarian must have a university degree in Veterinary Science or Veterinary Medicine and must be licensed by the CV to be considered qualified to apply for the VSAH inspection service. Each non-veterinary inspector must have at least a high school diploma. All newly-hired inspection personnel receive six weeks of on-the-job training. No inspection personnel are permitted to have any outside employment. All veterinarians working in poultry inspection receive two days of training each year in SSOP, PR/ HACCP systems and testing programs for *E. coli*, *Salmonella sp*, and *Listeria monocytogenes* at VSAH headquarters. Additional two to four days of PR/HACCP training is provided by an outside consultant firm. Each VIC assigned to a U.S. certified establishment has attended this training.

The system of payment for inspection personnel has not changed since Israel first achieved eligibility to export to the U.S. some 35 years ago. All RVOs, VICs, and line inspectors in the slaughter facilities are full-time employees of the Israeli Poultry Board, which is co-owned by the government and the poultry farmers, and whose Chairman is an official nominated by the government. The Poultry Board collects fees from the establishments for the services of the inspection personnel. In the further-processing facilities, the non-veterinary inspection personnel are employed by the local municipal government councils and are paid from fees collected by these government agencies from the establishments for inspection services rendered. No inspection personnel receive any direct remuneration of any kind from the establishments, nor are they permitted to engage in any outside employment.

In case of illness or other absence on the part of inspection personnel in establishments certified for U.S. export, relief is provided from a pool of qualified officials: In the Haifa region, there are one reserve veterinarian and one inspector for relief in slaughter and

processing establishments. In the Beit Dagan region, the relief pool consists of one reserve veterinarian and three inspectors.

7.1.4 Authority and Responsibility to Enforce the Laws

VSAH has the authority and responsibility to enforce the applicable laws relevant to U.S. certified establishments. VSAH has the authority to approve establishments for export to the United States and has the responsibility for withdrawing such approval when establishments do not have adequate and/or effective controls in place to prevent, detect, and eliminate product contamination or adulteration. The RVOs are in charge of verifying and evaluating the implementation of the official guidelines and instructions.

Although the CCA has the legal authority and responsibility to enforce all FSIS requirements, some FSIS requirements were not enforced in four of the seven establishments audited. For example:

- One establishment did not have cleaning procedures and a sanitation monitoring program for the ice storage room
- One establishment did not consider the location of the raw product reconditioning station and did not protect products from the possibility being contaminated or adulterated during the hand-washing process
- One establishment did not identify all the hazards reasonably likely to occur in the hazard analysis
- One establishment did not maintain the minus 26 degree Celsius finished product freezer in good repair
- One establishment did not have supporting documentation for the lack of Certificate of Analysis (COA) lot identification that would link ingredients to specific RTE products
- One establishment did not maintain the spice room in a sanitary condition
- One establishment did not maintain the room utilized for the storage of product labels in a manner to prevent the creation of insanitary conditions

7.1.5 Adequate Administrative and Technical Support

VSAH has the administrative and technical support to effectively implement and enforce FSIS requirements throughout Israel's poultry inspection system. Oversight of the private laboratories performing the testing for *E. coli* has been, as of the time of this audit, provided by the National Agency for Laboratories and the Department of Health, both of which provide certification. Oversight of the government-owned and -operated residue and microbiology laboratories is performed by the Israel Laboratory Accreditation Authority, an autonomous member of the Ministry of Industry and Trade. The CV provides a table to the laboratory management, which contains all FSIS-approved methodologies; and the SOPs ensure that they are used for U.S.-eligible products.

A central steering committee, which includes members from the VSAH, Industry Extension, officers of the Ministry of Agriculture and the Ministry of Health, and Plant Protection officials, decides annually which compounds will be included in the residue

program. The sampling program is designed proportionally to the production by each slaughter establishment. The RVO divides the total residue samples to be taken between the establishments in their region. Each month the RVO notifies the VIC of the number of samples scheduled to be taken. Samples are not requested for specific testing: All samples have an equal chance of being analyzed for any residue; a random selection is performed on all samples upon their arrival at the residue laboratory.

Samples for *Salmonella* testing in slaughter establishment are scheduled by the RVO. *Listeria monocytogenes* and *Salmonella sp* verification sampling for Read-To-Eat (RTE) products are scheduled by the VIC. The CV has developed specific sampling guidelines (Directives) for RTE products.

7.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of the inspection service in Beit Dagan and interviewed key inspection personnel. The records review focused primarily on food safety hazards and included the following:

- Organizational structure of the VSAH and its authority
- Procedures for payment of inspectors
- Internal review reports
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Sampling and laboratory analyses for residues
- Sampling procedures for microbial testing in RTE products
- Sanitation, slaughter and processing inspection procedures and standards
- Enforcement program, policies, and authority
- Enforcement records documenting the suspension of an establishment's ability to export

No concerns arose as a result of the examination of these documents:

7.3. Regional Offices Audit

The auditor conducted a review of inspection system documents at the regional offices located in Beit Dagan and Haifa and interviewed the RVOs. The records review focused primarily on food safety hazards and included the following:

- Organizational structure and regulatory authority
- Periodic supervisory reviews from establishment
- Monthly activity reports submitted by the VIC
- Monthly activity reports submitted by the RVO
- Residue sampling request and results
- Microbiological sampling request and results

- HACCP certification report
- HACCP audits conducted for U.S. certified establishments

No concerns arose as a result of the examination of these documents:

7.4 Local Inspection Offices Audit

Records were reviewed and interviews were conduct in each of the local inspection offices located in each establishment audited. The auditor determined that inspection system controls were in-place but in some U.S. certified establishments some FSIS requirements were not enforced. Details can be found in section 7.1.4 and in the individual establishment reports.

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of seven establishments; two slaughter/processing establishments and five processing establishments. There were no delistments or NOIDs issued by the VSAH during this audit.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

No residue laboratories were audited.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check sample programs. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

The following laboratories were audited:

- The government microbiology laboratory in the Kimron Veterinary Institute located in Beit Dagan
- The private microbiology section of the Institute For Food Microbiology located in Nesher
- The private microbiology section of Milouda Laboratories located in Ashrat

No concerns arose as a result of the audits of these laboratories.

10. SANITATION CONTROLS

As stated previously, FSIS focuses on five areas of risk to assess an exporting country's poultry inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Israel's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, Israel's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

10.1 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in the seven establishments audited were found to meet the basic FSIS regulatory requirements, with the following non-compliances:

- In one establishment, procedures were in place to evaluate the effectiveness of their Sanitation SOP and their procedures therein to prevent direct contamination of products or adulteration, but the establishment failed to provide written procedures for the cleaning of the ice storage room and also failed to include the ice storage room in their pre-operational and operational sanitation monitoring program.

Specific non-compliances are documented in the attached individual establishment checklists.

10.2 Sanitation Performance Standards

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SPS were met, according to the criteria employed in the U.S. domestic inspection program. The SPS in the seven establishments audited were found to meet the basic FSIS regulatory requirements, with the following non-compliances:

- In one establishment, condensate was observed on the ceiling and under the refrigeration unit located directly over the ice storage compartment that was used to store ice for the turkey chiller. Unidentifiable black material was observed on the ceiling and under the refrigeration unit. Condensate, rust, and a buildup of unidentifiable dark material were observed on the fan guards located under the refrigeration unit and over the ice storage compartment.

- In one establishment, a written procedure for the prevention removal of condensation was in place to prevent direct product contamination and adulteration, however, during the on-site audit of the establishment, condensate was observed on the ceiling and under a refrigeration unit located over product in two non-kosher holding coolers.
- In one establishment, an establishment employee working in the spice storage room was observed opening and emptying a paper bag filled with breading crumbles into a stainless steel combo bin. The bag was opened and emptied over the combo bin. During this process, the outside of the bag came into direct contact with the combo bin and the breading crumbles.
- In one establishment, the room utilized for the storage of spices, the weighing of spices and the general preparation of the ingredients for finished products was not maintained in a sanitary condition or in a condition to facilitate good housekeeping practices.
- In one establishment, the location of the reconditioning process for raw poultry products did not protect products from the possibility of being contaminated or adulterated during the hand-washing process.
- In one establishment, the minus 26 degree Celsius finished product freezer was not maintained in good repair.
- In one establishment, the room utilized for the storage of product labels was not maintained in a manner to prevent the creation of insanitary conditions.

Specific non-compliances are documented in the attached individual establishment checklists.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors review is Animal Disease Controls. These include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Israel's inspection system had adequate controls in place. No deficiencies were noted.

The United States' Animal and Plant Health Inspection Service (APHIS) has placed restrictions on poultry products from Israel: Due to the presence in Israel of Exotic Newcastle Disease and Highly- Pathogenic Avian Influenza H5N1, poultry for export to the U.S. must be heated to a minimum temperature of 74° C and the importer is required to have a Veterinary Import Permit.

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that FSIS auditors review is Slaughter/Processing Controls. These include humane handling and slaughter, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls for cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of testing programs for generic *E. coli* in slaughter establishments.

12.1 Humane Handling and Slaughter

No deficiencies were observed.

12.2 HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and adequately implemented HACCP programs. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program. The HACCP programs in the seven establishments audited were found to meet the basic FSIS regulatory requirements, with the following non-compliances:

- In one establishment, the hazards that may be introduced into the process during the rework of contaminated and/or adulterated products were not identified.
- In one establishment, the hazards associated with the outside of the packaging material for the breading crumbles were not identified.
- In one establishment, supporting documentation for the lack of Certificate Of Analysis lot identification that would link ingredients to specific RTE products was not included in the HACCP plan.

Specific non-compliances are documented in the attached individual establishment checklists

12.3 Testing for Generic *E. coli*

Israel has adopted the FSIS regulatory requirements for testing for generic *E. coli.*

Two of the seven certified establishments were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was conducted as required in the two slaughter establishments audited.

12.4 Testing for *Listeria monocytogenes*

Five of the seven establishments audited were required to meet the basic FSIS regulatory requirements for testing for *Listeria monocytogenes* and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for *Listeria monocytogenes* was conducted as required in the five processing establishments audited.

13. RESIDUE CONTROLS

The fourth of the five risk areas that FSIS auditors review is Residue Controls. These include sample handling and frequency, timely analysis, data reporting, tissue matrices for

analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

No residue laboratories were audited.

Although actual laboratory audits were not within the scope of the current audit, performance was assessed through records reviewed and interviews conducted at the CCA, regional, and local inspection offices. No deficiencies were observed.

Israel's National Residue Testing Plan for 2009 was being followed and was on schedule.

14. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors review is Enforcement Controls. These include the enforcement of inspection requirements and the testing programs for *Salmonella* and *Listeria monocytogenes*, and for *E. coli* O157:H7 in establishments that produce certain beef products.

14.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments whenever U.S.-eligible products were being produced.

14.2 Testing for *Salmonella* Species

Israel has adopted the FSIS regulatory requirements for testing for *Salmonella.*

Two of the seven establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program. Testing for *Salmonella* was conducted as required in the two slaughter establishments audited.

14.3 Testing for *E. coli* O157:H7

None of the eight establishments was required to meet the basic FSIS regulatory requirements for testing for *E. coli* O157:H7.

14.4 Species Verification

At the time of this audit, Israel was required to conduct species verification on certain products eligible for export to the US. Species verification was being conducted properly in the five establishments in which it was required. Two samples are taken by the VIC monthly in each of the five further-processing establishments and sent to the laboratory in the Kimron Veterinary Institute for testing.

14.5 Periodic Reviews

Periodic supervisory reviews of certified establishments were being performed and documented as required.

14.6 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market. No poultry or poultry meat is imported for use in U.S.-eligible products.

Adequate controls were found to be in place for oversight over private laboratories used for analysis of U.S.-eligible products, security items, shipment security, and products entering the establishments from outside sources.

15. CLOSING MEETING

An exit meeting was held on August 6, 2009 in Beit Dagan with the CCA. At this meeting, the preliminary findings, and conclusions were presented by the auditor.

The CCA understood and accepted the preliminary audit findings.

Don Carlson, DVM
Senior Program Auditor

Don Carlson, DVM

16. ATTACHMENTS

Establishment reports
Israel's comments on the Draft Final Audit Report (when they become available)

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
Maof, Ltd. Industial Area Beer Tuvia, 83100	07/15/09	003	Israel
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Don Carlson		[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.	X
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	
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. Enforcement	X
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. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Israel Establishment 003, July 15, 2009. Operations: Turkey slaughter & cut-up

11/51 The establishment had procedures in place to evaluate the effectiveness of their Sanitation SOP and their procedures therein to prevent direct contamination or adulteration of products, but the establishment failed to provide written procedures for the cleaning of the ice storage room and also failed to include the ice storage room in their pre-operational and operational sanitation monitoring program. The construction of the ice storage room was completed January 22, 2009 and the use of ice was included in the HACCP plan. The HACCP plan was reassessed at this time. During the audit of the establishment, management personnel stated that the ice storage room was cleaned daily. Veterinary Inspection Service personnel did not adequately verify the adequacy and effectiveness of the Sanitation SOPs and the procedures specified in the establishment's Sanitation SOP and therefore did not identify the establishment's omission of cleaning procedures and a sanitation monitoring program for the ice storage room. [References: 9 CFR § 416.14, 416.13 (c) and 416.17]

41 During the on-site audit of the establishment, condensate was observed on the ceiling and under the refrigeration unit located directly over the ice storage compartment that was used to store ice for the turkey chiller. Unidentifiable black material was observed on the ceiling and under the refrigeration unit. Condensate, rust and a buildup of an unidentifiable dark material was observed on the fan guards located under the refrigeration unit and over the ice storage compartment. Condensate was not dripping onto the ice and no product was affected. [9 CFR § 416.2 (d)]

41 The establishment had a written procedure for the control of condensation in place and a monitoring procedure to prevent direct product contamination and adulteration, however, during the on-site audit of the establishment, condensate was observed on the ceiling and under a refrigeration unit located over product in two non-kosher holding coolers. Even though product was not affected, the establishment removed the product that was located under the condensate, held the product for evaluation and reconditioning and proposed to restore sanitary conditions of the cooler. [9 CFR § 416.2 (d)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson. DVM	Don Carlson, DVM 7/15/2009

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 (Shean) / Hodu Tov (Shean) Ltd. Beit-Shean	08/03/09	008	Israel
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[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 SSOPs 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	X
40. Light	
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. Enforcement	X
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. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Israel Establishment 008, August 3, 2009 Operations: Chicken & Turkey slaughter & processing

39/51 During the on-site review of the establishment, the minus 26 degree Celsius finished product freezer was observed to have extensive broken and torn metal ceiling and wall panels throughout the freezer. There were many areas of corrosion and deterioration of the wall panels, ceiling panels and the freezer door. Many areas of uncovered insulation were observed around the framework of the freezer door and the damaged wall panels. There were cracks and deterioration of the floor of the freezer and the floor wall junctions. All of the products stored in this freezer were boxed in cardboard boxes and there was no evidence of contaminated or adulterated product. The establishment had a procedure for preventive maintenance, but the records for monitoring this freezer did not document any deficiencies on April 20, 2009. The establishment documented a rusty door on June 26, 2009. These records did not reflect the conditions observed during the on-site review of the freezer. The Veterinary Inspection Service inspection records reviewed did not identify the conditions described in this section of the establishment report.
[References: 9 CFR § 416.1 and 416.2 (b)]

38/39/51 During the on-site review of the establishment, the room utilized for the storage of product labels was not maintained in a manner to prevent the creation of insanitary conditions. Equipment, equipment parts, paper, plastic, and accumulation of miscellaneous debris were observed on the floor under the shelves used to store the product labels. The label boxes were not stored in a manner to facilitate good housekeeping practices. The establishment did not have a procedure for the periodic cleaning of the label storage room and did not have records documenting sanitary conditions of this room. The Veterinary Inspection Service inspection records reviewed did not identify the conditions described in this section of the establishment report. [9 CFR § 416.1 and 416.2 (a) and (b)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 8/03/2009

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 TZVI Meat Specialities M.P. Beit She'an Valley	08/02/09	022	Israel
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[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.	X
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	X
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. Enforcement	X
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. *Listeria monocytogenes* and *Salmonella* (RTE)	
59.	

60. Observation of the Establishment

Israel Establishment 022, August 2, 2009 Turkey & Chicken RTE processing

22/51 The hazard analysis for the receiving step for the ingredients used in the production of Ready-To-Eat (RTE) products did not identify any hazards reasonably likely to occur in this step because each ingredient was accompanied by a Certificate of Analysis (COA). One FSIS label approval for a RTE Pastrami product and the COAs for the ingredients used in the production of this product were reviewed. Some of the COAs had lot numbers and could be traced to the production lot, but other COAs for ingredients did not have traceable lot number identification. The last reassessment of the HACCP plan conducted by the establishment was July 26, 2009. Records for June 2009 documenting the HACCP plan were reviewed. The establishment did not have supporting documentation for the lack of COA lot identification that would link ingredients to specific RTE products. The Veterinary Service did not adequately verify the adequacy of the establishment's HACCP plan. Inspection records reviewed did not identify that the traceability of COAs for ingredients was incomplete. [References: 9 CFR § 417.5 (a) (1) and (2) and 417.8]

38/39/51The room utilized for the storage of spices, the weighing of spices and the general preparation of the ingredients for finished products was not maintained in a sanitary condition or in a condition to facilitate good housekeeping practices. Spices and ingredient mixtures were stored haphazardly throughout the room with no organization. There was evidence of spilled spices throughout the room. There was an open floor drain along one wall. One sticky board used for the monitoring of pest and rodents was located behind a spice storage shelve and could not be easily accessed for evaluation by the pest contractor or the quality assurance personnel. The establishment had written procedures and monitoring records for the spice room, but the records reviewed did not reflect the conditions observed during the on-site review of this area. The Veterinary Inspection Service inspection records reviewed did not identify the conditions described in this section of the establishment report. [9 CFR § 416.1, 416.2 (a) and (b)]

46/51 The reconditioning of raw poultry meat that had been dropped onto the floor was conducted in a plastic crate with a cutting board bottom. The crate was located on a shelf-extension of the employee hand-washing sink. The location of the reconditioning process did not protect products from the possibility of being contaminated or adulterated during the hand-washing process. The establishment had a written procedure in their Sanitation SOP for the reconditioning of meat dropped onto the floor and records documenting the daily monitoring of this procedure. The Sanitation SOP was last evaluated March 9, 2009. The location of the reconditioning process and possibility of contamination or adulteration of reconditioned product was not identified in the Sanitation SOP records reviewed for June, 2009. The Veterinary Inspection Service inspection records reviewed did not identify the conditions described in this section of the establishment report. [9 CFR § 416.1 and 416.4 (d)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 8/02/2009

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
Yehiam Meat Products Kibbutz Yehiam	07/28/ 2009	104	Israel
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[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 SSOPs 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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
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	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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. *Listeria monocytogenes* & *Salmonella* (RTE)	
59.	

60. Observation of the Establishment

Israel Establishment 104, 07/28/2009 Chicken & turkey processing

After the review of the establishmet's food safety system, which includes their food safety programs and records which support their programs and the Veterinary Inspection Services' programs, procedures, and records, there were no significant findings to report after consideration of the nature, extent, and degree of all observations.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 7/28/2009

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 Ltd. Beit-Shean	07/29/2009	108	Israel
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[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 SSOPs 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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
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	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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.	

60. Observation of the Establishment

Israel Establishment 108, July 29, 2009 Turkey& Chicken RTE processing

After the review of the establishmet's food safety system, which includes their food safety programs and records which support their programs and the Veterinary Inspection Services' programs, procedures, and records, there were no significant findings to report after consideration of the nature, extent, and degree of all observations.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 7/29/2009

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
Tnuva Galil Kiryat Shmona	07/22/09	209	Israel
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[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.	X
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
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. Enforcement	X
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. *Listeria monocytogenes* & *Salmonella* (RTE)	
59.	

60. Observation of the Establishment

Israel Establishment 209, July 22, 2009; Turkey and Chicken RTE processing

15/51 The procedure addressing condensation and the disposition of finished product that had been contaminated or potentially contaminated by condensate stated that after an evaluation of the product, the product could receive a lethality heat treatment as part of the reconditioning process. Also the establishment's *Listeria* program stated that finished product that tested positive for *Listeria monocytogenes*, could receive a lethality heat treatment to recondition the finished product. When reviewing the HACCP flow chart, the rework processing steps did not provide an entry for these products into the process. The hazard analysis did not identify the hazards that may be introduced into the process during the rework of these products. The establishment had not identified all the hazards reasonably likely to occur during the reassessment of their HACCP plan. The Veterinary Inspection Service did not adequately verify the adequacy of the HACCP plan and therefore did not determine that the HACCP plan did not meet FSIS requirements and did not document that the establishment did not identify all the hazards reasonably likely to occur during their review of the establishment's HACCP plan and the records documenting the HACCP plan. [References: 9 CFR § 417.2, 417.4 (c), and 417.8]

15/46/51 During the on-site review of the spice storage room, an establishment employee was observed opening and emptying a paper bag filled with breading crumbles into a stainless steel combo bin. The bag was opened and emptied over the combo bin. During this process, the outside of the bag came into direct contact with the combo bin and the breading crumbles. The receiving step in the HACCP hazard analysis considered biological and physical hazards for the ingredients, but not for the hazards associated with the outside of the packing material. The establishment failed to identify these hazards during daily Sanitation Performance Standards (SPS) monitoring of this area, during the reassessment of their HACCP plan, and during the evaluation of their Sanitation SOPs. The Veterinary Inspection Service did not adequately verify the adequacy of the HACCP plan and did not determine that the HACCP plan did not meet FSIS requirements by not identifying hazards reasonably likely to occur during their daily verification of this area, review of HACCP and Sanitation records (verification records reviewed from May 25 through July 22, 2009), or during the June supervisory review. The employee received counseling/training for Good Manufacturing Practices. The bread crumbles were held for evaluation.
[9 CFR § 416.4(d) and 417.2 and 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 7/22/2009

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
Soglowek Ltd. 2000 Shlomi	07/26/09	219	Israel
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Don Carlson, DVM		[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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
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	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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. *Listeria monocytogenes* & *Salmonella* (RTE)	
59.	

60. Observation of the Establishment

Israel Establishment 219, July 26, 2009; Turkey & Chicken RTE processing

After the review of the establishmet's food safety system, which includes their food safety programs and records which support their programs and the Veterinary Inspection Services' programs, procedures, and records, there were no significant findings to report after consideration of the nature, extent, and degree of all observations.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Don Carlson, DVM	Don Carlson, DVM 7/26/2009