USDA

United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
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OCT 31 2019

Dr. Parthi Muthukarasam
Director
Food Import/Export Division
Canadian Food Inspection Agency
1400 Merivale Road, T2-6-268
Ottawa ON K1A 0Y9

Dear Dr. Muthukarasam,

The Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of the Canadian Food Inspection Agency (CFIA) meat, poultry and processed egg products inspection system from November 26 through December 13, 2018, as part of FSIS' continued review and assessment of Canada's inspection system. Enclosed is a copy of the final audit report.

CFIA has provided information in response to the audit findings. The comments received from the CFIA are included as an attachment to the final audit report, which will be posted on the FSIS website at: https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports. FSIS continues to review the information provided by CFIA, and the outcome of that review will be provided in a separate letter.

For any questions regarding the FSIS 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 IN

CANADA

NOVEMBER 26 THROUGH DECEMBER 13, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT, POULTRY, AND EGG PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

September 18, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from November 26 through December 13, 2018. The purpose of the audit was to determine whether Canada's food safety inspection system governing meat, poultry, and egg products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Canada currently exports meat and poultry that is thermally processed-commercially sterile, ready-to-eat (RTE) salt-cured, RTE fully cooked without subsequent exposure to the environment, RTE fully-cooked, RTE dried, RTE acidified/fermented (without cooking), raw intact, raw non-intact, not-ready-to-eat (NRTE) otherwise processed, and egg products to the United States.

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

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

Government Oversight (e.g., Organization and Administration)

- The Canadian Food Inspection Agency (CFIA) allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CFIA routine chemical residue program.
- In 13 of 14 audited establishments, the FSIS auditors identified deficiencies due to inadequate enforcement of sanitation standard operating procedures (sanitation SOP) and sanitation performance standards (SPS) requirements by CFIA inspection personnel.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- In the sole establishment audited that was operating under the HACCP-Based Inspection Program for swine, during the veterinary disposition of retained carcasses, CFIA did not require pluck (heart, lung, and liver) or viscera to be presented for final disposition by the veterinarian when a carcass was railed out for pathology. In another establishment, caul (omental) fat was being harvested prior to CFIA evisceration inspection for the presence of pathology. The establishment did not demonstrate how it would maintain segregation of harvested fat as a batch or a similar system for proper disposition of the product.

Government Hazard Analysis and Critical Control Points (HACCP) System

- In six of 14 audited establishments, the FSIS auditors identified deficiencies related to HACCP plan design, monitoring, and recordkeeping.

Government Microbiological Testing Programs

- The CFIA does not require poultry establishments to collect and analyze samples for microbial organisms at the pre-chill location.
- Unfinished tasks were not properly documented as required in the CFIA's laboratory standard operating procedure.
- The tracking sheet related to analytical method MFLP76 did not indicate the date and time when the sample was put in and taken out of the incubator. The tracking sheet also did not indicate whether the sample remained in the incubator for the specified duration.

During the audit exit meeting, the CFIA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CFIA's documentation of proposed corrective actions to determine future equivalence verification activities.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Canada's food safety system from November 26 through December 13, 2018. The audit began with an entrance meeting held on November 26, 2018, in Ottawa, Canada, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Canadian Food Inspection Agency (CFIA)

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing meat, poultry, and egg products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Canada is eligible to export meat and poultry that is thermally processed-commercially sterile (TPCS), ready-to-eat (RTE) salt-cured, RTE fully-cooked without subsequent exposure to the environment, RTE fully-cooked, RTE dried, RTE acidified/fermented (without cooking), raw intact, raw non-intact, not-ready-to-eat (NRTE) otherwise processed, and egg products to the United States.

The following products are eligible for export from Canada to the United States.

Process Category	Product Category	Eligible Products
Raw Product - Non-Intact	Raw ground, comminuted, or otherwise non-intact beef	Beef and Veal - All Products Eligible except Finely Textured Beef; Low Temperature Rendered Product; Partially Defatted Beef Fatty Tissue; and Partially Defatted Chipped Beef
Raw Product - Non-Intact	Raw ground, comminuted, or otherwise non-intact meat - other (sheep, goat)	Goat, Lamb, Mutton - All Products Eligible
Raw Product - Non-Intact	Raw ground, comminuted, or otherwise non-intact pork	Pork - All Products Eligible
Raw Product - Non-Intact	Raw ground, comminuted, or otherwise non-intact poultry	Poultry - All Products Eligible
Raw Product - Non-Intact	Raw ground, comminuted, or otherwise non-intact poultry - other (duck, geese, squab)	Ratites – All Products Eligible except Mechanically Separated
Raw Product - Intact	Raw intact beef	Beef and Veal - All Products Eligible
Raw Product - Intact	Raw intact meat - other (Sheep, Goat)	Goat, Lamb, Mutton - All Products Eligible
Raw Product - Intact	Raw intact pork	Pork - All Products Eligible

Process Category	Product Category	Eligible Products
Raw Product - Intact	Raw intact poultry	Poultry - All Products Eligible
Raw Product - Intact	Raw intact poultry - other	Ratites - All Products Eligible
Thermally Processed - Commercially Sterile	Thermally Processed - Commercially Sterile	Meat and Poultry - All Products Eligible
Not Heat Treated - Shelf Stable	NRTE otherwise processed meat	Meat - All Products Eligible
Not Heat Treated - Shelf Stable	NRTE otherwise processed poultry	Poultry - All Products Eligible
Not Heat Treated - Shelf Stable	RTE acidified/fermented meat (without cooking)	Meat - All Products Eligible
Not Heat Treated - Shelf Stable	RTE acidified/fermented poultry (without cooking)	Poultry - All Products Eligible
Not Heat Treated - Shelf Stable	RTE dried meat	Meat - All Products Eligible
Not Heat Treated - Shelf Stable	RTE dried poultry	Poultry - All Products Eligible
Not Heat Treated - Shelf Stable	RTE salt-cured meat	Meat - All Products Eligible
Not Heat Treated - Shelf Stable	RTE salt-cured poultry	Poultry - All Products Eligible
Heat Treated - Shelf Stable	NRTE otherwise processed meat	Meat - All Products Eligible
Heat Treated - Shelf Stable	NRTE otherwise processed poultry	Poultry - All Products Eligible
Heat Treated - Shelf Stable	RTE acidified/fermented meat (without cooking)	Meat - All Products Eligible
Heat Treated - Shelf Stable	RTE acidified/fermented poultry (without cooking)	Poultry - All Products Eligible
Heat Treated - Shelf Stable	RTE dried meat	Meat - All Products Eligible
Heat Treated - Shelf Stable	RTE dried poultry	Poultry - All Products Eligible
Heat Treated - Shelf Stable	RTE salt-cured meat	Meat - All Products Eligible
Heat Treated - Shelf Stable	RTE salt-cured poultry	Poultry - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE fully-cooked meat	Meat - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE fully-cooked poultry	Poultry - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE meat fully-cooked without subsequent exposure to the environment	Meat - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE poultry fully-cooked without subsequent exposure to the environment	Poultry - All Products Eligible
Heat Treated but Not Fully Cooked - Not Shelf Stable	NRTE otherwise processed meat	Meat - All Products Eligible
Heat Treated but Not Fully Cooked - Not Shelf Stable	NRTE otherwise processed poultry	Poultry - All Products Eligible

Process Category	Product Category	Eligible Products
Product with Secondary Inhibitors - Not Shelf Stable	NRTE otherwise processed meat	Meat - All Products Eligible
Product with Secondary Inhibitors - Not Shelf Stable	NRTE otherwise processed poultry	Poultry - All Products Eligible
Product with Secondary Inhibitors - Not Shelf Stable	RTE salt-cured meat	Meat - All Products Eligible
Eggs/Egg Products	Egg products	Poultry - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Canada as controlled risk for bovine spongiform encephalopathy (BSE); free of classical swine fever, African swine fever, foot-and-mouth disease, swine vesicular disease, and Newcastle disease; and not currently affected by highly pathogenic avian influenza. Canada is eligible to export meat, poultry, and egg products to the United States.

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

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

Administrative functions were reviewed at CFIA headquarters, three regional offices, and 14 local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 14 establishments was selected from a total of 467 establishments certified to export to the United States. This included ten slaughter establishments and four processing establishments. The products these establishments produce and export to the United States include meat, poultry, and egg products.

During the establishment visits, the FSIS auditors paid attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety. The FSIS auditors assessed the CFIA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety

inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2, §381.196, and §590.925.

Additionally, FSIS audited one microbiological and one chemical residue laboratory to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• CFIA, Ottawa
	Regional Offices	3	• Toronto Regional Office, Toronto • Montreal Regional Office, Montreal • Winnipeg Regional Office, Winnipeg
Laboratories		2	• CFIA Calgary Laboratory, government, microbiological, Calgary • CFIA Saskatoon Laboratory, government, residue, Saskatoon
Beef, lamb, and veal slaughter establishment		1	• Establishment 99, Tri-Pet Holdings Inc., Toronto
Beef slaughter establishment		1	• Establishment 93, Cargill Ltd., High River
Beef, lamb, and veal slaughter establishment		1	• Establishment 11, Elbee Meat Packers Ltd., Toronto
Chicken, duck, and turkey slaughter establishment		1	• Establishment 274, Quebec Inc., Montreal
Duck slaughter establishment		1	• Establishment 255, King Cole Ducks Unlimited, Newmarket
Lamb slaughter establishment		1	• Establishment 136, Sungold Specialty Meats Ltd., Innisfail
Ratite slaughter establishment		1	• Establishment 466, Jacques Forget Ltd., St. Leonard
Pork slaughter establishments		2	• Establishment 10, Agromex Inc., Ange-Gardien • Establishment 663, FGO Organic Processing, Ingersoll
Beef, chicken, pork, and turkey processing establishment		1	• Establishment 36, Expresco Foods Inc., St. Laurent
Beef, pork, and chicken processing establishment		1	• Establishment 675, Protenergy Natural Foods Corp., Richmond Hill
Beef, pork, and turkey processing establishment		1	• Establishment 229, Premium Brands Operating, Waterloo
Pork processing establishment		1	• Establishment 1, Maple Leaf Foods Inc., Winnipeg
Egg product facility		1	• Establishment 36E, Global Egg Corporation, Etobicoke

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906);
- The Meat Inspection Regulations (9 CFR Parts 301 to the end);
- The Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*);
- The Poultry Products Inspection Regulations (9 CFR Part 381);
- The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*); and
- The Egg Inspection Regulations (9 CFR Part 590).

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

III. BACKGROUND

From July 1, 2015 to June 30, 2018, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 5,104,586,243 pounds of meat, poultry, and eggs exported to the United States. The products imported into the U.S. includes:

- 39,446,098 pounds of TPCS beef; 110,033 pounds of RTE beef fully-cooked without subsequent exposure to the environment; 23,391,927 pounds of RTE fully-cooked beef; 98,861 pounds of RTE dried beef; 39,418 pounds of RTE acidified/fermented beef (without cooking); 1,694,422,140 pounds of raw intact beef; 3,298,141 pounds of raw non-intact beef; 209,614,243 pounds of NRTE otherwise processed beef;
- 200 pounds of NRTE otherwise processed goat; 7,067 pounds of RTE fully-cooked lamb; 580,593 pounds of raw intact lamb; 3,533 pounds of raw non-intact lamb; 66,242 pounds of NRTE otherwise processed lamb;
- 17,197,650 pounds of TPCS pork; 6,451,927 pounds of RTE salt-cured pork; 33,725,132 pounds of RTE pork fully-cooked without subsequent exposure to the environment; 42,726,872 pounds of RTE fully-cooked pork; 854,569 pounds of RTE dried pork; 1,758,816 pounds of RTE acidified/fermented pork (without cooking); 2,194,441,048 pounds of raw intact pork; 6,767,680 pounds of raw non-intact pork; 167,839,432 pounds of NRTE otherwise processed pork;
- 1,670 pounds of RTE fully-cooked veal; 55,082,536 pounds of raw intact veal; 9,318 pounds of raw non-intact veal; 600 pounds of NRTE otherwise processed veal;
- 49,128,723 pounds of TPCS chicken; 1,617,665 pounds of RTE chicken fully-cooked without subsequent exposure to the environment; 170,556,721 pounds of RTE fully-cooked chicken; 83,793,586 pounds of raw intact chicken; 146,369,146 pounds of raw non-intact chicken; 54,331,544 pounds of NRTE otherwise processed chicken;
- 34,658,990 pounds of egg products;
- 164,926 pounds of TPCS duck; 4,993 pounds of RTE duck fully-cooked without subsequent exposure to the environment; 726,547 pounds of RTE fully-cooked duck; 5,502,238 pounds

of raw intact duck - other (ducks, geese, squab); 6,438 pounds of raw non-intact duck - other (ducks, geese, squab); 35,233 pounds of NRTE otherwise processed duck;
- 5,952 pounds of RTE turkey fully-cooked without subsequent exposure to the environment; 1,045,543 pounds of RTE fully-cooked turkey; 416 pounds of RTE dried turkey; 39,596,695 pounds of raw intact turkey; 18,927,610 pounds of raw non-intact turkey; and 118,909 pounds of NRTE otherwise processed turkey.

Of these amounts, additional types of inspection were performed on 98,241,944 pounds of meat, 67,064,275 pounds of poultry, and 4,296,891 pounds of egg products, including testing for chemical residues and microbiological pathogens *Escherichia coli (E. coli)* O157:H7, and non-O157 Shiga toxin-producing *E. coli* (STEC) O26, O45, O103, O111, 0121, and O145 in beef or veal; and *Listeria monocytogenes* (*Lm)* in RTE meat products; and *Salmonella* in egg products.

As a result of these additional inspections, a total of 741,932 pounds of meat were rejected at the POE for issues related to United States food safety requirements (e.g., off condition, ingesta, fecal material, extraneous material, pathological lesions, microbiological test results, etc.). A total of 185,921 pounds of poultry were rejected for issues related to U.S. food safety requirements. A total of 1,032,294 pounds of meat were refused entry for non-food safety requirements due to shipping damage, missing or invalid shipping marks, etc. and a total of 244,090 pounds of poultry were refused entry for non-food safety requirements due to shipping damage, missing or invalid shipping marks, etc.

The FSIS auditors visited seven establishments implicated in the above-mentioned POE violations, and focused on establishments presenting critical violations for the specified timeframe. The FSIS auditors concluded that CFIA's implementation of corrective actions accurately reflected commitments made in response to FSIS initial notification, follow-up, and closeout activities for each specific POE violation. The previous FSIS audit in 2016 identified the following findings.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The government inspectors may not have been conducting complete carcass-by-carcass post-mortem inspection to ensure freedom from contamination with feces, milk, or ingesta for reconditioned carcasses prior to applying mark of inspection.

Government Sanitation

- In 11 of 13 establishments audited, FSIS observed findings related to requirements of Sanitation Performance Standards (SPS). SPS findings are noted in their respective individual establishment checklist provided in Appendix A of the report.

Government HACCP System

- In two establishments, HACCP verification records did not include the result of the verification activities. Isolated HACCP findings are noted in their respective individual establishment checklist provided in Appendix A of this report.

The FSIS auditors reviewed the corrective actions provided in response to the 2016 audit and verified that the CFIA had adequately implemented the proffered corrective actions.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Canada's SRT responses and supporting documentation. During the audit, the FSIS auditor conducted interviews, reviewed records, and observed operations to determine whether Canada's food safety inspection system governing meat, poultry, and egg products is being implemented as documented in the country's SRT responses and supporting documentation.

The FSIS final audit reports for Canada's food safety inspection system are available on the FSIS website at: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

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

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

The CFIA is organized and managed by the national government as mandated through Canadian requirements. The CFIA ensures that the laws, regulations and procedures governing the meat (including beef, veal, pork, mutton, and goat), poultry (including chicken, turkey, duck, and ostrich), and egg products (including both pasteurized and unpasteurized egg products) inspection systems are enforced.

At the field level, the CFIA is organized into four operation area offices (Atlantic, Quebec, Ontario, and Western). Each of the four operation area offices is led by an Area Director General (ADG) who is assisted by the Area Chief Inspector (ACI), Regional Chief Inspector (RCI), and Inspection Manager (IM). The responsibilities of the RCI and IM are to review the Compliance Verification System (CVS) data reports to ensure awareness of food safety and inspection trends and to identify potential areas of concern; follow up with inspection staff to gather information when concerns are identified as a result of reviewing the CVS data reports; and communicate follow up findings, including justification and rationale up through the management chain of command to the ACI and ADG.

Each area is staffed with an Area CVS Coordinator and an Area Food Safety Enhancement Program (FSEP) Coordinator. The responsibilities of the Area CVS Coordinator are to support the delivery of the CVS in their area; respond to issues or questions about the CVS and the verification tasks from area operations staff and management; and review with Operations Specialists proposed revisions, additions, or deletions to the verification tasks received from Inspectors and Supervisors. Proposed revisions are sent to the National CVS Coordinator for

review and acceptance. The responsibilities of the Area FSEP Coordinator are to respond to FSEP issues or questions about verification tasks from the Area CVS Coordinator and Operations staff; or to complete a Verification Task Comments Submission Form whenever the need for a change to a verification task is identified.

The Regional Veterinary Officers at meat and poultry slaughter establishments and Food Processing Supervisors at meat, poultry, and egg products processing establishments are responsible for conducting periodic supervisory visits. These supervisory personnel are to complete the off-site and on-site components of supervisory oversight, in addition to providing verbal feedback and immediate reinforcement to the CFIA inspection personnel, and to providing required support to correct identified inconsistencies or deficiencies in establishments. The FSIS auditors verified that the regions assign competent and qualified government inspectors to the establishments eligible to export to the United States.

At the establishment level, inspection personnel ensure that all applicable verification tasks are assigned to the establishment, conduct verification tasks according to the national frequency, take and document enforcement actions when necessary to protect public health, and communicate verification task results to the establishment management. Inspection personnel utilize the web-based CVS, which is similar in function to FSIS' web-based Public Health Information System and is used by CFIA to identify patterns of compliance, indications of systemic problems, compliance with Canadian trading partners' regulations, and ensure uniformity of program delivery.

To record verification activities and the outcome thereof within the CVS, inspectors utilize three different type of documents, namely the Verification Worksheet (VW), Verification Report (VR), and Inspection Report - Corrective Action Requests (IR-CAR). The salient features of the VW include facility information and record of daily presence of inspectors at the establishments certified to export to the United States. Inspectors provide copies of IR-CAR to the establishment and assess the establishment's action plans submitted in response to CARs. The design of the VR is such that the inspector must follow up on any item that requires correction or is flagged for any concern. The enforcement actions consist of progressively stricter steps, which can range from holding the product under a CFIA tag to termination of the establishment's registration. The FSIS auditors interviewed the inspection staff and reviewed examples of VWs, VRs, IR-CARs, and closed CARs at all audited establishments; neither of these activities raised any concerns with the criteria associated with government oversight requirements.

The FSIS auditors reviewed the procedures and examples on how FSIS import requirements are received and transmitted from headquarters to different levels of inspection down to the inspectors at the establishments certified to export to the United States. The CFIA maintains an online web portal for export requirements for all countries to which Canada exports meat, poultry, and egg products. The website is updated as new import requirements are communicated from FSIS to Canada and is accessible to inspectors as well as establishments exporting meat, poultry, and egg products.

During a regional office audit, the FSIS auditors viewed the web page for the United States export requirements. The CFIA inspectors regularly review the portal to stay abreast of

importing country requirements. Features of the portal are analogous to the FSIS export library. In addition to the web page, the CFIA inspectors at facilities registered as eligible for exporting product to the United States are enrolled in an e-mail subscription service available through CFIA. The CFIA headquarters will then send alerts of updates to FSIS export requirements through the automated e-mail list to ensure all personnel are aware of any changes. The FSIS auditors did not identify any concerns as a result of this review.

The CFIA employs government inspectors to the establishments eligible to export meat, poultry, or egg products to the United States. The *Canadian Food Inspection Agency Act*, Sections 5, 6, and 13, vest authority in CFIA to appoint inspectors and veterinarians. The CFIA maintains written procedures addressing the hiring of inspection personnel and disciplinary actions to handle cases where employees have low performance or are falling short of meeting government ethics or other conditions of employment. The FSIS auditors reviewed an example of recent hiring records, employees' pay stubs, and identification badges. The CFIA trains employees regarding possible conflicts of interest issues; code of conduct training is a condition of employment and included as part of the initial training program. Additionally, an annual attestation that employees know, understand, and follow policies regarding code of conduct is completed by each employee. No concerns arose as a result of review of this criterion.

The FSIS auditors verified that the CFIA utilizes the *Meat Hygiene Training Implementation Guide*, which lists various job-specific required training for veterinarians and inspectors. Newly hired inspection staff must successfully complete a one-year training program, which is a combination of in-class and on-the-job segments before being assigned to independent positions. The Meat Programs Specialist may develop area-specific training sessions such as wet-labs or on-site sessions at the area office level. Targeted "refresher" courses may also be provided on-site, as required. The self-study training modules require completing post-training assessments prior to receiving completion certificates.

During the Winnipeg regional office audit, the RCI shared the training web page on the intranet related to the annual national training program. The program is organized into two modes (e-learning or in-class setting) of training delivery, training duration, and course prerequisites. The FSIS auditors reviewed digitally maintained records of a training delivered under the national meat processing school held from May 31- June 8, 2018 in Mississauga, Ontario. The FSIS auditors reviewed the course outline, participant list, and certificates of completion and determined that CFIA provides training to inspectors on an ongoing, annual basis and meets the needs of personnel based on routine performance assessments.

A network of government owned and operated laboratories located across Canada provides technical laboratory support to the CFIA and conducts official analytical testing on meat, poultry, and egg products to detect microbiological pathogens and chemical residues in samples of product destined for export to the United States. In addition to the government laboratories, CFIA also utilizes third party contracted laboratories as a cost-effective means of delivering sampling and testing activities. However, to qualify as a contract laboratory, the latter must achieve and maintain an accreditation to International Organization for Standardization / International Electrotechnical Commission (ISO/IEC) 17025, *General requirements for the competence of testing and calibration laboratories,* standards from one of the Canadian

accrediting bodies, the Standards Council of Canada (SCC), or the Canadian Association of Laboratory Accreditation (CALA).

The CFIA, through its partnership with the SCC, has an agreement for oversight of private accredited laboratories conducting analyses of food and food environmental surfaces for the industry. The purpose of this agreement is to describe the responsibilities of each party (CFIA and SCC) in a national program for the accreditation of laboratories performing tests under the Acts and Regulations. While CFIA administers and enforces the provisions of acts and requirements pertaining to technical support including approval or disapproval, the SCC focuses on assessing the efficacy of quality management systems in meeting the accreditation criteria including proficiency testing. Under the agreement, CFIA provides technical assessors who are trained and recognized as competent to assess laboratories' testing programs by the SCC.

Additionally, as part of its laboratory oversight, CFIA conducts several proficiency testing programs for laboratories that have been approved by CFIA or accredited through an arrangement under SCC or CALA. The FSIS auditors verified a sample of proficiency tests at both audited chemical residue and microbiological laboratories with no concerns identified. However, pertaining to the National Chemical Residue Monitoring Program (NCRMP), the FSIS auditors identified the following finding:

- The CFIA allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CFIA's routine chemical residue program.

At the audited establishments, the FSIS auditors observed deficiencies related to sanitation SOP and SPS indicating insufficient verification of sanitation by the CFIA. The deficiencies related to sanitation SOP included a failure to identify product residue from the previous day during pre-operational inspection, and cross contamination. The FSIS auditors found that multiple establishments were not maintained in a manner sufficient to prevent the creation of insanitary conditions. The SPS observations included deficiencies related to establishment pest control, establishment construction, maintenance of facilities, condensation, standing water, and a buildup of residues in the slaughter process. The CFIA had not identified nor documented the deficiencies that could lead to potential insanitary conditions affecting all audited establishments. The FSIS auditors identified the following finding:

- In 13 of 14 audited establishments, the FSIS auditors identified deficiencies related to enforcement of sanitation SOP and SPS requirements by CFIA inspection personnel.

The FSIS auditors verified that the CFIA's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

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

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; periodic supervisory visits to official establishments; and requirements for TPCS products.

Canadian regulatory requirements related to humane treatment and slaughter of livestock and poultry and ante-mortem and post-mortem inspections are prescribed in Part III, Sections 62 to 80 of the *Meat Inspections Regulations*. Specific sections of the regulations are devoted to the requirements for design and construction of pens, unloading docks, ramps, driveways, holding pens, and pre-slaughter pens that slaughter establishments must meet to ensure humane handling and slaughter of livestock. All holding and suspect pens are designed to provide drinking water to animals. Furthermore, an adequate supply of fodder is provided if the animals are held overnight. The FSIS auditors confirmed that Canada maintains standard operating procedures (SOPs) for the management of animal welfare in accordance with provisions defined in Section 4.4 of the *Meat Hygiene Manual of Procedures* (MOP).

Canada's legislation requires that no animal shall be slaughtered unless the animal has been subjected, within 24 hours before the time of slaughter, to an ante-mortem inspection performed by an official veterinarian or by an inspector under the supervision of an official veterinarian. The CFIA inspection personnel are required to conduct ante-mortem inspection on all livestock and poultry intended for export to the United States. The FSIS auditors verified all livestock presented for slaughter receive ante-mortem inspection at rest. The FSIS auditors also verified that 5-10 percent of bovine animals are observed in motion from both sides by a veterinarian or an inspector under the latter's supervision. Prior to ante-mortem inspection by CFIA and at the time of unloading livestock, an establishment employee observes and segregates animals showing any signs of weakness from normally appearing stock. Employees responsible for initial screening and segregation have received and read a copy of the MOP Chapter 4, Annex I, *"Introduction to Ante-mortem for Plant Employees"*.

At the poultry slaughter establishments, the CFIA's ante-mortem inspection of poultry begins with a review of accompanying flock sheets of each lot followed by ante-mortem inspection by a CFIA veterinarian or an inspector of birds in shipping crates either on the transport vehicle or in the staging area. Verification of ante-mortem procedures at the audited poultry slaughter establishments determined the observed process to be in accordance with CFIA's policies and standards.

The FSIS auditors reviewed the CFIA's BSE mitigation measures and specified risk material (SRM) controls in beef slaughter establishments. The FSIS auditors confirmed that in establishments slaughtering cattle, a BSE surveillance program was actively in operation to handle dead or dying animals exhibiting central nervous system disorders or cattle arriving in a non-ambulatory state. All such conditions are subjected to confirmatory tests for the presence of prions in brain matter. The FSIS auditors further verified procedures for stunning, dentition, and segregation of carcasses between 30 months of age or over, and removal and isolation of SRM and determined that establishments followed their programs as guided by CFIA's policy and standards.

Post-mortem inspection procedures for all red meat species are described in Chapter 17 of the MOP. Sections 17.7.3 and 17.7.9 of the MOP outline the inspection procedures and establishment's obligations to meet established facility requirements for beef and pork slaughter respectively. The FSIS auditors verified the implementation of the CFIA's post-mortem inspection procedures at two mixed species (bovine, ovine, & caprine), one ovine, one beef, one ratite and two swine slaughter establishments. The beef slaughter establishment was operating under the High Line Speed Inspection System, Canada's modernized beef slaughter inspection system. While auditing the High Line Speed Inspection System and touring the facility, the FSIS auditors observed the establishment's process controls in operation, which included presentation standard tests, pre- and post-evisceration tests and finished products standards tests. Online carcass trimmings and washing procedure followed the policies and procedures outlined in Annex B, Chapter 17 of the MOP.

Of the two audited pork slaughter establishments, one utilizes a traditional post-mortem inspection system while the other establishment operates under the HACCP-Based Inspection Program (HIP) for swine. Under HIP, establishments employ statistical process control, microbial interventions, and robust product testing, in conjunction with CFIA comprehensive verification of establishment's food safety programs at the key locations before allowing the mark of inspection for product safety. The FSIS auditors identified the following finding:

- In the sole establishment audited that was operating under HIP for swine, during the veterinary disposition of retained carcasses, CFIA did not require pluck (heart, lung, and liver) or viscera to be presented for final disposition by the veterinarian when a carcass was railed out for pathology. In another establishment, caul (omental) fat was being harvested prior to CFIA evisceration inspection for the presence of pathology. The establishment did not demonstrate how it would maintain segregation of harvested fat as a batch or a similar system

The FSIS auditors visited three poultry slaughter establishments, including a ratite slaughter establishment. Two of the audited establishments receive traditional inspection, while the third audited establishment operates an inspection system which has similarities to FSIS' New Poultry Inspection System (NPIS) in that the establishments conduct sorting activities prior to presenting the carcass to the CFIA online inspector.

In Canada, the modernized inspection system for poultry is known as the Modernized Poultry Inspection Program (MPIP). During the audit of the slaughter operations, the FSIS auditors determined that a government veterinarian is present at all the establishments while government inspectors are online verifying carcass by carcass. In MPIP, designated defect detection employees are responsible for the detection of carcass, cavity, and viscera defects on each carcass before and after evisceration. Establishment carcass defect detectors identify and remove condemnable carcasses before evisceration steps.

Through interviews and record reviews at all audit sectors including visits to the Toronto, Montreal, and Winnipeg regional offices, the FSIS auditors determined that Canada maintains government inspection of each carcass and parts in all United States-eligible meat and poultry slaughter establishments, and at least once per shift, during processing operations as required in Section 11.7.3 of the MOP. The FSIS auditors further confirmed that that inspection occurs once per shift as evidenced by reviews of the CVS verification worksheets which the inspectors use to record results of verification tasks conducted as well as to document daily presence. The FSIS auditors verified the continuous supervision in the establishments certified to export to the United States by reviewing the daily presence log section of the verification worksheet. No concerns arose as a result of this verification.

The FSIS auditors found that the CFIA provides continuous inspection coverage of egg product processing activities during all hours of operation at the audited establishment. No concerns arose as a result of verification of FSIS import requirements pertinent to continuous supervision at the United States eligible egg-processing establishment.

Periodic supervisory reviews are conducted to ensure that decisions made by inspection personnel are uniform, consistent, and in accordance with prescribed policies, procedures, and regulations; and to ensure uniformity and consistency in the delivery of verification activities across the inspection system. To achieve these objectives, the supervisors rely on a twofold approach, namely, the Quality Management System (QMS) and forecasting activities. The QMS is a supervisory tool to assess, improve, and report on the effectiveness of the CFIA inspection personnel activities. Forecasting is another supervisory tool that assesses the establishment's performance through a supervisor's on-site tour of the facility and review of the establishment's documents. Once the forecasting is completed, the information is documented in the CVS verification worksheet, and the issues identified therein are prioritized for food safety significance by assigning the corresponding CVS tasks as a follow up. At each audited establishment, the FSIS auditors examined samples of supervisory reviews and the associated documents discussed above.

The FSIS auditors confirmed the CFIA has legal authority and ensures food safety and other required consumer protections such as ante-mortem, labeling and humane handling requirements are met at establishments certified to export their products to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CFIA requires each official establishment to

develop, implement, and maintain written sanitation SOP to prevent direct product contamination or insanitary conditions.

Canada's legislation contains requirements for establishments certified to export to the United States to develop, implement, and maintain pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat, poultry, and egg products. In meat and poultry slaughter and processing establishments, these requirements are specified in the *Meat Inspection Regulations* (MIR) and outlined in the MOP. The legislation governing implementation and maintenance of sanitation in egg products establishments is stipulated in the PER and outlined in the *Processed Egg Manual*.

The FSIS auditors toured each meat, poultry, or egg products establishment to verify how the CFIA ensures that all establishments certified to export to the United States meet national and FSIS requirements pertaining to building, equipment, transport containers and outer premises, and maintained sanitary conditions. The FSIS auditors selected a sample of inspection verification records including work plans, work reports, and CARs. The establishment document review included monitoring records related to operational and pre-operational sanitation, prerequisite programs addressed through sanitary control measures, and other SPS requirements. The review indicated that inspection personnel routinely conduct scheduled and unscheduled CVS tasks applicable to establishment's sanitation program and document noncompliance in IR-CARs.

In one meat processing and one egg processing establishment, the FSIS auditors verified the actual activity of pre-operational sanitation inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of processing areas. The in-plant government inspection personnel conducted their activities in accordance with the establishment's procedures, including pre-operational record review of the establishment's monitoring results, an organoleptic inspection of food contact surfaces, and an assessment of SPS requirements. The FSIS auditors observed the CFIA inspectors conducting operational sanitation inspection procedures in all audited establishments and compared the conditions of all audited establishments to CFIA's inspection verification documentation. The FSIS auditors also verified the corrective and preventive measures establishments put in place to correct the findings identified in the 2016 audit of Canada and found them to be satisfactorily corrected.

All eligible processed egg establishments are required to have a sanitation program which identifies the establishment personnel responsible for carrying out the program and the equipment, chemical agents, and procedures necessary to ensure that clean and sanitary conditions are maintained. Equipment is cleaned and sanitized at the end of each day's operations as well as every four hours during operation or as needed such as when egg breaker equipment stops. Equipment is to be drained and dried after cleaning and sanitizing prior to operation. The PER requires inspection personnel to perform daily pre-operational inspection at processed egg establishments when egg products are intended for export to the United States. The document review conducted by the FSIS auditors at the local inspection offices confirmed that these requirements are routinely met.

The FSIS auditors concluded that the CFIA meets the core criteria established for this component. However, the FSIS auditors identified deficiencies with the CFIA's ability to consistently identify and enforce requirements for SPS and sanitation SOP as documented in the checklist in Appendix A. The CFIA has implemented requirements for establishments certified to export to the United States to develop, implement, and maintain pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat, poultry, and egg products.

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

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

Canada's legislation contains requirements for establishments certified to export to the United States to develop, implement, and maintain written HACCP programs. The HACCP programs are incorporated into a broader food safety system known as the FSEP, as outlined in Chapter 2 of the MOP. The FSEP is based on the principles of HACCP developed by the Codex Alimentarius Commission. The principal objective of the FSEP is to specify the minimum requirements for an effective food safety management system. For specific hazards that are reasonably likely to occur, the establishments have instituted critical control points (CCPs) described in their HACCP plans. The egg products establishments that ship product to the U.S. operate under HACCP.

The FSIS auditors also verified that official inspection personnel conduct daily HACCP verification activities under the CVS, as per the guidance in Chapter 18 of the MOP. At the audited slaughter establishments, the FSIS auditors confirmed that official inspection personnel also verify monitoring of fecal matter, milk, and ingesta contamination prior to the final carcass wash.

The CFIA inspection verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel performing monitoring, verification, corrective actions, and recordkeeping activities. The official HACCP verification activities also include direct observation or record review of CCPs for all production shifts, with results of verification being entered in the associated inspection records. However, the FSIS auditors observed deficiencies related to the HACCP plans at three establishments which included inadequate support for the CCP monitoring procedure and frequency, inadequate definition of the frequency of CCP verification procedures, and a CCP verification which did not require results of the direct observation activity. Additionally, deficiencies related to HACCP recordkeeping were observed at four establishments, which included CCP monitoring records that did not include initials of monitor, a corrective action record that did not document the elimination of the cause of the deviation, critical limits of a CCP monitoring record documenting temperature did not identify actual/quantifiable values, and verification records that did not include a time of when the verification activity was completed. The FSIS auditors identified the following systemic finding:

- In six of 14 audited establishments, the FSIS auditors identified deficiencies related to HACCP plan design, monitoring or recordkeeping.

The FSIS auditors determined through interviews of inspection personnel and Area FSEP Specialists that CFIA conducts comprehensive FSEP-HACCP audits as referenced in Section 4 of Chapter 18 of the MOP at all regulated establishments. For-cause or triggered FSEP-HACCP system audits coincide with an in-depth investigation conducted by a team consisting of program specialists from area offices and headquarters. Such combined audit and investigation activities occur in an expeditious manner to determine the root cause of HACCP or other food safety deviations. The FSIS auditors reviewed a sample FSEP audit document and concluded CFIA's policies and standards and required frequencies are applied when conducting these audits.

During the audits of the beef slaughter establishments, the FSIS auditors verified that establishments had conducted a hazard analysis and identified all known pathogens including *E. coli* O157:H7 and non-O157 STECs as microbiological hazards and applied supportable and validated control measures in their HACCP systems through either CCPs, prerequisite programs, or process controls and anti-microbial interventions. In the audited establishments handling raw beef, the FSIS auditors observed that the establishments had implemented appropriate control measures to ensure the safety of beef products. The control measures applied for pathogen reduction observed at these establishments were primarily steam/hot water pasteurization or organic acid sprays. All interventions are validated, and establishments are required to maintain supporting documentation as per the FSEP. The documents reviewed indicated the establishments have a product identification system and clearly identify the intended use of product.

The FSIS auditors verified that the TPCS products are produced under the establishment's HACCP plan that addressed all microbiological hazards associated with TPCS products. The FSIS auditors further verified that the in-plant inspector in-charge and the staff verify the establishment's compliance in accordance with CFIA guidance under Chapter 15 of the MOP. The FSIS auditors reviewed process schedules for products exported to the United States, incubation records (which continuously demonstrated the absence of abnormal containers or other defects related to under-processing), retort heat-distribution tests, and production records.

The FSIS auditors concluded that Canada's food safety system requires all establishments certified to export to the United States to develop, implement and maintain HACCP systems. However, the FSIS auditors identified deficiencies with the CFIA's ability to consistently identify and enforce HACCP requirements related to HACCP plan and recordkeeping as documented in the checklist in Appendix A.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes

random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat, poultry, and egg products inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS residue experts thoroughly reviewed the NCRMP for 2018, associated methods of analysis, and additional SRT responses outlining the structure of Canada's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit. Section 4 (1) of the Canadian *Food and Drugs Act* (FDA) prohibits adulterated product due, among others, to any poisonous or harmful substance including chemical residues. Section B.01.048 of the *Food and Drug Regulations* prohibits the sale of food of animal origin, which have been treated with certain drugs, specifically chloramphenicol, nitrofurans, clenbuterol, nitroimidazole compounds, diethylstilbestrol, and other stilbenes and derivatives of some of these compounds.

The main objectives of Canada's NCRMP include verifying compliance with Canadian maximum residue and contaminants limits, identifying trends, and assessing effectiveness of policies and program and success in achieving the objectives of the NCRMP. The design of the NCRMP follows principles outlined by the Codex Alimentarius Commission. Sampling under the NCRMP is statistically based and conducted year-round at various animal health and food safety sectors across Canada. The CFIA does not require product that is being tested for chemical residues under the routine NCRMP monitoring program to be placed on hold while awaiting test results. This is a finding reported under Part IV. Component One – Government Oversight.

Under the NCRMP, participating CFIA laboratories cumulatively conduct 50,000 tests on roughly 25,000 samples per year. The figures for contracted third party laboratories under the programs consist of approximately 170,000 analytical tests on roughly 32,000 samples. While CFIA laboratories analyze samples received under monitoring, directed, follow-up or investigatory programs, the major share of monitoring tests are analyzed at contracted laboratories in conjunction with testing conducted for baseline surveys. Regardless, whether an analysis is conducted in a CFIA or contracted laboratory, sample collection, storage, and shipment at the federally regulated establishments are the responsibility of government inspectors.

The responsibilities for monitoring food safety regarding chemical residues in Canada are shared by Health Canada (HC) and CFIA. Relevant directorates, bureaus, or agencies in HC deal with food safety policies, establishing standards and Maximum Residue Levels (MRLs) for pesticides and for the environmental contaminants as well as food additives. The Veterinary Drugs Directorate (VDD) provides the veterinary drug registration, which establishes MRLs under the FDA and the Pest Management Regulatory Agency (PMRA), which regulates pesticide registration and establishes MRLs under the *Pest Control Products Act*. In pesticides where no MRL is specified, the general MRL of 0.1 ppm applies.

The *Canada Agricultural Products Act* delegates CFIA with the authority to sample a variety of food commodities including meat, poultry, and egg products intended for domestic and foreign markets. The *Meat Inspection Act* gives the CFIA authority to inspect and sample meat products

in federally inspected establishments, as well as enforce and administer the provisions of the *Food and Drugs Act* as they relate to food. The *Food and Drugs Act* (Criminal Act) enables CFIA inspectors to sample if there is a reasonable and probable ground to believe that there has been a violation of the Act.

The FSIS auditors assessed the implementation of the NCRMP through interviews and record reviews conducted at the CFIA headquarters, regional, and local inspection offices as well as the government residue testing laboratory. The program is implemented on a fiscal year basis, which runs from April 1 to March 31 of each year. Sampling schedules, instructions and shipping material are provided to CFIA inspection staff assigned to meat, poultry, and egg products establishments. Laboratories receiving samples for analysis are tested for a suite of analytes. The FSIS auditors reviewed the procedures and examples when non-compliant results returned. When a noncompliance is detected, CFIA promptly takes appropriate action, which corresponds to the severity of public health risk and may range from notifying the implicated establishment or importer to requesting corrective and preventive action. Additional inspection activities include conducting further directed sampling or detention of adulterated product if product is not already recalled. As a deterrent to repeat violators, results are always published on the CFIA Web site.

At one local inspection office in a slaughter establishment, the CFIA inspection staff simulated sample collection and procedures for sample integrity, security, and completing sample documents followed by entering task completion in the CVS. Samples may be shipped to a CFIA laboratory or to a third-party contract laboratory. The FSIS auditors also observed an inspector sampling a swine carcass using a Kidney Inhibition Swab for sulfonamide and antibiotic screening in red meat species. At one of the audited regional offices, the officials present at the audit meeting demonstrated real time laboratory data receiving process including recent test results from a third party contracted laboratory, analysis, evaluation, and electronic warehousing of data at CFIA's Laboratory Sample Tracking System site.

For verification of Canada's chemical residue testing program, the audit scope included a review of a government operated testing laboratory located in Saskatoon, Saskatchewan. The audit activities consisted of interviews with the officials, document reviews, and concluded with a site visit to the chemical testing portion of the laboratory. This laboratory is ISO 17025 accredited, which the SCC administered. The SCC audits CFIA laboratories at least every two years. The CFIA indirectly oversees the laboratory through delegation of either the SCC or CALA under a Memorandum of Understanding (MOU) with the accrediting bodies mentioned above. The FSIS auditors reviewed the most recent accreditation audit of the laboratory that took place in January 2017. The audit identified some minor record keeping noncompliance, which were corrected and presented to the SCC. The corrective actions were acceptable to the SCC. The next audit is due in January 2019.

The FSIS auditors interviewed the analysts to assess their technical competency, training, and knowledge of the analytical methods used on the samples to detect chemical residues. The document review included an evaluation of management system documents, internal audit reports, and corrective action report in response to concerns raised in internal audits. Although the Saskatoon laboratory is a provider of proficiency testing to other CFIA and contracted

laboratories, the analysts in the laboratory participate in the inter-laboratory proficiency testing. The review of proficiency testing records revealed that all results reviewed were acceptable. Lastly, the FSIS auditors observed the laboratory personnel at the sample receiving area who were receiving samples, checking sample integrity and security, assigning the identification, and storing the samples in accordance with the laboratory's SOP. No concerns emerged as a result of the laboratory audit.

The CFIA continues to demonstrate the ability to meet the equivalence requirements for this component to present a chemical residue testing program, organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

Canada requires that establishments certified as eligible to export to the United States develop, implement, and maintain a generic *E. coli* sampling and testing program to verify process control as an indicator of intestinal and fecal contamination. Chapter 11, Annex T of the MOP specifies the requirements and instructions for government inspection personnel on how to verify if establishments certified to export to the United States are complying with this requirement. Slaughter establishments with FSEPs are permitted to choose an alternate generic *E. coli* sampling frequency if the establishment has data to show that the alternate frequency is based on a supportable decision made in the hazard analysis. The assessment of testing program, method of analysis, and review of test results at audited meat and poultry slaughter establishments confirms that these facilities comply with CFIA requirements. Those establishments that employ carcass sponging utilize statistical process control methods to evaluate testing results. The FSIS auditors identified the following finding during the audits of the poultry slaughter establishments:

- The CFIA does not require poultry establishments to collect and analyze samples for microbial organisms at the pre-chill location.

Meat, poultry, and egg products in Canada produced for domestic or foreign markets are subjected to microbiological testing. Under the provisions of the MOU between the CFIA and HC, the latter is responsible for establishing standards, policies, and guidelines relative to food safety, methods of analyses, and conducting health risk assessments. The design of sampling plans for meat, poultry, and egg products for microbiological testing are grouped into monitoring risk-based and directed sampling.

Sampling under the monitoring plan, also known as the National Microbiological Monitoring Program (NMMP), is unbiased, planned, and carried out annually. Risk-based testing monitors aspects of the food safety system that are known to be high risk. Routine sampling frequency is based on pre-determined relative risk criteria; whereas directed sampling on the other hand is triggered by several factors, including a positive sample in the monitoring program, consumer complaint, or concerns arising from an on-site inspection.

The CFIA has mandated these eligible establishments are to test for *E. coli* O157:H7 if they export raw beef products including beef trim, bench trim, head meat, cheek meat, tongue roots, weasand meat, hearts, coarse ground beef, and finely textured beef as these types of beef products may be used in production of finished raw ground beef product (FRGBP). The policy on control of *E. coli* O157:H7 contamination in raw beef products is laid out in Annex O, Chapter 4 of the MOP. The policy provides guidance to inspection personnel as well as industry on the measures required to control *E. coli* O157:H7 and non-O157 STECs. Requirements for these mandatory testing and frequencies are outlined in Annex D.2, Chapter 11 of the MOP.

At all audited beef slaughter and processing establishments, the FSIS auditors reviewed microbiological testing programs enforced by the CFIA to test raw beef products also known as precursor material (PM), which is intended for use in the production of FRGBP. The PM includes beef trim, bench trim, head meat, cheek meat, tongue roots, weasand meat, hearts, and primal or sub-primal cuts. Establishments use the N60 method to sample veal or raw beef product as described above at the grinding stage. The test sample of raw beef products requires a minimum collection of 60 pieces weighing to a total of 325 g per lot. For the purpose of ensuring microbiological independence, a lot is defined as up to five combos not weighing more than 4,500 kg; or alternatively, a pallet of boxes, tote, buggy, vat, or tub may represent a lot provided the weight of the lot remains not more than 4,500 kg.

At one slaughter establishment, the FSIS auditors observed the designated establishment employee collecting the sub-samples employing aseptic techniques. The employee followed the N60 procedures as described in the establishment's microbiological testing program for STECs. The FSIS auditors further verified the procedures for sample storage for later submission to an SCC or CALA accredited laboratory. Product is always held while awaiting initial or follow up testing results. Accredited laboratories are required to report the results to the operator as well as the Food Safety Division of CFIA.

Through document reviews at local inspection offices at the audited beef slaughter establishments, and in conjunction with interviews conducted at regional offices, the FSIS auditors confirmed that the CFIA tests beef trimmings for *E. coli* O157:H7 and non-O157 STECs in slaughter establishments eligible to export meat products to the United States. The CFIA testing plan is designated as M218 (Canada's risk-based verification sampling of beef intended for use in the production of fresh ground beef), whereby the production volume, compliance history, robustness of establishment's own testing program or the prevalence of *E. coli* O157:H7 and non-O157 STECs due to any seasonal variation are the key determinants for testing frequency.

Establishments are responsible for the collection of samples from the lot selected by the inspector. An establishment employee trained in N60 sampling collects the sample under the supervision of the inspector. Compliance Verification System (CVS) as discussed in Government Oversight component assigns the inspector verification task to ensure samples are collected, handled, secured and shipped in accordance with the establishment's documented procedure. The outcome of sampling verification task are recorded in the CVS accordingly.

The certificates of analysis reviewed at the audited establishments provided evidence that contracted laboratories were analyzing the samples using methods determined to be equivalent by FSIS for screening. For confirmatory testing, laboratories can employ either USDA/FSIS Microbiology Laboratory Guidebook method 5B.03 or any confirmation method determined to be equivalent by FSIS. The positive *E. coli* O157:H7 results obtained over the last 120 days under the CFIA monitoring program are used for the assessment of establishment's compliance history. An enhanced testing frequency is enforced if testing of PM returns a positive *E. coli* O157:H7 test result, or when an establishment experiences a high number or a rate of positive results for *E. coli* O157:H7, which may occur during a high event period. The FSIS auditors verified that in FY17 CFIA sampling conducted analytical tests on 1,410 samples collected under NMMP to detect *E. coli* O157:H7. The product tested under the NMMP ranges from domestic ground beef, imported ground beef, and domestic PM. The data reviewed shows that sampling for *E. coli* O157:H7 have a compliance rate of 99.76 percent.

The FSIS auditors verified that the CFIA conducts risk-based verification sampling of RTE meat and poultry products and conducts food contact surface sampling in federally inspected establishments that produce RTE product. The CFIA collects product and food contact surface samples for the same lot. The CFIA sampling frequency is based on three factors: the risk category of the products, the presence/absence of antimicrobial agents, and post-lethality treatments. RTE not-heated treated products, such as dry cured salted and dry cured fermented meat and poultry products are required to achieve a 5-log reduction of *Salmonella* in meat products and a 7-log reduction in poultry products in conjunction with the application of Good Manufacturing Practices (GMP) designed to minimize contamination. The establishment is responsible for validating the process, which must be acceptable to the inspector. Those establishments, which prepare RTE beef products without applying heat as lethality control (e.g., fermented), are also subjected to *E. coli* O157:H7 testing.

The FSIS auditors verified the effectiveness of the recall program at one of the audited establishments eligible to export RTE products to the United States. The FSIS auditors reviewed the government verification activities related to the efficacy of the recall program as well as corrective actions and preventative measures implemented by the establishment. Dry fermented product shipped from this establishment tested positive for the presence of *Salmonella* at the United States POE in December 2017, resulting in a recall. The FSIS auditors' review of the establishment's corrective actions and preventative measures did not raise any concern.

The FSIS auditors' review of the CFIA's microbiological testing data for *Lm* and *Salmonella spp*. in RTE meat and poultry products and of environmental swabs revealed that in FY 2017 under NMMP the CFIA analyzed a total of 2,064 samples collected from federally registered establishments and imported RTE products. The data reviewed shows that sampling attained a

compliance rate of 99.24 percent. In addition, TPCS products were sampled for commercial sterility and container integrity for the same fiscal year achieved 100 percent compliance and species verification sampling of imported raw and heat-treated meat and poultry products yielded the same compliance rate as for TPCS sampling.

During the audit of an egg processing establishment as it pertains to the microbiological sampling, the FSIS auditors examined the government and establishment testing program for processed egg products. Consistent with the provisions of Sub sections 4(3) and 9(26) of the Processed Egg Regulations PER), processed egg products produced domestically or imported are eligible for the marks of inspection if they are prepared and stored in a sanitary manner and must test negative for *Salmonella* and other pathogenic organisms of human health significance.

The FSIS auditors verified that CFIA, under various sampling plans, samples and tests egg products (including liquid, frozen, and cooked egg products) for *Salmonella spp*., *Lm*, coliforms, and aerobic colony counts, as well as compositional analysis to determine nutrients, moisture in dried products, and percent solids in frozen and liquid products. Sampling also included pre-operational and operational swabs. Samples are collected using aseptic techniques and are analyzed in CFIA laboratories. All lots of pasteurized egg products that fail analysis for *Salmonella*, *Lm*, or coliforms are ineligible for export to the United States. The FSIS auditors reviewed the data related to egg sampling and testing carried out under NMMP for shell and processed egg products, and the auditors determined that the compliance rate has achieved virtually 100 percent with cumulatively 635 samples tested in FY 2017. In addition, for the same testing year sampling of canned meat for commercial sterility, container integrity, and imported raw and RTE meat for species verification yielded 100 percent compliance.

The audit scope also included a visit to a government owned and operated microbiological laboratory located in Calgary. The selected laboratory has jurisdiction over official testing in eligible meat, poultry, and egg establishments. Analytical data reviewed indicated that the laboratory supported CFIA's major sampling programs including monitoring, baseline surveys, regulatory, follow-up, and investigative testing in response to consumer complaints. The FSIS auditors reviewed the most recent ISO 17025 accreditation audit conducted by the SCC at this laboratory. The current accreditation is expiring in April 2019. The SCC audit had identified findings in different aspects of the audit scope, which the FSIS auditors confirmed that the proffered corrective actions were acceptable to the SCC. The laboratory review also focused on analysts' qualifications, training records, proficiency testing programs, and results.

The audit of the laboratory concluded with a visit to a sample receiving area where the FSIS auditors observed how samples were received and examined for sample security, integrity, assigning of sample identification and sample storage. During the tour, the FSIS auditors interviewed analysts and reviewed analyst-generated records related to analytical data and equipment calibration. The documents reviewed were comparable to procedures described in the laboratory's SOP; however, the following inconsistencies with the laboratory's internal audit program (which uses an ISO 17025 checklist) were identified:

- Unfinished tasks were not properly documented as required in the CFIA's laboratory standard operating procedure.

- The tracking sheet related to analytical method MFLP76 did not indicate the date and time when the sample was put in and taken out of the incubator. The tracking sheet also did not indicate whether the sample remained in the incubator for the specified duration.

The FSIS auditors' analysis and on-site audit verification indicated that the CFIA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on December 13, 2018, in Ottawa, Canada, with CFIA. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

The FSIS auditors identified the following findings:

Government Oversight (e.g., Organization and Administration)

- The CFIA allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CFIA's routine chemical residue program.
- In 13 of 14 audited establishments, the FSIS auditors identified deficiencies due to inadequate enforcement of sanitation standard operating procedures (sanitation SOP) and sanitation performance standards (SPS) requirements by CFIA inspection personnel.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- In the sole establishment audited that was operating under the HACCP-Based Inspection Program for swine, during the veterinary disposition of retained carcasses, CFIA did not require pluck (heart, lung, and liver) or viscera to be presented for final disposition by the veterinarian when a carcass was railed out for pathology. In another establishment, caul (omental) fat was being harvested prior to CFIA evisceration inspection for the presence of pathology. The establishment did not demonstrate how it would maintain segregation of harvested fat as a batch or a similar system for proper disposition.

Government Hazard Analysis and Critical Control Points (HACCP) System

- In six of 14 audited establishments, the FSIS auditors identified deficiencies related to HACCP plan design, monitoring, and recordkeeping.

Government Microbiological Testing Programs

- The CFIA does not require poultry establishments to collect and analyze samples for microbial organisms at the pre-chill location.
- Unfinished tasks were not properly documented as required in the CFIA's laboratory standard operating procedure.
- The tracking sheet related to analytical method MFLP76 did not indicate the date and time when the sample was put in and taken out of the incubator. The tracking sheet also did not indicate whether the sample remained in the incubator for the specified duration.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Maple Leaf Foods Inc. . Maple Leaf Consumer Foods Inc. 870 Lagimodiere Boulevard Winnipeg Manitoba	11/27/2018	1	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	
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	
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.	
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60. Observation of the Establishment

38. A hole in the wall connecting the maintenance room to a production room would allow vermin into the production area.
46. Dirt and debris was collected in multiple places on the floor in the spice room, an area of a localized oil spill on the floor was also observed was creating an insanitary condition as pieces oil soaked paper and debris were posing a likelihood of spice contamination.
A bag of unidentifiable chemical stored near the spice room posed the possibility of product adulteration with the unknown chemical.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/27/2018

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
Agromex Inc. 168, Rue Lague Ange-Gardien Quebec	12/07/2018	10	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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
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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.	
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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	
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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
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60. Observation of the Establishment

46. Just prior to entering the wash cabinet swine carcasses passed through a final trimming station with three trimmers responsible to trim inedible tissues of the moving carcasses. The auditor observed a heavy build-up of trimmed waste around the trimmers boots and underneath the grid platform on the floor was creating insanitary conditions in evisceration room. Tongues and heads of swine carcasses on the evisceration line were rubbing against foot cover plate of trimming platform and aprons of employees on the platform. The trimming plate laden with blood and trim waste needed immediate attention by the establishment to maintain sanitary opearional conditions.

55. Veterinary disposition for retained carcass did not require pluck (heart, lung and liver) and viscera to be presented, as auditor noted that a retained carcass for veterinary disposition did not include either pluck or viscera.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/07/2018

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
Elbee Meat Packers Limited 1 Glen Scarlett Road Toronto Ontario	11/27/2018	11	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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
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8. Records documenting implementation.	
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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.	
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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	
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. 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
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60. Observation of the Establishment

22. The CCP verification records did not include a result of the direct observation activity, however included initials and time of the verification activity. A CCP deviation record for SRM removal did not document the elimination of the cause of the deviation.

38. A live insect (boxelder) was observed on the floor in the chemical storage area near an exterior door. No edible product was stored or transported in this area.
39. Peeling paint was observed on wire coverings above exposed carcasses on the final rail of the slaughter floor. A gap in the door of the shipping area for boxed product was observed due to degrading weather stripping.

46. Hair was observed on the rump of a carcass that had passed the final rail inspection station. The carcass was immediately trimmed and all carcasses after the last acceptable CCP check were reinspected.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/27/2018

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
Expresco Foods Inc. . 8205, Route Transcanadienne St-Laurent Quebec	12/05/2018	36	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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
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10. Implementation of SSOP's, including monitoring of implementation.	
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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	
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	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
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60. Observation of the Establishment

41. Heavy dripping of meat juices from combo bins stacked on upper shelves to one stored below and coupled with condensation the in raw meat was causing detectable malodor, wetting of bins, and soaking of the wooden pallets from moisture in the room. Although, no direct product adulteration noted, the conditions observed in the cooler could result in contamination if not addressed urgently. CFIA inspectors requested immediate correction and issued a CAR.

46. Spice room had an extensive oil spillage and water stagnation in one corner of the room was creating insanitary conditions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/05/2018

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
Global Egg Corporation . 17 Newbridge Road Etobicoke Ontario	12/07/2018	36E	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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20. Corrective action written in HACCP plan.	
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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	
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. 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.	

60. Observation of the Establishment
No non-compliance identified.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/07/2018

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
Cargill Limited 472 Avenue & Highway 2A North High River Alberta	11/29/2018	93	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.

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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	
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
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60. Observation of the Establishment

39. Overhead structure above exposed product in meat fabrication room had rust, loose plumbing material, and dirt accumulation around steel pipes were observed in multiple locations. Rubber weather strips supporting the cooler door had collected black greasy particles and were fayed at places. Although no product contamination was observed at the time of audit, if not addressed food safety of product be compromised. CFIA issued a corrective action report for all observation made during the audit.

41. Beaded condensation over the exposed product was observed on production rails at various locations in coolers and in the fabrication room. The CFIA inspection personnel took immediate enforcement actions and tagged the product.

45. Multiple plastic cutting boards had numerous jagged corners and surfaces with visible chipped plastic material which could potentially contaminate product with such material.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/29/2018

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
Tri-Pet Holdings Incorporated 70 Glen Scarlett Road Toronto Ontario	11/30/2018	99	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.

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19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
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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	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
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54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

60. Observation of the Establishment

10. Offal meat transfer tube was not identified as having meat/fat residues from previous operations prior to release for start of operations by the establishment and CCA
19. The establishment's HACCP Plan did not adequately define the frequency of CCP verification procedures.
39. Cooler wall had exposed insulation in one area, in another area wall and juncture between panels was damaged and in disrepair in carcass holding area.
45. A stainless steel product shovel in the same work room was observed to have a crack/break and slightly knurled edge.
46. Hide pulling procedure (hide pulling machine) was observed to routinely cause contamination of carcasses due to swinging of the hide after detachment.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/30/2018

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
Sungold Specialty Meats Ltd. 4312 - 51st Street Innisfail Alberta	11/30/2018	136	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	
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17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
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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	
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.	

60. Observation of the Establishment

39. Multiples holes of varying sizes were observed in the walls of production rooms are potential for rodent or pest entry into the rooms.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/30/2018

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
Premium Brands Operating Limited Partnership 443 Wismer Street Waterloo Ontario	11/28/2018	229	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.

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15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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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	
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	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.	
58.	
59.	

60. Observation of the Establishment

39. The doors leading to the RTE packaging areas and drying room where Post Lethality Exposed RTE product is transported were frayed. Peeling paint was observed on the metal arm of the bin dumper that was used for dumping raw product in the sausage kitchen.

41. Frozen condensate was observed above freezers where RTE product was held and blowing on to an area storing exposed ham. No direct product contamination was observed. Condensate was dripping from pipes in a cooler storing raw hams. No direct product contamination was observed.

46. Standing water was observed adjacent to a rack of raw hams that were being temporarily stored in a hallway.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/28/2018

United States Department of Agriculture
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Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
King Cole Ducks Limited. 15351 Warden Avenuer R.R. 3 Newmarket Ontario	12/05/2018	255	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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
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11. Maintenance and evaluation of the effectiveness of SSOP's.	
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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.	X
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	
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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	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
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. Testing for indicator organisms	X
59.	

60. Observation of the Establishment

16. The CCA does not require establishments to record actual/quantifiable values for all results of CCP monitoring; establishment records results of CCP as “acceptable” when the critical limit is actually an enumeration of carcass dressing defects (i.e. 7 or less is acceptable per monitoring event).

18. Establishment could not support the monitoring procedure and frequency as effective in ensuring the critical limit was met for cooling of duck carcasses; routine monitoring of carcass temperature after chilling occurs in the thigh location. Carcass temperature was observed to be above the critical limit, while temperature checked in the breast location of the carcass was observed to be an additional (approximate) 4 degrees Celsius higher than the thigh location.

45. Metal tubing formed in a circular shape used for air agitation of chilling tubs are constructed in a way which does not allow inspection to ensure they are adequately cleaned.

58. The CCA does not require poultry establishments to collect and analyze samples for microbial organisms at the pre-chill location; establishment therefore only collects sample at post chill to evaluate process control.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/05/2018

United States Department of Agriculture
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Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Jacques Forget Ltee. 2215 Chemin Comtois St-Louis de Terrebonne Quebec	12/04/2018	466	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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Salmonella Performance Standards - Basic Requirements	
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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	X
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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

60. Observation of the Establishment

39. Loose plumbing material and exposed insulation were observed over a product rail carrying the beef quarters to the processing room
41. Over the product beaded condensation were observed in multiple chilling rooms.
45. Multiple totes for storing raw meat product were cracked from different places and had jagged surfaces or splitting fine material posing potential for product contamination
46. Poor draining caused water pooling in evisceration room.
55. Caul (omental) fat was being harvested prior to evisceration inspection for the presence pathology

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/04/2018

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
FGO Organic Processing Ltd. 194338 19TH Line Ingersoll Ontario	12/06/2018	663	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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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	
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	
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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.	

60. Observation of the Establishment

22. Establishment monitoring records of a critical limit were insufficient to show who was performing monitoring of the CCPs at different times and locations through the day. Additionally, records of a pre-requisite program were not sufficient to support the program as being implemented effectively.

39/46. Facility had chipping paint in limited areas throughout, loose caulk, metal in disrepair and residue buildup at door frames of several coolers or handles of coolers.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/06/2018

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
Protenery Natural Foods Corp. 125 East Beaver Creek Road Richmond Hill Ontario	11/29/2018	675	Canada
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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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
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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.	

60. Observation of the Establishment

10. The CCA does not require daily monitoring of operational sanitation.

22. The CCP verification records did not include a time of when the verification activity was completed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/29/2018

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
Quebec Inc,Marvid Poultry Canada Montreal North	12/06/2018	9020-2516	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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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	
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	
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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. Testing For Indicator Oganism	X
59.	

60. Observation of the Establishment

The CCA does not require poultry establishments to collect and analyze samples for microbial organisms at the pre-chill location.

26. Numerous poultry carcasses exiting chiller had varying size of attached feathers.

38. Rust and grease were accumulating on kick plates on evisceration line; frayed rubber sleeves, loosening Teflon caulking were observed on plumbing around chillers.

41. Beaded condensation on exposed or boxed products were observed in multiple locations during the operation.

39/46. In the evisceration room some areas under the kill line troughs for collecting slaughter waste was missing which was resulting in product accumulation on the floor and thereby creating insanitary operational conditions.

46. a)Poultry carcasses exiting the chiller into the cutup room had residual water that was dripping on the product stored underneath or on employees working under or around the overhead carcass rail was creating insanitary working conditions.

b) At the poultry parts salvage station, the design of parts holding container did not have provisions water drainage or continuous water supply to prevent fat or other extraneous material accumulating in the container. Scum of fat, meat and extraneous material buildup was creating insanitary conditions.

c) Poor drainage due to clogged drains resulted in water pooling was creating insanitary conditions in the evisceration room.

58. The CCA does not require poultry establishments to collect and analyze samples for microbial organisms at the pre-chill location.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/06/2018

Appendix B: Foreign Country Response to Draft Final Audit Report

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AOUT AUG 26 2019

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

SUBJECT: **Canada's Response to the United States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit (November 26 – December 13, 2018) Report on the Evaluating of the Canadian Food Safety System Governing the Production of Meat, Poultry and Egg Products Exported to the United States of America**

Dear Dr. Michelle Catlin,

I would like to provide you with the Canadian Food Inspection Agency's response to the draft report of the USDA-FSIS audit in Canada conducted from November 26 to December 13, 2018.

Our response is comprised of two tables as listed below:

- Annex I: Response of the Canadian Food Inspection Agency (CFIA) to the United States Department of Agriculture, Food Safety and Inspection Service (USDA –FSIS) Draft Audit (November 26 – December 13, 2018) Evaluating the Food Safety Systems Governing meat, poultry, and egg products exported to the USA
- Annex II: Canadian Food Inspection Agency (CFIA) comments and suggested amendments to the United States Department of Agriculture, Food Safety and Inspection Service (USDA –FSIS) Draft Audit (November 26 – December 13, 2018) Evaluating the Food Safety Systems Governing meat, poultry, and egg products exported to the USA

The CFIA would appreciate an opportunity to discuss these points directly prior to the publication of the audit report. Some specific comments to be discussed can be found in Annex II.

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

Yours sincerely,

Dr. Parthiban Muthukumarasamy
Director
Food Import and Export Division

Attachments (2):
Annex I: Response of the Canadian Food Inspection Agency (CFIA) to the United States Department of Agriculture, Food Safety and Inspection Service (USDA –FSIS) Draft Audit (November 26 – December 13, 2018) Evaluating the Food Safety Systems Governing meat, poultry, and egg products exported to the USA
Annex II: Canadian Food Inspection Agency (CFIA) comments and suggested amendments to the United States Department of Agriculture, Food Safety and Inspection Service (USDA –FSIS) Draft Audit (November 26 – December 13, 2018) Evaluating the Food Safety Systems Governing meat, poultry, and egg products exported to the USA

Annex I

Response of the Canadian Food Inspection Agency (CFIA) to the United States Department of Agriculture, Food Safety and Inspection Service (USDA –FSIS) Draft Audit (November 26 – December 13, 2018)

Evaluating the Food Safety Systems Governing meat, poultry, and egg products exported to the USA

USDA-FSIS Draft Report Reference	USDA- FSIS draft report text	CFIA comments
Executive Summary and X. Conclusions and Next Steps	**Government Oversight (e.g., Organization and Administration)** -The CFIA allows inspection personnel to issue an export certificate intended for export to the United States before test results are known from CFIA's routine chemical residue program.	- The NCRMP is not a hold and test or lot by lot testing program – it is a true monitoring program conducted to monitor effectiveness of policies/programs that maintains consumer confidence in safety of food supply. As noted on page 18 of the report, if and when the CFIA becomes aware of any information– monitoring results included– that suggests that products are adulterated or out of compliance, (and regardless of products final destination); the Agency has the tools in place to protect consumers and to impose a hold and test program (directed/compliance testing) to ensure that (potentially) adulterated products are not distributed for human consumption. The CFIA evaluates laboratory results from the NCRMP and may request a health risk assessment from Health Canada to determine if there is an unacceptable risk for consumers. If the residue(s) pose an unacceptable health risk to consumers, the CFIA will initiate enforcement actions, including public warnings and recalls. Any such actions would also be communicated with foreign competent authorities if it is determined that the

		implicated product was exported. CFIA is not in agreement with the general statement on page 10 indicating that the CFIA had not identified nor documented the deficiencies that could lead to potential insanitary conditions affecting all audited establishments. The word "all" is not accurate and should be replaced with the word some.
	- Page 10 - The CFIA had not identified nor documented the deficiencies that could lead to potential insanitary conditions affecting all audited establishments.	-Following the audit, the CFIA inspector/veterinarian-in-charge of each establishment followed up on the deficiencies as part of the CVS inspection process by issuing a Corrective Action Request (IR-CAR). The operator has provided a written corrective action plan including the root cause of the issue, corrective actions and preventative measures. Subsequently, the CFIA inspector/veterinarian in charge of each establishment has provided written verification that all corrective actions were effective in addressing the findings, resulting in the IR-CAR being closed.
	-In 13 out of 14 audited establishments, the FSIS auditors identified deficiencies due to inadequate enforcement of sanitation standards operating procedures (sanitation SOP) and sanitation performance standards (SPS) requirements by CFIA inspection personnel.	-CFIA is of the opinion that the quantitative description creates a speculative understanding of the audit findings. CFIA therefore requests that the statement "*in 13 out of 14 establishments*" be removed.
	Government Statutory Authority and Food Safety and Other Consumer Protection Regulations -In the sole establishment audited that was operating under the HACCP -Based	-According to Section 83(3) of the *Meat Inspection Regulations*, it is acceptable for the viscera to not be

	operating under the HACCP -Based Inspection Program for swine, during the veterinary disposition of retained carcasses, CFIA did not require pluck (heart, lung, and liver) or viscera to be presented for final disposition by the veterinarian when a carcass was railed out for pathology.	*Regulations*, it is acceptable for the viscera to not be presented with the carcass during the inspection of a carcass retained at the veterinarian station as directed by the CFIA veterinarian in charge. During the audit it was observed that a carcass with dry fibrous adhesions was sent to the veterinary disposition rail without accompanying viscera. According to Chapter 17 of the CFIA Meat Hygiene, Manual Of Procedures dry fibrous adhesions is an operator managed condition which, as a stand-alone condition without systemic changes, is not listed as a condemnable condition in Canadian and US guidance material. It would not have been necessary to direct such an afflicted carcass to the CFIA veterinary held rail. Chapter 17 also states that carcasses sent to the CFIA veterinary held rail should be for veterinary disposition purposes only. As per the above reference, dry fibrous adhesions do not require veterinary disposition in either country. CFIA is of the understanding that the FSIS requirement for viscera to be sent with the carcass to the veterinary rail applies largely to condemnable carcasses. The carcass seen on the day of the audit did not exhibit a potentially condemnable condition. A supervisory review of procedures regarding the direction of carcass to the vet rail was conducted at the establishment to confirm compliance with procedures. If an isolated situation arises and the inspector is uncertain as to the degree/nature of pathology and or disposition of a condition that is seen on the carcass, as a precautionary measure, the carcass will be sent to the veterinary rail for examination and final disposition as a learning tool for all parties.

		References: 17.4 Maintaining Identity of the Animal http://www.inspection.gc.ca/food/archived-food-guidance/meat-and-poultry-products/manual-of-procedures/chapter-17/eng/1367723343665/1367723573062?chap=5#s10c5 Archived - Annex F: Disposition for Red Meat Species http://www.inspection.gc.ca/food/archived-food-guidance/meat-and-poultry-products/manual-of-procedures/chapter-17/annex-f/eng/1504808412701/1504808413342
	In another establishment, caul (omental) fat was being harvested prior to CFIA evisceration inspection for the presence of pathology. The Establishment did not demonstrate how it would maintain segregation of harvested fat as a batch or a similar system for proper disposition.	-CFIA procedures allow bulk harvesting of carcass parts prior to post mortem inspection if the operator has a HACCP Plan in place which clearly stipulates that the entire container (containing multiple tracked items) is condemned if only one of the contributing carcasses is condemned. In this case the condemned carcass and all the parts remain under inspection control until the operator disposes of them in accordance with the veterinarian's instructions. The particular establishment in question has written procedures in place requiring that when a carcass is found to be non-compliant following post-mortem inspection, all reconciled offal in the container collected before inspection must be discarded.
	Government Hazard Analysis and Critical Control Points (HACCP) System -In six of 14 audited establishments, the FSIS	-The deficiencies identified were followed up by the

	auditors identified deficiencies related to HACCP plan design, monitoring, and recordkeeping.	CFIA's inspector/veterinarian in charge of each establishment using the CVS inspection process. These findings have been addressed by the operator. CFIA is of the opinion that the quantitative description creates a speculative understanding of the audit findings. CFIA therefore requests that the statement "*in six out of 14 establishments*" be removed.
	Government Microbial Testing Programs -The CFIA does not require poultry establishments to collect and analyze samples for microbial organisms at the pre-chill location.	-CFIA policy requires the industry licence holder conduct post-chill testing for Salmonella, Campylobacter and Generic E. coli in all poultry species. At the present time CFIA does not require the poultry establishments to conduct pre-chill micro testing. That is because • CFIA requires dressing procedures to be completed before chilling , • CFIA does not allow the chiller to be part of the poultry dressing procedures. The evisceration procedures are based upon regulatory requirements, guidance documents, process control standards, which are validated by post-chill pathogen reduction program. Additionally, CFIA enforces a zero tolerance for fecal contamination, Septicaemia and Toxaemia during pre-chill poultry inspection and examination activities. **The regulatory requirements, process controls and pathogen reduction standards are explained as below**:

		1) Legislation for controlling contamination and conducting Pathogen Reduction Standards at the time of the audit before enforcing the *Safe Food for Canadians Regulations (SFCR)* Meat Hygiene Manual of Procedures, Chapter 19 http://www.inspection.gc.ca/food/archived-food-guidance/meat-and-poultry-products/manual-of-procedures/chapter-19/eng/1360962146879/1360962607138 2) Safe Food for Canadians Regulations in 2019: Safe Food for Canadians Regulations Section 47 (1) requires an operator must identify and analyze the biological, chemical and physical hazards that present a risk of contamination of a food. Reference: Safe Food for Canadians Regulations https://laws-lois.justice.gc.ca/eng/regulations/SOR-2018-108/FullText.html 1) Inspection standards: Both Modernized Poultry Inspection System (MPIP) and Traditional Inspection systems require prevention of contamination at all steps during evisceration. Reference: Controls on contamination http://inspection.gc.ca/food/food-specific-requirements-and-guidance/meat-products-and-food-animals/controls-on-contamination/eng/1545193097653/1545193144984 Dressing procedures and Preparation of edible parts http://www.inspection.gc.ca/food/food-specific-requirements-and-guidance/meat-products-and-food-

		animals/dressing-procedures-edible-parts/eng/1544042033189/1544042477514 **Process Controls:** 2) On-Farm Programs Canadian Poultry Farms have voluntarily implemented On-Farm Food Safety Program for controlling Biological, Chemical and Physical Hazards. The on-farm hazards are reported to CFIA before birds arrive at the slaughter establishment using Animal Information Documents (also known as Flock Sheets) 3) Process Controls during processing CFIA requires the slaughter establishments implement process controls which ensure the visibly contaminated carcass and viscera are removed at initial stages during processing and evisceration process remains under control at all times. Depending upon type of inspection the process controls are listed as below: a. Evisceration Standards (MPIP and Traditional) b. Presentation Standards (MPIP and Traditional) c. Defect Detection Standards (MPIP) d. Carcass Dressing Standards (MPIP) e. Poultry Rejection Process (MPIP) Reference: New SFCR based guidance to be published soon. Until new guidance is published, the archived guidance will be implemented located at the following URL: http://www.inspection.gc.ca/food/archived-food-guidance/meat-and-poultry-products/manual-of-procedures/chapter-

		19/eng/1360962146879/1360962607138 4) Reprocessing and Reconditioning: The poultry slaughter establishments are allowed reprocessing (for fecal contamination in cavity) and reconditioning (for pathological defects in cavity). Such carcasses require micro testing for validations. For results to be acceptable, the micro levels on reprocessed and reconditioned carcass should be very similar to normal carcass processed on same evisceration line. This is assesses using microbial levels using statistical process using geometric mean and Chi-square test. The geometric mean of treated carcasses must be equal to or less than that of line run production or is not significantly different as determined by statistical analysis. Reference: Poultry Off-line and On-line Reprocessing and Reconditioning Procedures http://www.inspection.gc.ca/food/food-specific-requirements-and-guidance/meat-products-and-food-animals/poultry-off-line-and-on-line-reprocessing-and-reco/eng/1540913576598/1540913800885 5) Antimicrobial usage in poultry establishments: As well, microbial control interventions, whether a chemical application or other (for example, steam or hot water vacuum, use of bacterial phages), can be integrated into a licence holders preventive control plan to manage microbial risks, however these controls must be validated and they must also, if applicable, comply with section 4 of the *Food and Drugs Act*. Antimicrobial usage is not a mandatory requirement in Canada. All the visible defects (including fecal

		contamination) need to be removed prior to chilling. The establishments may choose to use antimicrobials for controlling microbiological hazards. When an antimicrobial is used in a meat establishment, the licence holder will be required to follow guidance or meet an equivalent outcome. Reference: Microbial controls http://www.inspection.gc.ca/food/food-specific-requirements-and-guidance/meat-products-and-food-animals/microbial-controls/eng/1558623353675/1558623353914 **Pathogen Reduction Standards:** As part of measuring the effectiveness of the PCP programs Preventative Control Plan and/or intervention measures all licence holders of federal poultry slaughter establishments must implement pathogen reduction program. Licence holders must use a validated pathogen reduction standard for following pathogens: • Salmonella spp. • Campylobacter spp. • generic Escherichia coli (E. coli) – Biotype I Most of the establishments are using FSIS based Pathogen Reduction Standards. Reference: Poultry Pathogen Reduction Program http://www.inspection.gc.ca/food/food-specific-requirements-and-guidance/meat-products-and-food-animals/poultry-pathogen-reduction-program/eng/1539715737614/1539715737915
	-Unfinished tasks were not properly documented as required in the CFIA's laboratory standard operating procedure.	-At the time of the audit, Dec 03, 2018, the auditor noted that the items were not signed off by the Quality Manger, as completed by this date. It was explained that completed audit items are reviewed and verified as

		completed by the Quality Manager before they are signed off as completed. It is part of the Calgary Laboratory's regular practice and in conformance with their Quality Management System documentation that potentially completed items are reviewed, verified and signed off prior to each quarterly quality meeting by the Quality Manager. So, items completed in November 2018 would not be signed off until January 2019. The next quarterly quality meeting occurred on January 9th 2019. The items were verified and signed off prior to the meeting. Completion of items is a standing agenda item and completion of each unit's audit items are reviewed at each quarterly quality meeting by the management team according to the management system documentation.
	-The tracking sheet related to analytical method MFLP76 did not indicate the date and time when the sample was put in and taken out of the incubator. The tracking sheet also did not indicate whether the sample remained in the incubator for the specified duration.	- The Calgary laboratory records the date started on the tracking sheet related to analytical method 76. The tracking sheet also indicates the time the samples are placed into the incubator and the time they are taken out of the incubator. These two recorded times indicate the period of time the sample is in the incubator.

Annex II

Canadian Food Inspection Agency (CFIA) comments and suggested amendments to the United States Department of Agriculture, Food Safety and Inspection Service (USDA –FSIS) Draft Audit (November 26 – December 13, 2018)

Evaluating the Food Safety Systems Governing meat, poultry, and egg products exported to the USA

USDA-FSIS Draft Report Reference	USDA- FSIS draft report text	CFIA
IV Component One: Government Oversight (e.g. Organization and Administration)	Page 10 – ~~The CFIA allows inspection personnel to issue an export certificate intended for export to the United States before test results are known from CFIA's routine chemical residue program.~~ ~~In 13 of 14 audited establishments~~, the FSIS auditors identified deficiencies related to enforcement of sanitation SOP and SPS requirements by CFIA inspection personnel.	The CFIA requests that this statement is removed from the report as it has potential to mislead readers that Canadian meat is exported to the US without proper controls. Please see CFIA comments provided in Annex 1 about this finding. - – CFIA is of the opinion that the quantitative description creates a speculative understanding of the audit findings. CFIA therefore requests that the statement "*in 13 out of 14 establishments*" be removed.
VII Component Four: Government Hazard Analysis and Critical Control Point (HACCP) System	Page 15 – The FSIS auditor's identified the following ~~systemic~~ finding Page 16 – ~~In six of 14 audited establishments~~, the FSIS auditors identified deficiencies related to HACCP plan design, monitoring or recordkeeping.	The CFIA requests that the word "systemic" is removed from this statement as it overstates the relevance of the observations. – CFIA is of the opinion that the quantitative description creates a speculative understanding of the audit findings. CFIA therefore requests that the statement "*in six out of 14 establishments*" be removed.
IX Component Six: Government Microbiological Testing Programs	Page 22, second paragraph – Consistent with the provisions of Sub-sections 4(3) and 9(26) of the ~~poultry~~ Processed Egg Regulations (PER) …	Add "Sub" to the word "section", and replace the word poultry with processed.
X. CONCLUSIONS AND NEXT STEPS	Page 23, – ~~In 13 of 14 audited establishments~~, the FSIS auditors identified deficiencies due to inadequate enforcement of sanitation	Please see comments in the above sections.

	standard operating procedures (sanitation SOP) and sanitation performance standards (SPS) requirements by CFIA inspection personnel. – ~~In six of 14 audited establishments~~, the FSIS auditors identified deficiencies related to HACCP plan design, monitoring, and recordkeeping.	

Legend:

– Deletion in Red text

–Addition with Yellow highlight.