USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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APR 1 2 2017

Daniel Miller
Executive Director
Food Import/Export and Consumer Protection Directorate
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Ottawa ON K1A 0Y9

Dear Mr. Miller,

The Food Safety and Inspection Service (FSIS) onsite audit conducted from September 12 through September 30, 2016, predicates our continued review and assessment of Canada's inspection system. The outcome of our review of the additional information you provide will be provided in a separate letter. Enclosed is a copy of the final audit report. The comments received from the Government of Canada are included as an attachment to the report.

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

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN CANADA

September 12-30, 2016

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING THE PRODUCTION OF MEAT, POULTRY, AND EGG PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

April 10, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 12 - 30, 2016, to determine whether Canada's food safety inspection system governing the production of meat, poultry, and egg products remains equivalent to that of the United States with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. Canada is eligible to export raw and processed meat, raw and processed poultry, and egg products to the United States.

The audit focused on six main 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. In addition, the FSIS auditors verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the 2014 FSIS audit findings had indeed been implemented.

The FSIS auditors reviewed management, supervision, and administrative functions at the CCA headquarters, three regional offices, seven slaughter and processing establishments (two swine, two bovine, two poultry, one bovine/caprine), four processing-only establishments, one egg processing facility, one cold storage facility, and two laboratories to verify that the national system of inspection, verification, and enforcement is being implemented as required to maintain equivalence.

The FSIS auditors identified the following systemic findings and isolated 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 this 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.

During the audit exit meeting, the CCA committed to begin addressing the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite equivalence verification audit of Canada's meat, poultry, and egg products inspection system from September 12 - 30, 2016. The audit began with an entrance meeting held on September 12, 2016, in Ottawa, Canada with representatives from the Central Competent Authority (CCA), the Canadian Food Inspection Agency (CFIA), and three FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine, ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat, poultry, and egg products maintains equivalence to that of the United States, with the ability to export products, which are safe, wholesome, unadulterated, and properly labeled. This audit also included verification of corrective actions implemented by the CCA in response to the previous FSIS audit that occurred in 2014. The FSIS auditors were accompanied by representatives from the CCA and the regional and local inspection offices.

FSIS applied a risk-based procedure which 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) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA through a self-reporting process.

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 CCA headquarters, three regional offices, and 13 local inspection offices. The FSIS auditors evaluated the implementation of control systems in place, which ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) § 327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems; § 381.196, the FSIS regulations addressing eligibility of foreign countries for importation of poultry products into the United States; and § 590.900, the FSIS regulations addressing importation of egg products or

restricted eggs into the United States. Additionally, one government and one private laboratory were audited to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Canadian Food Inspection Agency (CFIA) – Ottawa
	Regional	3	• Toronto Regional Office - Toronto • Vancouver Regional Office - Vancouver • Montreal Regional Office - Montreal
Laboratories		2	• Calgary (Microbiology) - Calgary • Maxxam Analytics (Residue) - Burnaby
Slaughter and Processing Establishments		7	• Brooks, Alberta • Red Deer, Alberta • Abbotsford, British Columbia • Guelph, Ontario • St. Germain-de-Grantham, Québec • Ange-Gardien, Québec • Montréal, Québec
Processing Establishments		4	• Brantford, Ontario • Brampton, Ontario • Burlington, Ontario • Anjou, Québec
Egg Processing Establishment		1	• Abbotsford, British Columbia
Cold Storage Facility		1	• Calgary, Alberta

The audit was undertaken 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 Federal 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);
- Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) regulations;
- The Egg Products Inspection Act (21 U.S.C. 1031 et seq.); and
- The Egg Products Inspection Regulations (9 CFR Parts 590 and 592).

The audit standards applied during the review of Canada's food inspection system included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) the following subsequent equivalence determinations that have been made by FSIS under provision of the World Trade Organization's Sanitary/Phytosanitary Agreement.

Currently, Canada has equivalence determinations in place for the following:

- *Salmonella* testing of raw product;
    - Establishments select samples; and
    - Private laboratories are overseen directly by the government or the government-contracted entities analyze samples.
- *Escherichia coli (E. coli)* O157:H7 compositing of samples prior to screening test;
- High Line-Speed Inspection System (HLIS) and HACCP- Based Inspection Program (HIP) for bovine and swine slaughter respectively;
- Canadian residue control program;
- Generic *E. coli* testing for minor species,
- Ready-to- Eat (RTE) government verification testing program for *Listeria monocytogenes (Lm)* in meat and poultry;
- Microbiology Food Laboratory Procedure (MFLP) -16 analytical method for *E. coli* O157:H7 analysis in raw ground beef and beef components;
- Microbiology Food Health Protection Branch (MFHPB) -30 analytical method for *Lm* analysis in meat and eggs;
- MFLP-28 analytical method for *Lm* analysis in eggs;
- MFLP-29 analytical method for *Salmonella* spp. analysis in meat and eggs;
- MFHPB-20 analytical method for *Salmonella* spp. analysis in meat and eggs;
- MFHPB-10 analytical method for *E. coli* O157:H7 analysis in meat and eggs;
- MFLP-28 Bax® analytical method for *Lm* analysis in RTE products;
- MFLP-15 - The Detection of *Listeria* Species from Environmental Surfaces using the DuPont Qualicon BAX®;
- MFHPB-24 analytical method for *Salmonella* spp. analysis in foods by the VIDAS SLMTM screening method; and
- MFLP-20 analytical method, Genequence®, for *Salmonella* spp. analysis in meat and eggs.

III. BACKGROUND

Canada is eligible to export fresh and processed meat, poultry, and egg products to the United States and is not under any restrictions by the USDA's Animal and Plant Health Inspection Service (APHIS). Between January 1, 2013, and December 31, 2015, Canada exported approximately 4,809,876,862 pounds of meat and poultry products to the United States, of which 200,363,921 pounds were re-inspected at POE in the United States. A total of 1,652,553 pounds was rejected at POE, of which 129,871 pounds were failures due to various public health reasons, including the presence of fecal matter, ingesta, extraneous material, or failed analytical tests for correct species and pathology. Additionally, a total of 19,615,992 pounds of egg products was presented at POE for reinspection. A total of 60 pounds of egg products was rejected for reasons other than food safety and returned to Canada.

The audit included visits to the establishments implicated in these POE violations for which FSIS concluded that the CCA had satisfactorily worked with producing establishments to identify the root causes of the problems and institute appropriate corrective actions.

The FSIS final audit reports for Canada's food safety system are available on the FSIS Web site 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 reviewed was Government Oversight. The FSIS import eligibility requirements state that a foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the United States' meat, poultry, and egg products inspection system. The evaluation of this component included a review of documentation submitted by the CCA as support for the responses and corrective actions, as well as onsite record reviews, interviews, and observations made by the FSIS auditors at government offices and in the audited establishments.

There have been no major changes in the CCA's organizational structure since the last FSIS audit. The president of CFIA is the head of CCA. The CFIA's president is assisted by an Executive Vice President and eight branch Vice Presidents. The CCA's food safety mission is organized and executed by three specific branches: the policy and program branch, the operations branch, and the science branch. Each branch has its own head with a Vice President. The Vice President of the operations branch is mainly responsible for field operations.

At the field level, the CCA is organized into four areas: Atlantic area operation, Quebec area operation, Ontario area operation, and Western area operation. Each of the four area operation offices is led by the Area Director General (ADG), who is assisted by an Area Chief Inspector (ACI), a Regional Chief Inspector (RCI), and an Inspection Manager (IM). The responsibilities of Inspection Managers and Regional Directors are to review Compliance Verification System (CVS) data reports to ensure awareness of trends and 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 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 CVS in their area; respond to issues/questions about 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; complete a Verification Task Comments Submission Form whenever the need for a change to a verification task is identified; and participate as required in the completion of the Section 4 verification tasks.

The responsibilities of Regional Veterinary Officers (RVOs) at slaughter operations and Food Processing Supervisors (FPSs) at processing operations include conducting the periodic supervisory visits, completing the off-site and onsite components of supervisory oversight, providing verbal

feedback and immediate reinforcement to the inspection personnel, and providing required support to correct identified inconsistencies or deficiencies.

The regions assign competent and qualified inspectors to establishments eligible to export to the United States. At the establishment level, the inspection personnel are responsible for: ensuring that all applicable verification tasks are assigned to the establishment; conducting verification tasks according to the national frequency; taking and documenting enforcement action(s) when necessary to protect public health; communicating verification task results to the operator by issuing Verification Reports and Inspection Report - Corrective Action Requests (IR-CARs); assessing the operator's action plans submitted in response to Corrective Action Requests (CARs); following up on items requiring correction that were identified on the Verification Report; and following the regulatory enforcement actions and procedures.

The CCA maintains adequate administrative and technical support to operate its laboratory system. The CFIA's Laboratory Coordination Division (LCD) in Ottawa provides oversight for the private and government laboratory systems. Government and private laboratories are accredited by the Standards Council of Canada (SCC) and /or the Canadian Association for Laboratory Accreditation (CALA) for International Standard Organization (ISO) 17025 accreditation.

The CCA's inspection personnel utilize the CVS as a task-based inspection tool to verify that the food industry is continually complying with Canada's federal food safety regulations and policies. The CVS verification activities are documented on a verification worksheet, a verification report, and a corrective action request in an IR-CAR. Each item is described below.

- Verification worksheet: The main purpose of the verification worksheet is to identify any items requiring correction by the establishment that did not result in the issuance of an IR-CAR. In addition, verification worksheets also document the daily presence of the CCA's inspection personnel at the regulated establishments.

- Verification report: The verification report identifies the number of any IR-CARs that have been generated and issued to the establishment. The verification report is used to communicate to the establishment any items requiring correction that were identified during the completion of the verification tasks (other than those non-compliances recorded on an IR-CAR). All the information that appears in the verification report is automatically populated from the data entered by the inspector on the verification worksheet.

- IR-CAR: An IR-CAR is issued to an establishment by the CCA inspectors whenever the results of a verification task are rated unacceptable. The IR-CAR describes the non-compliance and requires the establishment management to implement corrective measures by providing an acceptable action plan by the date specified by the inspector. The IR-CAR also describes the information gathered during the follow-up inspection. An inspector can close an IR-CAR upon verification of an effective implementation of corrective action. If the inspector determines that the non-compliance has not been corrected, the inspector records the information gathered that supports the decision not to close the IR-CAR in the follow-up section of the IR-CAR, and the IR-CAR remains open. A copy of the follow-up section of the IR-CAR is provided to the establishment. The inspector initiates enforcement actions listed in Chapter 14 of the Meat Hygiene Manual of Procedures (MHMOP).

The enforcement actions consist of progressively stricter steps, which can range from holding the product under the CCA's tag to termination of the establishment's registration. An inspector requests a review by the management if an IR-CAR cannot be closed because of any unacceptable Corrective Action Plan (CAP), including lack of implementation or inadequate corrective actions proffered by the establishment. These IR-CARs are reviewed by CCA supervisors and inspection managers. All the supervisors and managers reviewing the IR-CAR must document their reviews and recommendations on an Enforcement Tracking Form.

The frequencies of inspection verification tasks are risk-based. The MHMOP provides guidance for the CCA inspection personnel on the verification process and describes the verification task procedures in detail. The MHMOP also specifies the required minimum frequency for the inspection personnel to conduct each task. The FSIS auditors observed in-plant inspection verification activities in all audited establishments and reviewed the CCA's verification documentation listed above, which included detailed inspection verification results. These verification activities included direct observation of operations and review of the establishments' records. The FSIS auditors verified through the review of trend analysis documentation that the CCA increases its pre-operational verification task frequency when the inspection personnel identifies non-compliances during hands on verification tasks for pre-operational sanitation inspection.

Periodic supervisory reviews are divided into supervisory oversight and forecasting activities. The supervisory oversight is a tool to assess, improve, and report on the effectiveness of the CCA inspection personnel's activities. In order to ensure uniformity and consistency in the delivery of verification activities across the inspection system, the inspection personnel are required to use a standard form "OG-2016-0805: Supervisory Oversight in Meat Establishments." This form consists of seven sections as follows: CVS Record Review, Compliance Verification, Export Certification, Import Product Verification, Slaughter, Forecasting, and Sampling.

Forecasting is another supervisory tool that assesses the establishment's performance through a comprehensive onsite inspection of the facility and review of the establishment's documents. Forecasting is conducted monthly in slaughter establishments and quarterly in processing establishments. The results of forecasting activity are rated as acceptable or not acceptable. 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 monthly CVS tasks. During the onsite audit, the FSIS auditors verified that RVOs and FPSs are conducting supervisory oversight and forecasting at all the audited establishments in accordance with the CCA requirements.

Since the last FSIS audit in 2014, the CCA has provided ongoing training programs to its inspection personnel. FSIS interviewed a number of the inspection personnel to assess their knowledge, skills, and abilities and reviewed their training records. In addition, the FSIS auditors observed in-plant inspection personnel and laboratory personnel while they were conducting their inspection activities. The FSIS auditors verified that both in-plant inspection and laboratory personnel have attended the ongoing training and have sufficient training to perform their inspection activities.

The FSIS analysis and onsite verification activities indicated that the CCA's meat, poultry, and egg products inspection system has organizational structure to provide ultimate control, supervision, and

enforcement of regulatory requirements. However, FSIS identified systemic and isolated findings in regard to post-mortem carcass-by-carcass inspection, sanitation, and HACCP requirements.

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 carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; and periodic supervisory visits to official establishments.

The evaluation of this component included an analysis of information provided by the CCA through the Self Reporting Tool (SRT), interviews, and observations during the onsite portion of the audit. During the onsite audit of seven establishments (two swine, two bovine, two poultry, and one ovine/caprine slaughter and processing), the FSIS auditors accompanied the CCA inspectors and observed the implementation of verification activities of the in-plant inspection personnel. The verification activities observed included ante-mortem inspection, humane handling and slaughter, post-mortem inspection, *Salmonella* and generic *E. coli* sample collection, verification of pre-operational and operational sanitation monitoring procedures, and HACCP verification activities including the zero tolerance verification.

The CCA has implemented an alternative post-mortem inspection system known as HACCP-based slaughter inspection program (HIP) for swine, high line speed inspection system (HLIS) for bovine, and modernized poultry inspection program (MPIP) in poultry. FSIS has previously determined these alternative post-mortem inspection systems as equivalent to the FSIS inspection system. The FSIS auditors noted that the audited slaughter establishments were in compliance with the CCA requirements regarding implementation of HIP, HLIS, and MPIP standards.

The FSIS auditors interviewed the establishments' quality control staff and the CCA's in-plant inspection personnel and reviewed both establishment and inspection-generated records related to monitoring and verification of the Critical Control Points (CCPs) in accordance with HIP, HLIS, and MPIP requirements.

The FSIS auditors observed in-plant inspection personnel conducting HACCP hands-on verification activities for zero-tolerance (feces, ingesta, and milk) CCPs prior to the final carcass wash. No deviation from the critical limits was observed by either the inspection personnel or the FSIS auditors on the day of the audit.

During the last FSIS onsite audit in 2014, the FSIS auditors reported that some of the audited slaughter establishments had placed the location of the zero tolerance CCP monitoring and verification after the final carcass wash without having sufficient supporting documentation. During the current audit and as part of FSIS follow up verification of previous audit findings, the FSIS auditors verified that in all of the slaughter establishments audited the establishments' written HACCP plans had placed the monitoring and verification of zero tolerance CCPs before the final carcass wash.

The FSIS auditors assessed ante-mortem and post-mortem inspection examinations through onsite record reviews, interviews, and observations of in-plant inspection personnel performing ante-mortem and post-mortem examinations in five red meat and two poultry slaughter and processing establishments audited. The CCA inspection personnel are required to conduct ante-mortem inspection in accordance with the CCA's regulations on all livestock and poultry intended for export to the United States. The CCA is also responsible for verifying that livestock and poultry are humanely handled and slaughtered in accordance with CVS-related tasks. In addition, the CCA must ensure that meat, poultry, and egg products eligible for export to the United States are from certified Canadian establishments. The FSIS auditors verified that the CCA is fulfilling these obligations.

The FSIS auditors observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented during post-mortem inspection. In the red meat slaughter and processing establishments, the FSIS auditors observed the performance of the in-plant inspection personnel examining the heads, viscera, and carcasses to assess whether the proper incision, observation, and palpation of required organs and lymph nodes are conducted in accordance with the CCA's requirements. The FSIS auditors noted that government inspectors appear to not be conducting 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 using a statistical sample. A request for an equivalence determination on the individual sanitary measure that fully clarified the procedure has not been submitted to FSIS for review prior to the FSIS auditors observing this issue. This could be a significant finding for FSIS and could be inconsistent with FSIS requirements (FMIA, 21 U.S.C. 604). FSIS and CFIA are now communicating to resolve this issue since FSIS inspection system requires reinspection of all carcasses with defective conditions by the government in-plant inspection personnel.

In the poultry slaughter establishments, FSIS observed the in-plant inspection implementation of both ante-mortem and post-mortem inspection procedures that are in accordance with the CCA's MPIP requirements. The CFIA ante-mortem inspection of poultry includes a review of the flock sheet followed by an inspection by a CFIA veterinarian or a designated CFIA inspector of birds in shipping crates either on the transport vehicle or in the staging area. The FSIS auditors noted that the audited establishments meet post-mortem inspection facility requirements as required by MPIP.

The FSIS auditors observed the functions of the in-plant inspection personnel who were conducting daily inspection verification activities in the audited establishments. These daily verification activities were being conducted properly and included direct observation of establishment activities and review of establishment records, including HACCP, Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), *Salmonella*, and generic *E. coli* sampling techniques and records.

During the onsite audit of the CCA headquarters and regional offices located in Toronto, Montreal, and Vancouver, the FSIS auditors verified that the CCA requires all establishments that produce non-heat treated RTE meat and poultry products for export to the United States to have documentation that validates their process as being capable of producing a 5-log (meat) or 7-log (poultry) reduction of *Salmonella.* The in-plant inspection personnel verify this through observation and document review at the establishment level. In addition, the inspection personnel located at the area offices and the Technical Expertise and Advice of the CCA verify the establishments' validation through record reviews.

The CCA regulates shell egg and processed egg products manufactured in federally inspected Canadian establishments. The legislation that governs processed egg products are the Canada Agricultural Products Act (CAPA), Food and Drugs Act (FDA), and Consumer Packaging and Labeling Act. The in-plant inspection personnel perform various tasks to ensure that processed egg products are being prepared, packaged, and labeled in a manner that meets the requirements for sanitation, operation, and maintenance in accordance with the CCA's Processed Egg Regulations. The FSIS auditors verified that the CCA has provided continuous inspection coverage in accordance with USDA's Egg Products Inspection Act requirements. The FSIS auditors noted and verified through document review that the frequency of pre-operational inspection examination is daily when producing product for export to the United States. The routine frequency for the domestic market is based on 50 percent inspection coverage of the total production time. The inspection samplings included microbiological, chemical residue, and compositional sampling. The inspection sampling is conducted per a pre-assigned frequency in accordance with a sampling plan assigned to each area. The Area Operations Specialist or Regional Specialist conducts the CCA's egg audit Program Review. These program reviews are conducted four times per year in egg processing establishments eligible to export to the United States.

The FSIS analysis and onsite verification activities indicated that the CCA's meat, poultry, and egg products inspection system has the legal authority and a documented regulatory framework to implement the CCA's regulatory requirements for this component. However, FSIS identified a significant finding related to the inadequacy of the CFIA's inspection post-mortem verification procedures for carcass-by-carcass inspection.

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 CCA requires each official establishment to develop, implement, and maintain written standard procedures to prevent direct product contamination or insanitary conditions.

At 13 establishments audited (seven slaughter and processing, four processing, one egg processing facility, and one cold storage), the FSIS auditors verified that each facility had developed and implemented sanitation programs in accordance with the provisions prescribed in section 34.2 of *Meat Inspection Regulations, 1990* requirements. Sanitation and pest management requirements are one of the seven foundational components within prerequisite programs upon which the HACCP plan of a food manufacturing establishment is built. Prior to developing HACCP plans, each certified establishment is required to develop and implement prerequisite programs to control the likelihood of introducing food safety hazards to the product through the work environment and operational practices.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs at all of the audited establishments and determined them to be in compliance with the regulations and policies in the MHMOP. In two of the audited establishments, the FSIS auditors also verified the actual pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of processing areas. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification inspection. The in-plant inspection personnel conducted this activity in accordance with the established procedures.

The FSIS auditors observed in-plant inspection verification of operational sanitation procedures in all audited establishments and compared their overall sanitary conditions to the CCA's documentation. These verification activities included direct observation of operations and review of the establishments' records. The FSIS auditors' record reviews included the establishments' sanitation monitoring and corrective action records over at least a three-month period at all establishments audited, as well as those of the CCA documenting inspection verification results, non-compliances, and supervisory reviews of establishments. The FSIS auditors noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishments. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of pre-operational and operational sanitation and any corrective actions taken. The sanitation programs in the audited establishments were found to be in compliance with the CCA's regulatory requirements as well as meeting FSIS regulatory requirements. There were no deficiencies observed as they relate to SSOP.

The FSIS auditors verified that the in-plant inspection personnel not only document their inspection verification findings in the CVS Verification Worksheet, Verification Report, and IR-CARs, but also verify the implementation of the establishments' corrective actions. FSIS also reviewed the supervisory reviews at all audited establishments and three regional offices. The audit showed the supervisory reviews were conducted as scheduled and that the reviews covered all aspects of the establishments' food safety programs including document analysis and onsite visits. In slaughter /processing establishments, these reviews are the responsibility of the RVO, while FPSs (also known as Complex Supervisors) conduct these reviews at processing establishments.

In 11 of 13 establishments audited, the FSIS auditors identified sanitation findings. The CCA committed to provide FSIS with corrective action plans which would be verified once they are implemented by inspection personnel.

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 inspection system is to require a HACCP plan or similar type of preventive control plan to maintain equivalence. The evaluation of this component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the onsite portion of the audit.

CFIA requires each federally registered establishment to develop, implement, and maintain a HACCP system that combines the following key elements to ensure the production of safe food:

- Prerequisite programs;
- HACCP plans (may include process controls, linked to a CCP, if applicable);
- Validation documentation; and
- Maintenance and reassessment procedures.

In federally registered establishments, CFIA uses the CVS to verify an establishment's compliance with their HACCP system. The verification and reporting of the specific task results by an inspector involves a set of sequential events that includes:

- Preparation for the verification;

- Gathering information to determine compliance;
- Assigning compliance level;
- Communicating results and actions required;
- Assessing operator's action plan;
- Follow-up; and
- File Maintenance.

At each audited establishment, the FSIS auditors interviewed the inspection personnel to assess their knowledge and skills for proper application of standards provided in FSEP and correct performance of CVS tasks as outlined in Chapter 18 of MHMOP. The FSIS auditors further reviewed a sample of CVS tasks and their associated frequencies, verification worksheets, verification reports, and corrective action requests. The FSIS auditors determined that CFIA-assigned inspectors to verify the design of an establishment's HACCP system at a minimum of once every 2 years in federally inspected establishments and document the results of the task as appropriate.

FSIS visited three regional offices and audited 11 meat and poultry slaughter and processing establishments, one egg processing establishment, and one cold storage facility to determine whether the CCA maintained adequate government oversight for the implementation of HACCP requirements. In addition, FSIS assessed the adequacy of HACCP program verification activities conducted by inspection personnel and establishment management at these audited establishments.

The FSIS auditors observed in-plant inspection verification activities and reviewed the monitoring and verification records generated by the establishment's operators and in-plant inspection personnel. As a result of two zero tolerance (fecal and ingesta contamination) violations identified during the United States POE examination, FSIS focused on zero tolerance control programs in audited establishments. The FSIS auditors conducted onsite observations and reviews of the zero tolerance control records generated over the past 90 days in all seven audited slaughter establishments. In addition, the FSIS auditors reviewed the in-plant inspector's associated zero tolerance verification records at these establishments. The review of the establishments' corrective actions in response to a deviation from zero tolerance critical limits indicated that all four parts of the corrective actions, in accordance with requirements consistent with 9 CFR 417.3, were addressed by establishment employees and verified by the inspection personnel. No non-compliance trends were detected as the result of these document reviews.

During the onsite document reviews and interviews of establishment and inspection personnel, the FSIS auditors identified the following HACCP record keeping findings in two of the 13 audited establishments:

- In two establishments, the HACCP verification records for the record review component did not document the results of the verification activities conducted by the establishments' personnel.

FSIS verified that the CCA has a regulatory definition for RTE products which states "Meat and poultry products which have been subjected to a process sufficient to inactivate vegetative pathogenic microorganisms or their toxins and control spores of food borne pathogenic bacteria so that the meat product does not require further preparation before consumption except washing, thawing or exposing the product to sufficient heat to warm the product without cooking it."

The CCA has implemented a zero tolerance policy for *Lm* and *Salmonella* spp. in all categories of RTE products destined for export to the United States. The zero tolerance also applies for *E. coli* O157:H7 in uncooked dry or semi-dry fermented products containing beef. The HACCP system must be validated to demonstrate that the level of *E. coli* O157:H7 in raw beef products is below the detectable level, i.e., no *E. coli* O157 is detected in a sample when tested with one of the approved methods (refer to Appendix 2 of this policy for the relevant information).

Except for isolated record keeping findings, the CCA continues to demonstrate the ability to effectively implement and verify its regulatory requirements for products that Canada is currently eligible to export to the United States.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The FSIS auditors reviewed Government Chemical Residue Testing Programs as the fifth of six equivalence components. The FSIS criteria for this component included the design and implementation of a program managed by the CCA that conducts effective regulatory activities to prevent chemical residue contamination of food products. To be equivalent, the program needs to include random sampling of muscle, internal organs, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of its residue testing plan and the process used to design it; a description of the actions taken to address unsafe residues as they occur; and oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

The evaluation of this component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the onsite portion of the audit. The FSIS auditors noted that the responsibility for monitoring food safety in Canada is shared by the CCA and Health Canada (HC). The HC's Food Directorate and its Bureau of Chemical Safety deal with food safety policies, establishing standards and maximum levels for contaminants, mycotoxins, natural toxins, and food additives. Additionally, the Veterinary Drugs Directorate (VDD) provides the veterinary drug registration, which establishes Maximum Residue Limits (MRLs) under the FDA and the Pest Management Regulatory Agency (PMRA), which regulates pesticide registration and establishes MRLs under the Pest Control Products Act (PCPA). The CAPA gives the CCA authority to sample products intended to be traded inter-provincially and internationally. The Meat Inspection Act (MIA) gives the CCA authority to inspect and sample meat products in federally inspected establishments. The MIA enables the CCA to enforce and administer the provisions of the FDA as they relate to food. The FDA enables CCA inspectors to sample if there is a reasonable and probable grounds to believe that there has been a violation of the FDA.

The National Chemical Residue Monitoring Program (NCRMP) program is implemented on a Canadian fiscal year basis that runs from April 1 to March 31. The sampling schedule under NCRMP is statistically randomized and specifies critical information, e.g., date, region, commodity, species, tissue, country of origin, laboratory, and sample number with each scheduled sample. Range of matrices targeted include meat and poultry, shell eggs, dairy products, honey, fresh and processed fruits, vegetables, and maple syrup. The scope of analytical testing covers a host of chemical groups known to be detected in meat, poultry, and other food groups. The chemical groups analyzed in meat, poultry, and

egg products include veterinary drugs, pesticides, contaminants (metals, mycotoxins, dioxins, furans, polychlorinated biphenyls, polycyclic aromatic hydrocarbons), anti-parasitics, coccidiostats, growth promoters, hormonal substances, nonsteroidal anti-inflammatory drugs (NSAIDs), and tranquilizers.

CFIA utilizes a combination of CFIA laboratories and accredited third party laboratories to analyze matrices for the presence of chemicals in meat, poultry, and egg products. The data from third party laboratories is transferred to CFIA. The data obtained from CFIA laboratories are tracked and recorded in the Laboratory Sample Tracking System in real time and evaluated for quality and then uploaded to a central database.

The FSIS auditors confirmed that the operational branch of CFIA administers the sampling plan, and mostly the inspection staff in the field collects samples, each of which is typically tested for a suite of analytes. The noncompliant results are followed up by policy and program and operations staff. The residue test results are published in reports on CFIA's Web site.

The FSIS auditors verified that CFIA has employed procedures comparable to the NCRMP's inspector-generated sampling in the slaughter establishments. Inspectors utilized Swab Test on Premises (STOP) for the presence of antibiotics in red meat species or Kidney Inhibition Swabs (KIS) for Sulfonamide screening of suspected swine herds. Matrices from all in house positives are automatically shipped to laboratories for confirmation.

During the onsite audit of a private residue chemical laboratory in Burnaby, the FSIS auditors interviewed the quality management personnel who conduct the internal audits of this laboratory. The internal audit scope included sample handling; sampling frequency; timely analysis; data reporting; analytical methodologies; tissue matrices; equipment operation; detection levels; recovery frequency; percent recoveries; intra-laboratory check samples; and quality assurance programs, including standards books and corrective actions. The FSIS auditors' review of the internal and external audit reports and corresponding follow-up reports found no concerns within the CCA's implementation of its chemical residue program.

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

The FSIS auditors' review found no concerns with the CCA's chemical residue testing program. Canada's meat inspection system has regulatory requirements for a chemical residue testing program that is organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, unadulterated, and meet all equivalence criteria.

Canada requires all slaughter establishments to develop and implement sampling and testing programs for the indicators of fecal contamination in order to assess the effectiveness of its slaughter and dressing process control during the production of raw meat. CFIA conducts its own verification testing under the National Microbiological Monitoring Program. Inspection personnel routinely verify that results related to statistical process control are correctly evaluated. As outlined in Chapter 11, Annex T of MHMOP, all United States-certified establishments slaughtering livestock and poultry must implement sampling and testing for generic *E. coli* in a an equivalent manner consistent with the requirements set forth in 9 CFR Parts 381 and 310, respectively.

The FSIS auditors verified that all slaughter establishments audited had developed, implemented, and maintained *E. coli* testing programs consistent with the standards established in the aforementioned annex. The review of official documents revealed that inspection personnel had verified establishments' compliance with the generic *E. coli* testing requirements. Inspectors' verification ensures the following: the sample collector is designated in the written plan; the written plan addresses the location of sampling, randomness, and sample integrity; appropriate sampling methodology is used; the laboratory is using an appropriate method for analysis; results are correctly evaluated; and establishments take appropriate corrective action when they exceed levels that indicate adequate process control. The FSIS auditors further verified the analytical results and test methods for tests conducted in the last 90 days. No concerns arose as a result of the verification of the CCA's *E. coli* testing program.

The FSIS auditors verified that in beef the CCA has microbiological testing programs in place for *E. coli* O157:H7 and non-O157 Shiga toxin-producing Escherichia coli (STEC) which includes O26, O103, O111, O121, O45, and O145 in beef manufacturing trimmings destined for export hereafter referred to as precursor material (PM).

Chapter 4, Annex O of MHMOP outlines the policies on the control of *E. coli* O157:H7contamination in raw beef products and Chapter 5 describes the testing program for *E. coli* O157:H7 and non-O157 STEC in raw beef products including domestic and imported PM intended for use in raw ground product. Chapter 11, Annex D-2 of MHMOP delineates CFIA risk-based Shiga toxin-producing verification sampling on PM produced at the United States-certified establishments.

CFIA mandates establishments to include beef trim, bench trim, head meat, cheek meat, tongue roots, weasand meat, hearts, coarse ground beef, and finely textured beef products in their testing programs. Additionally, if other raw beef components such as primal or sub-primal cuts (e.g., chucks, top round, sirloin cuts, etc.) are destined for use in the finished raw ground beef products (FRGBP), these components must also be tested. Establishments must implement a robust testing protocol for each production lot of any type of PM that is destined for use in preparation of FRGBP. The test used must satisfy the conditions listed in Chapter 4, Annex O section 5.3 of the MHMOP. Testing regimen must be based on N-60 collection method for trimmings where a minimum of 60 sub-samples must be examined per lot. A lot cannot exceed five combos and cannot weigh more than approximately 10,000 pounds. A minimum of 325 g of material from each lot shall be collected and submitted for testing. At least 65 g of material (12 pieces weighing 5 or 6 g each) would be collected from each combo in a five-combo lot. Establishments may follow an alternate method as long as the fundamental requirement of the policy is satisfied. CFIA requires beef slaughter and processing establishments producing PM and conducting robust N-60 sampling and testing programs to identify and document high event period (HEP) criteria. HEP allows for adequate identification of implicated and suspect products beyond the

products that were reported positive. The requirements of HEP are contained in Section 9 of Chapter 4, Annex O of MHMOP.

The CCA conducts risk-based verification sampling of beef trimmings intended for use in the production of FRGBP. The government testing builds upon features that take into consideration a multitude of inherent risks with the PM to be used in the production FRGBP, e.g., seasonality, production volume, and historical testing and inspection data. It has been designed to verify the effectiveness of control measures for *E. coli* O157 in place at establishments that produce PM. Products targeted for sampling under this plan are all types of PM.

The CCA's M 201 sampling plan has been designed for all federally registered establishments that produce FRGBP. Domestic beef trimmings and chucks intended for use in raw ground beef are tested under the M 218 testing program. Under this verification sampling program, establishments that produce PM intended for use in FRGBP are targeted to verify the effectiveness of the slaughter establishment's control measures for *E. coli* O157:H7. While the preceding two testing programs are designed to verify the effectiveness of control measures for *E. coli* O157:H7 in place at establishments domestically, M 219 tests imported beef trimmings and chucks intended to be used in raw ground beef. When *E. coli* O157:H7 is detected in a sample under any testing program, the sampled lot is considered adulterated and a set of measures are taken in accordance with the policy contained in Section 5.3.3.1.4 of Chapter 5 of MHMOP.

Establishments have been divided into four categories based on their production volume: extra-large, large, medium, and small. Current sampling frequencies for establishments have been outlined in the National Microbiological Sampling Guidelines and Assessment Criteria. Generally, products will be sampled at all establishments at a normal frequency. A compliance history including a positive *E. coli* O157:H7 result from M 218 testing of PM or M 201 testing of the product downstream will be taken into account when placing an establishment on enhanced frequency of testing for the next 120 days. Such a decision will be made by the Area Program Specialist within the Meat Inspection Program of CFIA.

Chapter 11, Annex D-2 of MHMOP lays out specific requirements for United States export pertaining to the M 201 verification testing plan. The plan is a risk-based verification sampling procedure and accepted laboratory methodology. This verification sampling has been designed by the CFIA for slaughter establishments producing raw beef manufacturing trimmings for export to the United States. Participation in this program is mandatory for abattoirs in order to maintain their eligibility for export to the United States. The program requires the samples be collected by the establishment under the supervision of the CFIA Veterinarian in Charge (VIC) and submitted by the operators to private laboratories for the analysis of STEC. The establishment management is responsible for collection of samples from the lot that has been selected by the CFIA inspector under sampling plan M 218. The operator's written procedure for the collection and submission of samples for analysis is approved by the VIC.

The documents reviewed at two beef slaughter establishments and the government inspection records, in conjunction with the interviews conducted at the regional offices and with inspection staff, the FSIS auditors verified the implementation of the CFIA's mandated testing for *E.coli* O157:H7 and non-O157 *STEC* sampling and testing program and confirmed that implementation of the program was as written.

The FSIS auditors further reviewed a random set of certificates of analysis for *E.coli* O157:H7 and *non*-O157 *STEC* for the test results and analytical methods employed at each bovine slaughter establishment audited and confirmed the tests were being conducted at the stated frequencies and appropriate methods were employed. A review of CVS tasks pertaining to verification of microbiological data supported the verification frequency as stated in MHMOP. No concerns arose as a result of the review of microbiological testing results.

CFIA conducts verification sampling and testing in all federally registered egg processing establishments. This includes sampling of liquid, frozen, or dried eggs for *Aerobic Plate Count (APC), Coliforms, Salmonella* spp., and *Lm*. FSIS' review of the sampling methodology and results did not identify any concerns.

The CCA also has microbiological testing programs for *Salmonella* in raw and RTE products, *Campylobacter* in raw poultry products, and *Lm* in RTE products. CFIA mandates that all establishments eligible to export to the United States manufacture product for which USDA has established performance standards for *Salmonella* in livestock and poultry and *Campylobacter* in poultry must test for pathogens and meet the current United States standards. CFIA publishes the standards in MHMOP and updates them as required. CFIA's policies pertaining to *Salmonella* and *Campylobacter* testing are listed in Chapter 11, Annex U of MHMOP.

The FSIS auditors reviewed the CCA's *Salmonella* sampling and testing program at all audited establishments slaughtering livestock and poultry, and *Campylobacter* in poultry slaughter establishments. The FSIS auditors verified the implementation of the program within the certified establishments by the in-plant personnel, and the results and records from the program. The FSIS auditors also verified that the certified establishments conduct pathogen reduction performance standard *Salmonella* testing for raw meat product and *Campylobacter* in poultry carcasses. The sampling and testing of carcasses for *Salmonella* species is performed by the establishment and is verified by the CCA weekly in all certified establishments that slaughter livestock and poultry. The FSIS auditors' review of at least 3 months of records at the audited slaughter and processing establishments (two bovine, two swine, two poultry, and one ovine/caprine) identified that no *Salmonella* or *Campylobacter* set failures had occurred. Canada considers all RTE products produced at establishments eligible to export to the United States as Category 1[1] products. This policy is outlined in Chapter 4, Annex H of MHMOP.

The FSIS auditors noted that CFIA has employed three types of sampling to test for *Lm* in RTE meat and poultry establishments eligible to export to the United States. These are explained below:

- Monitoring Sampling (CFIA): random, unbiased RTE meat and poultry product and environmental food contact surface (FCS) sampling to verify HACCP processes and compliance;

[1] According to Health Canada's Listeria policy, RTE products are categorized as:
Category 1 – products in which growth of *Lm* can occur
Category 2A – limited growth of *Lm* to levels not greater than 100 CFU/g throughout stated shelf-life
Category 2B – growth of *Lm* will not exceed 0.5 log CFU/g throughout stated shelf-life

- Risk-Based Sampling (CFIA): targeted, and as the name implies is risk-based RTE meat and poultry for FCS and environmental sampling. Sampling frequency is based on establishments' relative risk level (RRL).
- Risk-Based Verification Sampling (CFIA/Industry): This CFIA sampling plan is implemented by establishments under CFIA supervision with a sampling frequency based on establishment RRL; and results of the analysis are sent to directly to CFIA's e-mail portal. Data gathered from these analyses is utilized for trend analysis. Product or FCS-tested positives trigger CFIA follow-up sampling.

There are six government food microbiology laboratories in Canada that are administered by managers who report to their respective Laboratory Directors (LDs). LDs report to an Executive Director (ED), of which there are four, one for each geographically-based laboratory network. These EDs in turn report to the Chief Science Operating Officer, who reports to the Vice President of Science Branch. Alongside this reporting structure, food microbiology laboratory activities are coordinated by the LCD in Ottawa through timely communication on important issues as well as regular conference calls. Food microbiology laboratory managers, along with representatives from the LCD, make up the Food Microbiology Working Group, whose mandate is to direct the development, delivery, and advancement of the CFIA's food microbiology testing program and discuss issues for consistency and continuity throughout the laboratory network. Communication with operations and programs branches is typically coordinated through the LCD, including reporting and interpretations of results, as well as the discussion of issues related to planning and sample delivery.

The FSIS auditors reviewed one government microbiological laboratory located in Calgary during the audit. The review included the ISO accreditation of the laboratory for microbiological testing from the Standards Council of Canada (SCC) accreditation body. The scope of accreditation of this laboratory issued on February 11, 2016 and expiring on October 8, 2016, contains all microbiological analyses methods necessary to support the CCA's verification testing for the certified establishment samples that the CCA submits to this laboratory for the verification of the food safety system. The FSIS auditors interviewed the laboratory personnel and reviewed laboratory documents related to analyst training and qualifications; sample receipt; timely analysis; analytical methodologies; recording and reporting results; and third party check samples. The FSIS auditors' review of the provided documents found no concerns within the CCA's implementation of government microbiological testing programs.

The audit indicated that Canada's meat, poultry, and egg products inspection system has a microbiological testing program that is organized and administered by the national government, and that the CCA has implemented sampling and testing programs to verify its system.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on September 30, 2016, in Ottawa with CFIA. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors. The CCA understood and accepted the findings. FSIS identified findings related to post-mortem inspection procedures that do not ensure carcass-by-carcass inspection that raise significant questions about the Canadian system and will need to be addressed by the CCA in order to maintain on-going equivalence to the United States' system. Additional findings in the Government Sanitation and Government HACCP Systems components were noted and detailed in individual establishment checklists.

The FSIS auditors identified the following systemic and isolated 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 this 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.

During the audit exit meeting, the CCA committed to begin to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

APPENDICES

APPENDIX A: Individual Foreign Establishment Audit Checklist

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. Brantford, ON, Canada	09/19/16	007	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

46/51: Other Requirements – Sanitary Operations
a) In the cooking room the overhead structures, steel pipes, vents, motors and other machinery was rusty covered with a thin layer of residues from deep frying of product was creating insanitary operative condition and were potential for product cross contamination. At the time of audit production line in question was not operating.
b) In the chemical storage room located adjacent to production room had chemicals spilled on floor, dirt and water collected in corners. Floors were observed with extensive detached plaster to hamper cleaning of spilled chemicals.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
International Audit Staff	

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. Ange-Gardien, QC,Canada	09/22/16	10	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

55/51: Post-mortem Inspection

The government inspectors were not conducting 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.
The auditor also noted that Carcass Presentation Station was positioned after post mortem inspection station. Section 6.2 annex C of Manual of Procedure which requires “operator to ensure that carcasses and their parts are presented for post-mortem inspection in such a way as to permit proper examination by CFIA inspectors.” This requirement implies the positioning of carcass presentation needs to be prior to post mortem inspection.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
International Audit Staff	

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
JBS Food Brooks, AB	09/15/2016	38	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
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. Enforcement	X
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. Monthly Review	
58.	
59.	

60. Observation of the Establishment

22/51: HACCP – Ongoing Requirements
The establishment's HACCP verification records for record review component did not document the results of the verification activities conducted by the establishment's personnel. The establishment's HACCP plan did document the results of the verification for its direct observation component.

39/51: Other Requirements – Establishment Construction/Maintenance
The FSIS auditor observed several small holes on the ceiling and on the overhead structures in the production areas and over exposed products. No direct product contamination observed by the FSIS auditor at this time. However, this condition may create an insanitary condition.

55/51: Post-mortem Inspection
The government inspectors were not conducting 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.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff	

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 Ltd Guelph, ON, Canada	09/15/16	51	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

39/51: Other Requirements – Establishment Construction/Maintenance
Unfilled holes around pipes were observed in a wall separating processing and packing material room.

46/51: Other Requirements – Sanitary Operations
The shipping box room was utilized to store used hooks which were in contact with containers. One of the shipping containers for edible product was placed on the floor.

55/51: Post-mortem Inspection
The government inspectors were not conducting 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.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
International Audit Staff	

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
Vanderpol's Egg LTD Vancouver, BC	09/21/2016	66 E	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff		[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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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. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff	

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
Ailments Sunchef Inc. Anjou, QC,Canada	09/23/16	70	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	International Audit Staff		[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.	
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24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
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27. Written Procedures	
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29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

41/51: Other Requirements – Ventilation
Condensation had formed over a metal bar of an oven above exposed RTE chicken product. Condensation and or carcass juices from overhead condensation collecting covers were coalescing above the exposed poultry product in the de-boxing room.

45/51: Other Requirements – Equipment and Utensils
Several cracked totes for inedible products were observed in edible or inedible rooms.

46/51: Other Requirements – Sanitary Operations
A knife sterilizer in RTE production room was not maintained in sanitary manner to sterilize knife. Water in the sterilizer was at room temperature and had organic residue. Discarded napkins and some dirt collected around corners of more than one production room.
Same colored plastic sheath were used to cover edible products and also as trash liners or as cover over pallets to protect shipments.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
International Audit Staff	

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
Versacold Calgary, AB	09/16/2016	S 206	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff		[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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25. General Labeling	
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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	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff	

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
Sofina Foods Abbotsford, BC	09/27/2016	92 C	Canada
	5. NAME OF AUDITOR(S) International Audit Staff		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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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. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

39/51: Other Requirements – Establishment Construction/Maintenance
The FSIS auditor observed several small holes, exposed insulation, and beaded condensate on the ceiling and on the overhead structures in the production areas and over exposed products. No direct product contamination observed by the FSIS auditor at this time. However, this condition may create an insanitary condition.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff	

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
Olymel S.E.C. Red Deer, AB	09/19/2016	270 A	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff		[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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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	
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Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
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29. Records	
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	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

22/51: HACCP – Ongoing Requirements
The establishment's HACCP verification records for record review component did not document the results of the verification activities conducted by the establishment's personnel. The establishment's HACCP plan did document the results of the verification for its direct observation component.

39/51: Other Requirements – Establishment Construction/Maintenance
The FSIS auditor observed several small holes on the ceiling and on the overhead structures in the production areas and over exposed products. No direct product contamination observed by the FSIS auditor at this time. However, this condition may create an insanitary condition.

40/51: Other Requirements – Light
There was insufficient illumination (720 LUX) at the CFIA inspection station for verification of establishment procedures for controlling fecal material, ingesta, and milk. CFIA requires a minimum of 1000 Lux illumination for inspection stations.

46/51: Other Requirements – Sanitary Operation
Swine carcasses that were identified for dressing defects (including fecal or ingesta contamination) or pathological defects were in direct contact with each other on the trim line creating an opportunity for cross contamination.

55/51: Post-mortem Inspection
The government inspectors were not conducting 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.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff	

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
Marvid Poultry Montreal, QC, Canada	09/26/16	274	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	International Audit Staff		[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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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	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

39/51: Other Requirements – Establishment Construction/Maintenance
A shallow pit with waste water collected in was observed in the evisceration room.

46/51: Other Requirements – Sanitary Operations
Dirt and debris collected around doors to production rooms. Product accumulated on floors and waste observed in evisceration room.

55/51: Post-mortem Inspection
Gizzards and chicken breast were being harvested in containers with no supply of fresh water (over flow).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
International Audit Staff	

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
Tender Choice Foods Inc. Burlington, ON, Canada	09/20/16	275	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	International Audit Staff		[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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Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

41/51: Other Requirements – Ventilation
The turkey processing line had a generalized condensation problem in the cutting/processing room. Heavily beaded condensation were observed over the exposed product in multiple locations in turkey processing room, product storages rooms, ceiling over product transfer equipment and over the ceilings of passages along the product flow to other cooling rooms.

45/51: Other Requirements – Equipment and Utensils
Rusty motors/overhead structures and leaky pipes were observed during the tour of facility in different production area. A multiple steel totes for edible product storage had broken and cracked edges. Badly rusty overhead chains supporting electrical fixtures and electrical cords with residue buildup were observed at multiple workstations in the processing rooms.

46/51: Other Requirements – Sanitary Operations
Water pooling in the shipping room due to poor drainage was creating insanitary conditions. Dirt and debris collected around entrances of more than one production areas requiring management attention.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
International Audit Staff	

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
Abattoir St-Germain Inc. . St. Germain-de-Grantham, QC, Canada	09/21/16	454	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

41/51: Other Requirements - Ventilation
In the shipping room, the veal and lamb carcass were exposed to railings covered with scattered beaded condensation. The CFIA inspection team retained the affected product for evaluation and disposition and issued a CAR to the establishment.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
International Audit Staff	

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
Cardinal Meat Specialists Lrd. Brampton, ON, Canada	09/15/16	752	Canada
	5. AUDIT STAFF		6. TYPE OF AUDIT
	International Audit Staff		[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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Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
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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	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

46/51: Other Requirements – Sanitary Operations
Due to a poorly placed drain, water pooling and stagnancy was observed on the ground at the shipping and loading dock which could attract insect and flies in the premises or in the establishment.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
International Audit Staff	

APPENDIX B: Canada's Response to Draft Final Audit Report (when available)

Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

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MAR 3 0 2017

Jane H. Doherty
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 (September 12-30, 2016) 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 Jane,

I am pleased to provide you with the Canadian Food Inspection Agency's response to the draft report of the FSIS audit in Canada conducted from September 12, 2016 to September 30, 2016.

Our response is comprised of two tables as listed below:

- Table 1: Response of the Canadian Food Inspection Agency (CFIA) to the findings identified in the (USDA-FSIS) Draft Audit Report carried out from September 12 to September 30, 2016 in order to Evaluating of the Canadian Food Safety System Governing the Production of Meat, Poultry and Egg Products Exported to the United States of America;

- Table 2: CFIA's comments and suggested amendments to the findings identified in the (USDA-FSIS) Draft Audit Report carried out from September 12 to September 30, 2016 in order to Evaluating of the Canadian Food Safety System Governing the Production of Meat, Poultry and Egg Products Exported to the United States of America .

The CFIA would appreciate an opportunity to discuss these points prior to the publication of the audit report.

.../2

Canada

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,

Barbara Doan
Director
Food Import and Export Division

c.c.: Tom Graham, OPS, CFIA

Attachments (2):
Table 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 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.

Table II- CFIA's comments and suggested amendments to the Unites States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit (September 12-30, 2016) Report on the Evaluating of the Canadian Food Safety System Governing the Production of Meat, Poultry and Egg Products Exported to the USA

Table I

Response of the Canadian Food Inspection Agency (CFIA) to the Unites States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit (September 12-30, 2016) Report on the Evaluating of the Canadian Food Safety System Governing the Production of Meat, Poultry and Egg Products Exported to the USA

USDA-FSIS Draft Report Reference	USDA-FSIS Draft Report Text with Canada's Suggested Changes (as track changes, please print in colour)	CFIA Comments
1-Executive Summary and X.CONCLUSIONS AND NEXT STEPS.	**Government Statutory Authority and Food Safety and Others Consumer Protection Regulations** • The government inspectors may not have been conducting complete carcass-by-carcass post-mortem inspection to insure freedom from contamination with feces, milk, or ingesta for reconditioned carcasses prior to applying mark of inspection.	The issue is being addressed outside of this audit process. Please note that a letter on carcass by carcass inspection was sent to you on March 29, 2017 in response to USDA-FSIS's letter dated February 23, 2017. For this reason, the CFIA is strongly of the opinion that this issue should not be recorded as a finding at the time of this audit, nor be referenced in the audit report.
	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 this report.	Most of the SPS findings (building and equipment maintenance findings) were already identified by the local CFIA inspectors prior to the FSIS audit and were in the process of being addressed using the normal Compliance Verification System (CVS) process. In those establishments an Inspection Report- Corrective Action Request (IR-CAR) was issued. The operators provided a written action plan outlining the corrective actions. The CFIA inspectors/veterinarians-in-charge of each establishment conducted follow-up activities to

		ensure all corrective actions were implemented and effective. The CFIA requests that these comments be rephrased or removed throughout the audit 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 deficiencies identified were followed up by the CFIA's inspector/veterinarian-in-charge of each establishment using the normal CVS inspection process. These findings have been addressed and the follow-up activities conducted by the establishment's personnel are being documented. These issues are now resolved.

Table II

CFIA's comments and suggested amendments to the Unites States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit (September 12-30, 2016) Report on the Evaluating of the Canadian Food Safety System Governing the Production of Meat, Poultry and Egg Products Exported to the USA

USDA-FSIS Draft Report Reference	USDA-FSIS Draft Report Text with Canada's Suggested Changes (as track changes, please print in colour)	CFIA Comments
II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY	Page 5 • ~~MFLP-80~~ MFHPB-10 analytical method for E. coli 157.H7 analysis in meat and eggs;	
IV. COMPONENT ONE: GOVERNMENT OVERSIGHT	Page 6- There have been no major changes in the CCA's organizational structure since the last FSIS audit. ~~The Chief Executive Officer (CEO) of the inspection system heads the CCA~~. ~~The CEO~~ **The president of CFIA is the head of CCA. The CFIA's president** is assisted by an Executive Vice President and eight branch Vice Presidents.	
V. COMPONENT TWO	**Page 10-last paragraph** In addition, the inspection personnel located at the area offices and the ~~Food Safety Division~~ **Technical Expertise and Advice** of the CCA verify the establishments' validation through record reviews.	"Food Safety Division" no longer exists.

	Page 11-first paragraph The CCA regulates shell egg and processed egg products manufactured in federally inspected Canadian establishments. The legislation that governs processed egg products are the *Canada Agricultural Act (CAP A), Food and Act (FDA), and Consumer Packaging and Labeling Act.* The in-plant inspection personnel perform various tasks to ensure that processed egg products are being prepared, packaged, and labeled in a manner that meets the requirements for sanitation, operation, and maintenance in accordance with the CCA's ~~processed egg product regulations~~ *Processed Egg Regulations.*	
VI. COMPONENT THREE: GOVERNMENT SANITATION ·	**Page 12-last paragraph** In 11 of 13 establishment audited, the FSIS auditors identified sanitation findings~~. These issues should have been identified and corrected by the inspection personnel prior to the onsite audit~~. The CCA committed to provide FSIS with corrective action plan which would be verified once they are implanted by inspection personnel	**The statement "these issues should have been identified and corrected by inspection personnel prior to the onsite audit" is a subjective statement not a reported finding. CFIA is of the opinion that the sentence should be deleted.**
IX.COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	**Page 16-4th paragraph** The FSIS auditors verified that in ~~all slaughter species~~ **beef** the CCA has microbiological testing programs in place for E.coli O157:H7 and non-O157:H7 Shiga toxin-producing Escherichia coli (STEC) which includes O26, O103, O111, O121, O45, and O145 in beef manufacturing trimmings **destined for export** hereafter referred to as precursor material (PM).	**CFIA has a requirement for E. coli O157:H7 testing for all beef while the testing for non-O157:H7 STEC is an export requirement only.**

	Page 16-6th paragraph The test used must satisfy the conditions listed in Chapter 4, ~~Appendix 2 of MHMOP~~ **Chapter 4, Annex O section 5.3 of the MHMOP** Testing regimen must be based on N-60 collection method for trimmings where a minimum of 60 sub-samples must be examined per lot.	