USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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JAN 14 2016

Richard Flohr, Acting Director
Food Import/Export Division
Canadian Food Inspection Agency
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Ottawa ON K1A 0Y9

Dear Mr. Flohr,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Canada's meat, poultry, and egg products inspection system from May 28 through June 13, 2014. 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.

For technical questions regarding the FSIS audit report, please contact Dr. Shaukat H. Syed, Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or by electronic mail at international.audit@fsis.usda.gov.

If you have any other 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

May 28 - June 13, 2014

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING THE PRODUCTION OF MEAT, POULTRY, AND EGGPRODUCTS INTENDED FOR EXPORT TO THE UNITED STATES OF AMERICA

January 14, 2016
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) on May 28 through June 13, 2014, 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, (2) Statutory Authority and Food-Safety Regulations (SAFSR), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs. In addition, the auditor verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the November 2012 FSIS audit findings had been implemented.

The FSIS audit team reviewed management, supervision, and administrative functions at the CCA headquarters, two regional offices, five slaughter and processing establishments (two porcine, two bovine, and one poultry), three RTE processing only establishments, one egg processing facility, and one government laboratory to verify that the national system of inspection, verification, and enforcement were being implemented as required to maintain equivalence.

The 2014 audit results indicate that the CCA's food safety inspection system meets the core criteria for all six equivalence components. FSIS identified operational (or procedural) weaknesses related to government oversight, sanitation, and microbiological testing.

During the exit meeting on June 13, 2014, the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions for the short-term and long-term prevention of recurrence of on-site audit findings. FSIS will evaluate any information provided by the CCA including the submission of the CCA's proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions. FSIS expects the CCA response within 60 days of the issuance of this report.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site equivalence verification audit of Canada's meat, poultry, and egg inspection system from May 28 through June 13, 2014.

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 Animal and Plant Health Inspection Service (APHIS). Between November 10, 2012, and May 28, 2014, Canada exported approximately 2,310,876,297 pounds of meat and poultry products to the United States of which 101,499,649 pounds were re-inspected at Port-of-Entry (POE) in the United States. A total of 906,933 pounds was rejected at POE, of which 89,415 pounds were for failures of public health significance because of *Listeria monocytogenes* (*Lm)* or fecal contamination. Additionally, a total of 19,615,992 pounds of egg products were presented at POE for re-inspection. A total of 60 pounds of egg product was rejected for reasons other than food safety and returned to Canada.

This audit was conducted pursuant to the specific provisions of the United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 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 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 Point (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).

FSIS verified whether Canada was following the Canadian laws, regulations, and procedures under equivalence determinations that FSIS has made for Canada under provisions of Sanitary/Phytosanitary Agreement. In addition, subsequent equivalence determinations have been made by FSIS for Canada. They are as follows:

- *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* O157:H7 compositing of samples prior to screening test,
- High Line-Speed Inspection System (HLIS) and HACCP Based Inspection Program (HIP) for bovine and porcine slaughter respectively,
- Canadian residue control program,
- Generic *E. coli* testing for minor species,
- RTE government verification testing program for *Listeria monocytogenes* in meat and poultry,
- MFLP-16 analytical method for *E. coli* O157:H7 analysis in raw ground beef and beef components,
- MFHPB-30 analytical method for *Listeria monocytogenes* analysis in meat and eggs,

- MFLP-28 analytical method for *Listeria monocytogenes* 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,
- MFLP-80 analytical method for *E. coli* O157:H7/NM analysis in meat and eggs,
- MFLP-28 Bax® analytical method for *Listeria monocytogenes* 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.

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify whether Canada's food safety inspection system governing meat, poultry, and egg products continues to be equivalent to that of the United States, with the ability to produce and export products that are safe, unadulterated, wholesome, and properly labeled. To achieve this goal, the audit focused on six program components with the objective of determining whether each component is and can maintain its system equivalence. The six equivalence components are the following: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs.

FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA), the Canadian Food Inspection Agency (CFIA), in response to the November 2012 FSIS audit were being implemented. FSIS further verified whether actions taken by the CCA in response to POE violations identified since the November 2012 FSIS audit were appropriate, including follow-up implementation of corrective actions by the establishment and the CCA, and verification of those actions required by the CCA in response to five POE violations: zero tolerance contamination (fecal material), *Listeria monocytogenes* (*Lm*)(2), pathology, and contamination of product exported to the United States from Canadian establishments which were identified by FSIS during POE verification testing.

III. AUDIT METHODOLOGY

For this equivalence verification audit, FSIS utilized its established four-phase process: plan, execution (on-site), evaluation, and feedback. Each phase is described below.

The first phase involved a document and data analysis of previous audit observations, corrective actions, and other available information. FSIS examined the CCA's performance within the six equivalence components, data on exported product types and volumes, POE testing results, and other data collected since the last FSIS audit in 2012. In addition, the FSIS auditor reviewed information obtained directly from the CCA, through a Self-Reporting Tool (SRT), outlining the structure of the inspections system and identifying any changes that have occurred since the last FSIS audit. This comprehensive analysis served as the basis for planning the on-site audit itinerary.

The second phase is the on-site audit or execution phase. FSIS verified the CCA's oversight activities through on-site document reviews, interviews, observations, and site visits. The FSIS auditors were

accompanied throughout the audit by representatives from the CCA. The FSIS auditors reviewed management, supervision, and administrative functions at the CCA headquarters in Ottawa, Toronto, and Montreal Regional Offices; five slaughter and processing establishments (two porcine, two bovine, one poultry slaughter and processing); and three RTE processing only establishments, one egg processing facility, and one government laboratory to verify that the national system of inspection, verification, and enforcement were being implemented as required to maintain equivalence.

FSIS audited the GTA Microbiology Laboratory, a government laboratory located in Ontario, which is conducting microbiological testing of official samples. During this laboratory review, the FSIS auditors interviewed the inspection personnel to assess the CCA's oversight activities for implementation of approved microbiological testing programs. During the establishment visits, FSIS auditors paid attention to the extent to which the government and industry interact to meet the equivalence standards and other requirements and prevent noncompliances that could pose risk to public health. The auditors looked closely at CCA's ability to provide oversight through supervisory reviews conducted in accordance with Title 9 CFR 327.2 and 381.196.

The third phase was evaluation. FSIS conducted an evaluation of all data collected on-site to determine whether CCA performance design and execution were consistent with the information provided to FSIS in the SRT and other submitted documents. FSIS conducted an exit meeting with the CCA representatives to convey all findings and discuss next steps.

The final phase of the audit is feedback, which begins with this draft audit report providing the CCA with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report. Then, FSIS and the CCA mutually develop an action plan to address any issues raised by the audit. These issues will be tracked by FSIS until resolution and will be automatically included as areas of special emphasis in the next on-site verification audit.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components reviewed was Government Oversight. FSIS' import eligibility requirements state that an equivalent 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 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 on-site record reviews, interviews, and observations made by the FSIS auditors at government offices and in the audited establishments. One of the CFIA' s proposed corrective actions in response to FSIS 2012 audit findings was to establish an office to improve and further correlate inspection activities and decisions made by all levels of the inspection program. The FSIS auditors interviewed CFIA's headquarters staff and learned that this office has been established as a pilot project following the 2012 audit. The CFIA is analyzing the inspection data gathered by this office to assess the effectiveness of the implemented pilot project. CFIA stated that an analysis of this pilot program was not available for FSIS to review, as the analysis is still ongoing; however, FSIS was able to review inspection data at the Area Office level. CFIA was able to provide information requested by FSIS auditors including trend analysis of noncompliances identified by inspection personnel, and the associated link to the follow-up increase of inspection verification tasks generated when noncompliance was identified at the establishment level, which was one of the concerns previously identified in the 2012 audit.

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 is assisted by one Executive Vice President and eight branch Vice Presidents. The CCA food safety mission is organized and executed by three specific branches; the policy and program branch, operations branch, and 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 and designated as 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 Executive Director who is assisted by an Associate Executive Director and Regional Directors that vary in number depending on the number of regions found in an area. The regions assign competent and qualified inspectors to eligible establishments for export to the United States.

The CCA maintains adequate administrative and technical support to operate its laboratory system. The CFIA's Laboratory Coordination Division 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 ISO 17025 accreditation.

The CCA's inspection personnel utilize the Compliance Verification System (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 in a verification worksheet, verification report, and corrective action request in an Inspection Report – Corrective Action Request (IR-CAR). Each item is described below.

- Verification worksheet - The main purpose of the verification worksheet~~s~~ is to identify any items requiring correction by the establishment that did not result in 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 IR-CAR 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-CARs). All the information that appears in the verification report is automatically populated from the data entered by the inspector on the verification worksheet.

- Inspection Report - Corrective Action Request (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 forces 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 as per Chapter 14 of the

Manual of Procedures (MOP). The enforcement actions consist of progressively stricter steps, which can range from holding the product under CCA's tag to termination of the establishment's registration. An inspector requests a review by the management if a IR-CAR cannot be closed because of any unacceptable conditions, 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 CCA's MOP provides guidance for the CCA inspection personnel on the verification process and describes the verification task procedures in detail. The MOP 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 establishment's associated records. The FSIS auditors verified through the review of trend analysis documentation that the CCA increases it pre-operational verification task frequency when the inspection personnel identifies non-compliance during hands on verification task for pre-operational sanitation inspection.

Periodic supervisory reviews are divided into Quality Management System (QMS) and Forecasting activities. The QMS is a supervisory tool to assess, improve, and report on the effectiveness of the CCA inspection personnel activities. The QMS ensures uniformity and consistency in the delivery of verification activities across the inspection system. Supervisory visits using the QMS are being conducted at the frequency of at least once per quarter.

Forecasting is another supervisory tool that assesses the establishment performance through a supervisor's on-site tour of the facility and review of the establishment's documents. Forecasting is being conducted monthly in slaughter establishments and quarterly in processing establishments. The results of forecasting activity are rated as pending or complete, 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 CVS tasks. The forecasting activity is documented in the QMS by the supervisors to follow up on during subsequent forecasting activity. During the on-site audit, the auditors examined a sample of QMS supervisory and forecasting reports for a six-month period at all the audited establishments. Both QMS and forecasting activities were being implemented in accordance with the CCA requirements.

Since the last FSIS audit in 2012, 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 auditor's observed in-plant inspection personnel and laboratory personnel while they were conducting their inspection activities. The FSIS auditor has 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 auditors identified several findings related to the CCA's oversight during the headquarters, regional, and establishment audits. The on-site audit findings indicate a need for the CCA to improve its government oversight activities concerning components number (2) Statutory Authority and Food-

Safety Regulation findings related to the CCA conducting zero-tolerance verification after the final carcass wash in two establishments; (3) Sanitation findings related to inadequate enforcement of Sanitation Performance Standards (SPS) measures for proper maintenance of establishment's structures; (4) HACCP Systems findings related to inadequate enforcement of HACCP requirements including audit findings related to the location of the zero tolerance CCP being placed after the final carcass wash; and (6) Microbiological Testing Programs findings related to inadequate official sampling for RTE verification sampling program. Analysis of these findings is discussed later in this report.

In summary, the FSIS auditors identified observations related to Government Oversight in four other components that require the CCA's attention: Statutory Authority and Food Safety Regulations; Sanitation; HACCP Systems; and Microbiological Testing Programs equivalence components. Based on an analysis of documentation, observations performed and an analysis of food safety impacts, FSIS determined that Canada's inspection system does support the finding that the CCA meets the core equivalence criteria for this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS' requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling and slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory reviews to the establishments certified to export to the United States. The CCA enforces 14 Federal Acts and their associated regulations to exert its legal authority. The evaluation of this component included an analysis of information provided by the CCA through SRT, interviews, and observations during the on-site portion of the audit.

During the audit of four slaughter and processing establishments (two porcine and two bovine), FSIS 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 *Escherichia coli (E. coli)* sample collection, verification of pre-operational and operational sanitation monitoring procedures, and HACCP verification activities including the zero tolerance verification.

The two porcine and one of the two bovine slaughter establishments audited had employed a non-traditional post-mortem inspection system known as HACCP-based slaughter Inspection Program (HIP) for porcine and high line speed inspection system (HLIS) for bovine. FSIS has previously determined these alternative post-mortem inspection systems provided an equivalent level of inspection to FSIS inspection. The auditors noted that these three audited establishments were in compliance with HIP and HLIS 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 Point (CCP) in accordance with HIP and HLIS requirements.

FSIS observed in-plant inspection personnel conducting HACCP hands-on verification activities for zero-tolerance (feces, ingesta, and milk) CCP. No deviation from the critical limits was observed by either the inspection personnel or the FSIS auditors on the day of the audit. The auditors noted that the establishment's written HACCP plan had placed the monitoring and verification of zero tolerance CCP after the final carcass wash in one porcine and one bovine slaughter establishments. The FSIS auditors requested and reviewed the establishment's decision-making documents, which included monitoring data collected at the Finished Products Standard Testing station located before the final carcass wash. The analysis of the data did not support the establishment's decision for placing the CCP monitoring location after the final carcass wash.

The FSIS requirement for the CCA verification of zero tolerance is prior to the final carcass wash primarily because this point best presents the opportunity for the in-plant inspectors to observe visible fecal material, ingesta, or milk contamination prior to the material being washed off in the final carcass wash and is the point in the inspection process for the determination as to whether carcasses are eligible to receive the mark of inspection. The FSIS auditors noted that the CFIA in-plant inspection personnel at these two audited establishments conduct CFIA's zero-tolerance verification of establishment's procedures for controlling of feces, ingesta, and milk after the final carcass wash. In light of the establishments not having sufficient support to demonstrate that fecal content is prevented from contaminating the carcass prior to the final carcass wash, FSIS also questions the adequacy of the CFIA inspection verification procedures. FSIS notes that microbiological data show that the level or frequency of contamination with microbial organisms representative of the digestive tract content would not be sufficient support rationale on this issue because the FSIS inspection requirements are based, in part, on preventing the contamination in the first place. Consequently, unless CFIA is able to provide alternative procedures that support designating the verification point for zero tolerance after the final carcass wash, FSIS considers this sanitary measure to not be equivalent. Because this is a significant finding that will impact the overall equivalency of the CFIA inspection system, CFIA must respond with either correcting the location at which zero tolerance verification occurs or providing an appropriate rationale for implementing an alternative inspection procedure within 60 days or FSIS will deem the inspection system to not be equivalent.

FSIS assessed ante-mortem and post-mortem inspection examinations through on-site record reviews, interviews, and observations of in-plant inspection personnel performing ante-mortem and post-mortem examinations in four red meat and one poultry slaughter and processing establishments audited. The CCA inspection personnel are required to conduct ante-mortem inspection in accordance with the CCA regulation on all livestock and poultry intended for export to the United States. The CCA is also responsible for verifying that livestock is humanely handled and slaughtered, and that good manufacturing practice is followed in poultry. In addition, the CCA must ensure that meat, poultry, and egg products eligible for export to the United States are from certified Canadian establishments that are eligible to export to the United States. The FSIS auditor verified that the CCA is fulfilling these obligations.

FSIS also 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 conducted in accordance with the CCA requirements.

In the poultry slaughter establishment, FSIS observed the in-plant inspection implementation of both ante-mortem and post-mortem inspection procedures that are in accordance with the CCA's 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, in addition to, birds suspended in shackles on the line moving towards the stunning facilities. The FSIS auditors noted that the audited establishments meet post-mortem inspection facility requirements, including having a distortion-free mirror, sufficient shadow-free lighting, on-line hand rinsing facilities, hang back racks, a receptacle for condemned carcasses and parts, and start/stop switches.

FSIS also 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), SPS, *Salmonella*, and generic *E. coli* sampling techniques and records.

During the on-site audit of the CCA-HQ and the Regional office in Toronto, FSIS 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 office and the Food Safety Division of the CCA verify the establishment's validation through record review.

The CCA regulates Shell Egg and Processed Egg Products manufactured in federally inspected Canadian's establishments. The legislation that governs Processed Egg Products are the Canada Agricultural Products Act, Food and Drugs Act, and Consumer Packaging and Labelling Act. The in-plant inspection personnel perform various tasks to ensure that processed egg is 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. FSIS verified that the CCA has provided continuous inspection coverage in accordance with USDA's "Egg Products Inspection Act" requirements. The auditor 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% 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 Egg Specialist or Regional Manufactured Food 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 auditor verified that program reviews were conducted properly in accordance with the CCA requirements.

The FSIS analysis and on-site verification activities indicated that Canada's meat, poultry, and egg inspection system has the legal authority and a documented regulatory framework to implement CFIA' regulatory requirements for this component. However, FSIS has major concerns in regard to the adequacy of the CFIA inspection verification procedures for its zero tolerance verification activities in

two audited establishments. CFIA must provide supporting documentation within 60 days concerning the location of the official verification of the zero tolerance.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was Sanitation. An equivalent inspection system must provide requirements for all areas of sanitation, sanitary handling of products, and for the development and implementation of SSOP equivalent to requirements in the FSIS inspection system.

FSIS reviewed legislation, regulations, official instructions, and guidelines to verify that the CCA requires that the United States-eligible establishments have developed and maintained sanitation programs to prevent direct product contamination and the creation of insanitary conditions. The frequency of SSOP and SPS (CCA's Prerequisite Programs) inspection verification tasks are risk-based. The CCA's Manual of Procedures (MOP) not only provides direction for the CCA inspection personnel on the verification process but also describes the verification task procedures in detail. MOP also identifies the required minimum frequency at which the CCA inspection personnel must conduct each task. The FSIS auditors verified through the review of trend analysis documentation that the CCA increases it pre-operational verification task frequency when the CCA inspection personnel identify non-compliance during hands on verification task for pre-operational sanitation inspection.

FSIS reviewed sanitation plans and records related to the design and implementation of sanitation programs at the audited establishments. The FSIS auditors verified whether actual pre-operational inspection at two establishments were adequate by observing the in-plant inspection personnel conducting pre-operational sanitation verification inspection. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification inspection. The 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 the overall sanitary conditions of all audited establishments to the CCA documentation. These verification activities included direct observation of operations and review of the establishment's associated records. The FSIS auditors' record review included the establishment sanitation monitoring and corrective action records over at least a 3-month period at all establishments audited, as well as those of the CCA documenting inspection verification results, non-compliance, and supervisory reviews of establishments. The auditors noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date. The SSOP in the establishments audited were found to meet FSIS regulatory requirements as 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 establishment's corrective actions. FSIS also reviewed the supervisory QMS records at all nine establishments audited and two regional offices. These reviews contained sections on sanitation, HACCP, supervisory controls, ante- and post-mortem inspection, removal and control of specified risk materials, facility construction and maintenance, RTE control programs, non-compliance reports, and the follow-up to previous findings. The audit showed the supervisory reviews were conducted as scheduled at the area and regional offices; and that the reviews covered the required categories.

FSIS identified SPS findings related to the maintenance and cleaning of overhead structures above exposed product areas in four of the establishments audited. The FSIS auditors did not observe any direct product contamination. FSIS noted that some of these deficiencies were at one establishment implicated in the FSIS-identified POE violation for *Lm* in December 2013. In this establishment, the deficiencies were found in the processing area where the RTE prosciutto ham is exposed to the environment after its lethality step in the process. These SPS findings show a systematic breakdown in the CCA oversight of SPS issues since none of these findings had been identified or resolved prior to FSIS audit by the in-plant inspection personnel or during periodic supervisory reviews. The FSIS auditors' observations included:

- In Establishment A:
    - RTE product slicing and packaging rooms were not maintained in a manner to facilitate maintenance of sanitary conditions: Unsealed or inadequately sealed openings of ceilings and walls, loose white pipe insulated covering and residue buildup on pipe covering were observed;
    - RTE Slicing Room: Caulking loose around RTE product pass-through window from casing removal room; and
    - RTE Press Room: Refrigeration unit - rust developing on stainless steel corner of the unit and condensation drain assembly from unit.
- In Establishment B:
    - RTE Room: Refrigeration units' insulated pan drain used during cleaning of overheads are open ended and above exposed and non-exposed product areas throughout the RTE slicing and packaging room;
    - RTE Product Coolers: Some rails and ceiling objects were developing rust and most rail switch pistons have rust on the units; and
    - RTE product slicing and packaging rooms were not maintained in a manner to facilitate maintenance of sanitary conditions: Unsealed or inadequately sealed openings of ceilings and walls, loose white pipe insulated covering and residue buildup on pipe covering was observed.
- In Establishment C:
    - Cutting Room: Rust on ceiling electrical junction over blue conveyor belt carrying trim to trim sorting hopper; and
    - Carcass Cooler: Some rails and ceiling objects above exposed product were observed to be developing rust and most rail switch pistons have extensive rust on the unit.
- In Establishment D:
    - Carcass Cooler: Exposed insulation and overhead beaded condensation were observed on the ceiling in the corner of the first carcass cooler (carcass hotbox). There was no observed dripping of condensate.

On the day of the audit, the CCA took immediate enforcement action on issues identified in this component, and the establishment took immediate corrective actions that the CCA verified with measures to prevent further reoccurrence. Others deficiencies were scheduled to be corrected and to be verified by the CCA with corrective action verification scheduled to occur after the FSIS audit.

FSIS analysis determined that the CCA meets most of the equivalence criteria for this component. Though there was no direct product, contamination issues identified with the SPS deficiencies cited above, FSIS has serious concerns over implementation of SPS requirements. The SPS issues in general are a repetitive observation from previous audits identifying a need of greater awareness on the part of inspection personnel and their immediate supervision.

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

The fourth of the six equivalence components that the FSIS auditors reviewed was HACCP. The inspection system needs to require a HACCP plan or similar type of preventive control plan to maintain equivalence. The evaluation of HACCP component included an analysis of information provided by the CCA through SRT, interviews, and observations during the on-site portion of the audit.

The Food Safety Enhancement Program (FSEP) is the CCA's approach to develop, implement, and maintain HACCP systems in all federally inspected establishments. The objective of FSEP is to specify minimum requirements for an effective food safety HACCP system. FSEP requires establishments to verify that they can control food safety hazards in their operation. The CCA verifies the design of an establishment's HACCP system at a minimum of once every two years in federally inspected establishments. HACCP tasks are divided into two tasks (4103 New HACCP plan and 4104 HACCP prerequisite programs) commonly known as Group 4 tasks. Each task instructs inspection personnel to verify the effectiveness of operator reassessment concerning 1) product description, 2) product ingredients and incoming material hazard identification, 3) process step hazard identification, 4) cross-contamination hazard identification, 5) CCP determination, and 6) reassessment of process control. Information collected during verification review must meet FSEP requirements.

FSIS went to two regional offices and audited eight meat and poultry slaughter and processing establishments 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 on-site observations and reviews of the zero tolerance control records generated over the past six months in all five 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 establishment's corrective actions in response to 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 on-site document reviews and interviews of establishment and inspection personnel, the FSIS auditors identified the same HACCP recordkeeping findings in two of the nine establishments audited. The HACCP verification records reviewed did not document the time of verification activities associated with the calibration of monitoring instruments (thermometer) by the responsible establishment's employee.

FSIS verified that the CCA implemented zero tolerance policy for *L. monocytogenes* 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 FSIS analysis and on-site audit verification activities determined that the CCA continues to demonstrate the ability to satisfy the equivalence requirements for this component that are articulated by the FSIS import regulations (9 CFR 327.2).

VIII. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAMS

The FSIS auditors reviewed Chemical Residue Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include 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 plan and the process used to design the plan; a description of the actions taken to address unsafe residue 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 SRT, interviews, and observations during the on-site 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 (MRL) under the Food and Drugs Act and the Pest Management Regulatory Agency (PMRA), which regulates pesticide registration and establishes MRL under the Pest Control Products Act (PCPA). The Canada Agricultural Products Act gives CCA authority to sample products intended to be traded inter-provincially and internationally. The Meat Inspection Act (MIA) gives CCA authority to inspect and sample meat products in federally inspected establishments. The CCA's Meat Inspection Act enables CCA to enforce and administer the provisions of the Food and Drugs Act (FDA) as they relate to food. The FDA (Criminal Act) enables CCA inspectors to sample if there is a reasonable and probable ground to believe that there has been a violation of the FDA.

Through document review, the auditors 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. An audit of a residue laboratory was not in the scope of this audit.

FSIS analysis and audit verification activities of Canada's chemical residue testing program as designed and implemented indicated that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component that are articulated in FSIS import regulations (9 CFR 327.2-meat) (9 CFR 381.196-poultry) (9 CFR 590.900-egg products). The FSIS auditor found no concerns with the CCA's chemical residue control program. Therefore, FSIS determined that Canada's chemical residue control program does support the finding that the CCA's meat inspection system continues to maintain equivalence for this component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditors reviewed was 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.

The evaluation of this component included a review and analysis of Meat Hygiene Manual of Procedures (MHMOP), and Red Meat and Poultry Products Microbiological Sampling Plans and Criteria, which contains the regulatory requirements for establishments exporting eligible products to the United States.

The FSIS auditors verified that the CCA has microbiological testing programs in place for generic *E. coli* in all slaughter species and *E. coli* O157:H7 and non-O157 STEC in beef manufacturing trimmings. The CCA also has microbiological testing programs for *Salmonella* in raw and RTE products, *Campylobacter* in raw poultry products, and *Lm* in RTE products.

Testing for generic *E. coli:*

The CCA requires that certified establishments that export product to the United States have a microbiological sampling and testing program to show process control for livestock and poultry carcasses for generic *E. coli*. The CCA has established performance standards criteria for verifying process control for generic *E. coli* which are consistent with those listed in 9 CFR 310.25 (meat) and 381.94 (poultry). The FSIS auditors verified, through document reviews, that the meat and poultry slaughter and processing establishments audited, had implemented this generic *E. coli* testing requirement. Establishments maintain written procedures for sample collection. Inspection personnel verified that the sample collector is designated in the written plan; that the written plan addresses the location of sampling, randomness, and sample integrity; that appropriate sampling methodology is used; that the lab is using an appropriate method for analysis; that results are correctly evaluated; and that establishments take appropriate corrective action when they exceed levels that indicate adequate process control. Carcasses were being sampled by the establishment personnel and sent to the accredited private

laboratory. The auditors review of the establishment's in-plant program and records identified no concerns.

The testing program for *E. coli* O157:H7 and non-O157 Shiga-toxin producing *E. coli* in raw beef products:

The auditors verified implementation of the CFIA's non-O157 STEC sampling and testing program. The CFIA schedules randomized sample collection in each applicable establishment and directly observes and verifies the establishment collection and sample security. The establishment submits the sample to an accredited laboratory where it is analyzed with CFIA approved methods. The laboratory is required to send all test results individually to the CFIA inspection staff at the establishment and to the establishment itself for CFIA's security of the test results. Non-O157 STEC are not currently subject to specific regulatory provisions in Canada and for this reason the CFIA has implemented a non-O157 verification sampling program through export requirements. The FSIS auditors verified implementation of the program as written.

The CCA has mandated *E. coli* O157:H7 testing by the establishment for beef trim and other raw beef components that are used for the production of ground beef products subject to mandated testing, including trim (trim derived from primal and sub-primal cuts), head meat, cheek meat, weasand meat, hearts, and finely textured beef. Establishments must determine for each of these products whether any part of their production may be used in the manufacture of ground beef or other non-intact product. If so, that product must be tested at a determined frequency based on the annual volume of production. The FSIS auditor verified at two audited beef establishments that the CCA conducts verification sampling for raw ground beef routinely in accordance with FSIS's *E. coli* O157:H7 equivalence criteria and CFIA's sampling plan.

The CCA allows the compositing samples before the screening test for *E. coli* O157:H7 is conducted. FSIS OPPD has determined this practice to be equivalent. The FSIS auditor verified at the audited beef slaughter establishments that this procedure is performed in the manner that FSIS determined to be equivalent. A sample that causes a positive reaction with the CCA-recognized screening test is a presumptive positive for *E. coli* O157:H7. Presumptive positive results must be considered as positive results by the establishment unless the presumptive positive is later confirmed as negative at which time the product can be released.

The CCA conducts risk-based verification sampling of beef trim and other raw beef components that are used for the production of ground beef. The sampling plan is based on multiple factors such as seasonality (April to September), production volume, and historical testing and inspection data to verify the effectiveness of their control measures for *E. coli* O157:H7. If the establishment commingles beef trim and other raw beef components that are used for the production of ground beef from different suppliers, the sample is to be collected prior to commingling.

During the previous FSIS audit of Canada in 2012, FSIS identified lack of detailed documents outlining required steps when product was positive for *E. coli* O157:H7. The FSIS auditors verified the implementation of the Process Awareness Program. This program outlines guidance to establishments in order to comply with the CCA's revised policy (May 17, 2013) on the control of *E. coli* O157:H7 contamination in raw beef products. The FSIS auditors verified the following:

- The CCA is notified of every establishment presumptive positive result for *E. coli* O157:H7 by the establishment;
- The establishment conducts an independent investigation for each of these positive results; and
- The CCA verifies and documents the establishment's response to positive and presumptive results.

The sampling frequency is outlined in the National Microbiological Sampling Plans and Assessment Criteria (available only to CCA staff). Generally, all establishments will be sampled at a normal frequency. A compliance history, including a positive *E. coli* O157:H7 result from testing of precursor material or testing of the finished raw ground beef product downstream will be taken into account when placing an establishment on enhanced frequency of testing for the next 120 days.

For raw beef components not amenable to excision sampling (e.g. finely textured beef), a minimum of five sample units of approximately 200 g each must be collected from a lot that has been assembled according to the establishment's lot definition with the sample units representative of the whole lot.

The FSIS auditor observed the sampling technique used by establishment personnel to collect the samples in two bovine slaughter establishments. The technique they used is acceptable. Additionally, the auditor reviewed and verified establishment and the CCA *E. coli* O157:H7 verification sample results. No concern arose as the result of review of microbiological testing results.

Testing for *Salmonella* species in raw products:

FSIS has previously determined that the CCA's *Salmonella* sampling program is equivalent to that of FSIS. Canadian establishments eligible to export to the United States are subject to FSIS Performance Standard for *Salmonella* and must manufacture meat and poultry products in accordance to the applicable standard. The establishments are required to test products for *Salmonella* according to a written sampling program.

The FSIS auditors reviewed the CCA's *Salmonella* sampling and testing program, the implementation of the program within the certified establishment by the in-plant personnel, and the results and records resulting from the program. FSIS auditors verified that the certified establishments conduct pathogen reduction performance standard *Salmonella* testing for raw meat product. 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. The FSIS auditor's review of at least three months of records at the audited slaughter and processing establishments (two bovine, two porcine, and one poultry) identified that no *Salmonella* set failures had occurred.

The FSIS auditor's verification review of the CCA's *Salmonella* testing verification program indicated that CCA inspection personnel at the audited slaughter and processing establishments verify the establishments' sampling program yearly. Additionally, CCA inspection personnel follow protocol to routinely evaluate and verify (weekly during sample set testing) that the establishments follow all the requirements listed in their written testing program. CVS Worksheets document that the results of the verification of the company's sampling, sample storage, transportation, and processing, etc. are working correctly and according to directions; that performance standards are met; and that the establishments

are required to take corrective action when the standards are not met (sample set failures). The planning of the verification is made using the CVS Verification Worksheet as described previously. The CCA inspection personnel do not take carcass *Salmonella* verification samples. The CCA performs documented analyses of the results of microbiological testing programs to demonstrate an ongoing effectiveness of the inspection system for *Salmonella* performance standards.

All positive *Salmonella spp.* samples go through full serological investigation including the serotyping sub-typed, when required by the CCA or establishment. The procedure for taking samples and checking records was reviewed by the FSIS auditors. The CCA conducts risk analysis for *Salmonella* in raw products in accordance with Codex Principles and Guidelines for the Conduct of Microbial Risk Assessment. The auditors determined that *Salmonella* testing is conducted in accordance with this international standard, which FSIS has determined to be equivalent.

***Listeria monocytogenes* and *Salmonella* in RTE product:**

The CCA has microbiological testing programs for *Salmonella* and for *Listeria monocytogenes* (*Lm)* in RTE products. FSIS' equivalence criteria for *Lm* in RTE products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post lethality exposed RTE products, product contact surfaces, and the environment at a frequency that ensures that the establishments' control measures are effective.

The CCA's MOP requires that all establishments eligible to export RTE products to United States treat all products as Category 1 products, there being a zero tolerance for *Lm* in the United States. The CCA conducts risk-based verification sampling of RTE meat and poultry products and food contact surface sampling in federally inspected establishments that produce RTE product. The CCA collects product and food contact surface samples for the same lot. The CCA sampling frequency is based on three factors: the risk category of the products, presence/absence of antimicrobial agents, and post-lethality treatments.

The CCA in-plant inspection personnel and supervisors are required to verify the results of establishment testing and to institute enforcement actions if necessary. The CCA uses the testing done by its in-plant personnel and by the establishment to conduct trend analysis. The establishments are required to submit their testing results to the CCA at a dedicated e-mail address. The CCA conducts follow-up sampling (product and FCS) which is triggered by industry results.

However, during the 2014 audit the FSIS auditor's document review at the CCA's headquarters, two regional offices, three RTE processing establishments, and one government microbiological laboratory identified that the CCA is not fully meeting RTE equivalence criteria because the CCA's current RTE verification program does not include ongoing sampling and testing of environmental (non-food contact surface (NFCS)). The CCA's current RTE ongoing verification sampling program is solely based on the official finished sampling of product and food contact surfaces. The CCA RTE ongoing verification sampling program does not collect samples or test for the presence of *Lm* on non-food contact surfaces (environmental). This aspect of the CCA's RTE verification sampling program does not fully meet FSIS' RTE verification sampling equivalence criteria for the CCA. FSIS needs a response from the

CCA within 60 days that demonstrates the effective implementation of equivalence criteria for the control program for *Lm* in RTE products.

The document review showed that testing conducted under establishment's self-monitoring program includes product sampling for Alternative 1, product and product contact surface sampling for Alternative 2, and product, product contact surface, and environment sampling for Alternative 3. Export certification will only be granted for batches of product that have tested negative.

The FSIS auditor reviewed on-site one CCA microbiological laboratory (GTA at Toronto, Ontario) 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 November 6, 2013, and expiring on June 25, 2017, 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. This lab was testing for *Salmonella* in RTE product using MFLP 29 method and for *Lm* in RTE product using MFLP 28 method. The testing for *E. coli* O157:H7 is performed by using MFLP 30/80 method. These methods were found to be equivalent by FSIS.

The auditor reviewed documents pertaining to the government-operated laboratories. The document audit focused on personnel qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. No deficiencies were identified in the review of these documents which covered a period of at least three months.

During the laboratory visit, the FSIS auditor reviewed at least 90 days of documents pertaining to the sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. In addition, the auditor reviewed training records and the results of proficiency testing. Proficiency testing is proceeding as designed with all methods being conducted at least every other year. There were no deficiencies identified during the review of documents during the laboratory audit and all results of proficiency testing reviewed were acceptable.

The audit indicated that Canada's meat, poultry, and egg product 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. FSIS analysis of the CCA's control measures and on-site audit verification activities of the CCA microbiological testing program as designed and implemented showed that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component that are articulated by the FSIS import regulations 9 CFR 327.2-meat) (9 CFR 381.196-poultry) (9 CFR 590.900-egg products). However, FSIS has concern related to the CCA's *Lm* verification program in which the CCA must provide supporting documentation within 60 days after receiving this report.

X. CONCLUSIONS AND NEXT STEPS

The 2014 audit results indicate that the CCA's food safety inspection system meets the core criteria for all six equivalence components. However, FSIS identified three operational (or procedural) weaknesses related to government oversight, sanitation, and microbiological testing that raise significant questions

about the Canadian system's will need to be addressed by the CCA in order to maintain on-going equivalence to the United States' system.

During the exit meeting on June 13, 2014, the CCA noted that it has already begun to address the audit findings by implementing immediate corrective actions for the short-term and long-term prevention of recurrence of on-site audit findings. FSIS will evaluate any information provided by the CCA including the submittal of the CCA's proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions. FSIS expects the CCA response within 60 days of the issuance of this report.

APPENDICES

APPENDIX A: Individual Foreign Establishment Audit Checklist

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
LES VIANDES DU BRETON INC. 150, CHEMIN DES RAYMOND, RIVIERE-DU-LOUP, QC, G5R 5X8	06/05/2014	12	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 06/05/2014 Est #: 12 (Porcine S/P)(Canada)

22/51: The establishment's HACCP verification records for calibration of monitoring instruments did not document the time [9 CFR part 417.5 and 417.8].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	Nader Memarian

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 Inc./ Aliments Sofina Inc. 145 East Drive Bramalea, ON, L6T 1B9	06/04/2014	014C	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Kenneth E. Witek – SPA, CSO		[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	
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. CFIA RTE Official Verification Sampling	X
59.	

60. Observation of the Establishment Sofina Foods Inc./Aliments Sofina Inc.- Bramalea, ON, Est. 014C, RTE Processing, 06/04/2014

39/51 Various deficiencies in the maintenance and cleaning of overhead structures and walls were observed by the FSIS auditor. Observation included unsealed or inadequately sealed openings of ceilings and walls, lose white pipe insulated covering and residue buildup on pipe covering in the Ready-to-Eat (RTE) product slicing and packaging rooms. Additionally it was observed that in the,

- RTE Room: Refrigeration units insulated pan drain used during cleaning of overheads are open ended and above exposed and non-exposed product areas throughout the RTE slicing and packaging room. There was no observed product contamination however this may create an insanitary condition.
- RTE product Coolers: Some rails and ceiling objects were developing rust and most rail switch pistons have rust on the units both above exposed product area. There was no observed product contamination however this may create an insanitary condition.

[Regulatory reference: CFIA Meat Inspection Regulations, §28]

58/51 Equivalence criteria for *Listeria monocytogenes* in RTE products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment (non-food contact surfaces) at a frequency that ensures that the establishments' control measures are effective. A review of inspection documents at this establishment revealed that the CCA only conducts verification sampling of post-lethality exposed RTE products and food contact surfaces. The CCA verification sampling did not include non-food contact surfaces (environmental) at this establishment in order to verify the effectiveness of establishment's RTE control measures.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Kenneth E. Witek – SPA, CSO	

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
Les Oeufs Bec-O Inc., 830 rue Lanoie, Upton, Québec	06/02/2014	20	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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

Date: 06/02/2014 Est #: 20 (Egg Processing) (Canada)

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
Nader Memarian. DVM	Nader M

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 AGRI-BIO INC 999 RUE INDUSTRIELLE, ST-AGAPIT, QC, G0S 1Z0	06/06/2014	22	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 06/06/2014 Est #: 22 (Poultry S/P) (Canada)

22/51: The establishment's HACCP verification records for calibration of monitoring instruments did not document the time [9 CFR part 417.5 and 417.8].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Cargill Limited 165 Dunlop Drive, Guelph, ON, N1L 1P4	06/05 & 06/2014	051	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Kenneth E. Witek – SPA, CSO		[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	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Cargill Limited - Guelph, ON: Est. 051, Beef Slaughter/Processing, 06/05-06/2014

22/51 The establishment's written HACCP plan has placed the monitoring and verification of zero tolerance (fecal, ingesta, and milk) critical control point (CCP) after the final carcass wash. The establishment's decision making documents and monitoring data collected at the Finished Products Standard Testing (FPST) stations does not support the selection of the zero tolerance CCP location being after the final carcass wash. The monitoring data indicated that the establishment had identified fecal materials 1 time in the last 90 days and took appropriate action however, the ability to detect fecal, ingesta, and milk would be difficult once the carcass has passed through the following steps in the process 1) carcass wash, 2) hot water pasteurization (CCP 4B) and 3) post-evisceration lactic acid application prior to the establishment conducting their Final Carcass Inspection (zero-tolerance) (CCP 5B) which also includes a FPST station at that same location. [9 CFR 417.5(a)(2)]

39/51 Various deficiencies in the maintenance and cleaning of overhead structures were observed by the FSIS auditor. Observations included:

- Cutting Room: Rust on ceiling electrical junction over blue conveyor belt caring trim to trim sorting hopper
- Carcass Cooler-4:Some rails and ceiling objects developing rust and most rail switch pistons have extensive rust on the unit this was above an exposed product area

[Regulatory reference: CFIA Meat Inspection Regulations, §28]

51 The FSIS requirement for the CCA verification of zero tolerance is prior to the final carcass wash primarily because this point best presents the opportunity for the in-plant inspectors to observe visible fecal material, ingesta, or milk contamination prior to the material being washed off in the final carcass wash and is the point in the inspection process for the determination as to whether carcasses are eligible to receive the mark of inspection. The FSIS auditor noted that the CFIA in-plant inspection personnel at this establishment conduct CFIA's zero-tolerance verification of establishment's procedures for controlling of feces, ingesta, and milk after the final carcass wash. [9 CFR 307.2(g), 310.3, 310.17(a), 310.18(a), and 318.2(b) and (d)].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Kenneth E. Witek – SPA, CSO	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tri-Pet Holding Incorporated 70 Glen Scarlett Rd. Toronto, ON	06/02/2014	099	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Kenneth E. Witek – SPA, CSO		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Tri-Pet Holding Incorporated - Toronto, ON: Est. 099 Beef Slaughter/ Processing, 06/02/2014

39/51 The FSIS auditor identified that exposed insulation and beaded condensation was observed on the ceiling of the first carcass cooler (carcass hot box). There was no observed dripping of condensate however this condition may create an insanitary condition. [Regulatory reference: CFIA Meat Inspection Regulations, §28]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Kenneth E. Witek – SPA, CSO	

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
SUPRALIMENT S.E.C. 25 EST, ROUTE 125, ST-ESPRIT DE MONTCALM, QC, J0K 2L0	06/03/2014	129	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		X ON-SITE AUDIT ☐ DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 06/03/2014 Est #: 129 (Porcine S/P)(Canada)

22/51: The establishment's written HACCP plan has placed the monitoring and verification of zero tolerance (fecal, ingesta, and milk) critical control point (CCP) after the final carcass wash. The establishment's decision making documents and monitoring data collected at the Finished Products Standard Testing (FPST) station, located before the final carcass wash, does not support the selection of the zero tolerance CCP location being after the final carcass wash. The monitoring data indicated that the establishment had identified fecal materials in 22 out of 1638 tests at FPST station from December 2013 to May 2014. [9 CFR 417.5(a)(2)]

51: The FSIS requirement for the CCA verification of zero tolerance is prior to the final carcass wash primarily because this point best presents the opportunity for the in-plant inspectors to observe visible fecal material, ingesta, or milk contamination prior to the material being washed off in the final carcass wash and is the point in the inspection process for the determination as to whether carcasses are eligible to receive the mark of inspection. The FSIS auditor noted that the CFIA in-plant inspection personnel at this establishment conduct CFIA's zero-tolerance verification of establishment's procedures for controlling of feces, ingesta, and milk after the final carcass wash. [9 CFR 307.2(g), 310.3, 310.17(a), 310.18(a), and 318.2(b) and (d)].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	

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
ALIMENTS TRIUMPH INC. Location Address: 485, Rue Des Entrepreneurs Quebec	06/09/2014	250	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		X ON-SITE AUDIT ☐ DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 06/09/2014 Est #: 250 (RTE) (Canada)

58/51: Equivalence criteria for *Listeria monocytogenes* in Ready-to-Eat (RTE) products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment (non-food contact surfaces) at a frequency that ensures that the establishments' control measures are effective. A review of inspection documents at this establishment revealed that the CCA only conducts verification sampling of post-lethality exposed RTE products and food contact surfaces. The CCA verification sampling did not include non-food contact surfaces (environmental) at this establishment in order to verify the effectiveness of establishment's RTE control measures.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian. DVM	Nader Memarian

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
Santa Maria Foods ULC 10 Armthorpe Road Brampton, Ont., L6t 5M4	06/03/2014	473A	Canada
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Kenneth E. Witek – SPA, CSO		[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	O
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. CFIA RTE Official Verification Sampling	X
59.	

60. Observation of the Establishment Santa Maria Foods ULC - Brampton, Ont.: Est. 473A, RTE Processing, 06/03/2014

39/51 Various deficiencies in the maintenance and cleaning of overhead structures and walls were observed by the FSIS auditor. Observation included unsealed or inadequately sealed openings of ceilings and walls in multiple Ready-to-Eat (RTE) product "Clean Rooms". Additionally it was observed that in Clean Room 3:

- Slicing Room: Caulking loose around RTE product pass through window from casing removal room (above exposed product area, no product contamination observed)
- Press Room: Refrigeration unit – rust on stainless steel corner of the unit and condensation drain assembly from unit (above exposed product area, no product contamination observed)

[Regulatory reference: CFIA Meat Inspection Regulations, §28]

Note: Clean Room 3 is where the establishment process the RTE Prosciutto ham that was implicated in the FSIS identified POE violation for *Lm* on December 2, 2013.

58/51 Equivalence criteria for *Listeria monocytogenes* in RTE products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment (non-food contact surfaces) at a frequency that ensures that the establishments' control measures are effective. A review of inspection documents at this establishment revealed that the CCA only conducts verification sampling of post-lethality exposed RTE products and food contact surfaces. The CCA verification sampling did not include non-food contact surfaces (environmental) at this establishment in order to verify the effectiveness of establishment's RTE control measures.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Kenneth E. Witek – SPA, CSO	

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

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Tower 2, 6th Floor
Ottawa, Ontario
K1A 0Y9

Tel.: (613) 773-5491
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MAY 29 2015

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International Audit Staff, Office of International Affairs
United States Department of Agriculture
Food Safety and Inspection Service
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Washington, DC 20250
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SUBJECT: Canada's Response to Draft Final Report of an Audit Conducted in Canada, May 28 – June 13, 2014. Evaluating the Food Safety System Governing the Production of Meat, Poultry, and Egg Products Intended for Export to the United States of America

Dear Dr. Syed,

I am pleased to provide you with the Canadian Food Inspection Agency's response to the draft audit report for the FSIS audit in Canada conducted from 28 May 2014 to 13 June 2014.

The CFIA response is comprised of the two attached tables. One table contains the CFIA's responses to the audit findings, and the other contains CFIA's comments on and requested changes to the text of the audit report.

I would like to draw specific attention to two key points regarding the text of the draft final report:

- Section VI, Component Three: Sanitation:
  For the reasons described in our response, the CFIA is requesting the operating level for this component be identified as being "adequate" in the final report.

- Section X, Conclusions and Next Steps:
  The CFIA requests that you reconsider the statement that "The 2014 audit results indicate that the CCA's food safety inspection system is performing at an "adequate" level meeting the core criteria for all six equivalence components". This message was not conveyed to the CFIA at the audit closing meeting, where the overall message conveyed was positive, and no establishments had been delisted or given a Notice of Intention to Delist (NOID). For these reasons, the

CFIA is requesting the performance assessment be adjusted to an "average" level in the final report.

In light of the importance the Agency attaches to these points, I am requesting that we hold technical discussions prior to the publication of the audit report.

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,

Terence McRae

Terence McRae
Director, Food Import and Export Division

c.c.
Dr. Ashok Mengi, FIED CFIA
Tom Graham, OPS, CFIA

Attachments (2) :
Response of the Canadian Food Inspection Agency (CFIA) to Findings Identified in the United States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit Report on the Equivalency of the Canadian Meat, Poultry and Egg Inspection System (RDIMS # 6316053)

Response of the Canadian Food Inspection Agency (CFIA) to the Unites States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit Report on the Equivalency of the Canadian Meat, Poultry and Egg Inspection System (RDIMS #6570369)

Response of the Canadian Food Inspection Agency (CFIA) to Findings Identified in the United States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit Report on the Equivalency of the Canadian Meat, Poultry and Egg Inspection System

From May 28 through June 13, 2014, the USDA-FSIS conducted an audit to determine whether Canada's food safety inspection system governing the production of meat, poultry, and egg products remains equivalent to that of the Unites 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 eggs products to the United States.

This document summarizes the USDA-FSIS findings identified during the audit and the CFIA's response. These issues were extracted from the USDA-FSIS draft final audit report received on January 29, 2015.

Relevant Component/Section of the USDA-FSIS FINDINGS	**CFIA RESPONSE**
Component 1 – Government Oversight, Component 2 - Statutory Authority and Food Safety Regulations and Component 4 – Hazard Analysis Critical Control Point (HACCP) Systems Monitoring and verification of zero tolerance CCP after final carcass wash.	The CFIA will develop a Compliance Verification System (CVS) task for red meat high line speed establishments to verify the absence of fecal, ingesta and milk contamination before the carcass wash. The results of this task will be reviewed at the end of a 6 month period. The data so collected will be utilized to decide whether or not to change the program requirements for the CCP location (i.e., instruct industry to move the location of the CCP).
Component 3 – Sanitation SPS findings related to neglected maintenance of overhead structures above exposed product areas	Several of the issues described were identified by the CFIA prior to the USDA-FSIS audit. At the time of the audit, these findings were in the process of being addressed by local CFIA staff using the normal CVS process. As part of the CVS inspection process, the CFIA's inspector/veterinarian in charge of each establishment followed up on the deficiencies. An Inspection report- Corrective Action Request (IR-CAR) was issued to each operator. The operators provided written action plans which contained the root cause of the issue, corrective actions and

	preventative measures. Once the deadline to implement the corrective actions passed, the CFIA's inspectors/veterinarians in charge of these establishments followed up and ensured all measures taken were effective. These issues are now resolved.
Component 4 – Hazard Analysis Critical Control Point Documentation of the time of verification activities associated with the calibration of monitoring instruments.	The deficiencies, as described, were followed up by the CFIA's veterinarian in charge of each establishment using the normal CVS inspection process. This finding has been addressed and the time of verification associated with the calibration of monitoring instruments is now being documented.
Component 6 – Microbiological Testing Programs Testing for the presence of *Listeria monocytogenes* on non-food product contact surfaces (environmental).	The CFIA's Meat Hygiene Manual of Procedures (MHMOP) CH.11, Section 11.7.3.2.2.2.2.1 on Ready-to-eat meat has been updated to include NFCS testing. Please refer to the link below: http://www.inspection.gc.ca/food/meat-and-poultry-products/manual-of-procedures/chapter-11/united-states-of-america/eng/1369760600830/1369760663694

Response of the Canadian Food Inspection Agency (CFIA) to the Unites States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Draft Audit Report on the Equivalency of the Canadian Meat, Poultry and Egg Inspection System

USDA-FSIS Draft Report Reference	USDA-FSIS Draft Report Text with Canada's Suggested Changes (as track changes, please print in colour)	CFIA Comments
IV. COMPONENT ONE: GOVERNMENT OVERSIGHT	One of the CFIA's proposed corrective actions in response to FSIS 2012 audit findings was to establish an office to improve and further correlate inspection activities and decisions made by all levels of the inspection program. The FSIS auditors interviewed CFIA's headquarters staff and learned that this office has been established as a pilot project following the 2012 audit. The CFIA is analyzing the inspection data gathered by this office to assess the effectiveness of the implemented pilot project. <u>CFIA stated that an analysis of this pilot program was not available for FSIS to review</u>, as the analysis is still ongoing; however, FSIS was able to review inspection data at the Area Office level. CFIA was able to provide information requested by FSIS auditors including trend analysis of non-compliances identified by inspection personnel, and the associated link to the follow-up increase of inspection verification tasks generated when noncompliance was identified at the establishment level, which was one of the concerns previously identified in the 2012 audit.	**Status update on what is underlined on the left:** **The intent of the IVO Pilot Project was to develop, test and recommend strategies for the implementation of a structured audit approach for the evaluation of inspection integrity in CFIA food inspection programs.** **The intelligence gathered during the pilot was analyzed and captured in the Close Out Report which is comprised of Lessons Learned, Recommendations for Steady State Implementation and Survey Results from staff involved in the pilot process.** **The project demonstrated the value of an arms-length audit function to identify trends and minimize inspection delivery challenges. Based on success of the pilot project, the Inspection Verification Office was officially launched by Minister Ambrose in June of 2014.**

	The CCA maintains adequate administrative and technical support to operate its laboratory system. ~~National Laboratory Operations~~The CFIA's Laboratory Coordination Division 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 ISO 17025 accreditation. The CCA's inspection personnel utilize the Compliance Verification System (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 in a verification worksheet, verification report, and corrective action request (CAR). Each item is described below. • Verification worksheet - The main purpose of the verification worksheets is to identify any items requiring correction by the establishment that did not result in issuance of ~~a CAR~~an Inspection Report - Corrective Action Request (IR-CAR). In addition, verification worksheets also document the daily presence of the CCA's inspection personnel at the regulated establishments. The Worksheet is for use by the inspector only and not for presentation to the operator. • Verification report - The verification report identifies the ~~CAR~~ number of any an Inspection Report - Corrective Action Request (IR-CAR)s~~CARs~~	

	that have been generated and issued to the establishment. The verification report is presented to the operator and 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 ~~CARs~~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. • Inspection Report - Corrective Action Request (IR-CAR). ~~Corrective action request- A CAR~~An IR-CAR is issued to an establishment by the CCA Inspectors whenever the results of a verification task are rated unacceptable. The ~~CAR~~ IR-CAR describes the non-compliance and forces the establishment management to implement corrective measures by providing an acceptable action plan by the date specified by the inspector. The ~~CAR~~ IR-CAR also describes the information gathered during the follow-up inspection. An inspector can close a ~~CAR~~ 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 ~~CAR~~ IR-CAR in the follow-up section of the ~~CAR~~IR-CAR, and the ~~CAR~~ IR-CAR remains open. A copy of the follow-up section of the ~~CAR~~ IR-CAR is provided to the establishment. The inspector initiates enforcement actions as per Chapter 14 of the	

	Manual of Procedures (MOP). The enforcement actions consist of progressively stricter steps, which can range from holding the product under CCA's tag to termination of the establishment's registration. An inspector ~~requests a review by the management~~can request a CFIA Management Review Team be formed if a CAR cannot be closed because of any unacceptable conditions, including lack of implementation or inadequate corrective actions proffered by the establishment. ~~These CARs are reviewed by~~The Management Review Team which includes CCA supervisors and inspection managers will review these CARs. ~~All the supervisors and managers reviewing the CAR must document their reviews and recommendations~~This review and accompanying recommendations will be documented on an Enforcement Tracking Form. The frequencies of inspection verification tasks are risk-based. The CCA's MOP provides guidance for the CCA inspection personnel on the verification process and describes the verification task procedures in detail. The MOP 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 establishment's associated records. The FSIS auditors verified through the review of trend analysis documentation that the CCA increases it pre-	

	operational verification task frequency when the inspection personnel identifies non-compliance during hands on verification task for pre-operational sanitation inspection. ~~Periodic supervisory reviews are divided into Quality Management System (QMS) and Forecasting activities.~~ The QMS is a supervisory tool to assess, improve, and report on the effectiveness of the CCA inspection personnel activities. The QMS ensures uniformity and consistency in the delivery of verification activities across the inspection system. Supervisory visits using the QMS are being conducted at the frequency of at least once per quarter. ~~Forecasting is another supervisory tool that assesses the establishment performance through a supervisor's on-site tour of the facility and review of the establishment's documents. Forecasting is being conducted monthly in slaughter establishments and quarterly in processing establishments.~~ Evaluating the delivery of a forecasting activity by inspectors is one of the components of the QMS on-site reviews conducted by the supervisors. As part of the QMS on-site evaluation, the supervisor will accompany and observe the inspector conduct a forecasting activity. The forecasting activity requires the inspector to conduct a monthly on-site tour of the facility and evaluate potential weaknesses that could necessitate prioritizing the delivery of corresponding CVS inspection tasks within the next 4 weeks. Depending	**Forecasting is an activity conducted by the inspector. During the QMS, the supervisor will observe the inspector conduct a forecasting activity.** **Forecasting is conducted monthly in all meat establishments, slaughter and processing.**

	on the severity of the finding, the CVS inspection task will be delivered immediately by the CFIA inspector. The results of forecasting activity are rated as pending or complete~~, 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 CVS tasks. The forecasting activity is documented in the QMS by the supervisors to follow up on during subsequent forecasting activity~~. During the on-site audit, the auditors examined a sample of QMS supervisory and forecasting reports for a six-month period at all the audited establishments. Both QMS and forecasting activities were being implemented in accordance with the CCA requirements. Since the last FSIS audit in 2012, 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 auditors observed in-plant inspection personnel and laboratory personnel while they were conducting their inspection activities. The FSIS auditor has 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 auditors identified several findings related to the CCA's oversight during the headquarters, regional, and establishment audits. The on-site audit findings indicate a need for the CCA to improve its government oversight activities concerning components number (2) Statutory Authority and Food-~~Safety~~ Regulation findings related to the CCA conducting zero-tolerance verification after the final carcass wash in two establishments; ~~(3) Sanitation findings related to inadequate enforcement of Sanitation Performance Standards (SPS) measures for proper maintenance of establishment's structures;~~	**This overall message was not conveyed to CFIA at the audit closing meeting. At the closing meeting the overall message was positive and no establishments were delisted or have been given a NOID.** **The CFIA does not agree with the sanitation and HACCP System aspects associated with the following statement: "a need for the CCA to improve its government oversight activities".. CFIA has placed considerable effort since the last 2012 FSIS audit to increase its government oversight activities:** **1. CFIA's behavioural expectations of inspection staff have been modernized to promote and encourage the values and attitudes expressed through unique behaviours of courage, rigour and respect.** **2. The Inspection Verification Office was officially launched by Minister Ambrose in June of 2014. The IVO is established to oversee the performance of the food safety inspection system, increase its delivery oversight, identify trends and minimize inspection delivery challenges.** **3. CFIA monitors inspection verification data at the national and regional levels.** **For the rationale behind the (3) Sanitation deletion, see comments under VI. COMPONENT THREE: SANITATION**

	(4) HACCP Systems findings related ~~to inadequate enforcement of HACCP requirements including audit findings related~~ to the location of the zero tolerance CCP being placed after the final carcass wash; and (6) Microbiological Testing Programs findings related to inadequate official sampling for RTE verification sampling program. Analysis of these findings is discussed later in this report. In summary, the FSIS auditors identified observations related to Government Oversight ~~in four other components~~ that require the CCA's attention: Statutory Authority and Food Safety Regulations; ~~Sanitation;~~ HACCP Systems; and Microbiological Testing Programs equivalence components. Based on an analysis of documentation, observations performed and an analysis of food safety impacts, FSIS determined that Canada's inspection system does support the finding that the CCA operates at an "adequate" level for this component.	**The CFIA disagrees with this statement. There are different philosophies of how HACCP systems are designed and where CCPs should be located. Both the Canadian and FSIS HACCP systems have the same outcome: zero-tolerance (feces, ingesta, and milk) CCP.** **As a result, no deviation from the critical imits was observed by either the inspection personnel or the FSIS auditors on the day of the audit. This being said, the CFIA will pursue additional action in relation to this matter (please refer to the "Response of the Canadian Food Inspection Agency (CFIA) to Findings" table, for Component 1, 2 and 4).**
V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS	~~The CCA is also responsible for verifying that livestock is humanely handled and slaughtered, and that good manufacturing practice is followed in poultry.~~The CCA is also responsible for verifying that livestock and poultry are humanely handled and slaughtered.	**In Canada, poultry are recognized as food animals and all humane handling laws also apply to poultry. Therefore, we propose the statement to be reworded.**

	The CCA regulates the grading and preparation of Shell Egg and Processed Egg Products ~~manufactured~~ prepared in federally ~~inspected Canadian's establishments~~registered Egg Stations. The ~~provisions~~ legislation that governs Processed Egg Products are the Canada Agricultural Products Act, Food and Drugs Act, and Consumer Packaging and Labelling Act. The in-plant inspection personnel perform various tasks to ensure that processed egg is 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. FSIS verified that the CCA has provided continuous inspection coverage in accordance with USDA's "Egg Products Inspection Act" requirements. The auditor 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 weekly~~based on 50% 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 Egg Specialist or Regional Manufactured Food 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 auditor verified that program reviews were conducted properly in accordance with the CCA requirements.	

VI. COMPONENT THREE: SANITATION	FSIS identified SPS findings ~~because of the neglected~~related to the maintenance and cleaning of overhead structures above exposed product areas in four of the establishments audited. The FSIS auditors did not observe any direct product contamination. FSIS noted that some of these deficiencies were at one establishment implicated in the PSIS-identified POE violation for Lm in December 2013. In this establishment, the deficiencies were found in the processing area where the RTE prosciutto ham is exposed to the environment after its lethality step in the process. ~~These SPS findings show a systematic breakdown in the CCA oversight of SPS issues since none of these findings had been identified or resolved prior to FSIS audit by the in-plant inspection personnel or during periodic supervisory reviews.~~ The FSIS auditors' observations included: In Establishment A: • RTE product slicing and packaging rooms were not maintained in a manner to facilitate maintenance of sanitary conditions: Unsealed or inadequately sealed openings of ceilings and walls, loose white pipe insulated covering and residue buildup on pipe covering were observed; • RTE Slicing Room: Caulking loose around RTE product pass-through window from casing removal room; and • RTE Press Room: Refrigeration unit- rust developing on stainless steel corner of the unit and condensation drain assembly from unit.	**Several of the issues identified by FSIS, were also identified by CFIA prior to the USDA-FSIS audit. As a result these findings were in the process of being addressed by local CFIA staff using the normal CVS process.** **Also, establishment of the Inspection Verification Office marks a very concrete step by the CFIA to strengthen the performance of its food safety inspection system including its oversight of SPS issues** **For these reasons, the CFIA is of the opinion that the choice of words in this section paints an inaccurate picture of the actual situation. We therefore request the reference to CCA oversight of SPS issues be deleted and that the performance level of this component be noted as adequate in the final report.**

	In Establishment B: • RTE Room: Refrigeration units' insulated pan drain used during cleaning of overheads are open ended and above exposed and non-exposed product areas throughout the RTE slicing and packaging room; • RTE Product Coolers: Some rails and ceiling objects were developing rust and most rail • switch pistons have rust on the units; and • RTE product slicing and packaging rooms were not maintained in a manner to facilitate maintenance of sanitary conditions: Unsealed or inadequately sealed openings of ceilings and walls, loose white pipe insulated covering and residue buildup on pipe covering was observed. In Establishment C: • Cutting Room: Rust on ceiling electrical junction over blue conveyor belt carrying trim to trim sorting hopper; and • Carcass Cooler: Some rails and ceiling objects above exposed product were observed to be developing rust and most rail switch pistons have extensive rust on the unit. In Establishment D: • Carcass Cooler: Exposed insulation and overhead beaded condensation were observed on the ceiling in the corner of the first carcass cooler (carcass hotbox). There was no observed dripping of condensate.	

	FSIS analysis determined that the CCA meets ~~most of~~ the equivalence criteria for this component. Though there was no direct product, contamination issues identified with the SPS deficiencies cited above, FSIS has ~~serious~~ some concerns over implementation of some of the SPS requirements. ~~The SPS issues in general are a repetitive observation from previous audits identifying a need of greater awareness on the part of inspection personnel and their immediate supervision.~~ Therefore, the CCA is operating at ~~a borderline~~an "adequate" level for this component.	
VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS	The Food Safety Enhancement Program (FSEP) is the CCA's approach to develop, implement, and maintain HACCP systems in all federally inspected establishments. The objective of FSEP is to specify minimum requirements for an effective food safety HACCP system. FSEP requires establishments to verify that they can control food safety hazards in their operation. The CCA verifies the design of an establishment's HACCP system at a minimum of once every two years in federally inspected establishments. HACCP tasks are divided into two tasks (~~4101~~ 4103 New HACCP plan and ~~4102~~ 4104 HACCP ~~prerequisite programs~~System) commonly known as Group 4 tasks. Each task instructs inspection personnel to verify the effectiveness of operator reassessment concerning 1) product description, 2) product ingredients and incoming material hazard identification, 3) process step hazard identification, 4) cross- contamination hazard identification, 5) CCP determination, and 6) reassessment of process control. Information collected during verification review must meet FSEP	

	requirements.	
IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS	However, during the 2014 audit the FSIS auditor's document review at the CCA's headquarters, two regional offices, three RTE processing establishments, and one government microbiological laboratory identified that the CCA is not fully meeting RTE equivalence criteria because the CCA's current RTE verification program does not include ongoing sampling and testing of environmental (non-food contact surface (NFCS)). The CCA's current RTE ongoing verification sampling program is solely based on the official finished sampling of product and food contact surfaces. The CCA RTE ongoing verification sampling program does not collect samples or test for the presence of Lm on non-food contact surfaces (environmental). This aspect of the CCA's RTE verification sampling program does not fully meet FSIS' RTE verification sampling equivalence criteria for the CCA. FSIS needs a response from the CCA within 60 days that demonstrates the effective implementation of equivalence criteria for the control program for Lm in RTE products.	**NFCS sampling by operators in US eligible establishments is a requirement under MHMOP Chapter 11.** **This sampling is done under CFIA oversight and in the event of any positive NFCS result the CFIA will conduct the appropriate CVS task and issue an Inspection Report/ Corrective Action Request (CAR). Corrective actions must be taken by the operator, which will be evaluated by CFIA. The recommended procedure for NFCS testing and follow-up procedure is described in MHMOP Chapter 4 (Section 5.4 and Appendix 6).** **Mandated samples must be tested in private accredited laboratories.**
X. CONCLUSIONS AND NEXT STEPS	The 2014 audit results indicate that the CCA's food safety inspection system is performing at an "adequate" level meeting the core criteria for all six equivalence components. However, FSIS identified ~~three~~ two operational (or procedural) weaknesses related to government oversight, ~~sanitation,~~ and microbiological testing that ~~raise significant questions about the Canadian system's~~will need to be addressed by the CCA in order to maintain on-going equivalence to the United States' system.	**The CFIA does not agree with the overall "adequate" level rating for its inspection system. This message was not conveyed to CFIA at the audit closing meeting. At the closing meeting the overall message was positive and no establishments had been delisted or given a Notice of Intention to Delist (NOID).**