



United States Department of Agriculture

DEC 9 13

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Dear Dr. Muthukumarasamy:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Canada's meat inspection system from October 22 through November 9, 2012. FSIS has received your comments and has incorporated the information into the report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov).

Sincerely,

A handwritten signature in blue ink, appearing to read "Shaukat H. Syed".

Dr. Shaukat H. Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement and Audit

Enclosure

DEC 9 11

**FINAL REPORT OF AN AUDIT CONDUCTED**

**IN CANADA**

**OCTOBER 22 THROUGH NOVEMBER 9, 2012**

**EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING THE  
PRODUCTION OF MEAT PRODUCTS INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA**

**Food Safety and Inspection Service  
United States Department of Agriculture**

## *Executive Summary*

This report describes the outcome of an on-site ongoing equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from October 22 through November 9, 2012 to verify whether Canada's food safety system governing slaughter and processing continues to be equivalent to that of the United States (U.S.), with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. The focus of the audit was on the ability of the Central Competent Authority (CCA), the Canadian Food Inspection Agency (CFIA), to regulate red meat, poultry, and egg products.

FSIS reviewed and verified the information provided by the CFIA through the Self Reporting Tool (SRT) submitted on April 1, 2010, prior to the onsite. The onsite audit scope included two red meat slaughter establishments, four meat processing establishments producing ready-to-eat (RTE) meat products, and one egg processing establishment. Additionally, FSIS visited five government offices, including the CFIA headquarters, and two private laboratories conducting microbiological and chemical residue testing. Determinations concerning the effectiveness of Canada's food safety program focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems (HACCP), (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs.

The audit showed CFIA is performing "adequate" in maintaining equivalence and meeting the criteria for all six components; however, the following concerns indicate a need for improvement of CFIA's oversight of HACCP in particular, although sanitation and humane handling, as described in later sections of the report, also need attention.

- Non-compliances in HACCP implementation were noted during the on-site audit in the delisted beef slaughter Est. 38 - the same beef slaughter establishment that had the large 2010 recall and then follow-up CFIA independent investigation and related report titled "Food Safety – Independent Review of XL Foods Incorporated Beef Recall 2012." Est. 38 also had humane handling and sanitation non-compliances.
- Non-compliances in Sanitation Performance Standard were noted during the onsite audit of the one swine slaughter establishment.
- Additional requests for further clarification on CFIA's RTE policy and more information regarding Shiga-Toxin Producing *Escherichia coli* program through an SRT update are pending.

For all the above non-compliances, the CFIA took immediate corrective actions and instituted long-term preventive measures to strengthen its establishment and system-wide regulatory oversight. CFIA's plan is clearly described with thirty actions that are already underway to develop and implement a sustainable internal inspection oversight role that allows continuous system improvement. In particular, CFIA immediately implemented verification procedures and trend analysis of HACCP critical limit deviations. Furthermore, CFIA is establishing an office to improve and further correlate activities and decisions made by all levels of its inspection program. If these actions continue to be effectively implemented, the system weaknesses should be remedied and equivalence maintained.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AES	Area Egg Specialist
CALA	Canadian Association of Laboratory Accreditation
CAR	Corrective Action Request
CCA	Central Competent Authority
CFR	Code of Federal Regulation
CFIA	Canadian Food Inspection Agency
CVS	Compliance Verification System
<i>E. coli</i>	<i>Escherichia coli</i>
FCS	Food Contact Surfaces
FDA	Food and Drugs Act
FSEP	Food Safety Enhancement Program
FSIS	Food Safety and Inspection Service
HC	Health Canada
HIP	HACCP based Inspection System in Pigs
HLIS	High Line Speed Inspection System in beef
IIC	Inspector-in-Charge
KIS	Kidney Inhibition Swab
<i>Lm</i>	<i>Listeria monocytogenes</i>
MIA	Meat Inspection Act
MIR	Meat Inspection Regulations
MOP	Meat Hygiene Manual of Procedures
MRL	Maximum Residue Limits
NCRMP	National Chemical Residue Monitoring Program
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
POE	Point-of- Entry
RES	Regional Egg Specialist
RTE	Ready – to – Eat
RVO	Regional Veterinary Officer
QMS	Quality Management System
<i>Salmonella spp.</i>	<i>Salmonella species</i>
SCC	Standards Council of Canada
SPS	Sanitation Performance Standards
SRT	Self Reporting Tool
SSOP	Sanitation Standard Operating Procedures
ST	Shiga toxin
STEC	Shiga-Toxin Producing <i>Escherichia coli</i>
STOP	Swab Test on Premises
TPC	Total Plate Count
VDD	Veterinary Drugs Directorate
VIC	Veterinarian-In-Charge

## **1. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an on-site audit of Canada's meat, poultry, and egg products inspection system from October 22 through November 9, 2012.

The audit began with an entrance meeting held on October 23, 2012 in Ottawa with the participation of representatives from the Central Competent Authority (CCA), the Canadian Food Inspection Agency (CFIA) and representatives from the United States Embassy in Canada, and the FSIS audit team.

## **2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

This was a routine ongoing equivalence verification audit. The audit objective was to ensure that Canada's food safety inspection system for meat, poultry, and egg products continues to be equivalent to that of the United States. In establishing the scope of the audit, FSIS used risk-based criteria to select the types of establishments, laboratories and government offices for the onsite audit. The onsite portion of the audit included visits to meat and egg establishments, as noted in table below. Poultry operations were verified through records review and interviews with government officials.

Furthermore, FSIS visited CFIA Establishment 38, XL Foods (currently, JBS Food Canada Inc.), in order to better understand the corrective actions put in place before allowing shipment of product to the U.S. to resume. Establishment 38 product was subject to a recall by CFIA because of the loss of process control and the distribution of adulterated product within the U.S. and Canada. The plant was delisted on September 13, 2012, prior to this audit and relisted on December 7, 2012, after CFIA submitted corrective actions that included the details pertaining to new operational policy in response to the establishment's *E. coli* O157:H7 test results and retraining of inspection personnel. Although the establishment remained delisted during the audit, it was operating for the domestic Canadian market, thus allowing the FSIS auditors to observe production and inspection activities, in addition to the records surrounding the recall.

As indicated previously, FSIS used a risk-based procedure to determine the audit scope, which included an analysis of country performance within six equivalence components; production types and volumes; frequency of prior audit-related on-site visits; point-of-entry (POE) testing results; and specific oversight activities and testing capacities of government offices and laboratories. The scope of the audit was based on an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CFIA through a self-reporting process. The Self Reporting Tool (SRT) provides information about the current structure of the country's inspection system and serves as a tool to identifying any significant changes in the CFIA system that have occurred since the last audit.

The FSIS auditors were accompanied throughout the audit by representatives from the CCA or from the area, regional, and local inspection offices. Determinations of program effectiveness focused on performance within the following six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems (HACCP), (5) Chemical Residues Control Programs, and (6) Microbiological Testing Programs.

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

In order to verify the CFIA's ability to provide consistent government oversight, a sample of seven establishments was selected by FSIS from 373 establishments certified to export meat products to the United States.

The previous FSIS audit (2009) identified concerns with the CFIA's supervisory oversight of its inspection personnel at the local level, especially with regard to verification activities related to establishment sanitation. During the current audit, particular attention was paid to the extent to which supervisors and in plant inspectors interact with each other to prevent non-compliances and to verify that the establishments control hazards, with an emphasis on the CFIA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2 and in accordance with CFIA procedures.

Additionally, private laboratories conducting microbiological and chemical residue testing were audited to verify if CFIA ensures that criteria established by FSIS for the use of private laboratories were being met.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	Ottawa
	Area Office	1	Ontario Area Office in Guelph, Ontario
	Regional Offices	3	Regional Office in Toronto, Ontario South Regional Office in Calgary, Alberta Regional Office in Quebec City, Quebec
Laboratories (microbiological and residue testing)		2	Silliker JR Laboratories, Burnaby, British Columbia Maxxam Analytics Limited, Mississauga, Ontario
Establishments		7	Est. 340, Santa Maria Foods ULC, Toronto Ontario, Processing establishment Est. 513, Britco Pork, Inc., Langley, British Columbia, Slaughter/ pork processing establishment Est. E-66, Vanderpol's Egg Ltd, Abbotsford, British Columbia Egg product establishment Est. 169A, Aliments Prince, S.E.C. Cornwall, Ontario, Processing establishment Est. 67, Montreal QC, processing establishment Est. 38, XL Foods Inc., West, Brooks, Alberta Slaughter/beef processing establishment Est. 1, Maple Leaf Foods, Winnipeg, Manitoba Processing establishment

### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

The audit was undertaken under the specific provisions of 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. Title 7)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the PR/HACCP regulations
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
- The Poultry Products Inspection Regulations (9 CFR Part 381)
- The Egg Products Inspection Act (21 U.S.C. 1031 et seq.)
- The Egg Products Inspection Regulations (9 CFR Parts 590 and 592)

The audit standards used to conduct the audit of the Canadian food inspection system are: Canadian laws, regulations, and equivalence determinations that the FSIS has made for Canada under provisions of Sanitary/Phytosanitary Agreement. The following equivalence determinations have been made for Canada:

- *Salmonella* testing of raw product
  - Establishments select samples
  - Private laboratories which are overseen directly by the government or the government contracted bodies analyze samples
- *Listeria monocytogenes* testing of ready-to-eat (RTE) products
  - Establishments select samples
  - Private laboratories; which are overseen directly by the government or the government contracted bodies 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 beef and pork 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
- MFLP-20 analytical method, Genequence®, for *Salmonella* spp. analysis in meat and eggs

#### **4. BACKGROUND**

Canada is eligible to export fresh and processed meat, poultry, and egg products to the United States, and is not under any restrictions by the Animal and Plant Health Inspection Service (APHIS). Between October 1, 2011 and September 30, 2012, Canada exported 1,442,314,920 pounds of meat and poultry products to the United States of which 68,145,483 pounds were re-inspected at Port-of-Entry (POE) in the United States. A total of 755,811 pounds were rejected at POE, of which 166,211 pounds were for failures of public health significance because of *Lm*, *E. coli* O157H7, or fecal contamination. Additionally, a total of 16,127,747 pounds of egg products presented at POE for re-inspection. A total of 49,802 pounds of egg product were rejected for reasons other than food safety and returned to Canada.

The findings of the last on-site audit conducted during 2009 resulted in issuing Notices of Intent to Delist (NOIDs) to three establishments and another three establishments were delisted by CFIA from the list of Canadian establishments eligible for export to the United States. Except for the beef slaughter establishment, the current scope did not include any establishments audited during the previous on-site audit. The implementation of corrective actions at other establishments for the findings observed during 2009 audit was verified through review of documents submitted by CFIA.

#### **5. GOVERNMENT OVERSIGHT**

The first of the six equivalence components that auditors reviewed was Government Oversight. The auditor verified that the inspection system was organized and administered by the national government of Canada and provided standards equivalent to those of the federal system of meat and poultry inspection in the United States (U.S.).

The CFIA is headed by the President who is the Chief Executive Officer of the inspection system. The President reports to the Minister of Agriculture and Agri-Food and holds the rank of a deputy head of a federal government department. The President is assisted by one Executive Vice President and eight branch Vice Presidents. The Executive Vice President acts as President in the President's absence. In addition to Executive Vice-President, the Chief Food Safety Officer also assists the President and Chief Veterinary Officer (CVO) held by the same official who directly reports to the President. Although, structurally, the Agency is organized into several distinct administrative and technical branches, the policy and program branch, operations branch and science branch are involved in executing the agency's mission of food safety. Each branch has its own head with a Vice President or an equivalent title. The Vice President of Operations branch is mainly responsible for field operations and is assisted by an Associate Vice President and three Directors and five Executive Directors. Each of the three Directors is responsible for emergency management, food recall, and emergency response, and branch management services directorates, respectively. At the field level, the CFIA 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 CFIA has developed a process to certify and decertify establishments and maintains a list of facilities that are eligible to export to the U.S. CFIA's authority to enforce a single standard of

inspection in U.S. certified establishments is drawn from the provisions contained in Canada Agricultural Products Act, Food and Drugs Act, Meat Inspection Act, and the regulations associated with each Act.

The CFIA maintains official controls over construction, facilities, and equipment. The routine verification and documentation of inspection activities associated with general sanitation, on-going Sanitation Standard Operating Procedures (SSOP), HACCP, and other on-going requirements are conducted by inspection personnel and are documented.

CFIA continues to maintain direct authority over inspection personnel, and these individuals are paid directly by the national government. Inspectors are assigned to the U.S. - eligible establishments at the regional level. The auditors verified that the CFIA has criteria for hiring and training new veterinarians and inspectors. On-going training is provided for Canadian domestic and U.S. requirements. The CFIA regularly assesses the need for training inspection staff and delivers training through classroom sessions, and on-line training portals. There is a system for performance evaluations for both veterinarians and inspectors.

The CFIA maintains adequate administrative and technical support to operate Canada's laboratory system. National Laboratory Operations in Ottawa provides oversight for the private and government laboratory systems. Government and private laboratories are accredited by the Standards Council of Canada (SCC) for ISO 17025 accreditation. Major accreditation audits are conducted every two years. A Memorandum of Understanding has been signed by the SCC and the CFIA, which outlines CFIA responsibilities to provide or approve audit team members, i.e., Technical Assessors for the SCC audit teams. Audit teams for the laboratories are comprised of CFIA and other technical audit experts. Laboratories participate in proficiency testing schemes organized by the CFIA and other programs organized by third-party providers.

The inspection staff at the CFIA utilizes the verification tool known as Compliance Verification System (CVS) to verify that industry is continually complying with Canada's federal food safety regulations and policies. The CVS is a task-based verification system that has many analogous features to FSIS' retired Performance Based Inspection System (PBIS) and was verified and found in compliance by the FSIS auditors.

The following link provides additional details about Compliance Level under CVS. The information is consistent with the information provided by CFIA through the SRT.

<http://www.inspection.gc.ca/english/fssa/meavia/man/ch18/step3e.shtml>

The documentation of CVS activities utilizes three types of documents, namely a) verification worksheet, b) verification report, and c) corrective action request (CAR).

The daily presence of inspectors at the establishments eligible to export to the U.S. is documented in the verification worksheet, the first of these three documents. The FSIS auditors verified verification worksheets. A series of CVS activities are captured on the verification worksheet including:

- the tasks that have been performed,
- the applicable rating or code for the activities performed in lieu of a Verification Task to assess compliance e.g.;

- establishment information and proof of daily presence;
  - activities conducted to assess compliance;
  - level of compliance (rating) or code assigned to each task; and
  - items requiring correction.
- references the CAR number, if applicable,
  - any items requiring correction that do not pose food safety concerns and that are being corrected by the establishment do not result in a CAR; however, the following situations result in the issuance of a CAR:
    - written programs that do not meet regulatory requirements;
    - incomplete findings that affect the integrity and effectiveness of the operator's written program; and
    - incomplete findings that result in situations in which potential hazards are not controlled.

One purpose of the verification worksheets is to identify any items requiring correction that did not result in a CAR. The auditors noted that the verification worksheet lacks the mechanism that is necessary to document repetitive non-compliances and to detect trends.

The second of the three documents identified above is called the verification report. The verification report identifies the CAR number of any 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 CARs). All the information that appears in the verification report is automatically populated from the data entered by the inspector on the verification worksheet.

The third CVS recording document is the CAR. A CAR is issued to an establishment by CFIA Inspectors whenever the results of a verification task are rated unacceptable. The CAR describes the non-compliance and advises the establishment operator that he/she must implement corrective measures by providing an acceptable action plan by the date specified by the inspector. The CAR also describes the information gathered during the follow-up inspection. An inspector can close a CAR upon verification of an effective implementation of corrective action. If the inspector determines that the situation of non-compliance has not been corrected, the inspector records the information gathered that supports the decision not to close the CAR in the follow-up section of the CAR, and the CAR remains open. A copy of the follow-up section of the CAR is provided to the operator. 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 CFIA's tag to termination of the establishment's registration. An inspector requests a review by the management if a CAR cannot be closed because of any unacceptable conditions, including lack of implementation or inadequate corrective actions proffered by the operator. Upper management, up to the inspection manager, then reviews the CAR. All the supervisors and managers reviewing the CAR must document their reviews and recommendations on an Enforcement Tracking Form. It is noted that not all observations made by the inspection staff result in issuance of a CAR as they are recorded on a verification worksheet and later followed

by the establishment if the concerns identified by the inspector have been addressed. Chapter 18 of MHMOP describes the policies and procedures related to CVS.

The procedures on CVS task specific to verification of U.S. Import Requirements are described in Chapter 11- Exports of the Meat Hygiene MOP. In addition, CFIA has established a certification procedure that ensures establishment compliance with these requirements prior to shipping product with respect to:

- Categorization of RTE meat and poultry products and classification of RTE establishments' labeling
- *Salmonella* and *Campylobacter* sampling
- Generic *E. coli* sampling
- Retained water requirements
- Risk-based Shiga Toxins-Producing *E. coli* Verification Sampling plan for Beef Trimmings and *Lm* in RTE products.

The auditors verified the supervisory structure within CFIA, which relies on the Quality Management System (QMS), a supervisory tool used to assess, improve, and report on the effectiveness of CFIA inspection staff activities. The QMS is an integral component of CVS, which ensures uniformity and consistency in the deliverance of verification activities across the inspection system. The auditors verified that the veterinarian-in-charge (VIC) assigned to a slaughter establishment conducts a verification of on-line inspectors at the frequency of two reviews each quarter. Further verification into the supervisory structure revealed that the Regional Veterinary Officer (RVO) is the second level supervisor to provide the oversight at slaughter establishments at the frequency of at least once per quarter. In processing establishments, QMS verification activities are the responsibilities of the complex supervisor (CS). The auditors examined a sample of QMS and determined that the CS conducts these verification activities at a frequency of three on-site verifications plus one file review (discussed below) with each inspector per year. It is important to note that the CS must select a different establishment each time he or she conducts the QMS review at the stated frequency. The CS verifies that the processing inspector is meeting performance standards at each of his/her assigned establishments.

Forecasting activities are also important feature of the CVS used by the supervisors. The forecasting activity requires an on-site tour of the facility be conducted each month with the inspectors to prioritize a particular task that the inspector needs to follow and complete. Food safety related tasks always precede the non-food safety tasks. Prior to conducting the forecasting activity, the supervisors review the results of the CVS task performed by the inspector assigned to the processing or slaughter establishment. The Complex Supervisor, who provides the oversight in processing establishments, performs this task on a quarterly basis. In a slaughter establishment the RVO conducts forecasting activity with the VIC, in turn the VIC or his/her designee (a trained inspector) performs this task on a monthly basis with the other inspection staff working under the latter. Section 18.7.2.5 of the MHMOP lists codes used on the verification worksheet. The activity code for forecasting is 9010. 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 Quality Management System (QMS) by the supervisors' to follow up on the subsequent forecasting activity.

Chapter 18 of the MOP provides standards and frequencies for the QMS. The quality verifications performed at federally registered meat establishments are subject to supervisory oversight, which essentially is a periodic supervisory review required by FSIS from its exporter as an import requirement.

There were no systemic findings in CFIA's meeting the criteria established for organizational structure and staffing, ultimate control and supervision, the assignment of competent qualified inspectors, the authority and responsibility to enforce the laws, adequate administrative and technical support including laboratory oversight, and the application of procedures and standards that are equivalent to the U.S. requirements.

During the onsite portion of the audit, the auditors examined a sample of QMS supervisory reports from a three-month period at the two slaughter and four processing establishments. No concerns were identified in any of the reports from the six establishments. However, the auditors observed sanitation non-compliances at both slaughter plants and HACCP non-compliances at the one delisted beef slaughter establishment. CFIA performed immediate corrective actions. These findings are further described in the Sanitation and HACCP components.

FSIS auditors' analysis of CFIA controls, forecasting procedures, reviews, and documentation supports CFIA's ability to provide oversight and enforce laws to ensure that adulterated or misbranded products are not exported to the United States. CFIA has an infrastructure of supervisory policy and procedures at the national, technical, scientific, and operational branch levels. The audit supports that CFIA's procedures for the assignment of competent qualified inspectors, adequate administrative and technical support, and the application of procedures and standards are equivalent. The CFIA independent investigation and related report titled "Food Safety – Independent Review of XL Foods Incorporated Beef Recall 2012" supports Canada's nationwide oversight of its inspection program. However, the onsite audit findings indicate a need for CFIA to focus oversight activities on sanitation and HACCP inspection activities. Therefore, the results of the audit support that CFIA receive an "adequate" government oversight equivalence determination.

## **6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. FSIS equivalence criteria require that the CCA have the legal authority and associated responsibility to ensure that adulterated or misbranded product is not exported to the U.S. The CFIA states that it enforces 14 Federal Acts and their associated regulations. The CFIA relies on the Meat Inspection Act and its related regulations to exert its legal authority in the establishments eligible to export to the U.S. and to ensure that they meet FSIS equivalence criteria set out in this component.

To reinforce CFIA's authority to ensure the safety of the meat food supply, the Senate of Canada on October 17, 2012, also adopted the Safe Food for Canadian Act. The salient features of the Safe Food for Canadians (SFC) Act include the following main points:

- Enhanced inspection and enforcement authority. With the adoption of the SFC Act, the Government of Canada has new authorities that will result in clearer rules for Canadian food commodity exporters and trading partners. The main new authority that did not exist in any of the former food safety statutes is the power to request a warrant over the phone. In addition, the legislation provides authority that is more explicit to an inspector to pass through or over private property to get to a place for inspection purposes or to take photographs.
- Tougher penalties for deliberate adulteration by introducing:
  - consistent food inspection practices across all food commodities;
  - increasing some existing fines, and introducing new fines and penalties;
  - giving the CFIA the ability to require regulated parties to have traceability systems;
  - including a prohibition against selling food commodities that have been recalled;
  - introducing new and stronger prohibitions against deceptive practices, tampering and hoaxes;
  - giving the CFIA the ability to require the registration or licensing of regulated parties and establishments; and
  - prohibiting the importation of unsafe food commodities.
- The SFC Act is consistent across commodities. In addition, the Act supports better import and export controls. The legislation also provides the CFIA the authority to certify all food commodities for export, allowing for a consistent approach to Canadian export certification.

Humane Handling and Slaughter of Livestock. The CFIA regulations governing humane handling and slaughter of livestock are prescribed in Part III, Section 61, titled “examination, inspection, humane treatment and slaughter, packaging and labeling.” Additional policies and procedures on the humane handling and slaughter of livestock are also described in the Chapter 12 of the Meat Hygiene Manual of Procedures (MOP), “Guidance on animal welfare topics.”

One beef slaughter establishment was documented for its non-compliances related to requirements for premises, design, and construction requirements. The auditors noted that the operator was not complying with section 3.5.1.1.1 of MOP for live animal receiving and holding which states every registered establishment in which food animals are slaughtered shall have all floors, ramps, gangways and chutes constructed and maintained in a manner that provides secure footing for food animals during movement and prevents injury during movement; however, the auditors observed that facility conditions existed that had potential to cause injury to animals. The corrective action was implemented immediately.

Ante-Mortem Inspection of Animals. The regulations governing ante-mortem inspection of animals are prescribed in Part III, Section 61, titled “examination, inspection, humane treatment and slaughter, packaging and labeling.” CFIA inspection personnel are required to conduct ante-mortem inspection in accordance with the regulation on all livestock and poultry intended for export to the U.S. This is coordinated and verified by an official veterinarian at slaughter establishments.

Post-Mortem Inspection of Carcasses and Parts. CFIA inspection personnel are required to conduct post-mortem inspection on all livestock and poultry intended for export to the U.S.

Verification takes place through the CVS. This is coordinated and verified by an official veterinarian at the establishment. The authority to conduct post-mortem inspection is prescribed in section 12. (1) of the Meat Inspection Act and Part III of Section 61 of the Meat Inspection Regulation of 1990 on humane handling and slaughter of livestock.

The two slaughter establishments audited had employed a non-traditional post mortem inspection system known as high line speed inspection system (HLIS) for beef and HACCP-based slaughter Inspection Program (HIP) for swine, respectively. As noted in the section on legal basis for the audit and audit standards, FSIS found HLIS equivalent in a letter to CFIA on March 2, 2006. In the letter, FSIS evaluated the HIP program and determined that there were no substantial differences between HLIS for beef and the HIP approach for hogs. On this basis, FSIS found HIP equivalent.

The current audit included both types of inspection systems, and the auditors were able to verify the inspection system in beef and swine establishments. The details of the HLIS and HIP can be found at the following websites, respectively:

<http://www.inspection.gc.ca/english/fssa/meavia/man/ch17/annexbe.shtml>

<http://www.inspection.gc.ca/english/fssa/meavia/man/ch17/annexc3e.shtml>

Through the auditor's interviews of the plant's Quality Control Officials and CFIA's VIC, reviews of the beef slaughter establishment and inspection service monitoring and verification records, and the on-site tour of the establishment; the auditor determined that the beef slaughter establishment was conforming to HLIS standards that FSIS determined to be equivalent. The following features of the HLIS program were verified:

- Facility requirements:
  - Lighting, carcass center spacing, CFIA inspection/plant employee space requirements, sanitizers, Shewhart test stations and presentation standards (PS) for the heads, viscera, and carcasses, Product Standards test stations, carcass cooler rework/trim station and line speed indicator
- General Inspection Procedures:
  - Routine post-mortem inspection of red meat carcasses conducted by CFIA inspectors,
  - The inspector observed the surfaces of the tongue after it had been palpated by a plant employee,
  - The inspector observed the cut surfaces of the internal pterygoid and external masseter muscles after they are incised by a plant employee,
  - The inspector incised and observed the cut surfaces of parotid, medial retropharyngeal, and mandibular lymph nodes,
  - The inspector observed the lateral retropharyngeal (atlantal) lymph nodes and palpates the dorsal surfaces of the lungs,
  - The inspector observed the hepatic lymph node, internal, external, and cut surfaces of the heart after an establishment employee presented the opened heart for inspection.
  - The inspector visually examined the spleen and the kidneys.
  - Carcass inspection was conducted on an un-split carcass in the case of steers and heifers but must be conducted on the split carcass of mature animals (cows and bulls).

- Random Testing Guideline - The following process control verification activities were observed being conducted by the establishment operating under HLIS:
  - Finished Product Standard (FPS) checks
  - Presentation checks
  - Shewhart Control Chart checks

During the onsite audit of a HIP establishment, the FSIS auditor verified that it is the responsibility of the establishment's carcass defect detector to identify all defective conditions, referred to as an operator managed condition (OMC), and to decide whether the carcass is to be railed out for trimming, or the defective condition will be corrected online. Carcass defect detectors use an in-plant marking system approved by the VIC to identify all OMC defects. Carcass defect trimmers removed conditions identified as OMC or CFIA-OMC either on-line or on the operator held rail. No carcass left the final carcass approval area until all defects and their associated tagging/identification marks had been removed by the carcass trimmers.

CFIA verifies that the plant process control monitors are accredited company employees who perform evisceration testing, presentation testing, finished product standards testing, and rework verification testing. These monitors must be proficient in the detection, scoring, recording, and process action activities associated with the process controls for which they are accredited and in accordance with the HIP.

All post-mortem inspection station activities remain a CFIA responsibility. Except where noted in this HIP program, post-mortem activities were performed as described in section 17.7, Chapter 17 of the MOP. CFIA inspectors working online are responsible for identifying specified pathological conditions that affect a part of or the entire carcass.

CFIA Verification Activities. The CFIA performs daily periodic monitoring and verification functions with respect to the operator's testing and recording activities, as well as employee performance to ensure the satisfactory application of the HLIS program. These activities also include randomly scheduled daily correlation tests but may also include unscheduled or spontaneous correlation tests if deemed necessary by the VIC or delegate. Daily activities are documented on the Verification Worksheet, Verification Report, and CAF.

Controls over Condemned Materials. The establishments maintain receptacles that are specifically designated for inedible or condemned material. They are clearly identified as inedible or condemned material, must be leak proof, and covered. The CFIA maintains control over the destruction of condemned material. The CFIA has specific requirements for the removal of specified risk materials (SRM). All SRMs must be removed prior to exporting to the US.

Controls over Establishment Construction, Facilities, and Equipment. The CFIA has official control over establishment construction, facilities, and equipment. The CFIA website offers a Reference Listing of Accepted Construction Materials, Packaging Materials, and Non-Food Chemical Products for use in establishments operating under the authority of the Agency. The document titled "Section 2 tasks.pdf" lists the inspection procedures to be performed at establishments and storage warehouse. The Chapter 4 (inspection procedures) part 4.1.2 pertaining to construction and maintenance states: There is also a "Verification Task Procedure" 1.2.20 for CFIA to verify equipment maintenance and calibration at least once/year.

Daily Inspection. All inspection personnel maintain a “verification worksheet,” a standard CFIA form to document their daily inspection verification activities. The verification worksheet is maintained at all U.S. certified establishments. Worksheets are available for review at the CFIA level, as well as at the regional and area level. These reviews are documented in quarterly performance reports. Chapter 18.pdf provides the required period for which documents (Est. task profile, task tracking table, verification worksheet, verification report, HACCP system design verification report, CAR) must be retained at the establishment. The CFIA maintains daily inspection in the certified establishments when product is being produced for the U.S. (Chapter 11.7.3.3.2 continuous supervision states that meat food products must be prepared under continuous supervision.)

Periodic Supervisory Visits to Official Establishments. Periodic supervisory reviews in slaughter establishments are carried out by the RVO and in processing establishments by the Complex Supervisor. These reviews are part of the Quality Management System (QMS), which is used to evaluate the adequate implementation of the Compliance Verification System (CVS). The QMS evaluates the performance (delivery) of inspection by CFIA personnel assigned to the establishments and identifies where the quality of the regulatory process can be improved. The CVS inspection tasks encompass all aspects of regulatory compliance verification in accordance with the Canadian Meat Inspection Regulations and include verification of compliance of certified establishments with United States export requirements. Supervisory visits are conducted using quality verifications within the QMS. Quality verifications are conducted within each work site at an established frequency. Each slaughter establishment is considered a work site, where processing establishments may be grouped into a complex. In this case, the QMS verification frequency is based on the number of inspectors and the amount of files generated from that work site and not based on the number of establishments. The document QMS Verification CA 65 was provided to the auditor as an example of a checklist that is used during the supervisory visits.

The FSIS assessment of the equivalence criteria applicable to Statutory Authority and Food Safety Regulations revealed that the CFIA has the legal authority and associated responsibility to ensure that adulterated or misbranded product is not prepared for export to the U.S. The CFIA met these criteria through enforcement of 14 Federal Acts and their associated regulation. The CFIA continues to rely on the meat inspection act and its related regulations to exert its legal authority at the establishments eligible to export to the U.S. to meet FSIS equivalence criteria set out in this component. CFIA has statutory authority and food safety regulations that auditors found to be equivalent.

## **7. SANITATION**

The auditors reviewed Sanitation as a third of the six equivalence components. Auditors verified that the inspection system provided requirements for sanitation, for sanitary handling of products, and for development and implementation of sanitation standard operating procedures. These requirements are contained in the following documents:

<http://www.inspection.gc.ca/english/fssa/meavia/man/ch18/step3e.shtml>

All certified slaughter and processing establishments are required to meet sanitation requirements. The CFIA inspection personnel routinely verify the requirement that SSOPs have an identified frequency, and that the establishment employee responsible for implementation and maintenance of these procedures is identified. The inspection personnel also are required

routinely to verify that the structure of the facility, structural equipment, and additional sanitation performance are up to the standard requirements.

The FSIS auditors' verification of this component included a review and analysis of the information provided by the CFIA in the SRT and observations made during the onsite audit. The auditors reviewed legislation, regulations, official instructions, and guidelines and verified that the CFIA requires and verifies that establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. The FSIS auditors' record review included monitoring and corrective action records over at least three-month period from the seven establishments, as well as those of CFIA documenting verification, non-compliance, and supervisory reviews of establishments across Canada.

In addition, the FSIS auditors observed CFIA conducting pre-operational and operational sanitation inspection procedures in all audited establishments and compared the conditions of all audited establishments to the CFIA documentation. There were concerns in the beef slaughter establishment that was also audited in 2009. The following SSOP non-compliances were observed and then corrected by CFIA inspection personnel in the above noted beef establishment.

- A number of plastic containers used to store edible product had pieces of meat and fat in them.
- During the pre-operational sanitation, scraps of meat and fat were observed on conveyor belts used to transport sub- primal parts to the cooler.
- Hard plastic conveyor belt made of individual pieces/modules not completely together to make a complete conveyor belt was observed the boning room was a potential source for product contamination. Some of the pieces of the conveyor belt were missing, and spaces approximately 3 inches were created that could allow product to fall out and create sanitation non- compliances.
- A carcass cooler in a slaughter establishment that was ready to receive carcasses for chilling had overhead beaded condensation.
- In the evisceration room, floors and walls were not maintained in a manner to facilitate maintenance of sanitary conditions. During the pre-operational sanitation, pieces of meat and fat were observed in crevices and shallow pits on the floor and walls. In addition, floors and walls were collecting moisture water in crevices.
- Protective trays under ventilators and blowers were dusty with some paper in them, demonstrating that they had been not cleaned for some time and could contaminate the product, especially when blowers and ventilators were turned on, blowing dust particles on boning tables below.

The following Sanitation Performance Standard (SPS) related non-compliances were observed in the swine slaughter establishment:

- Overhead rails and other structures (pipes) were observed with flaking paint and rust.
- Containers and combos used for edible product in daily operation with liners (plastic) on the side were observed to be touched by the passing employees. There was not sufficient space in these processing rooms, and some areas were overcrowded by combos with product. An unsanitary apron with attached stickers from the previous day's operation and holes was observed in the legroom.

- An unsanitary glove used during the previous operation was observed in the plastic container used for edible product.

In accordance with FSIS audit procedures, discussions were held with CFIA regarding each of the findings outlined above. The auditors verified that each establishment corrected the above noted deficiencies. While the inspection staff seemed well versed in handling each of the specific findings, further efforts should be made in developing the ability to identify these findings as they occur and in preventing them from occurring.

The FSIS auditors also reviewed the supervisory QMS records at all establishments audited as well in regional offices. These reviews found sections on sanitation and SSOP, HACCP, supervisory controls, ante and post-mortem inspection, removal and control of specified risk materials, facility construction and maintenance, RTE controls, in-plant CFIA supervision, non-compliance reports, and the follow-up to previous findings. The audit showed the supervisory reviews were conducted as scheduled at the HQ, Regional, and area offices; that the reviews covered the required categories; and that the reviews accurately reflected the condition in the inspected establishments with the exceptions noted in this and the HACCP component. In the swine slaughter establishment, two of the non-compliances were corrected immediately and verified by the CFIA inspector. In beef slaughter establishment, some deficiencies were corrected immediately (for instance, the general condition of floors and walls in the evisceration room), while others were scheduled to be corrected and to be verified by CFIA officials with corrective action verification scheduled to occur after the FSIS audit.

FSIS auditors concluded that CFIA has “adequate” equivalent policies and practices in place.

## **8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components that the FSIS auditors reviewed was HACCP. The evaluation of this component included a review and analysis of the information provided by the CFIA in the SRT and observations during the on-site audit. Further information on HACCP requirements can be found at the following CFIA portal:  
<http://www.inspection.gc.ca/food/fsep-haccp/eng/1299855874288/1299859914238>

The Food Safety Enhancement Program (FSEP) is the CFIA’s approach to encourage and support the development, implementation, and maintenance of HACCP systems in all federally registered establishments. The objective of FSEP is to specify minimum requirements for an effective food safety management system. FSEP provides a mechanism for operators of establishments to demonstrate their ability to control food safety hazards in order to ensure that food is safe for the consumer. In addition, it enhances the establishments’ ability to achieve and maintain compliance with the relevant regulatory requirements. FSEP is based on the principles of the HACCP system developed by the Codex Alimentarius Commission. HACCP is an internationally recognized, science-based food safety system, designed to prevent, reduce, or eliminate potential biological, chemical, and physical food safety hazards. A HACCP system is the responsibility of the establishment. FSEP specifies the requirements for an effective HACCP system. The design of an establishment’s HACCP system is verified a minimum of once every two years in every meat and poultry establishment. HACCP tasks are divided into two tasks (4101 HACCP plan and 4102 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.

The auditors verified that the CFIA inspection system required each official establishment certified to export to the United States develop, implement, and maintain a HACCP plan.

FSIS requires that the inspection system will continuously verify establishment production and that the inspection system has an effective enforcement program, which provides that establishments take action to correct process deviations that result in food safety hazards, determine how noncompliant product would be handled, ensure that no safety hazards exist after the corrective actions are taken, and define measures to prevent recurrence. Auditors determined that these requirements were met in all establishments audited onsite except the one beef slaughter Est. 38 that was delisted at the time. The main findings from Canada's own independent reviews and FSIS' audit of delisted Est. 38 are described below and then followed by CFIA's corrective actions. These CFIA review reports can be found on the following website: <http://www.inspection.gc.ca/food/consumer-centre/food-safety-investigations/xl-foods/assessment-of-establishment-38/eng/1350996393353/1350996638312?chap=3>

The main CFIA observations of Est. 38 operations in 2012 included:

- Lack of detailed documents outlining required steps when product was positive for *E. coli* O157:H7, or when there were a high number of positives in a production period;
- Inconsistent trend analysis on positive samples; there were incidences of HEP with positive test results for *E. coli* O157:H7 that resulted in a trend of detected positive results that should have been investigated for probable cause, the root cause of the problem should have been established, the CFIA inspectors should have been notified, and corrective action should have been proffered.
- Insufficient recordkeeping related to ongoing monitoring and validation of processes, procedures, and prerequisite programs related to equipment maintenance (e.g., 12 of 100 water nozzles clogged in the primary carcass wash area); and
- Deficiencies in sampling techniques and procedures, such as inconsistent sampling and no establishment-monitoring program.

As a result of the delistment on September 13, 2012, and prior to re-enlistment of Est. 38 on December 7, 2012, the CFIA implemented enhanced inspection of corrective actions to address sanitation, slaughter/dressing, and other operational controls; employed policies and procedures to react to plant *E. coli* O157H: 7 positive sample results in response to multiple positives, and execute analysis and verification of preventive actions to prevent recurrence of HACCP system violations. The actions were effectuated at the Local, Branch and National levels of the inspection system.

In regards to the RTE program, FSIS auditors verified that the CFIA's inspectors verified that certified establishments reassess their HACCP plans as required by conducting the HACCP system design and reassessment tasks. Inspectors routinely verify test results associated with establishment sampling under the CVS. Supervisors are required to conduct QMS reviews to

ensure that inspectors are carrying out their activities as outlined in the CVS. This includes sampling activities associated with RTE products and the specific policy updates.

In conclusion, CFIA operates an “adequate” HACCP equivalence system in its establishments nationwide. Based on the audit, HACCP criteria were met in all establishments except the one delisted establishment, and those non-compliances were addressed. Because of its own investigation, the CFIA increased frequencies of the verification testing of establishment’s *E. coli* O157:H7 monitoring program from once a month to once a day in order to identify a developing trend. CFIA’s increased verification as a preventive measure was effective. Since the December 14, 2012, re-listment, there have been no POE zero tolerance violations from the detection of *E. coli* O157:H7 pathogen in the product from Est. # 38. The recently published CFIA report titled “Food Safety – Independent Review of XL Foods Incorporated Beef Recall 2012” at Est. 38 provides a thorough analysis of the problems followed by a list of 30 recommendations to address nationwide corrective and preventive measures.

## **9. CHEMICAL RESIDUES CONTROL PROGRAMS**

The Chemical Residues Control Program was the fifth of the six equivalence components of CFIA’s program to be audited. The FSIS criteria for chemical residues include a program managed by the CFIA and established to carry out effective regulatory activities to prevent contamination of food products with chemical residues. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CFIA must provide a description of the basis for its residue plan and the process used to design the plan. The plan must describe the actual operations of its residue plan. The CFIA must provide a description of the actions taken to deal with unsafe residues as they occur. The CFIA must have access to and supervision of analytical laboratories that have the capability to assure the validity and reliability of test data, as well as measures to deter recurrence of residue violations.

The responsibility for monitoring food safety in Canada is shared by the CFIA and Health Canada (HC). HC’s Food Directorate, and its Bureau of Chemical Safety deals 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, establishing Maximum Residue Limits (MRL) under the Food and Drugs Act and the Pest Management Regulatory Agency (PMRA), which regulates the pesticide registration, establishing MRL under the Pest Control Products Act (PCPA).

The Canada Agricultural Products Act gives CFIA authority to sample products intended to be traded inter-provincially and internationally and the Meat Inspection Act (MIA) gives CFIA authority to inspect and sample meat products in federally registered establishments. The CFIA’s Meat Inspection Act enables CFIA to enforce and administer the provisions of the Food and Drugs Act (FDA) as they relate to food. The FDA (Criminal Act) enables CFIA inspectors to sample if there is a reasonable and probable ground to believe that there has been a violation of the FDA.

The auditors reviewed the information in the SRT and verified that the inspection system has an organized governmental program established to carry out effective regulatory activities to prevent contamination of food products with chemical residues; that the CFIA manages this

program and provides direction, coordination, and oversight; that the various elements of the program are conducted by the CFIA in conjunction with the government laboratories at Saskatoon, Calgary etc.; and that the program has sufficient resources from Headquarters, the central laboratory at Saskatoon, other governmental and various private laboratories, and regional and in-plant personnel. The auditors also verified the previously submitted laws, regulations, and implementation documents defining the legal authority of the CFIA to organize and implement a residue control program. This legal authority prescribes the conditions for the use of chemicals in the production of meat and poultry products, prohibits the use of compounds that may present unacceptable public health risks, and provides the ability to control and monitor industrial and environmental chemicals that may lead to contamination and provides the ability to enforce these laws and regulations.

The auditors verified that the design of the Canada National Residue Program includes the required criteria including a description of the basis for the residue plan and the process used to design the residue plan. The residue plan also describes the various sampling schemes, lists the selected matrices for each compound, and includes a rationale and process for the choice of chemical compounds.

The CFIA conducts random sampling and testing of internal organs, muscle, and fat for targeted residues. Random sampling and testing of internal organs is captured in Laboratory Services Test System. The CFIA began collecting data through CVS in April 2010. The Science Committee process is the main means of hazard identification and prioritization of chemical hazards in foods by CFIA. Sampling and testing activities are based on the general Codex principles adapted to specific situations.

The auditors verified that the implementation of the current year's sampling plan at the headquarters, laboratory, regional, and in-plant levels was proceeding in the manner outlined in the plan, and that sampling was occurring on time and in the manner designated. Analyses were completed in a timely manner, and results were distributed as directed. Additionally, the auditors verified that the plan contained appropriate internal actions to be taken if a result was in question, what screening methods were involved, and what confirmation methods could be used.

This component also requires the government to establish measurements to deter recurrent residue violations (including chronic violators). Measures reported in the SRT include the following:

- The Residue and Antimicrobial System (RAMS) tracks repeat residue violations.
- Each violation triggers an investigation. The investigation begins in the region by violator trace-back. CFIA then assesses the extent /frequency of the violation.
- Depending on the investigation, CFIA can take actions such as holding product, testing the product at the expense of the violator, or holding the entire herd (regional variations are possible).
- The slaughterhouse may refuse an individual producer's animals for slaughter at its discretion.
- CFIA/Animal health group investigates the cause of the repeated violations.

The 2012 National Chemical Residue Monitoring Program (NCRMP) submitted to FSIS has been reviewed by the FSIS auditors in conjunction with FSIS' Office of Public Health and Science (OPHS). As a part of the on-site verification, auditors interviewed CFIA officials at HQ, RVO, area and local offices, and a chemical laboratory to verify the implementation of NCRMP. The main purpose of the NCRMP is to verify compliance with Canadian MRLs, tolerances, and food safety standards and to:

- Identify trends and gauge the effectiveness of policies/programs
- Demonstrate the equivalence of the Canadian residue control system to trading partners
- Demonstrate that the NCRMP is based on Codex principles
- Ensure that foods will be largely compliant with MRLs
- Ensure that sampling activity is random and statistically-based
- Ensure shipments are not held pending results for routine monitoring testing, carcasses testing positive for the presence of chemical residues are condemned.
- Ensure that sampling occurs at many locations
- Ensure that samples are tested "as sold" (no preparation such as cooking or washing) received
- Implement the program on a fiscal year basis (April 1 to March 31)
- Statistically randomized sampling schedule specific date, region, commodity, species, and tissue, country of origin, laboratory, and sample number for identification purposes
- Ensure that a sampling plan is provided to CFIA Operations and samples are collected by CFIA inspection staff for residue testing
- Ensure that each sample is typically tested using several single and multi-residue analytical methods

For CYs 2012-2013, the NCRMP is scheduled to perform following activities:

- Domestic meat:
  - Twenty production classes, which include both major and minor species
  - Includes 5982 samples and 80,632 scheduled analyses
- Domestic eggs: 629 samples and 6135 scheduled analyses
- Imported eggs (U.S. origin): 500 samples and 5945 scheduled analyses

During the audit of a private laboratory, Silliker JR Laboratories in Burnaby, British Columbia, the laboratory was conducting analysis of samples for the presence of chemical residues. The FSIS auditors focused on the general capabilities of the laboratory including facility, equipment, as well as personnel organization and qualifications. In addition, the auditor reviewed analytical methods, recordkeeping, sample handling and traceability, corrective actions, inter-, intra-, and international proficiency testing programs and results, and accreditation. The CFIA provides proficiency testing to the private laboratory from the Saskatoon government laboratory every third month.

An ISO 17025 certification report from an on-site audit of a Silliker JR Laboratories was reviewed, in conjunction with the intra-laboratory audit corrective action requests where non-compliance was identified. The auditors concluded that Silliker JR Laboratories was conducting analysis for the presence of chemical that met the above criteria essential for the operation of a residue laboratory. Additionally, all certifications, including ISO 17025 were verified and were found to be current.

In conclusion, FSIS determined that the Chemical Residue Control Programs component included a program managed by the CFIA that was established to carry out effective regulatory activities to verify that food products are not contaminated with chemical residues. The inspection system identified the laws, regulations, and other decrees that serve as the legal authority for the implementation of this program. The CFIA provided a description of the basis for its residue plan and the process used to design the plan. The plan described the actual operations of its residue plan. The CFIA provided a description of the actions taken to deal with unsafe residues as they occur. The CFIA had access to and supervision of analytical laboratories that have the capability to ensure the validity and reliability of test data. The auditors also concluded that the private laboratories conducting analyses for the presence of chemicals met the criteria essential for the operating residue laboratories. Because of verification of this component auditors determined that CFIA is equivalent to the U. S. system for this component.

## 10. MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditors reviewed was Microbiological Testing Programs used by the CCA. Canada has microbiological testing programs for generic *E. coli* in all slaughter species and *E. coli* O157:H7 in beef. CFIA has already submitted information related to non-O157 STEC testing, which is awaiting equivalence determination by FSIS. Canada also has microbiological testing programs for *Salmonella* in raw and RTE products, *Campylobacter* in raw poultry products, and *Listeria monocytogenes (Lm)* in RTE products. The FSIS auditors verified that the system has implemented *Salmonella*, generic *E. coli* in raw pork and beef, and *E. coli* O157:H7 in beef, as well as *Salmonella* and *Lm* in RTE product sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome. Testing programs also include testing of egg products for the presence of *Lm* and *Salmonella*.

During the audit of CFIA's HQ, the auditors 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.

One private microbiological laboratory (Maxxam at Mississauga) was reviewed onsite during this audit. 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. The *Salmonella* testing for bovine, porcine, and chicken carcasses is done using the FSIS' MLG 4 method. The generic *E. coli* testing of bovine, porcine, ovine, chicken, turkey and ratite carcasses is performed by MFHPB-34 method. All above noted methods were found to be equivalent by the FSIS. During the laboratory visit, the auditor observed some of the methods being analyzed in accordance with specified standard operating procedure. In addition to testing conducted by private laboratories, CFIA conducts its own verification testing on raw, RTE and egg product for analysis of pathogen of public health concerns.

Sampling and Testing Livestock Carcasses for Generic *E. coli* in all certified establishments were verified through document reviews at HQ and Regional offices, and onsite at the two slaughter establishments. CFIA has established performance standards for generic *E. coli* that are consistent with those listed in 9 CFR 310.25. In the visited slaughter establishments,

carcasses were being sampled by the establishment personnel and sent to the one private laboratory. Written procedures existed for sample collection. Inspection personnel verified that the sample collector is designated in the written plan; the written plan addresses the location of sampling, randomness, and sample integrity; appropriate sampling methodology is used; the lab is using an appropriate method for analysis; results are correctly evaluated; and establishments take appropriate corrective action when a violation occurs.

FSIS observed the sampling technique in two slaughter establishments and verified the results of the sample and the technique used to collect the samples, which were acceptable.

Testing Program for *E. coli* O157:H7 was evaluated by the FSIS auditors and determined to be equivalent. The FSIS auditor reviewed the documents provided by the CFIA in the SRT and determined the following:

The CFIA has mandated testing by the establishment for beef trim and other raw beef components that are used for the production of ground beef. Trim as well as other raw beef components, such as chucks, head meat, cheek meat, weasand meat, and hearts may be used to produce ground beef. Operators must determine, for each of these products, whether or not part of their production may be used in the manufacture of ground beef. If so, that product must be tested at a determined frequency based on the annual volume of production.

Each federally registered establishment producing ground beef or ground veal will be sampled by CFIA ten times this year. This plan was reviewed at the de-certified beef slaughter establishment 38.

- The CFIA method for compositing of samples prior to screening tests for *E. coli* O157:H7 is equivalent. At the time of the audit the procedure was not being performed.

The confirmation of positive for *E. coli* O157:H7 is performed by a biochemically-identified *Escherichia coli* isolate that is serologically or genetically determined to be "O157" if it meets at least one of the following criteria: positive for Shiga toxin (ST) production; positive for Shiga toxin genes (*stx*); or genetically determined to be "H7."

A sample that causes a positive reaction with a CFIA recognized screening test is a presumptive positive for *E. coli* O157:H7. Presumptive positive results must be considered as positive results by the operator unless the presumptive positive is confirmed as negative. In the case that presumptive positive result impacts another establishment (e.g. product tested at the receiving step was a presumptive positive), the operator performing the test must have a prior agreement with the supplier as to whether a presumptive positive is accepted as a positive result, or a complete laboratory confirmation will be performed to determine either a positive or negative result.

No concern arose as result of review of micro testing of *E. coli* O157:H7 at beef slaughter establishment.

Testing Program for *Salmonella* in raw products met equivalence criteria. The certified establishments conduct pathogen reduction performance standard *Salmonella* testing for raw meat product. Inspection personnel routinely verify that performance standards are met and the establishment takes corrective action when the standards are not met. Canadian establishments eligible to export to the U.S. meat products that are subject to an FSIS Performance Standard for

*Salmonella* must manufacture these products in accordance to the applicable standard. In order to demonstrate that they do, the establishments must test products for *Salmonella* according to a written sampling program. The FSIS has found that the Canada *Salmonella* sampling program is equivalent to that of FSIS.

All positive *Salmonella spp.* samples are going through full serological investigation including the serotyping sub-typed, when required by CFIA or other client (establishment). The procedure for taking samples and checking records was reviewed by the FSIS at both; auditor document review and onsite. The CFIA 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.

Testing Program for *Lm* is well documented and in place to conduct government instituted testing of RTE products that are exported to the US. The CFIA directive and memo regarding RTE products was disseminated to inspectors and establishments through the CFIA external website on Feb 27, 2009. Official testing of RTE products for *Lm* and *Salmonella* is done following a hold and test procedure. All of the products tested remain under the control of the operator pending the receipt of test results. RTE meat product from a lot that tested positive for *L. monocytogenes* is not eligible for export to the USA. Sampling Plan M200 is a random sampling plan for all risk categories (1, 2A, 2B) of domestic RTE meat products (including fermented and dried cured meat products; e.g., cured sausages, prosciutto). Note that this year, sampling under this plan is linked to sampling under M205 and that each establishment producing RTE meat products will be sampled two times this year.

The CFIA and FSIS have been in communication through electronic means, and numerous teleconferences and meetings to discuss Canada's RTE programs. The CFIA has provided information on recent changes or modification to its RTE programs. Currently, FSIS is reviewing the latest changes to CFIA's RTE policies for an equivalence determination. FSIS will communicate its decision on the equivalence of Canada's RTE program once it makes a determination. Expedience of these equivalence processes is contingent upon the receipt of the requested documents. On July 29, 2013 FSIS received CFIA's *Lm* and *Salmonella* testing program for RTE product exported to the US. FSIS intends to complete its evaluation of the program by August 15, 2013.

The auditors verified that the current equivalency agreement as referenced in the Section 3 of this report, states that the government verification testing program for *Lm* in RTE products includes specific provisions for official sampling of product contact surfaces and product and oversight of verification sampling conducted by operators.

As a result of reviewing CFIA information submitted in response to the SRT and a number of POE violations related to RTE products, in 2012 FSIS engaged CFIA in responding to a number of concerns related to CFIA RTE verification activities for *Lm* product and environmental testing and performance standards, including those addressing the lethality processes for not heat treated, not fully cooked ready-to-eat product and environmental sampling for *Lm*, as well as RTE product labeling. CFIA submitted an action plan in March 2012 and amended it in April 2012 to address concerns related to labeling to clearly identify RTE products as defined by the U.S, *Lm* tolerances, post-lethality exposure corrective actions related to finding *Lm* positives on product contact surfaces, and application of lethality processes to dry-cured products.

In conclusion, modifications to the CFIA microbiological testing program and its STEC program are still under review by FSIS, as well as the validation of *Salmonella* lethality procedure, which has not been completed by CFIA. Based on its overall review, FSIS concludes the CFIA meets the “adequate” equivalence criteria but will need to submit supporting documentation in noted areas to maintain its equivalence.

## EXIT MEETING

An exit meeting was held on November 9, 2012, in Ottawa with the CFIA officials. The preliminary findings from the audit were presented by the FSIS lead auditor. The CFIA understood and accepted the audit findings.

## 11. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The audit showed CFIA is performing “adequate” in maintaining equivalence and meeting the criteria for all six components; however, additional supporting documentation is needed for equivalence to be maintained.

- CFIA needs to send an update regarding the status of a proposed office it intend to establish to enhance the correlative activities and decision making process at all level of CFIA at Est. 38. FSIS is requesting that the update accompany the response to the draft audit report or that CFIA provide a date by which the update will be provided.
- CFIA needs to send its response for further clarification on its RTE policy and information regarding Shiga-Toxin Producing *Escherichia coli* program through an SRT update.

There are also concerns related to CFIA’s ability to assess, improve, and report on the effectiveness of its inspection staff activities to ensure uniformity and consistency in the deliverance of verification activities across the inspection of Sanitation and HACCP components. These findings require the immediate attention of the CFIA. Immediate short term corrective actions were performed while auditors were present at the establishments, but the effective implementation of long term corrective actions is still pending and expected in response to the audit. Additional findings are summarized below:

- Sanitation
  - In the swine slaughter establishment audited, there was inconsistent implementation of requirements for SPS.
  - In the delisted beef slaughter establishment, there were pre-operational and operational sanitation non-compliances. In addition, the design and construction requirements for premises did not comply with the section 3.5.1.1.1 of MOP for live animal receiving and holding. The provision states that, “every registered establishment in which food animals are slaughtered shall have all floors, ramps, gangways and chutes constructed and maintained in a manner that provides secure footing for food animals during movement and prevents injury during movement.”
- HACCP
  - Non-compliances in HACCP implementation were noted in the delisted beef slaughter Est. 38 - the same beef slaughter establishment that had the large 2010

recall and then follow-up CFIA independent investigation and related report titled “Food Safety – Independent Review of XL Foods Incorporated Beef Recall 2012.” Est. 38 also had humane handling and sanitation non-compliances. The CFIA must implement trend analysis and address preventive measures to resolve multiple critical limit deviations in Est. 38.

- Continuing weaknesses in CFIA’s review of Est 38’s HACCP system showed need for both immediate establishment and nationwide corrective preventive measures.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Maple Leaf Foods, 870 Lagimodier Blvd., Winnipeg, MB, R2J 0T9	2. AUDIT DATE 11/05/2012	3. ESTABLISHMENT NO. 001	4. NAME OF COUNTRY Canada
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Canada, Est. 001, Maple Leaf Foods, November, 05, 2012, (BTB, Pilot Est.)

The selection of establishment 01 for the current audit occurred due to the fact that the originally chosen establishment for the audit establishment 96 voluntarily dropped out from audit itinerary.

The auditor reviewed a sample of establishment’s food safety programs which included an assessment of HACCP plans and the pre requests programs supporting the plant’s HACCP system. In addition, the auditor verified the establishment’s lot identification procedure and product traceability system. The auditor also examined the establishment’s microbiological testing program which included the review of the voluntary testing to verify the efficacy of its SSOP, and the CFIA instituted enforcement of environmental and production testing for the pathogens of interest in RTE establishments.

During the entrance meeting with the CFIA inspection staff at the establishment 01, the auditor learned that the establishment (Maple Leaf Foods) is a participant in FSIS-CFIA pilot program within the broader umbrella project known as “Beyond the Border” also abbreviated “BtB” The extent of plant’s activity under the pilot is captured at the end of the checklist.

The establishment prepares its meat food product under multiple HACCP plans. However, as stated above only a sample of food safety plans was chosen for review. Therefore, in consistent with the strategy, the HACCP plans, hazard analysis, decision making documents and record associated with the monitoring and verification of critical limits were reviewed in details for raw not ground (O3C) and fully cooked/hot shelf stable/post lethality exposed (O3G) processes. The review of HACCP plan for O3C process category especially assisted in understanding of controls in relation with the establishment’s participation in BtB project. The establishment had a control point for the receiving raw product as establishment intends to use product received from its sister establishment (est. 7 Maple Leaf, Brandon)

For the review, the auditors selected two of the eight HACCP plans under which the establishment producing the product for the U.S exports. The HACCP plan for Ham Stuffed in Casings produced under the category O3G covers the hazards likely to occur from product being exposed to the post lethality environment. The evaluation all aspects HACCP system, prerequisite program and control measures did not result in any concerns.

As a part of review of establishment’s microbiological verification testing program, the auditor reviewed establishment’s microbiological verification program including testing of RTE product for the presences of *L. mongcytogenes* and *Salmonella spp.* and found them in compliance with the CFIA mandated RTE Risk-Based Verification sampling plan as per MOP Ch4, Annex I. The auditor observed that the establishment was conducting CFIA mandated environmental testing including testing to detect *Listeria spp.* on food contact surfaces with a frequency per MOP Chapter 4, Annex H, section 5.2.3.

The auditor noted that the CFIA enforced risk-based sampling of RTE meat products (M200RB) and environmental (M205RB) sampling was on target at this establishment.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Lakeside Packers: XL Foods  Highway 1 West, Brooks, AB T1R 1C6	2. AUDIT DATE 11-02-12	3. ESTABLISHMENT NO. 38	4. NAME OF COUNTRY Canada
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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.	X	39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	X
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 10/29/12 Est. 38 Lakeside Packers: XL Foods, S/Bdv

13/51 In the SSOP pre-operational procedure the statement of the de-assemble and re-assemble inspected equipment was missing. This non-compliance was observed by the FSIS auditor and was scheduled for the corrective action by the establishment management 9 CFR 416.16 (a).

39/51 In the evisceration room the auditor noted that floors and walls were not built with impervious material that would facilitate thorough cleaning and prevent moisture collection. 9CFR 416.2(b) (1) & (2).

45 Multiple conveyor belts in boning room had greasy spots on them which could be potential source for food product contamination 9 CFR 416.3a.

45/51 A table saw had head meat build up particles from the previous day operation. This deficiency was corrected by the establishment management 9 CFR 416.3a.

45 A number of plastic containers used to store edible product had pieces of meat and fat in them 9 CFR 416.3(a).

45 Scraps of meat and fat were observed on conveyor belt used to transport sub- primal parts to cooler. The similar findings were also observed during the pre-op verification of the evisceration room in the same establishment 9 CFR 416.3a.

45 Broken and missing conveyor modules in boning room were posing a potential source for product contamination. This non-compliance was scheduled to be corrected by the establishment management 9 CFR 416.3 (a).

46/51 A carcass cooler in a slaughter establishment which was ready to receive carcasses for chilling was observed with overhead beaded condensation. The cooler was retained by CFIA. 9 CFR 416.3(a)

46/51 The protective trays under ventilators and blowers were dusty which were potential to contamination to the product especially when blowers and ventilators were turned on dust particles were blown on boning tables bellow. This non-compliance was scheduled for corrective action 9 CFR 417a.

52/51 Restraining steel frames meant to keep animal moving forward to knocking box were not effective in serving the purpose, instead these frames were falling on animals' head or back as animals balk backward in excitement and fear. This deficiency was immediately corrected by the establishment management. 9CFR 313.1(a) &313.2(a)

52/51 Steel Bolts protruding out of the wall into the alleyway were exposing livestock to self inflicting injures as animals were moving to knock box for stunning. This deficiency was corrected while audit was still in progress by the establishment management. 9CFR 313.1(a) &313.2(a)

<p>61. NAME OF AUDITOR Oto Urban, DVM</p>	<p>62. AUDITOR SIGNATURE AND DATE</p>
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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Vanderpol's Eggs Limited 3911 Mt. Lehman Rd. Abbotsford, BC V4X2N1, Canada	2. AUDIT DATE 10-30-12	3. ESTABLISHMENT NO. E-66	4. NAME OF COUNTRY Canada
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 10/30/12 Est # E-66 Vanderpol's Eggs Limited; Eggs:

13/51 The missing record of the corrective action completion was observed by the FSIS auditor in two non-compliances in the establishment sanitation records. This deficiency was scheduled for corrective action by the company management 9 CFR 416.16(a).

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Les Produits Alimentaires Viau Inc. 6625 Rue Ernest Cormier Laval, Quebec, H7C 2V2	2. AUDIT DATE 11/01/2012	3. ESTABLISHMENT NO. 67	4. NAME OF COUNTRY Canada
5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Canada, Est. 67, Les Produits Alimentaires Viau Inc. November 01, 2012 (RTE-Red Meat)

The establishment operated under three HACCP plans which include plans for cooked product, fresh sausage and cured product (brine injected product). For the purpose HACCP plans review, the auditor chose to review the hazard analysis, HACCP plan, monitoring record of CCP, a sample of documents in association with deviation from critical limits and implementation of corrective actions for the cured (injected) ham. The product produced under this HACCP plan for cured ham falls within the HACCP process category 03G (fully cooked/ not shelf Stable/post-lethality exposed). The products for the U.S export include Ham-capicall-pulled pork. The establishment control hazards identified in the hazard analysis at the 5 critical control points (CCP) which include the brine preparation, injection of brine, cooking, cooling and packaging steps. The critical limit for the preparation of brine is a range for in-going Sodium Nitrate ( $\text{NaNO}_3$ ). The range of ingoing  $\text{NaNO}_3$  is given as  $\leq 200$  to  $\geq 100$ . The auditor reviewed 90 days worth of monitoring and verification of record associated with this CCP and did not have any concerns.

The auditor reviewed the hazard analysis and the control measures associated with cooking and cooling steps, and also analyzed monitoring and verification data to determine the efficacy of food safety programs. The review of Compliance Verification System verification tasks and the periodic supervisory reviews (Quality Management System) did not reveal any recent deviation for the cooking or cooling steps.

The auditor also reviewed the decision making documents, monitoring, verification, and calibration procedures and record associated with modified atmospheric packaging (MAP) step. The critical limit set to be zero tolerance for leaks in seal vacuum (full vacuum) and MAP concentration of  $\text{O}_2$  set to be as from  $\geq 1.0$  to  $\leq 3.0$ . The manufacturer issued gas detection meter are used to monitor the residual gas concentration in the packages. Deviation from the critical limit triggers cessation of operations at this step. Other measures include immediate reporting to the quality control and verification of the compliance with the packaging process to the last monitoring check.

The second HACCP plan reviewed was for fresh sausages. The purchase requisition for raw product used for fresh sausages does not require that a shipment accompany certificate analysis. However, the letter of guarantee is verified that the raw product originates from federally inspected establishment and has met all the CCP for the O3B.

The auditor observed that establishment for each of its HACCP plan had procedures for returned/rework program. The returned and or reworked product if met the plant standards and verified to be in compliant with the CFIA regulatory requirements is eligible to export to any importing countries. In fact the compliance verification system assigns tasks (other tasks) for inspector to determine the soundness and wholesome of the product.

In order to determine the effectiveness of verification activities conducted by the inspection staff at this processing facility, the auditor requested the resident and relief inspector to conduct an unscheduled task related to the cook step. The auditor learned that the completion of a multistep task varies from an hour to days before inspector could decide that task was acceptable or was unacceptable. The CVS has flexibility when it comes to completion of task as a task started by an inspector not necessarily to be completed by the same inspector. Thus a task pertaining to the cooking or cooling for example can be completed by more than one inspector and in more than 24 hours period. As a result if corrective action is needed for a task could not always be the inspector who initiated the original task. The task which was initiated at the auditor's request was only completed partially and found to be acceptable for up to that specific step.

As a part of review of establishment's microbiological verification testing program, the auditor reviewed establishment's microbiological verification program including testing of RTE product for the presences of *L. mongcytogenes* and *Salmonella spp.* and found them in compliance with the CFIA mandated RTE Risk-Based Verification sampling plan as per MOP Ch4, Annex I. The auditor observed that the establishment was conducting CFIA mandated environmental testing including testing to detect *Listeria spp.* on food contact surfaces with a frequency per MOP Chapter 4, Annex H, section 5.2.3.

The auditor noted that the CFIA enforced risk-based sampling of RTE meat products (M200RB) and environmental (M205RB) sampling was on target at this establishment.

10/51 During the operational sanitation the auditor observed that the conveyor belts on slicing equipment in slicing rooms had cracks that would impede thorough cleaning of the belts.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Aliments Prince,, S.E.C. 2330 Industrial Park Drive Cornwall, ON, K6H 7N1	2. AUDIT DATE 10/31/2012	3. ESTABLISHMENT NO. 169A	4. NAME OF COUNTRY Canada
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. 169A Aliments Prince, S.E.C. (Further Processing Red Meat) October 31, 2012

The establishment 169A is a meat processing establishment producing ready-to-eat (RTE) products under HACCP process categories 03H (heat treated/not fully cooked/not shelf stable), O3F (heat treated/shelf stable/not fully cooked) and O3G (fully cooked/not shelf stable/post lethality exposed). Under process category O3F, the establishment exports to the US, sliced pork bacon and under O3G it exports bacon bits and diced fully cooked bacon.

The on-site audit of the establishment consisted of a verifications of SSOP, implementation of Food Safety Enhancement Program (FSEP) requirements HACCP requirements for RTE products and the document review of the establishment food safety programs. The Canadian Food Inspection Agency (CFIA) inspectors led the site visit to conduct operational sanitation. The auditor selected a range of documents for the review that included establishment's lot identification, recall and mock recall procedure, Hazard Analysis and Critical Control Point (HACCP) plans, Sanitation Standard Operation Procedure (SSOP) program and Microbiological verification program. The review also included 90 days worth record of the daily monitoring, verification and equipment calibration record of the programs cited above. The concluding phase of the audit consisted of the document review of inspection verification record and interviews of CFIA's supervision and inspection incharge assigned to this establishment.

The auditor selected to review the plants hazard analysis and HACCP plan for sliced bacon products (O3F) and confirmed that the establishments had identified the hazards associated with the production of the product and placed measures to control hazards. The auditor also confirmed that the establishment produced the product in compliance with the CFIA's procedures as listed in the Manual of Procedures (MOP) Chapter 11 amendment section 11.7.3.2.2.2.1. The auditors further confirmed through review of Compliance Verification Tasks (CVS) related to the verification that the IIC had reviewed establishment's control program and found them adequate.

The auditor reviewed establishment' microbiological verification program including testing of RTE product for the presences of *L. mongcytogenes* and *Salmonella spp.* and found them in compliance with the CFIA mandated RTE Meat Risk-Based Verification sampling protocol as per MOP Ch4, Annex I. The auditor observed that the establishment was conducting CFIA mandated environmental testing including testing to detect *Listeria spp.* on food contact surfaces with a frequency per MOP Chapter 4, Annex H, section 5.2.3.

The auditor noted that the CFIA enforced risk-based sampling of RTE meat products (M200RB) and environmental (M205RB) sampling was on target at this establishment.

16/51 While reviewing the critical limit for the residual oxygen concentration not to exceed 0.3% at the modified atmospheric packaging step , the establishment did not provide scientific evidence that the residual oxygen at the indicated level would not pose health hazard.

61. NAME OF AUDITOR

Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Santa Maria Foods UL 353 Humberline Drive, Toronto, Ont M9W 5X3	2. AUDIT DATE 10/29/2012	3. ESTABLISHMENT NO. 340	4. NAME OF COUNTRY Canada
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	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.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Canada, Est. 340 Santa Maria Foods, October 29, 2012 (Red Meat Further Processing)

The establishment 340 is a processing establishment operating under HACCP processing category O3E producing ready-to-eat (RTE) salt cured meat products and as such the product is not considered post lethality exposed. For the U.S export the plant manufacture prosciutto and other varieties of prosciutto (eg, extra lean type). The on-site audit of the establishment consisted of a verifications of pre-operational and operational sanitation, implementation HACCP requirements for RTE products and the document review of the establishment food safety programs. The Canadian Food Inspection Agency (CFIA) inspector led the site visit to conduct pre-operational and operational sanitation. The auditor selected a range of documents for the review that included establishment's lot identification, recall and mock recall procedure, Hazard Analysis and Critical Control Point (HACCP) plans, Sanitation Standard Operation Procedure (SSOP) program and Microbiological verification program.

The auditor reviewed establishment' microbiological verification program including testing of RTE product for the presences of *L. mongcytogenes* and *Salmonella spp.* and found them in compliance with the CFIA mandated RTE Meat Risk-Based Verification sampling protocol as per MOP Ch4, Annex 1. The auditor observed that the establishment was conducting CFIA mandated environmental testing including testing to detect *Listeria spp.* on food contact surfaces with a frequency per MOP Chapter 4, Annex H, section 5.2.3. The auditor noted that the CFIA enforced risk-based sampling of RTE meat products (M200RB) and environmental (M205RB) sampling was on target at this establishment.

The review also included 90 days worth record of the daily monitoring, verification and equipment calibration record of the programs cited above. The concluding phase of the audit consisted of the document review of inspection verification record and interviews of CFIA's supervision and inspection incharge assigned to this establishment. The following observations made during the audit of the site and document reviews:

10/51 In the slicing room the auditor observed that the two circular blades ready to be used on slicing machines had multiple areas covered with the rust. The finding if not corrected had potential risk to public health. The CFIA inspector leading the audit rejected the blades and requested plant to take immediate corrective action. The establishment corrected the problem immediately.

13/51 During the review of document related to SSOP, the auditor noted that at multiple occasions either sanitation deviations or corrective actions or both were not completely described by the plant responsible person. The auditor also noted that the CFIA inspector seemed to overlook the inconsistencies as Compliance Verification System (CVS) tasks conducted at the establishment did not capture the non-compliance.

61. NAME OF AUDITOR  
Alam Khan, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION BritcoPork Inc., Donald's Fine Foods 22940 Fraser Highway Langley, British Columbia V2Z 2T9	2. AUDIT DATE 10-29-12	3. ESTABLISHMENT NO. 513	4. NAME OF COUNTRY Canada
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	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.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 10/29/12 Est #: 513 BritcoPork Inc., Donald's Fine Foods S/B

10/51 Unidentified speck on porcine carcass was observed by the FSIS auditor in the cooler. This non-compliance was immediately corrected by the CFIA and establishment management 9 CFR 413.13(c).

13/51 In the SSOP pre-operational procedure the statement of the de-assemble and re-assemble inspected equipment was missing. This non-compliance was observed by the FSIS auditor and was scheduled for the corrective action by the establishment management 9 CFR 416.16 (a).

45 Stainless steel cart used for meet transport inside of the main processing area was observed without smooth edges. This equipment is difficult to clean. This deficiency was observed by the CFIA Veterinary-in-Charge (VIC) and it was scheduled for the corrective action by the establishment 9 CFR 416.3.

45 Unidentified matters were observed on the electric cable plug hanging over the processing table in the main processing room. This deficiency was observed by the CFIA VIC and it was scheduled for the corrective action by the establishment management 9 CFR 416.3.

45 Overhead rails and other structures (pipes) observed in different stages of the repair from flaking paint and rust. Some of the equipment is still rusty (long screw of the unidentified purpose). This deficiency was observed by the CFIA VIC and it was scheduled for the corrective action by the establishment management 9 CFR 416.3(a).

46/51 Containers and combos used for edible product in daily operation with liners (plastic) on the side were observed to be contacted by the passing employees. There is not sufficient space in these processing rooms and some areas were overcrowded by combos with product. This deficiency was observed by the FSIS auditor and was conformed CFIA (VIC. This deficiency was scheduled for the corrective action by the CFIA and establishment officials 9 CFR 416.4(a).

47 An unsanitary apron with attached stickers from previous day operation and holes in it was observed in the leg room. This deficiency was observed by the CFIA VIC and it was immediately corrected by the establishment 9 CFR 416.5(b).

47/51 An unsanitary glove used during the previous operation was observed in the plastic container used for edible product. This deficiency was observed by the FSIS auditor and was immediately corrected by the establishment management 9 CFR 416.5(b).

61. NAME OF AUDITOR  
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE



Canadian Food Inspection Agency    Agence canadienne  
d'inspection des aliments

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**NOV 18 2013**

Dr. Shaukat Syed  
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Telephone: 202-720-6400  
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**SUBJECT: Comments on the Draft Final Report from FSIS Regarding the on-site Audit of Canada's Meat Inspection System from October 22 – November 9, 2012**

Dear Dr. Syed:

Please find enclosed the Canadian Food Inspection Agency (CFIA) comments on the FSIS draft final audit report dated August 15, 2013.

I trust that this information will provide further clarification on Canada's meat inspection system related findings.

Should you have further questions, please do not hesitate to contact my office.

Sincerely,

Parthiban Muthukumarasamy, MVSc., PhD  
Acting Director  
Meat Programs Division

Attachment

c.c.: Dr. Yves Labbé, National Manager, International Programs, MPD, CFIA  
MPD Systems Review, CFIA  
Ron Jones, USDA-FSIS

**Canada**

## Response of the Canadian Food Inspection Agency (CFIA) to the United States Department of Agriculture (USDA) Audit Report on the Equivalency of the Canadian Meat Inspection System

From October 22 through November 9, 2012, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an audit of Canada's Meat, Poultry, and Egg Products inspection System.

This document summarizes the FSIS issues identified during the audit and the CFIA's response. These issues were extracted from the audit report received on August 15, 2013.

FSIS Findings	CFIA RESPONSE
<p>1. CFIA needs to send its response for further clarification on its RTE policy and information regarding Shiga-Toxin Producing <i>Escherichia coli</i> program through an SRT update.</p>	<p>The CFIA submitted the CFIA <i>Listeria monocytogenes</i> control policy to FSIS and requested it be assessed for equivalency with the FSIS policy. FSIS responded on June 14, 2013 with additional questions to which the CFIA replied on July 29, 2013.</p> <p>The CFIA provided information on the Shiga-Toxin Producing <i>Escherichia coli</i> program through an SRT update on September 30, 2013. Answers were provided to remaining questions (Y1, Y1a, Y1b, Y1c, Y1d, Y2, Y13b and Y21). Annex D.2 «CFIA risk-based Shiga toxin-producing <i>E. coli</i> verification sampling of beef trimmings for abattoirs eligible for export to the USA» has been updated and available to CFIA inspectors on July 2nd, 2013.</p>
<p>2. As a result of reviewing CFIA information submitted in response to the SRT and a number of POE violations related to RTE products, in 2012 FSIS engaged CFIA in responding to a number of concerns related to CFIA RTE verification activities for Lm product and environmental testing and performance standards, including those addressing the lethality processes for not heat treated, not fully cooked ready-to-eat product and environmental sampling for Lm, as well as RTE product labeling. CFIA submitted an action plan in March 2012 and amended it in</p>	<p>The proposals for modifications to the CFIA microbiological testing program and its STEC program are still under review by FSIS.</p> <p>The CFIA though letter dated July 29, 2013 notified the FSIS regarding its intent to develop the <i>Salmonella</i> lethality procedure. These salient features of this proposal were shared with FSIS and their response is awaited. The CFIA will be able to finalize the procedure after receiving a response from the FSIS</p>

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<p>April 2012 to address concerns related to labeling to clearly identify RTE products as defined by the U.S, Lm tolerances, post-lethality exposure corrective actions related to finding Lm positives on product contact surfaces, and application of lethality processes to dry-cured products.</p> <p>In conclusion, modifications to the CFIA microbiological testing program and its STEC program are still under review by FSIS, as well as the validation of <i>Salmonella</i> lethality procedure, which has not been completed by CFIA.</p> <p>Based on its overall review, FSIS concludes the CFIA meets the "adequate" equivalence criteria but will need to submit supporting documentation in noted areas to maintain its equivalence.</p>	
<p>3. CFIA needs to send an update regarding the status of a proposed office it intend to establish to enhance the correlative activities and decision making process at all level of CFIA at Est. 38. FSIS is requesting that the update accompany the response to the draft audit report or that CFIA provide a date by which the update will be provided.</p>	<p>As the CFIA moves forward with its modernization agenda, accountable and increased oversight will play an integral role in delivery of the System Performance component of the CFIA's Improved Food Inspection Model.</p> <p>Future design includes permanent establishment of the Inspection Verification Office (IVO). At this present time, CFIA is working with Treasury Board to access funding earmarked in the 2013 Budget. Pursuant to recommendations stemming from the independent review of the 2012 XL Foods Inc., the IVO will be established to oversee the performance of the food safety inspection system. Implementation date is planned for 2014.</p> <p>The IVO will provide increased capacity to assess the delivery of the inspection program in order to facilitate continuous system improvement by:</p> <ol style="list-style-type: none"> <li>1. Strengthening oversight by assessing and measuring inspection activities at the field level and identifying overall best practices and areas of improvement in our</li> </ol>

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	<p>food safety inspection system.</p> <ol style="list-style-type: none"> <li>2. Establishing an analytical function that will be responsible for trending and prioritizing systemic trends from an operational perspective.</li> <li>3. Collaborating with current operational systems performance mechanisms to improve oversight credibility and accountability.</li> <li>4. Where warranted, providing trend analysis data to other Agency Branches when challenges in policy design are noted from an operational implementation perspective.</li> </ol>
<p>4. There are also concerns related to CFIA's ability to assess, improve, and report on the effectiveness of its inspection staff activities to ensure uniformity and consistency in the deliverance of verification activities across the inspection of Sanitation and HACCP components. These findings require the immediate attention of the CFIA. Immediate short term corrective actions were performed while auditors were present at the establishments, but the effective implementation of long term corrective actions is still pending and expected in response to the audit.</p>	<p>The CFIA is in the process of re-engineering its Quality Management System (QMS) as a means of better measuring and monitoring the overall effectiveness and consistency of delivery of inspection programs.</p> <p>The Agency has completed a Uniformity Project that consists of a series of on-site and file reviews to assess whether inspection activities are being delivered consistently across all regions and provinces. Data collected has been analyzed and working groups are currently working on addressing key findings.</p> <p>The CFIA is further strengthening inspector training by launching a series of new national training initiatives. For example, a Supervisor School for new and existing supervisors to enhance food safety culture through supervision will commence shortly.</p>
<p>5. One purpose of the verification worksheets is to identify any items requiring correction that did not result in a CAR. The auditors noted that the verification worksheet lacks the mechanism that is necessary to document repetitive non-</p>	<p>The information from the verification worksheet is entered into the CVS data base and a query can be run at any time to show repetitive non-compliances or to detect trends.</p>

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<p>compliances and to detect trends.</p>	
<p>6. The onsite audit findings indicate a need for CFIA to focus oversight activities on sanitation and HACCP inspection activities.</p>	<p>The CFIA is currently enhancing programs to address questions of frequency and thoroughness of sanitation inspections. A CVS update session with specific guidance for pre-operational inspection and sanitation is planned for this year.</p>
<p>7. In addition, at Est. 38, the design and construction requirements for premises did not comply with the section 3.5.1.1.1 of MOP for live animal receiving and holding. The provision states that, "every registered establishment in which food animals are slaughtered shall have all floors, ramps, gangways and chutes constructed and maintained in a manner that provides secure footing for food animals during movement and prevents injury during movement."</p>	<p>Concerns noted by the auditors regarding live animal receiving and holding were immediately corrected by the establishment at the time of the audit. This was verified by CFIA inspection staff onsite immediately following the audit and found to be satisfactory. The effectiveness of these corrective measures is verified on an ongoing basis and remains satisfactory one year after implementation.</p>
<p>8. Sanitation:</p> <ul style="list-style-type: none"> <li>• In the swine slaughter establishment audited, there was inconsistent implementation of requirements for SPS.</li> <li>• In the delisted beef slaughter establishment, there were pre-operational and operational sanitation non-compliances.</li> </ul> <p>While the inspection staff seemed well versed in handling each of the specific findings, further efforts should be made in developing the ability to identify these findings as they occur and in preventing them from occurring.</p>	<p>The CFIA is in the process of re-engineering its Quality Management System (QMS) as a means of measuring and monitoring the overall effectiveness and consistency of delivery of inspection programs.</p> <p>The Agency has completed a Uniformity Project that consists of a series of on-site and file reviews to assess whether inspection activities are being delivered consistently across all regions and provinces. Data collected has been analyzed and working groups are currently working on addressing key findings.</p> <p>The CFIA is further strengthening inspector training by launching a series of new national training initiatives. For example, a Supervisor School for new and existing supervisors to enhance food safety culture through supervision will commence shortly.</p>
<p>9. Non-compliances in HACCP implementation were noted in the delisted beef slaughter Est. 38 - the same beef slaughter</p>	<p>Comments noted by the auditors regarding humane handling non-compliances were corrected by the establishment at the time</p>

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<p>establishment that had the large 2010 recall and then follow-up CFIA independent investigation and related report titled "Food Safety - Independent Review of XL Foods Incorporated Beef Recall 2012." Est. 38 also had humane handling and sanitation non-compliances. The CFIA must implement trend analysis and address preventive measures to resolve multiple critical limit deviations in Est. 38.</p> <ul style="list-style-type: none"> <li>Continuing weaknesses in CFIA's review of Est 38's HACCP system showed need for both immediate establishment and nationwide corrective preventive measures.</li> </ul>	<p>of the audit. This was verified by CFIA inspection staff onsite immediately following the audit and found to be satisfactory. The effectiveness of these corrective measures is verified on an ongoing basis and remains satisfactory one year after implementation.</p> <p>On May 17, 2013, the CFIA published a revised policy on the control of <i>E. coli</i> O157:H7 contamination in raw beef products. The policy requires establishments to develop and implement a High Event Protocol (HEP) and take action if sampling of beef trim produces a positive rate statistically significantly greater than 5%.</p> <p>This policy requires establishments to report any HEP to CFIA inspectors and to perform root cause analysis. In addition to this requirement, the CFIA will increase inspection activities when a high event period is reported. This policy also requires that slaughter establishments share plant trend analysis data with CFIA inspectors on a regular basis. In situations of positives, CFIA inspectors will have to review and approve the action plan proposed by the establishment.</p> <p>In addition, Operator's Process Awareness Program of the revised policy is designed to identify trends and deviation patterns so that the operator can initiate appropriate corrective and preventative actions prior to development of an out of control situation (HEP).</p> <p>CFIA is currently delivering further training to inspection staff in relation to the revised policy.</p>
<p>10. The main CFIA observations of Est. 38 operations in 2012 included:</p>	<p>As a result of the delistment on September 13, 2012, and prior to re-enlistment of Est. 38 on December 7, 2012, the CFIA</p>

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<ul style="list-style-type: none"> <li>• Lack of detailed documents outlining required steps when product was positive for <i>E. coli</i> O157:H7, or when there were a high number of positives in a production period;</li> <li>• Inconsistent trend analysis on positive samples; there were incidences of HEP with positive test results for <i>E. coli</i> O157:H7 that resulted in a trend of detected positive results that should have been investigated for probable cause, the root cause of the problem should have been established, the CFIA inspectors should have been notified, and corrective action should have been proffered.</li> <li>• Insufficient recordkeeping related to ongoing monitoring and validation of processes, procedures, and prerequisite programs related to equipment maintenance (e.g., 12 of 100 water nozzles clogged in the primary carcass wash area); and</li> <li>• Deficiencies in sampling techniques and procedures, such as inconsistent sampling and no establishment-monitoring program.</li> <li>• In conclusion, CFIA operates an "average" HACCP equivalence system in its establishments nationwide. Based on the audit, HACCP criteria were met in all establishments except the one delisted establishment, and those non-compliances were addressed.</li> </ul>	<p>implemented enhanced inspection of corrective actions to address sanitation, slaughter/dressing, and other operational controls; employed policies and procedures to react to plant <i>E. coli</i> O157:H7 positive sample results and in response to multiple positives, and execute analysis and verification of preventive actions to prevent recurrence of HACCP system violations. These actions were implemented not only at Est. 38 but also at all other establishments across Canada that manufacture raw beef products.</p> <p>Because of its own investigation, the CFIA increased frequencies of the verification testing of establishment's <i>E. coli</i> O157:H7 monitoring program from once a month to once a day in order to gather compliance data for review. CFIA's increased verification as a preventive measure was effective. Since the December 14, 2012, re-listment, there has been no POE zero tolerance violations from the detection of <i>E. coli</i> O157:H7 pathogen in the product from Est. 38. The recently published CFIA report titled "Food Safety- Independent Review of XL Foods Incorporated Beef Recall 2012" at Est. 38 provides a thorough analysis of the problems followed by a list of 30 recommendations to address nationwide corrective and preventive measures.</p> <p>In 2012, CFIA enhanced the delivery of CVS tasks at Est. 38, including Pre-operational Sanitation (Onsite), Dressing Procedures, and General Food Hygiene. The delivery of CVS in Est. 38 continues to be higher than the minimum required frequency.</p> <p>Enhanced inspection of the operator's corrective actions has been implemented at Est. 38. In accordance with the national policy, CFIA inspection staff is notified of every presumptive positive result for <i>E. coli</i> O157:H7 and the operator conducts an</p>
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	<p>independent investigation for each of these events. CFIA oversight of the operator's response to positive/ presumptive positive is verified and documented using CVS task 7.1.10. In addition, Operator's Process Awareness Program of the revised policy is designed to identify trends and deviation patterns so that the operator can initiate appropriate corrective and preventative actions prior to development of an out of control situation (HEP). CFIA oversight of the operator's process awareness is verified and documented using CVS task 7.1.12.</p>
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