USDA

United States Department of Agriculture

Food Safety and
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Dr. Gustavo Rossi, Director
Animal Industry Division
Ministerio De Ganaderia, Agricultura Y Pesca
Direccion General De Servicios Ganaderos
Ruta Nacional N° 8 Brigadier Gral. Juan Antonio Lavallejanio Lavalleja – Km 17,500
Montevideo, Uruguay

Dear Dr. Rossi,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Uruguay's meat inspection system from March 29 through April 15, 2016. Enclosed is a copy of the final audit report. The comments received from the Government of Uruguay are included as an attachment to the report.

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

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN URUGUAY

March 29 to April 15, 2016

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

June 29, 2016
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 29 to April 15, 2016, to verify that Uruguay's food safety system governing the production of meat continues to be equivalent to that of the United States. Uruguay is eligible to export beef, lamb, and pork products to the United States.

The audit focused on six system equivalence components: Government Oversight (Organization and Administration), Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), Sanitation, Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residue Control Programs, and Government Microbiological Testing Programs.

The previous FSIS audit of Uruguay's meat inspection occurred from March 24 to April 11, 2014. During the course of the 2014 audit, FSIS identified findings within the equivalence components for Sanitation and Government Microbiological Testing Programs. During the current audit, FSIS verified that the corrective actions proffered to FSIS by Uruguay to remedy the 2014 findings were effectively implemented.

The 2016 FSIS audit showed that the Central Competent Authority (CCA) provides sufficient oversight over its inspection personnel and meets its regulatory requirements. The FSIS review of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirm that the components of Uruguay's meat inspection system continue to meet United States core requirements. However, FSIS identified operational (or procedural) weaknesses related to Sanitation Performance Standards (SPS) and HACCP. An analysis of these findings did not identify any systemic findings which represented an immediate threat to public health. In addition, the pre-audit and post-audit point-of-entry (POE) sampling detected Ethion in imported products. Ethion is not allowed in meat product in the United States. However, these POE findings require immediate implementation of the CCA proposed corrective and preventive measures.

During the audit exit meeting on April 15, 2016, the CCA committed to address the preliminary findings. FSIS will evaluate the adequacy of CCA's proposed corrective actions once received and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Uruguay's food safety system from March 29 to April 15, 2016. The audit began with an entrance meeting held on March 29, 2016, in Montevideo with the participation of representatives from the Central Competent Authority (CCA) – the General Directorate of Livestock Services (*Dirección General de Servicios Ganaderos*, DGSG) of the Ministry of Livestock, Agriculture and Fisheries (*Ministeriode Ganaderia, Agricultura y Pesca* - MGAP) and the FSIS auditor. The CCA's representatives accompanied the FSIS auditor throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine on-going equivalence verification audit. The audit objective was to verify that Uruguay's food safety system governing the production of meat continues to be equivalent to that of the United States.

FSIS applied 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 site visits, point-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included data collected by FSIS over a three-year timeframe in addition to information obtained directly from the CCA, through the Self-Reporting Tool (SRT), outlining the structure of the country's inspection system and identifying any significant changes which have occurred since the last audit.

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residues Testing Programs, and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative functions at CCA headquarters and six local inspection offices, during which the auditor evaluated the implementation of those management control systems in place that ensure that the national system of inspection, verification, and enforcement was being implemented as intended. This evaluation included on-site verification of the implementation of those corrective actions proffered to FSIS by Uruguay to remedy the 2014 audit findings. The FSIS auditor verified that these actions were effectively implemented.

A sample of six establishments was selected from the 26 establishments certified to export to the United States. During the establishment visits, the FSIS auditor closely examined the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through periodic supervisory reviews conducted in an equivalent manner as provided in Title 9 of the

Code of Federal Regulations (CFR) Section 327.2 (i.e., the FSIS regulations addressing equivalency determinations for foreign country inspection systems).

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

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• CCA (DGSG) – Montevideo
Laboratories		2	• One government microbiological laboratory - Montevideo • One government chemical residue laboratory - Montevideo
Establishments		6	• Four bovine slaughter and processing establishments – Canelones, Cerro Largo, Montevideo, and Lavalleja • Two bovine processing establishments – Maldonado and Fray Bentos

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

- The Federal Meat Inspection Act (Title 21 United States Code [U.S.C.] Section 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (Title 7 U.S.C. Section 1901), and
- The Federal Meat Inspection Regulations for Imported Products (Title 9 CFR Part 327).

The audit standards applied during the review of Uruguay's meat inspection system included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

III. BACKGROUND

Uruguay is eligible to export beef, lamb, and pork products to the United States. From March 25, 2014, to March 25, 2016, FSIS' import inspectors performed 100 percent re-inspection for labeling and certification on 177,861,061 pounds of beef, lamb, and pork products exported by Uruguay to the United States. FSIS also performed re-inspection on 23,854,952 pounds at POE for additional types of inspection (TOI). During this time frame, a total of 457,557 pounds were rejected by FSIS import inspectors. This included a total of six chemical residue POE violations with Ethion from two of the United States-certified establishments.

The current audit included a visit to an establishment implicated in the Ethion POE violations, for which the CCA is working with the establishment to identify the root cause of the problem and to institute appropriate corrective actions. The CCA's current proposed corrective actions related to Ethion POE violations are further described under component five..

The prior FSIS final audit reports for Uruguay's Food Safety System are available on the FSIS' website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION & ADMINISTRATION)

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

The FSIS auditor noted that there have been no major changes in the CCA's organizational structure since the last FSIS audit conducted in 2014. The General Directorate of Livestock Services (*Dirección General de Servicios Ganaderos*, DGSG) of the Ministry of Livestock, Agriculture and Fisheries (*Ministeriode Ganaderia, Agricultura y Pesca* MGAP) is the CCA. The CCA's meat inspection system is directed from the central headquarters in Montevideo. There are no districts or regional levels, therefore, all field personnel are supervised directly from the headquarters. The DGSG consists of four Divisions: The Animal Industry Division (División Industria Animal, DIA), the Veterinary Laboratories Division (División de Laboratorios Veterinarios, DILAVE), the Animal Health Division (División de Salud Animal, DSA), and the Livestock Control Division (División de Controlar de Semovientes, DICOSE).

The DIA is the central competent authority (CCA) responsible for official control of slaughter and processing establishments including those facilities that are eligible to export to the United States. The DIA has five field departments: the Department of Slaughter Establishments (*Departamento Establecimientos de Faena*, DEF), the Department of Processing Establishments (*Departamento Establecimientos Industrializadores,* DEI*)*, the Department of International Trade (*Departamento de Control de Comercio Internacional,* DCCI), whose responsibilities include oversight of cold-storage facilities, the Technical Department (*Departamento Técnico,* DT), whose activities include establishment approval and coordination of the microbiology and residue programs, and the Technology Department.

The DEF is divided into three areas; each has an assigned supervisor known as Area Supervisors. The Area Supervisors are in charge of verifying and evaluating the implementation of the official guidelines, resolutions, and instructions by conducting periodic supervisory reviews. At the establishment level, the in-plant inspection personnel consist of the Official Veterinary Inspector (IVO) and a number of non-veterinary inspectors. At the United States-certified establishments, the non-veterinary inspectors perform daily official controls and inspection activities with slaughter and processing establishments under direct supervision of the IVO. The FSIS auditor verified that the inspection personnel assigned to United States-certified establishments are full time paid government employees.

The CCA has the legal authority and the responsibility to issue, implement, and enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States. The CCA has the authority to approve establishments for export to the United states, but also has the responsibility for withdrawing such approval when establishment do not have adequate and/or effective controls in place to prevent, detect, and eliminate product contamination or adulteration. The CCA's authority to enforce inspection regulatory requirements is specified in Uruguay's Law on Animal Health Police No. 3606 of April 13, 1910, Veterinary Inspection Official Rules of Origin of Goods Animal and Order No. 369/983. The CCA ensures uniform implementation of regulatory requirements through its periodic supervisory reviews.

The FSIS auditor accompanied and observed the function of the Area Supervisors who are responsible for conducting the periodic (monthly) supervisory reviews. During the periodic supervisory reviews, the Area Supervisors verify requirements for ante-mortem inspection, humane handling and slaughter, post-mortem inspection, microbiological sampling programs including *Escherichia coli* O157:H7 (*E. coli* O157:H7) and other Shiga toxin-producing *E. coli* (STEC) sample collection in raw product (slaughter establishment) and *Listeria monocytogenes (Lm)* and *Salmonella* sample collections in ready-to-eat (RTE) product (processing establishments), verification of pre-operational and operational sanitation monitoring procedures, and HACCP verification activities including the review of Critical Control Points (CCP). The Area Supervisors document their monthly supervisory review results using a standard form (*Auditoria De Supervision)* in accordance with the CCA requirements. The FSIS auditor verified that the overall sanitary condition of the audited establishments on the day of the on-site audit are the same as documented in the periodic supervisory review reports except those conditions that are currently being reported as audit findings under the Sanitation and HACCP components.

The FSIS auditor visited four bovine slaughter and two bovine processing establishments. The CCA's staffing requirements in all establishments including the United States-certified establishments requires at least two veterinarians and five food inspectors in each slaughter establishment and at least one veterinarian and two food inspectors in each processing establishment. The FSIS auditor correlated the number of the veterinarians and food inspectors, who conduct post-mortem inspection activities, in each audited establishment with the maximum slaughter rate and concluded that the CCA has provided a sufficient number of inspection personnel for the existing production volume and slaughter line speed. However, the CCA did not have a written staffing standard based on species slaughter and line speeds to ensure sufficient staffing in the event that there is an increase in production volume in the United States-certified establishments.

The CCA presented the FSIS auditor with evidence of ongoing training since the last FSIS audit in 2014. The CCA's training courses have covered such subjects as Pathogen Reduction/HACCP, Sanitation, Good Manufacturing Practices (GMP), microbiological and chemical residue sampling methodology, traceability, animal health and welfare, and specific export requirements concerning United States equivalence requirements. The FSIS auditor interviewed a number of the inspection personnel to assess their knowledge, skills, and abilities and reviewed their training records from 2014 to 2016. The auditor confirmed that the

inspection personnel have attended the ongoing trainings and have sufficient training in performing inspection activities.

FSIS observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirm that the CCA has organizational structures and administrative controls to support its inspection system, and that the CCA is enforcing applicable regulatory requirements.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; and periodic supervisory visits to official establishments.

The FSIS auditor verified that the CCA maintains its statutory authority and regulatory requirements as outlined in the official documents including resolutions and circulars issued in accordance with Uruguay's Law No. 3606 and Order No. 369/983. These documents outline Uruguay's regulatory requirements to protect public and animal health in both live animals and animal products. There were no regulatory or significant policy changes by either FSIS or Uruguay since the last FSIS audit.

During the on-site audit of four slaughter and two processing establishments, the FSIS auditor verified that continuous inspection is provided daily at the audited establishments. The FSIS auditor interviewed inspection personnel; reviewed in-plant inspection generated records; and observed the functions of the in-plant inspectors while conducting their daily inspection verification activities. These daily verification activities included direct observation of the production process and review of the establishment records, including HACCP (monitoring, verification, and corrective action), Sanitation Standards Operating Procedures (SSOPs), Sanitary Performance Standards (SPSs), GMP, and sampling techniques and records.

The FSIS auditor verified that an in-plant IVO conducts ante-mortem inspection on the day of slaughter by reviewing the incoming registration and identification documents including Movement Permit (Guía de propiedad y tránsito) and Animal Health Certificate (Certificado official de embarque a faena). In Uruguay, cattle must be identified with one visual and one radio-frequency tag with a unique number. In accordance with the CCA's ante-mortem requirements, the IVO observes all animals at rest and in motion from both sides in designated holding pens in order to determine whether they are fit for slaughter. Each establishment has a designated observation pen for further examination of suspect animals. The FSIS auditor observed and verified that all animals have access to water in all holding pens (including the pens used for suspect animals), and that if animals are held overnight, feed and water are provided. The FSIS auditor noted that the IVO verifies humane handling and slaughter (animal

welfare) requirements on a daily basis which includes but not limited to the evaluation of the stunning and sticking activities. The Area Supervisor also verifies and documents the proper implementation of this requirement during their monthly supervisory reviews. The FSIS auditor concluded through on-site record review, interviews, and observations that the CCA's requirements concerning ante-mortem inspection examination (Order No. 369/983) and humane handling/slaughter of livestock (DIA Order 11/23/1983, Manual Procedure of 03/28/2011, and Law No. 18.834, 11/04/ 2011) were being implemented and properly documented in all audited slaughter establishments in accordance with the CCA's requirements.

The FSIS auditor also assessed the proper implementation of post-mortem inspection examinations through reviews of inspection records, interviews, and observations of post-mortem inspection examinations in all four audited bovine slaughter establishments. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented. Both in-plant veterinary and non-veterinary inspectors are adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditors observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes are made in accordance with the CCA requirements (Order No. 369/983).

The FSIS auditor observed that the appropriate Animal and Plant Health Inspection Service (APHIS) requirements for the control of foot-and-mouth (FMD) disease were being met at all audited slaughter establishments. An in-plant inspection personnel examines the coronary band for each foot as well as the lips and snout of each individual animal slaughtered. In addition, the FSIS auditor noted that establishment employees measured the pH for each half carcass after it had gone through the maturation chamber in accordance with the CCA's requirements.

During the audit of the processing establishments, the FSIS auditor noted that the in-plant inspection personnel apply a traceability mechanism throughout the entire production process to ensure that products destined for export to the United States are not commingled with other products. The traceability process also included the inspection verification of the incoming products originating from an approved source.

The FSIS auditor reviewed in-plant inspection generated non-compliance reports (NRs) at all six audited establishments. The FSIS auditor verified that the inspection personnel had identified and adequately documented non-compliances in NRs. The inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's preventive and corrective actions.

FSIS observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirms that the CCA's meat inspection system continues to have both legal authority and a regulatory framework to implement regulatory requirements equivalent to those governing the United States' system of meat inspection.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA must provide general requirements for sanitation, sanitary handling of products, and SSOPs.

The evaluation of the sanitation component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit. The auditor noted that the CCA has adopted FSIS' sanitation regulatory requirements prescribed in Title 9 CFR Part 416.

The FSIS auditor reviewed the establishments' sanitation programs and associated records related to the development, implementation, and maintenance of sanitation programs at the audited establishments. The auditor also assessed the inspection personnel's ability to verify and enforce the regulatory requirements for sanitation at the establishment level. The assessment included review of the official inspection verification records, of the establishment's sanitation monitoring records, of documented corrective actions generated by the establishment, and of the actual sanitary conditions in the production areas. The auditor verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or adulteration. Each program included maintenance and improvement of sanitary conditions through routine assessment of the establishment's hygienic practices. The FSIS auditor confirmed that the in-plant inspection personnel conduct daily verification procedures of the implementation of the establishments' sanitation programs. The inspection verification activities consisted of a combination of document reviews and hands-on inspections.

In two audited establishments, the FSIS auditor verified the implementation of the pre-operational inspection verification by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification inspection. The in-plant inspection personnel conducted this activity daily and in accordance with the CCA's instructions. The in-plant inspection personnel's hands-on verification procedures begin after the establishment personnel conducted their pre-operational sanitation and determined that the facility is ready for in-plant inspector pre-operational sanitation verification activities.

The FSIS auditor also followed and observed the in-plant inspection personnel's verification of operational sanitation procedures at all of the audited establishments. These verification activities included direct observation of operations while product was being processed and review of the establishments' records for that process. The FSIS auditor reviewed the establishments' sanitation monitoring and corresponding inspections' verification records for the same time period. The auditor noted that the inspection and establishment records documented the verification, implementation, and monitoring of sanitation procedures and any corrective actions taken. The inspection personnel also verified that the establishment employees responsible for the implementation and monitoring of sanitation procedures properly authenticated sanitation records with their initials or signatures and the date.

During the on-site tour of the establishments, the FSIS auditor observed some isolated findings related to enforcement of SPS requirements on the ceiling or on the overhead structures in the production areas over exposed products among the six audited establishments.

The FSIS auditor did not observe any direct product contamination or adulteration on the day of the audit. The establishments and the inspection personnel made commitments to take immediate action to correct these issues and address any potentially affected product. FSIS believes that the above isolated findings may indicate a need to increase surveillance by the inspection personnel in verifying and enforcing SPS requirements.

The analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs and the CCA continues to maintain sanitation requirements.

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

The fourth of the six equivalence components that the FSIS auditors reviewed was HACCP. The inspection system must require that each official establishment develop, implement, and maintain a HACCP plan; and verify the effectiveness of processes and process controls. The evaluation of the HACCP component included an analysis of information provided by the CCA through the SRT, interviews, and observations made during the on-site portion of the audit. The FSIS auditor noted that the CCA has adopted FSIS' HACCP regulatory requirements prescribed in Title 9 CFR Part 417.

The FSIS auditor visited four slaughter and two processing establishments to assess the adequacy of the CCA's oversight and verification procedures performed by the inspection personnel. At the establishment level, the auditor observed the actual verification activities conducted by the in-plant inspection personnel and reviewed the associated verification records generated by the inspection personnel. The auditor noted that the in-plant inspection personnel at the audited establishments conduct daily verification of the establishment's HACCP plans in accordance with the CCA's instructions. The in-plant inspection verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The in-plant inspection daily HACCP verification activities also included direct observation or record review of Critical Control Points (CCPs) for all production shifts with results of verification being entered in the associated inspection records.

The FSIS auditor conducted an on-site observation and document review of CCPs in all the audited establishments including the zero tolerance (feces, ingesta, and milk) CCP control\records generated in four audited slaughter establishments. At each slaughter establishment, the FSIS auditor together with the in-plant inspection personnel observed the establishment's employee conducting hands-on HACCP monitoring and verification activities for the zero-tolerance CCP. Neither the FSIS auditor nor the inspection personnel observed any deviations from the critical limits. The FSIS auditor also reviewed the establishment and the in-plant inspections' zero tolerance records. Both establishment (monitoring, verification, and

corrective action) and the in-plant inspection (verification) records documented a few deviations from the critical limits and related corrective actions taken by the establishment. Furthermore, the FSIS auditor confirmed that the physical CCP location for inspection verification activities was before the final carcass wash in all slaughter establishments audited.

During the on-site document reviews and interviews of establishment and inspection personnel, the FSIS auditor identified the following HACCP findings:

- In one establishment, the establishment's HACCP monitoring records did not document the time of the monitoring activities conducted by the establishment's personnel,
- In one establishment, the establishment's HACCP verification records for record review component did not document the time of the ongoing verification activities conducted by the establishment's personnel, and
- In one establishment, the establishment's HACCP plan did not include returned product in its flow chart or hazard analysis.

The CCA informed FSIS that the above HACCP record-keeping findings would be corrected and verified immediately in order to comply with the regulatory requirements. FSIS believes that the HACCP findings may indicate a need to improve the knowledge base of inspection personnel concerning HACCP requirements.

The FSIS auditor visited four bovine slaughter establishments to observe and verify actual operations concerning removal, segregation, and disposal of specified risk material (SRM). In particular, the auditor verified the implementation of the CCA's requirements through record reviews, interviews, and direct observations made during both ante-mortem and post-mortem inspection examinations. There have been no major changes in the CCA's SRM control and verification program since the FSIS audit in 2014. The CCA's program had been described in detail in the previous audit report. The FSIS auditor concluded that the SRM control and verification program continues to be implemented properly in all audited establishments.

The analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain HACCP programs for each processing category.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE CONTROL PROGRAMS

The FSIS auditor reviewed Government Chemical Residue Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that carries out effective regulatory activities to prevent chemical residue contamination of food products. To be considered equivalent to FSIS' residue control program, the CCA's program needs to include random sampling of internal organs, fat, and muscle from carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. In addition, the CCA needs to identify the laws, regulations, or other Orders that serve as the legal authority for the implementation of the program; provide a description of its residue sampling and testing plan

and the process used to design the plan; describe the actual operation of its residue plan and actions taken to deal with unsafe residues as they occur; and provide oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

The CCA's legal authority for control of residues in products of animal origin includes but not limited to the following laws, Orders, and resolutions:

- Law No. 3606 (April 13, 1910),
- Law No. 13.835, Article 144 (January 7, 1970),
- Law No. 16.736, Article 285 (January 5, 1996),
- Order No. 369/983 (October 7, 1983),
- Order No. 296/984 (July 25, 1984),
- Order No. 332/991 (July 25, 1991),
- Resolution No. 11A/2010 (January 19, 2010),
- Resolution No. 193/011 (November 14, 2011), and
- Resolution No. 361/014 (March 18, 2014).

The evaluation of this component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit. The FSIS auditor verified that the CCA manages the national residue program, including providing direction, coordination, and oversight. The auditor noted that the implementation of the plan at the CCA's headquarters, chemical residue laboratory, and in-plant inspection levels is conducted in accordance with the CCA's National Biological Residues Program (PNRB) Manual. The CCA publishes PNRB manual to harmonize PNRB practices and to disseminate the policies, procedures, and requirements throughout the country. The manual, procedures, and guidelines are reviewed and updated when necessary, and then approved by the Director of the DGSG.

The Coordination Unit of the DIA is in charge of sending the current version of the manual to inspection personnel including IVOs in the United States-certified establishments. The CCA's residue coordinator and the DILAVE design the annual sampling plan. The analytical testing is conducted at DILAVE and external laboratories. At the establishment level, IVOs receive monthly sampling plans, select the herds to be sampled, collect and prepare samples, and send samples to the designated laboratory in accordance with the CCA's instructions. The Area Supervisors ensure that IVOs comply with PNRB procedures and guidelines. The PNRB sets the groups and their compounds, the total number of samples to be taken, Maximum Residue Limits (MRLs), Detection Limit (DL), and the laboratories conducting the analysis on both live and slaughtered animals.

During the on-site audit of the DILAVE laboratory residue section, the FSIS auditor interviewed the quality management unit personnel who conduct the annual audits of DILAVE, and the laboratory accreditation unit personnel who conduct the annual audits of external residue laboratories located in Brazil and Argentina. The DILAVE residue laboratory audit scope included sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation, detection levels, recovery frequency,

percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

The FSIS auditor reviewed the following annual laboratory audit reports:

- Xenobiotics Residue Laboratory Annual Audit Reports; August 15, 2013 and May 20, 2015. This is a private laboratory located in Buenos Aires, Argentina.
- Microbiotics Residue Laboratory Annual Audit Reports: August 16, 2013, October 28, 2014, and March 9, 2016. This is a private laboratory located in Campinas, Brazil.
- DILAVE Residue Laboratory Annual Audit Reports: November 17, 2014 and September 21, 2015. This is a government laboratory located in Montevideo, Uruguay. DILAVE is accredited by the Uruguayan Accreditation Body or "Organismo Uruguayo de Acreditación" (OUA) in accordance with ISO 17025.

The FSIS auditor's review of these annual audit reports and corresponding follow-up reports found no concerns within the CCA's implementation of its chemical residue program.

From October 20, 2015, to March 29, 2016 (start of on-site audit), FSIS detected the pesticide Ethion in six shipments of Beef Boneless Manufacturing Trimmings shipped from two Uruguayan establishments. This was in violation of United States regulations found in Title 9 CFR Section 327.3(a) pertaining to not permitting adulterated products offered for importation into the United States. Ethion is not an approved substance for pesticide use in the United States and accordingly, Ethion is not a Generally Recognized As Safe (GRAS) compound in food products, as defined in Section 201(s) of the United States Federal Food, Drug and Cosmetic Act. Since March 29, 2016 through May 2, 2016, there have been three additional residue POE violations in three new establishments. During the on-site audit, the CCA introduced a number of new corrective and preventive measures in addition to those that was already provided to FSIS prior to the on-site audit. The CCA's proposed corrective and preventive measures include the following:

- Effective March 31, 2016, the CCA temporarily suspended the registration of veterinary products containing Ethion in accordance with resolution 183.
- The CCA distributes the "List of Observed Premises" to all United States-certified establishments. This list contains information regarding premises/farms of origin of animals where chemical residues are detected.
- The IVOs are to monitor daily slaughter schedule and collect targeted residue samples from slaughtered cattle belonging to the List of Observed Premises.
- The official laboratory (DILAVE) purchased and now is in process of installing new equipment and implementing a method with a 10 ppb limit of detection. Until completion of this process, the Organophosphates (including Ethion) samples are analyzed in an external laboratory that has less than 10 ppb limit of detection.
- The CCA's MRL was reduced from 2500 ppb to 10 ppb.
- The CCA collects extra Organophosphates residue samples from United States-certified establishment in addition to what has been already assigned for PNRB. The auditor noted that the CCA collected 35 samples from 21 of the 26 United States-certified establishments in February 2016.

Currently, the CCA is reviewing the implementation and effectiveness of its proposed corrective actions and preventive measures in response to Ethion POE violations. FSIS requests that the CCA provides a detailed description of the effectiveness of its corrective actions. FSIS will evaluate the adequacy of CCA's proposed corrective actions once received, and base future equivalence verification activities on the information provided.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The evaluation of this component included an analysis of the information provided by the CCA through the SRT, interviews with the inspection and laboratory personnel, and review of the inspection verification testing procedures for microbiological sampling including *Salmonella* and *Lm* in RTE products and *Salmonella* spp., *E. coli* O157:H7, and STEC in raw bovine products exported to the United States.

The CCA has a *Salmonella* official sampling and testing program for chilled livestock carcass that is consistent with the FSIS *Salmonella* performance standards in Title 9 CFR Section 310.25(b). The CCA schedules one *Salmonella* set per year that consists of 82 samples from heifers/steers carcasses (58 samples from cows/ bulls carcasses) with one positive sample considered acceptable from heifers/steers and two positive samples considered a set failure. An establishment failing its first *Salmonella* set must take immediate corrective action after which a second set of samples is collected within 60 days. If the establishment fails to meet the performance standard on the second sample set, then the establishment must take corrective actions and reassess its HACCP, and another sample set is collected within 30 days. If an establishment fails three consecutive sample sets, it is removed from the list of establishments eligible to export to the United States.

The CCA also conducts verification activities to monitor a slaughter establishment's generic *E. coli* testing program in chilled livestock carcasses. The testing program complies with FSIS equivalence criteria. The FSIS auditor's review of records associated with establishments generic *E. coli* testing and inspection's *Salmonella* verification testing program did not raise any concerns.

The CCA has identified *E. coli* O157:H7 and six additional non-O157 STECs (O26, O45, O103, O111, 0121, and O145) in beef manufacturing trimmings as adulterants and has established a zero-tolerance policy. The CCA requires in-plant inspection personnel to review and verify establishment's documents including sampling methodology and testing results. The United States-certified slaughter establishments are required to conduct routine sampling of beef manufacturing trimmings in accordance with N-60 methodology. The in-plant inspection personnel also conduct independent N-60 official verification sampling that includes daily official verification sampling and weekly official verification sampling. Since the last FSIS audit

in 2014, the CCA has added two new procedures to its official control program. First, the CCA included the daily N-60 sampling plan to its official verification plan. Second, the CCA permitted the use of accredited private laboratories to conduct analysis for E. coli O157:H7 and STECs in raw beef products destined for export to the United States.

During the on-site audit of the slaughter establishments, the FSIS auditor accompanied and observed the in-plant inspection personnel conducting *Salmonella* and O157:H7/STEC official sampling verification activities including the actual sample collection by the inspection personnel on the day of the audit. The FSIS auditor verified that in-plant inspection personnel have received training on sample collection methodology and the responsible individuals have the knowledge and skills to implement this type of testing on an ongoing basis.

The CCA requires RTE processing establishments that produce post-lethality exposed product to control *Lm* by adopting one of the three alternatives in accordance with Title 9 CFR Section 430.4(b). The CCA requirements mirror FSIS' "Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products." In accordance with the CCA requirements, an RTE product is considered to be contaminated when the product either comes in direct contact with equipment or food contact surface contaminated with *Lm*, *Listeria spp,* or any *Listeria* like organism.

FSIS equivalence criteria for *Lm* in RTE products control program states that on an ongoing basis, the CCA should verify the implementation and effectiveness of the control measures in each establishment certified for export to the United States by conducting official verification sampling of post-lethality exposed RTE products, product contact surfaces, and the environment (non-food contact surface (NFCS)) at a frequency that ensures that the establishments' control measures are effective. The previous FSIS audit conducted in 2014 reported that the CCA did not have written instruction and had not conducted verification sampling of food contact surfaces (FCS) or the environment. During the current on-site audit, the FSIS auditor reviewed the CCA's written instruction (DGSG No. 98/016 – dated February 26, 2016) and verified that the CCA has implemented an official ongoing verification-testing to test for product, FCS and NFCS. Furthermore, the CCA instructed the inspection personnel to collect RTE product samples prior to shipment of RTE products to the United States. Establishments are required to hold the product for sampling results. Although the Uruguay inspection system is designed to ensure prevention of product contamination with *Lm* regardless of whether the RTE product supports growth of *Lm* or not, if the RTE product tests positive for either *Lm* or *Salmonella,* it is not eligible for export to the United States.

The FSIS auditor observations of inspection personnel sample collection methodology, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirms that there have been no other changes to the CCA's microbiological testing programs since the last FSIS audit. The CCA's microbiological control programs had been described in detail in previous audit report.

During the on-site audit of the DILAVE laboratory microbiology section, the FSIS auditor interviewed the quality management unit personnel who conduct the annual audits of DILAVE, and the laboratory accreditation unit personnel who conduct the annual audits of private

microbiology laboratories located in the United States-certified establishments. The DILAVE microbiology laboratory audit scope included analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, and recording and reporting of results. The FSIS auditor review of the annual audits conducted in DILAVE microbiology section and four private laboratories located in four of the audited establishments found no concerns.

Based on the document analysis and on-site audit verification including observations, document reviews, and interviews conducted with officials from Uruguay and the microbiological laboratory, FSIS determined that Uruguay's meat inspection system has regulatory requirements for a microbiological sampling and testing program that is organized and administered by the national government as intended.

X. CONCLUSION AND NEXT STEPS

The FSIS audit showed that the CCA provides sufficient oversight over its inspection personnel and meets its regulatory requirements. The FSIS review of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirm that the components of Uruguay's meat inspection system continue to meet United States core requirements. However, FSIS identified operational (or procedural) weaknesses related to SPS and HACCP. An analysis of these findings did not identify any systemic findings which represented an immediate threat to public health. In addition, the pre-audit and post-audit POE sampling detected Ethion in imported products. Ethion is not allowed in meat product in the United States. These POE findings require immediate implementation of the CCA proposed corrective and preventive measures.

During the audit exit meeting on April 15, 2016, the CCA committed to address the preliminary findings. FSIS will evaluate the adequacy of CCA's proposed corrective actions once received and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Matadero Carrasco S.A. Canelones	March 31, 2016	3	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: March 31, 2016, Est # 3 Canelones [S] (Uruguay)

22/51: HACCP – Ongoing Requirements
The establishment's HACCP monitoring records did not document the time of the monitoring activities conducted by the establishment's personnel.

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader Me March 31, 2016

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Pul S.A. Cerro Largo	April 6, 2016	7	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: April 6, 2016, Est # 7 Cerro Largo [S] (Uruguay)

15/51: HACCP – Ongoing Requirements
The establishment's HACCP plan did not include returned product in its flow chart or hazard analysis.

39/51: Other Requirements – Establishment Construction/Maintenance
The FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the cutting room. The auditor did not observe any direct product contamination. However, this condition may create an insanitary condition.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	April 6, 2016

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Establecimientos Colonia S.A. Fray Bentos	April 1, 2016	30	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: April 1, 2016, Est # 30 Fray Bentos [PJ) (Uruguay)

22/51: HACCP – Ongoing Requirements
The establishment's HACCP verification records for review of records component did not document the time of the ongoing verification activities conducted by the establishment's personnel.

39/51: Other Requirements – Establishment Construction/Maintenance
Numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the cutting room. The auditor did not observe any direct product contamination.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	April 1, 2016

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Erel S.A. Maldonado	April 8, 2016	135	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: April 8, 2016, Est # 135 Maldonado [P] (Uruguay)

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	April 8, 2016

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Solis Meat Uruguay Lavalleja	April 11, 2016	150	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: April 11, 2016, Est # 150 lavalleja [S] (Uruguay)

39/51: Other Requirements – Establishment Construction/Maintenance
The FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the cutting room. The auditor did not observe any direct product contamination. However, this condition may create an insanitary condition.

40/51: Other Requirements –Light
The CCA requires a minimum of 540 Lux lighting at the inspection surfaces. At the viscera inspection station, 514 Lux lighting was measured at the time of the audit. The inspection personnel took immediate corrective action.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader M. C April 11, 2016

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Las Piedras S.A. Montevideo	April 4, 2016	379	Uruguay
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: April 4, 2016, Est # 379 Montevideo [S] (Uruguay)

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader M April 4, 2016

Appendix B: Foreign Country Response to Draft Final Audit Report

MINISTERIO DE GANADERÍA
AGRICULTURA Y PESCA
REPÚBLICA ORIENTAL DEL URUGUAY

MINISTERIO DE GANADERIA, AGRICULTURA Y PESCA
DIRECCION GENERAL DE SERVICIOS GANADEROS
DIVISION INDUSTRIA ANIMAL

RUTA NACIONAL N° 8 BRIGADIER GRAL. JUAN ANTONIO LAVALLEJA – KM 17,500
MONTEVIDEO, URUGUAY TEL.: (598) 22204000

Montevideo, June 27, 2016

Ms. JANE H. DOHERTY
INTERNATIONAL COORDINATION EXECUTIVE
USDA/FSIS
WASHINGTON, DC

Dear Ms. Doherty,

I refer to your request to provide comments regarding the information in the audit report made by Dr. Nader Memarian, after his on-site audit of Uruguay's meat inspection system, from March 29 through April 15, 2016.

At present, we have studied it and have found no objections to Dr. Memarian's information in the audit report and we have no further comments to make to the document.

Looking forward to hearing from you, I remain yours most faithfully,

DR. GUSTAVO ROSSI
DIRECTOR