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Dear Dra. Robano,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Uruguay's meat inspection system from March 24 through April 11, 2014. 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 number (202) 720-0676, or via electronic mail at international.audit@fsis.usda.gov.

Sincerely,

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

Enclosure

URUGUAY
FINAL AUDIT REPORT

December 11, 2014
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 24 to April 11, 2014, to determine whether Uruguay's food safety system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled.

The audit was designed to determine the equivalence of Uruguay's meat inspection system and focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, the audit also included one special emphasis area. FSIS verified the implementation that the corrective actions proffered by the Central Competent Authority (CCA) in response to the February 2010 audit finding and determined that chemical residues laboratories from Argentina and Brazil were no longer being used.

The audit results indicate that Uruguay's food safety inspection system continues to maintain equivalence with the United States' system and is operating at an "adequate" level. The CCA meets the core criteria for all six equivalence components. However, areas of improvement were identified in the CCA's government oversight of sampling of food contact surfaces for microbiological testing and implementing requirements that include the evaluation of verification, corrective actions, record keeping, and hands-on verification of sanitation programs. During the exit meeting, the CCA noted that it had taken immediate actions to address the audit observations. FSIS will evaluate the CCA's corrective actions.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite equivalence verification audit of Uruguay's meat inspection system from March 24 to April 11, 2014.

Uruguay is eligible to export beef and lamb products to the United States. From October 1, 2012, to September 30, 2013, Uruguay exported 67,032,943 pounds of products to the United States, of which 9,395,367 pounds were re-inspected at United States Point of Entry (POE). A total of 194,067 pounds was refused at POE (e.g., labeling issues or packaging/transportation damage). Uruguay exports the following categories of beef products: thermally processed/commercially sterile, not heat treated-shelf stable, heat treated-shelf stable, fully cooked-not shelf stable, intact raw meat, product with secondary inhibitors-not shelf stable, and heat treated/not fully cooked-not shelf stable. Uruguay exports the following products to the United States: frozen boneless beef, frozen cooked beef, bresaola, tasajo, beef jerky, corned beef, meat extract, and dried beef. No ground beef is exported to the United States.

This audit was conducted pursuant to the specific provisions of United States laws and regulations listed below.

- 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 Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations

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

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Uruguay's food safety system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six equivalence components with the objective of determining whether each component continues to be equivalent to that of the United States. The six equivalence components are the following: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the February 2010 FSIS audit were being implemented.

The first special area of emphasis was to conduct a follow up examination of the CCA's corrective action in response to the previous FSIS audit, which was conducted from February 3 to March 11, 2010. During that audit, no notice of intent to delist (NOID) or delistment was issued. However, the FSIS audit team identified weaknesses in regard to inadequate processing of residue samples in private laboratories of Argentina and Brazil. In 2014, the FSIS auditor closely examined CCA's response to these 2010 findings and observed that the practice of using private laboratories for analyses of governmental samples in Argentina and Brazil was discontinued.

III. AUDIT METHODOLOGY

In conducting this on-going equivalence verification audit, FSIS utilized its established four-phase process: planning; execution (onsite); evaluation; and feedback. Each phase is described below.

The first phase involved document and data review and analysis of previous audit findings and other available information. Therefore, prior to conducting the 2014 onsite audit, the FSIS auditor examined CCA's performance within the six equivalence components using data for exported product types and volumes, POE testing results, and other data collected by FSIS since the last FSIS onsite audit in 2010. In addition, FSIS reviewed information obtained directly from the CCA, through a self-reporting process, outlining the current structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit. This comprehensive analysis served as the basis for first determining the performance level of the CCA's equivalent system and then planning the onsite audit itinerary.

The second phase of the audit was the onsite or execution phase. FSIS conducted this onsite audit to verify the CCA's oversight activities through onsite document reviews, interviews, observations, and site visits. The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA, the Department of Livestock, Agriculture and Fish (Ministerio de Ganaderia, Agricultura y Pesca - MGAP), including members from the establishment inspection offices.

Auditor reviewed management, supervision, and administrative functions at the CCA headquarters in Montevideo, and seven establishments (two bovine slaughter/processing, three bovine slaughter and two processing establishments) to determine whether the national system of inspection, verification, and enforcement is being implemented as required. During the establishment visits, particular attention was paid to the extent to which the CCA ensures the control of hazards and prevents non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with Title 9 CFR 327.2.

The FSIS auditor assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories during the planning phase and this execution phase. FSIS reviewed laboratory-related data collected prior to the 2014 audit through analysis of documents in the self-reporting tool (SRT). Second, FSIS conducted onsite interviews of inspection personnel and reviewed the CCA's laboratory audit reports at the CCA's headquarters and in the laboratory.

The third phase of the audit was an evaluation. FSIS conducted a post-audit evaluation of all data collected onsite to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents. FSIS conducted an exit meeting with the CCA representatives to convey all findings and discuss next steps.

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

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components reviewed was Government Oversight. FSIS import eligibility requirements state that the foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the system of meat inspection in the United States.

The evaluation of this component includes a review and analysis of documentation previously submitted by the CCA as support for the responses and corrective actions provided in the SRT, as well as onsite record reviews, interviews, and observations made by the FSIS auditor at government offices and audited establishments.

The CCA, the General Directorate of Livestock Services (*Dirección General de Servicios Ganaderos*, DGSG) of the Ministry of Livestock, Agriculture and Fish (*Ministerio de Ganadería, Agricultura y Pesca* MGAP) is in charge of meat and meat product inspection. The DGSG is responsible for four Divisions: The Animal Industry Division (*División Industria Animal*, DIA), the Division of Veterinary Laboratories (*División de Laboratorios Veterinarios*, DILAVE), the Division of Animal Health (*División de Salud Animal*, DSA), and the Livestock Control Division (*División de Controlar de Semovientes*, DICOSE).

The DIA is a body within the CCA in charge of the public health sector and the control of meat and meat products. 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 Department of Grading. The Department of Slaughter Establishments is divided into three areas; each has an assigned supervisor. All of the supervisors are stationed in Montevideo; there are no regional, provincial or area offices in Uruguay. MGAP ensures uniform implementation of regulatory requirements and is responsible for oversight of the official activities of inspection personnel at establishments eligible to export to the United States.

The CCA's authority to enforce inspection laws is specified in Uruguay's statute, *Law on Animal Health Police No. 3606 of April 13, 1910-Veterinary Inspection Official Rules of Origin of Goods Animal: meat, byproducts, derivatives and Meat Products, Order 369/983 of 10.07.1983*. This law is implemented through the MGAP Procedures Manual Oversight Functions (Department of the Slaughter – Department Industrializers Establishments).

The CCA has the legal authority and the responsibility to write, implement, and enforce requirements equivalent to those governing the system of meat inspection organized and maintained in the United States. To achieve these objectives, the CCA issues, distributes, and enforces a number of official circulars of inspection-related guidelines and instructions to inspection personnel.

The auditor conducted a review of inspection system documents at the HQ office and inspection offices in the seven audited establishments. These document reviews focused primarily on food safety hazards.

The FSIS auditor reviewed non-compliance reports (NRs) that were generated by in-plant inspection personnel at all seven audited establishments. FSIS noted that the inspection personnel had identified and documented deficiencies in NRs. The inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The auditor determined that the inspection personnel wrote non-compliance reports that adequately reflected the conditions in the establishments and verified the effectiveness of the establishment's corrective actions. The FSIS auditor also reviewed the last 3 months of written periodic supervisory reviews to assess the regulatory control actions taken by the inspection personnel and the adequacy of the establishment's corrective actions. The conditions in the audited establishments matched the supervisory reviews, and no non-compliance trends related to Sanitation Standard Operating Procedures (SSOP), HACCP, Sanitation Performance Standards (SPS), or slaughter activities were observed.

The FSIS auditor verified whether documented periodic supervisory reviews are performed in all establishments eligible for export to the United States. The auditor verified implementation of these reviews at the CCA headquarters and all seven audited establishments. The supervisors perform direct oversight evaluation of the United States-certified slaughter and processing establishments at least once per calendar month, following an established written procedure. In addition to establishment compliance (including GMPs, HACCP, SSOPs, facilities and equipment, animal welfare, and traceability), the procedure also includes specific evaluation of in-plant inspection personnel controls, including ante-mortem and post-mortem inspection, documentation, SSOP and HACCP-program verification, control of condemned product, security of stamps, seals, and other security items, microbiological and residue program controls, and verification of *Salmonella* and BSE controls.

The FSIS auditor verified that the CCA exercises its legal authority to require that the U.S.-eligible establishments develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or insanitary conditions. The slaughter, processing, and refrigeration storage establishments with Official Veterinary Inspection that have been authorized by the Livestock, Agriculture and Fisheries Ministry have implemented a Good Manufacturing Practices (GMP) system and have prepared the appropriate manuals.

Beginning in 2000, exporting establishments to the United States that were authorized by the Ministry of Livestock, Agriculture, and Fisheries implemented a Standardized Sanitation Operational Procedures (SSOP) system and prepared the appropriate manuals. These documents include the evaluation of written sanitation programs, monitoring and implementation of sanitation procedures, record review, and hands-on verification inspection of both pre-operational and operational procedures.

After a thorough review of all documents, onsite observations, and interviews, FSIS verified that Uruguay's government has maintained an equivalent organizational structure for performing oversight. The FSIS auditor interviewed inspection personnel at the CCA headquarters and at seven audited establishments, and reviewed daily inspection records generated by in-plant inspection personnel for the previous three months.

The auditor verified, through document review at the CCA, and audited establishments that inspection personnel assigned to the United States-eligible establishments are employees of the national government. The national government employs inspection personnel at all levels. All United States-eligible slaughter and processing establishments are staffed with at least two full-time veterinarians and at least five inspectors each; every processing facility has at least one veterinarian and at least two inspectors. The MGAP pays the inspection personnel salaries.

FSIS found that the CCA provides HACCP requirements equivalent to those of FSIS' SSOP, SPS, and HACCP regulatory requirements, periodic supervisory reviews, *Salmonella* spp. testing, and generic *E. coli* testing. In-plant veterinary officials and supervisors monitor, verify, and enforce the implementation of most of the SSOP, SPS, and HACCP regulatory requirements in the audited establishments.

The CCA maintains a cadre of competent and qualified personnel to ensure the production of safe, wholesome, and accurately labeled product in certified establishments. The management manual document section 1.1.2.1 describes the tasks of the Service Head and Veterinary Inspector, as well as processing establishment officials acting as Official Veterinary Inspection Service Heads, and Inspectors assigned to each of the authorized establishments. The Service Head will be responsible for management and, whenever necessary, will be able to delegate his authority to the Veterinary Inspector. The Veterinary Inspector(s) must conduct the activities required by their job and whenever directed by the Service Head, perform specifically assigned tasks.

The Animal Industry Division, within the General Bureau of Cattle Services, Ministry of Agriculture and Fisheries, is in charge of the authorization, registration, monitoring and certification of the establishments and meat products, thus approving it for human or animal consumption within the national territory and export. Section II (Decreto 369-983) defines "Authorized Establishments" as establishments that have been authorized by the Ministry of Agriculture and Fisheries (Ministerio de Agricultura y Pesca – MAP) and are controlled by the DIA.

Section III, Chapter I, Slaughter and Processing Establishment Authorization (Decreto 369-983), Art. 3, states: Authorization of applications submitted to the DIA must be accepted in order to receive authorization. To that end, the company's legal representatives and managers must sign applications. They must be prepared on paper with two copies, attaching the municipal authorization for the property to be used to build the establishment, granted by the appropriate Municipal Government. Along with the application, the interested company must file for approval of maps and specifications for the establishment to be built. This document describes, in detail, the procedures that an establishment must follow to obtain approval from MGAP to become certified for export as well as the actions that MGAP officials must take at each step of the approval process. According to a resolution of the Animal Industry Division dated on July 2, 1999, which approves the "Procedure to include lists of establishments in high demand markets" the following is stated:

This is the procedure to include plants in the list of establishments certified to export to United States:

1. The Animal Industry Division forms a Technical Commission to evaluate the establishment.
2. The Technical Commission studies the plans of the establishment.
3. It is verified that there are no pending corrections made during the process of habilitation.
4. Good Practices Manual of Processing is requested for evaluation process.
5. Implantation of a Standardized Preoperational and Operational Hygiene System (SSOP) is verified.
6. When the market requires, it is verified that the routine sampling for determination of generic *Escherichia coli* in carcasses is performed and the samples are processed in a laboratory authorized by the Directorate General of Livestock Services.
7. The implementation of a Hazard Analysis Critical Control Point System (HACCP) and Pathogen Reduction is verified:
 - a. The establishment is included in the sampling program for the determination of *Salmonella* in carcass, for five consecutive days.
 - b. The establishment must operate under the HACCP system for 20 consecutive days of work.
 - c. Within 20 days, there is a performance of an audit of the HACCP system of the plant.
8. The Technical Commission attends the establishment and assesses whether it complies with the rules of United States, both structurally and operationally.
9. The Technical Commission prepares a report including all actions taken and attaching the generated documentation. The report includes recommendations or denial of the approval to the Animal Industry Division."

The audit confirmed that Uruguay's meat inspection system is organized and administered by the government, and that the CCA officials are assigned to enforce laws and regulations governing meat inspection in official establishments. However, findings in the sanitation and microbiological testing components indicate a need for the CCA to improve its oversight activities. The verification activities of Uruguay's inspection system as designed and implemented showed that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component, as articulated by the FSIS import regulations (9 CFR 327.2).

FSIS has determined that Uruguay's inspection system operates at an "adequate" level for this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits in the U.S.-eligible establishments.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the onsite audit of the system. The FSIS auditor verified by reviewing manuals and procedures at MGAP that official inspection and verification activities are in accordance with the responses in the SRT and supporting documentation, and that the CCA continues to maintain equivalent legislative controls for this component.

During the CCA's headquarters audit, the FSIS auditor verified the CCA's regulatory authority as outlined in official legislation, circulars, and other instructions issued in accordance with MGAP inspection law. The auditor confirmed that the CCA provides the establishment inspection offices with the appropriate regulatory authority and guidance to enforce requirements for HACCP, sanitation, chemical residue and microbiological sampling, humane handling, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits in the U.S.-eligible establishments.

During the onsite audit of one bovine slaughter/processing establishment, the FSIS auditor observed the in-plant inspection verification activities for pre-operational sanitation, and in all seven establishments, operational sanitation procedures (described under Component Three), HACCP verification activities including the zero tolerance Critical Control Point (CCP) verification (described under Component Four); ante-mortem/humane handling inspection examination; post-mortem examination; and *Salmonella* spp. and generic *E. coli* sample collection (described under Component Six). In addition, during the onsite audit of one bovine slaughter and processing establishment, the FSIS auditor reviewed and observed the in-plant inspection verification activities for sampling and testing for *E. coli* O157:H7 and for RTE sampling and testing, respectively.

The FSIS auditor verified that in-plant Inspector Veterinario Oficial-IVO (Veterinarian-In-Charge) conducts ante-mortem inspection on the day of slaughter by reviewing the incoming registration and identification documents including:

- Animal welfare
- Compliance with Good Manufacturing Practices (GMP) and SSOP
- The Incoming Livestock form
- The Ownership and Transportation Guides

- The certificates for animals to be processed in export authorized refrigerated chambers
- Certificates issued by private veterinarians
- The identification of the group of animals
- The monitoring of the National Biological Residue Program
- The detection of mandatory reporting diseases
- Pen cards

In accordance with procedures outlined in the SRT, the IVOs observe 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 implementation of ante-mortem inspection complies with Uruguay's Decree 369/983 of 10/07/83, Section IV, Chapter II., and Title VII-Chapter I- Ante-mortem Inspection that FSIS has determined to be equivalent. The FSIS auditor further verified through onsite record review, interviews, and observations that the CCA's requirements concerning ante-mortem and humane handling/slaughter of livestock are being met in all audited slaughter establishments.

FSIS observed inspection personnel implementing the procedure for assessing the health of incoming animals. The procedure ensures that animals that display overall poor condition or signs of disease are slaughtered under special conditions, separated from the rest. It also ensures that animals requiring post-mortem examination are sent to the necropsy room to determine the cause of death and to rule out possible infectious-contagious diseases according to the Decree 369/983 of 10/07/83, Section IV, Chapter II, Articles 28, 33, 37 and Section VI, Chapter I, Articles 159 through 163. The auditor observed that the emergency slaughter facilities and necropsy rooms are completely separated from the establishment's slaughter and processing operation and that condemned carcasses and parts go directly for rendering.

The proper animal stunning procedure and controls were also verified to ensure that animals to be slaughtered undergo a type of stunning treatment that results in an immediate state of unconsciousness that lasts until death (reference document, Decree 369/983 of 10/07/83, Section VI, Chapter I, Articles 179 to 183).

FSIS assessed post-mortem inspection examinations through onsite record review, interviews, and observations of inspection activities in all audited slaughter establishments. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented. The objective of post-mortem inspection control is to ensure the hygiene of the operative processes, preventing visible contamination and reducing the probability of non-visible contamination as much as possible. Ensuring that meat, organs, and viscera are fit for human consumption occurs through systematic post-mortem inspection management and the identification of meat, organs, and viscera based on the fitness determination.

Both in-plant veterinary and non-veterinary inspectors were adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed inspection personnel

examining the heads, viscera, and carcasses with the proper incision, observation, and palpation of required organs and lymph nodes in accordance with Uruguay's Decree 369/983 of October 7, 1983, Section IV, Chapter III, Articles 39 through 44, Section XI, Article 320 and 321-Post-mortem Inspection, which FSIS has determined to be equivalent. The design of the post-mortem inspection stations, including proper lighting and the number of online inspectors, are in accordance with inspection requirements. The FSIS auditor also observed the functions of the offline veterinary inspectors who have an in-plant supervisory role to ensure continuous daily inspection and to conduct daily inspection verification activities in all audited establishments. These daily verification activities include direct observation and review of establishment's records, including HACCP, SSOP and SPS, and generic *E. coli* and *Salmonella* carcass sampling records.

The FSIS auditor verified that the CCA exercises its legal authority to require that the U.S.-eligible establishments develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or insanitary conditions. The CCA has adopted FSIS sanitation regulatory requirements prescribed in 9 CFR Part 416. The in-plant inspection personnel at all audited establishments verify sanitary conditions in accordance with methodology described in the CCA's Decreto 369-983, Section III, Chapter I. Their inspection includes the evaluation of written sanitation programs, monitoring, implementation of sanitation procedures, record review, and hands-on verification inspection of both pre-operational and operational procedures.

This directive (369-983) also provides instructions to the official inspection personnel to conduct a continuous and systematic assessment of establishment activities during routine verifications of sanitation issues, including maintenance of the facilities and industrial equipment; dressing rooms and restrooms; illumination; ventilation; water supply; waste water; pest control; cleaning and sanitization; hygiene, hygienic habits, and workers' health; and operational sanitary procedures. FSIS also assessed the adequacy of HACCP program verification activities conducted by inspection officials at the establishment level by observing verification activities and reviewing monitoring and verification records generated by establishment and in-plant inspection personnel at all audited establishments.

The stipulations of the government law 3.606 of April 13, 1910 and Decree 369/983 of October 7, 1983, define SRM in cattle as (1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia in all cattle treated as 30 months and older, and (2) the tonsils and the distal ileum of all cattle in accordance with OIE guidelines.

- The stipulations of this resolution only apply to processing plants that have been authorized to export to the United States of America.
- Those establishments must prepare specific written procedures to separate materials that have been declared a risk by United States of America health authorities so that they do not come in contact with products meant for that market. These procedures must be included in the establishments' pre-requirement programs.
- For the purposes of this resolution, procedures require that inspection personnel:
 - a. Remove and eliminate skulls, eyes, trigeminal ganglia, and tonsils;

- b. Remove the brain, cerebellum, and medulla oblongata, keeping them from coming in contact with products that are fit to be exported to the United States;
 - c. Remove the spinal cord in the processing area;
 - d. Removal of the spine and spinal ganglia from dorsal roots; and
 - e. Separate the entire small intestine from the large and lower intestine, treating them separately.
- Establishments are responsible to ensure strict compliance with the above procedure through their own control systems, generating auditable records.
 - The Official Service is responsible for monitoring the effectiveness of the procedures, in accordance with the resolution.
 - The Official Service publishes the resolution in the Official Diary and the Livestock, Agriculture and Fisheries web page.

The auditor visited one establishment that produces thermally-processed, commercially sterile product. The FSIS auditor verified that CCA maintains a regulatory definition for thermally processed/commercially sterile product. The CCA ensures that proper containers are used through its IIC's verification and HQ oversight.

The CCA maintains written requirements and performs verification procedure by the IIC to address proper closure of containers. HQ checks the procedure and documentation at least once a month. Certification of the thermic process is performed by the LATU (third party) which is the certification body that verifies the distribution and penetration of the temperature. The CCA maintains written requirements and verification procedures to ensure adequate thermal processing of containers by IIC controlling thermometers for water (mercury & graph) of the chosen autoclave.

The FSIS auditor verified that the CCA defines a "low acid" product as pH of 4.6 and aw 0.85. A minimum of 12D for *Clostridium botulinum* is required. The establishment must provide all necessary requirements for destruction of *Clostridium botulinum*, such as temperature, time, and addition of nitrites.

The FSIS auditor verified that the CCA maintains written requirements and procedures to address operations such as posting of process, retort traffic control, initial temperature of the product, number of autoclaves, vent, start of process cooling, size and type of product, and number of cans. All these procedures are controlled by the IIC.

Additionally, the CCA maintains written procedures to address recall procedures related to process deviation. In case of pathogen violation, the laboratory informs the IIC, HQ, and establishment. The IIC is in charge of the in-plant process of recall while the HQ has the oversight of the whole process.

Uruguay's meat inspection system has legal authority and a regulatory framework to implement requirements equivalent to those governing the United States' system of meat inspection. The analysis and onsite verification activities indicate that the CCA continues to maintain equivalence and is operating at an "average" level for this component.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components the FSIS auditor reviewed was sanitation. To be considered equivalent to FSIS' program, the CCA must provide requirements for all areas of sanitation, sanitary handling of products, and SSOP. Prior to the onsite portion of the audit, the auditor reviewed and analyzed Decree 369/983 of October 7, 1983, Section III, Chapters I and II. Once onsite, the auditor gathered additional information at the government offices and 7 of the United States-eligible establishments.

The SSOP program ensures the implementation of control and verification tasks and verifies that corrective actions and preventive measures are taken because of the direct product contamination. The following reference documents were generated:

- a. DGS Resolution of 12/20/96 - SSOP Implementation
- b. AID Circular 1/97 of 03/19/97 - SSOP Implementation
- c. Standardized Sanitation Operational Procedure (SSOP) Process Implementation Control Procedures Manual of March '97
- d. Circular 01/98 of 04/01/98 - Filling Out the Non-Compliance Notification form (Defect Classification Guide)

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at all audited establishments. In one of the audited establishments, the FSIS auditor verified the pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspection personnel's hands-on verification procedures begin after the establishment personnel conducted its pre-operational sanitation and determined that the facility is ready for in-plant inspector pre-operational sanitation verification activities. The in-plant inspection personnel conduct this activity in accordance with the CCA's established procedures.

The FSIS auditor followed the off-line inspector and observed in-plant inspection verification of operational sanitation procedures at all of audited establishments. These verification activities include direct observation of operations and review of the establishments' associated records. The FSIS auditor reviewed the establishment's sanitation monitoring and corresponding inspections' verification records for the same time period. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures authenticated these records with initials or signatures and the date. The following observations were noted during the on-site audit:

- At two establishments audited, a faulty door gasket and uneven floor at the entrance door created a gap between the door and floor, which created a potential for vermin or other contaminant entry into the production area including slaughter room. This condition creates insanitary conditions and a potential for product contamination.

- At four establishments audited, the FSIS auditor observed flies in the slaughter and processing areas. This condition creates insanitary conditions and a potential for product contamination.
- The rail and conveyor belts in the deboning room had excessive grease. This situation creates a possible contamination problem with the produced product.
- During the preoperational sanitation verification, dry meat and fat particles from the previous day of operation were observed on a few plastic holder supports in the deboning room. This condition creates insanitary conditions and a potential for product contamination.
- All non-compliances requiring immediate corrective action were corrected immediately while the remaining was scheduled for corrective action that was completed before the FSIS auditor left the country.

The FSIS auditor noted that the CCA has several documents that clarify establishment and inspection personnel responsibilities to prevent product contamination. The CCA documents that specify that effective measures are to be adopted to prevent contamination of the food material through direct or indirect contact with the contaminated material during the initial processing stages include the Decree 369/983 of October 7, 1983, Section III, Chapters I and II.

The FSIS auditor determined that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as development and implementation of SSOPs. In-plant veterinary officials and state supervisors enforce the regulatory requirements and monitor the ability of establishments to maintain sanitary conditions. The SPS noncompliance noted above were addressed. As a corrective action during the audit it was observed that the fly was captured (one fly was observed at each establishment during the audit). The issue of fly entry was being investigated with the assumption that flies were being carried by the incoming animals in their hair or through common communicative areas such as open doors, space under doors, etc. A focus on daily monitoring of fly presence following CCA verification is planned.

While improvements are needed in the oversight of verification activities related to sanitation recordkeeping and documentation of verification activities, FSIS analysis and audit verification activities of Uruguay's inspection system indicated that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. FSIS determined that Uruguay's inspection system does support that the CCA operates at an "adequate" level for this component.

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

The fourth of the six equivalence components reviewed was HACCP. The inspection system must demonstrate a HACCP plan or a similar preventative control plan.

The CCA's headquarters and seven establishments were visited to determine whether the MGAP and inspection offices maintained effective government oversight for the implementation of the CCA's meat food inspection system's HACCP requirements. In addition to focusing on the

HACCP plan design and implementation, the FSIS auditor verified the CCA's oversight activities through onsite record review, interviews, and observations of the implementation of the SRM Control Program at five audited bovine slaughter establishments.

HACCP

Uruguay has implemented Hazard Analysis and Critical Control Point Programs since December 1998. All establishments authorized to export meat and meat products to the United States of America must comply with HACCP system requirements. Authorized establishments are responsible for developing a HACCP program based on the implementation timeline indicated in the United States regulations. The objective of the HACCP program is to identify hazards, put in interventions that eliminates or controls the hazards, and then verify that the interventions are working as intended. The following reference documents were generated:

- a. AID Circular 2/1998 of 01/16/98: Hazard Analysis Critical Control Point Program Implementation
- b. AID Circular 4/1998 of 08/10/98: Official HACCP Plan Verification
- c. AID Resolution of 12/02/98: HACCP Plan Implementation
- d. Procedure 2001-5 of 09/23/01: Processing Plant HACCP Plan Validation Generic Procedure
- e. Current regulatory requirements of the purchasing markets
- f. Pathogen/Salmonella Reduction Program
- g. AID Processing Establishment Division Post-Mortem Inspection Zero (0) Tolerance Supervision Procedure for fecal matter, ingest and milk
- h. HACCP Plan Verification
- i. Responsible individual: the IIC
- j. Frequency: As established in the procedures, programs and verification

The FSIS auditor verified through record review and observation that the in-plant inspection personnel conducted daily verification of HACCP plans, including the evaluation of written HACCP programs, monitoring, verification, corrective actions, record keeping, and hands-on verification inspection. The in-plant inspection personnel verification of HACCP plans includes verification of CCPs for all production shifts.

At the five slaughter establishments audited, the FSIS auditor conducted an onsite review of the zero tolerance (feces, ingesta, and milk) CCP records generated over the past three months. In addition, the FSIS auditor reviewed the in-plant inspection's associated zero tolerance verification records. Both establishment and in-plant inspection monitoring and verification records documented some deviations from the critical limits. The review of the establishment's corrective actions in response to deviation from zero tolerance critical limits indicated that all four parts of the corrective actions, in accordance with 9 CFR 417.3, were addressed by slaughter establishment employees and verified by the inspection personnel. No non-compliance trends were detected as the result of these document reviews. Furthermore, the FSIS auditor verified the physical CCP monitoring location by observing inspection personnel conducting HACCP hands-on verification activities, as well as performing an independent direct monitoring

examination of livestock carcasses. No deviation from the critical limits was observed by the inspection personnel or by the FSIS auditor. The FSIS auditor also verified that the zero tolerance CCP monitoring location meets the CCA's requirement, including the adequate illumination for proper examination.

SRM Controls

The FSIS auditor conducted onsite audits of five bovine slaughter establishments to review the CCA's SRM control program. The auditor toured these slaughter establishments in their entirety to observe and verify actual operations concerning removal, segregation, and disposal of SRM. In particular, the FSIS auditor reviewed and verified the CCA's verification and control program for SRMs at both ante-mortem and post-mortem inspection examinations. In addition, the auditor thoroughly reviewed relevant documents and records generated by the slaughter establishments and in-plant inspection personnel, as well as conducted interviews with in-plant personnel.

The auditor noted that the CCA has requirements for removal, segregation, and disposal of SRM in cattle and requires that all SRM must be removed prior to export to the United States.

In accordance with the law 3.606 of April 13, 1910 and Decree 369/983 of October 7, 1983, the animal industry division director ordered the following:

1. The stipulations of this resolution will only apply to processing plants that have been authorized to export to the United States of America.
2. Those establishments must prepare specific written procedures to separate materials that have been declared risky by United States of America health authorities so that they are not exposed to products meant for that market. These procedures must be included in the establishments' pre-requirement programs.
3. For the purposes of this resolution, the following procedures will be required for cattle:
 - a. Remove and eliminate skulls, eyes, trigeminal ganglia, and tonsils;
 - b. Remove the brain, cerebellum, and medulla oblongata, keeping them from coming in contact with products that are fit to be exported to the United States;
 - c. Remove the spinal cord in the processing area;
 - d. Remove the spine and spinal ganglia from dorsal roots; and
 - e. Separate the entire small intestine from the large and lower intestine, treating them separately.
4. Establishments will be responsible for strict compliance with the above procedures through their own control systems and the creation of auditable records.
5. The Official Services will be responsible for monitoring the effectiveness of the procedures, in accordance with this resolution.
6. Notification of the Technical, Processing Establishment, and Manufacturing Establishment Departments and, through them, the involved companies.
7. Notification of the Livestock Service Office.
8. This resolution will be published in the Official Diary and the Livestock, Agriculture and Fisheries web page.

In the five bovine slaughter establishments audited, the FSIS auditor also verified through review of verification records and direct observation of inspection activities that the in-plant veterinarians identified and secured all animals exhibiting clinical signs of central nervous system (CNS) disorders at the ante-mortem inspection station. At each establishment visited, the auditor confirmed that the onsite veterinarians could appropriately identify the clinical signs associated with CNS disorders which include, but are not limited to: excitement or depression; deviation or rotation of the head; drooping of the lips, eyelids, cheeks, and ears; convulsions and tremors; paralysis; sudden onset of fainting; head pressing; aimless walking; ataxia; and blindness.

In-plant veterinarians are responsible for completing a suspect form for any animal that is subject to emergency slaughter. This form contains inspection information such as slaughter establishment number, animal identification number, species/breed of animal, sex, temperature, approximate weight, reason for emergency slaughter, as well as a brief description of the ante-mortem findings, the date, and the signature of the veterinarian who conducts the ante-mortem inspection. After the completion of emergency slaughter, which occurs in a designated facility adjacent but separate from the holding pens, a post-mortem/necropsy report documents the results of the veterinary examination. All animals that are subject to emergency slaughter are excluded from export to other countries. The FSIS auditor's review of documents and the related tracking system indicated that no product originating from animals undergoing emergency slaughter are exported to the United States.

The FSIS auditor observed stunning procedures through direct observation that were performed by electrocution. Regardless of animal age or carcass classification, all animals are considered and handled as 30 months of age or older in audited establishments with respect to SRM government control.

The CCA continues to demonstrate the ability to satisfy the equivalence for this component as articulated in FSIS import regulations (9 CFR 327.2). Therefore, FSIS determined that Uruguay's inspection system does support the finding that the CCA operates at an "average" level for this component.

VIII. COMPONENT FIVE: CHEMICAL RESIDUE CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residues 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 and carcass fats 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 decrees 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.

FSIS' residue experts thoroughly reviewed documentation pertaining to the design and implementation of the CCA's National Residue Program (NRP) prior to this audit. The in-depth review included an analysis of the 2013 residue monitoring plan as well as additional responses outlining the structure of Uruguay's chemical testing program provided in the SRT. The auditor conducted an onsite audit of the DILAVE residue laboratories.

The DILAVE organizational chart of veterinary laboratory division shows that the laboratory director oversees laboratory accreditation unit, quality assurance unit, regional laboratory units, (Paysandu, Tacuarembó, and Treinta y Tres) and the Biosecurity Commission. The following departments are part of this laboratory: food protection, veterinary product control, bacteriology, virology, biological resources, pathobiology, parasitology, and administrative department. Residue control is included under departments of food protection and veterinary product control.

The sample receiving area distributes samples to the micro or chemistry laboratory based on the analysis request. Received sample is registered in the "Log book" and the temperature must be below of 4°C. In case of the spoiled sample, the new sample is taken. Residue samples are tested monthly to complete the national residue plan. Residue violative results are sent to a coordinator who informs the IIC.

DIA/DGSG is in charge of administering testing policy for government laboratories as well as administering regulatory actions based on laboratory results. Intra, inter and international (Trieste, Italy) proficiency testing programs are administered to this laboratory. The Uruguayan "Organismo Uruguayo de Acreditación" (OUA) or Uruguayan Accreditation Body is responsible for accrediting country's residue and micro laboratories. DILAVE government laboratory is under DGSG in the organization chart and reports to DGSG. Every year the laboratory reports about its performance in the "laboratory annual report" that is sent to the DGSG. There is no fixed visit/audit program from DGSG to DILAVE, but the laboratory receives them several times a year for different issues. Additionally, the DGSG conducts annual audits of its residue laboratories that perform analysis of products that are destined for export to the United States. The FSIS auditor's review found no concerns with the CCA's chemical residue program.

2010 Audit Follow-Up Findings

During the previous FSIS audit in 2010, the auditor identified the following problem:

- Uruguay was sending some samples to private laboratories in Brazil and Argentina for residue analysis, although no equivalence determination had been made by FSIS for this alternative practice. Approximately 95 percent of the regulatory residue samples were analyzed in the official, government-owned, and operated DILAVE laboratory while the other 5 percent were sent to a private laboratory in Argentina (carbarnates, coccidiostats, and sedatives) and to a private laboratory in Brazil (nitroimidazoles).
- On March 19, 2010, Uruguay CCA informed FSIS that they reverted to the residue laboratory program initially determined equivalent by FSIS. All laboratory residue analysis

on product eligible for export to the United States would be performed at the official Uruguay laboratory. This corrective action was performed as stated and it was verified during this FSIS on-site audit.

During this 2013 audit, the FSIS auditor conducted follow-up verification of the CCA's corrective actions. The auditor interviewed inspection officials at the CCA's headquarters office and verified that the CCA performed the required corrective action.

Through the pre-audit review of the aforementioned documentation and during onsite observations, document reviews, and interviews of inspection personnel at the CCA and establishments, the FSIS auditor noted that the current year's residue sampling plan is proceeding in the manner outlined in the residue control plan.

FSIS determined that the Chemical Residue Control Programs component includes a national program managed by the CCA. The inspection system has appropriate laws, circulars, and other decrees that serve as the legal authority for the implementation of this program. The CCA has access to and supervises the activities of analytical laboratories that have testing capabilities to ensure the validity and reliability of test data.

Residue sampling results from May, and July 2013, showed three violations for chloramphenicol. There is no acceptable level for chloramphenicol in meat products. These violations occurred in product produced in three separate establishments (12, 150, and 8) from the three separate provinces of Florida, Paysandu, and Rivera. Investigation proceeded from the field veterinarian to the Animal Health Regional Office and eventually to the HQ. Laboratory analysis was performed in DILAVE laboratory. One violation occurred on May and two other violations were reported in July 2013. Thus far, corrective actions proffered by MGAP rely on identification of the farmer, information provided by local veterinarian regarding him not to administer chloramphenicol to animals in question, and animal feed analysis. Targeted sampling of 25 samples in 100 animals was performed and affected product was retained and not shipped to the United States. Conclusion of this investigation indicated that chloramphenicol occurs in crops through natural production by bacteria in soil. This conclusion was based on several research projects recently published on this subject. There is a sampling and testing program of beef product for chloramphenicol and affected product is not exported to the U.S.

FSIS analysis and audit verification activities of Uruguay's chemical residue testing program indicated that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component. FSIS determined that Uruguay's chemical residue testing program operates at an "average" level for this component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

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

During the audit of the CCA establishment inspection offices and the DILAVE laboratory, documents were discussed and reviewed describing the official inspection methodology for a continuous and systematic assessment of inspection activities during routine verifications of microbiological tests including *Salmonella* spp., generic *E. coli*, *E. coli* O157:H7, STECs and *Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products.

The FSIS auditor accompanied and observed the in-plant inspection verification activities for *Salmonella* and generic *E. coli* sample collection in all five slaughter establishments. In addition, the auditor observed and verified the implementation of *Lm* sampling programs in two processing establishments. The auditor visited one government official microbiological laboratory, DILAVE, in Montevideo.

The CCA has a *Salmonella* testing program for chilled livestock (cattle) carcass sampling that is consistent with the FSIS *Salmonella* Performance standards in 9 CFR 310.25(b). The CCA requires that regular *Salmonella* sample is tested once (1) in 15 days. When there is an export product chosen for the U.S., a set of 82 samples from beef carcasses is tested with one positive sample considered acceptable, and two positive samples considered a set failure. In cows/bulls, the numbers of sample tested (n) is 58 with maximum number of positives to achieve the standard (c) two. If an establishment fails three consecutive sample sets, it is removed from the list of establishments eligible to export to the United States. The suspension remains in effect until the establishment identifies the cause, takes proper corrective actions and preventive measures, and achieves the performance standard set based on number of samples tested (n) and maximum number of positives to achieve standard (c). The CCA's *Salmonella* performance standard for bovine/steers/heifers (n = 82, c ≤ 1) and cows/bulls (n = 58, c ≤ 2) is the same as FSIS' standards. The government laboratory DILAVE is using the MLG 4.06 method for *Salmonella* testing of bovine carcasses.

The CCA conducts verification activities that monitor an establishment's generic *E. coli* testing program in chilled livestock carcasses. The testing program complies with FSIS equivalence criteria by adopting the "Federal Register," Volume 61 No. 144, (July 25, 1996) "Rules and Regulations."

Uruguay has adopted the FSIS sampling program for generic *E. coli* in beef. The program was followed according to regulatory requirements in five establishments audited. Slaughter establishments with an Official Veterinary Inspection perform a Routine Analysis for Detection of *Escherichia coli* system. The purpose of these systems is to prevent the contamination and adulteration of meat products and to evaluate the efficiency of operating procedures intended to prevent product contamination. Frequency of sampling is determined according to volumes of slaughter. Analysis is performed at the laboratory of the establishment or in accredited laboratories. Results are recorded and sent to Official Veterinary Inspection and kept available. The method of analysis is being performed as described in the "Federal Register" Volume 61, No. 144, "Rules and Regulations".

While on site at five establishments, the FSIS auditor observed sampling and verified that the responsible individuals have the knowledge and skills to implement this type of testing on an

ongoing basis. Both the establishment and inspection personnel are familiar with the upper and lower control limits and the correct actions to be taken when the upper limits are exceeded. No such loss of process control was identified during the onsite audit and in the documents reviewed for the previous three months.

Uruguay is eligible to export raw and processed bovine and ovine, as well as processed pork (cooked) products to the United States. No ground beef is exported to the United States.

The CCA has identified *E. coli* O157:H7 in beef trimmings and components and six additional non-O157 STECs (O26, O45, O103, O111, O121, and O145) in beef manufacturing trimmings as adulterants and has established a zero-tolerance policy.

At the time of testing, the establishment defines the lot size and notifies the IVO of the decision when sampling begins, and whenever lot size is changed. The establishment official presents to the IVO the written meat products traceability program related to products destined for the United States market. The IVO files these documents. The Technical Department (DT) designs the official sampling protocol for routine and follow-up sampling to be approved by the Division Industrial Animal (DIA). The DT periodically evaluates the plan and revises it as scientific advances might require. DIA requires that all establishments implement their own sampling programs to be assessed by the IVO and enforced by one of the DIA five field departments the Departamento Establecimientos de Faena (DEF). DIA verifies that the sampling programs are maintained and current. Whenever sampling takes place, official or establishment generated, the entire lot of product is retained. The IVO remains knowledgeable of where the lot is located to ensure prompt recall if necessary. The analytical laboratory notifies the IVO and the establishment, in writing or electronically of the results of sample analysis. The sample processing time for *E. coli* O157:H7 and STECs requires two days by the screening method with PCR and seven days by confirmation method. The detection method used for *E. coli* O157:H7 in trimmings and components is MLG 5.07 and for STECs, MLG 5.04.

The location of the retained lot can be changed within the establishment, to another establishment, or to a storage facility only with prior authorization granted by the IVO. The authorization is granted contingent upon the establishment indicating in writing how the product will be handled within the traceability program.

The following describes each step of the sampling process:

- Establishment sampling (internal control)
 - Daily collection of one sample per lot conformed by 60 meat pieces
 - Samples are analyzed by a laboratory approved by DGSG
- Official sampling
 - Weekly collection of one sample conformed by 60 meat pieces from a lot of product in accordance with sampling dates established by the DT
 - The official sample must come from trimmings gathered from the same lot that is defined as cattle, from the same cattle supplier. Cattle from feedlots are given priority for sampling.
 - Samples are analyzed by the official laboratory of the Ministerio de Ganaderia, Agricultura y Pesca (MGAP) or in accredited laboratories.

- Number and size of samples
 - Samples are aseptically collected at a point in the process closest to the packaging step.
 - The sample is comprised of 60 pieces of meat.
 - Each piece has approximately 10cm x 5cm x3mm in size.
 - Throughout the production shift, 12 pieces are collected five times with meat pieces placed in properly identified sterilized bags.
 - At the end of production, there are five bags that weigh approximately 908 grams.
 - The temperature of the sample is written on the accompanying form and must not be allowed to exceed 4° C.
 - If the sample is not analyzed the same day it is collected, it must be refrigerated if it is not going to be analyzed within 24 hours.

- Handling of results; The following actions are taken when a positive result is obtained by sampling conducted by the establishment or the government:
 - The IVO is always notified of the results of the analysis of samples collected by the establishments. In the event of a positive sample, notification is sent up the chain of command in writing.
 - The IVO determines the final disposition of the affected lot of product that was retained.
 - The positive results obtained during official sampling are compared with the results obtained by the establishment's sampling for the same lot. In the event of a positive official sampling result and a negative establishment results for the same lot of product, the IVO issues the establishment a non-compliance notification and notifies the official laboratory of the finding.
 - The IVO verifies that the establishment implements corrective actions that include: a) Identify the cause of the deviation; b) Re-establish process control, after eliminating the cause of the deviation; c) Institute measures to prevent recurrence of deviations; d) Prevent non-compliant product from entering commerce; e) The IVO also verifies that the establishment reassesses its HACCP plan and the SSOPs including all records.
 - The IVO ensures that all product of the lot is disposed of in accordance with what the DIA determines. Final disposition could include further processing of the product for human and animal consumption.
 - The IVO documents all events in the process.

- The follow-up sampling after a positive result from official or establishment sampling:
 - The IVO initiates immediate follow up sampling.
 - Routine sampling is suspended.
 - The follow-up sampling includes collection of 16 samples of consecutive lots. For official sampling, a lot is comprised by cattle from one supplier while for the establishment the lot remains as defined at the initiation of sampling.
 - The IVO is in charge of sample collection as soon as possible, without waiting for the establishment to complete corrective actions.

- The IVO collects a maximum of two samples per production day or minimum sampling frequency is three samples per week.
- In the event of obtaining a positive result during follow up sampling, DIA determines the actions to be taken. In the case that the corrective measures implemented by the establishment are ineffective, DIA could suspend the activities of the establishment and take additional actions including suspension of certification.
- The training of officials and establishment personnel:
 - All personnel at the establishments exporting to the U.S., IVO personnel, DEF supervisors, and DT personnel will receive training prior to beginning of sampling at the establishments. In addition, personnel responsible for ensuring food safety at the establishments certified to export to the United States will receive training.
 - Training will be the responsibility of personnel in charge of DT and DEF as well as the Director and adjunct Director of the DIA.

The CCA has a verification-testing program in place to test for *Lm* and *Salmonella* species in RTE product that are eligible to be exported to the United States. In addition, the CCA requires that establishments exporting RTE products to the United States have a program in place to meet FSIS equivalence criteria for control of *Lm*. Three of the four establishments audited were producing ready-to-eat products required to meet the basic FSIS regulatory requirements for testing for *Listeria monocytogenes* and were evaluated according to the applicable regulations. Testing for *Listeria monocytogenes* was conducted properly in all establishments in which it was required. *Lm* and *Salmonella* testing for RTE product is sampled by government once (1) a week. Food contact surfaces (FCS) and environment are not tested by the government but by the establishment. In RTE product, *Salmonella* government testing uses the MLG 4.06 method with two days of detection (by PCR) and 10 days of confirmation of the organism. For detection of *Lm*, government product testing uses the MLG 8.09 method with five days detection time. Based on the FSIS auditor's interviews and review of inspection documents at the CCA headquarters in Montevideo and three audited processing establishments the auditor observed that:

- CCA did not have written guidance and had not conducted verification sampling of food contact surfaces (FCS) or the environment as stated in the above mentioned FSIS notification. The lack of ongoing CCA verification sampling of FCS and environment where post-lethality-exposed RTE products are handled established the fact that the CCA is not being consistent with FSIS' RTE equivalence criteria.

The CCA's DGSG has an oversight function over the DILAVE government laboratory, which is under DGSG supervision in the organization chart and reports to DGSG. Every year the laboratory reports on its performance in the "laboratory annual report" sent to the DGSG. There is no fixed visit/audit program from DGSG to DILAVE, but the laboratory receives them several times a year for different issues. Additionally, the DGSG conducts annual audits of its residue laboratories that perform analysis of products that are destined for export to the United States. The audits focus on application of approved FSIS Microbiology Laboratory Guidebook (MLG) methods: calibration of equipment; internal audits; traceability of samples and sample analysis; test kits; ISO 17025 requirements; and verification of corrective actions for previous findings.

Additionally, the government laboratory is audited by the Accreditation body and Certification body once a year.

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

FSIS concludes that based on the results of the overall microbiological component assessment, the CCA continues to meet the core equivalence requirements for this component. However, FSIS finds that the CCA operates at an "adequate" level because the CCA's ongoing RTE verification sampling was not fully implemented in accordance with FSIS' RTE equivalence criteria. FSIS expects that the CCA provides documentation describing the change in the CCA verification sampling to ensure that the FSIS standards are being met.

X. CONCLUSIONS AND NEXT STEPS

The audit results indicate that Uruguay's inspection system is operating at an "adequate" level for maintaining its equivalence. However, the onsite audit findings and the post-audit POE violations indicate that the CCA's government oversight of implementation of all requirements that include the evaluation of verification, corrective actions, record keeping, and hands-on verification of sanitation programs and microbiological testing could be improved.

The audit findings were conveyed by the FSIS auditor to the MGAP inspection officials at an exit meeting on April 11, 2014, in Montevideo. The CCA understood and accepted the need to address these findings to maintain its equivalence.

XI. ATTACHMENTS TO THE AUDIT REPORT

Attachment A: Individual Foreign Establishment Audit Checklist

Attachment B: The CCA's response to the Draft Final Audit Report (when it becomes available)

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Establecimientos Colonia S.A. Route Puente Puerto Km 310.700 Fray Bentos Uruguay	2. AUDIT DATE 3-28-2014	3. ESTABLISHMENT NO. 30	4. NAME OF COUNTRY Uruguay
	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	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.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: March 28, 2014 Est #: 30 Fray Bentos, [P] (Uruguay)

46/51 Container for the edible product was sitting on the top of container which contained inedible product and was identified with the red color as inedible. This deficiency was corrected immediately by the establishment officials and verified by the inspection personnel.

61. NAME OF AUDITOR
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 3/28/2014

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Erel S.A. Ruta 9 Km 142 San Carlos Uruguay	2. AUDIT DATE 4-7-2014	3. ESTABLISHMENT NO. 135	4. NAME OF COUNTRY Uruguay
	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: April 7, 2014 Est #: 135 Erel, San Carlos. [P] (Uruguay)

38 The presence of a fly was observed in the raw product processing area. This deficiency was corrected immediately by the establishment and verified by the inspection service by removing the flying pest from the processing area premises.

61. NAME OF AUDITOR
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

 4/7/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Canelones S.A. Canelones Uruguay	2. AUDIT DATE 3-31-2014	3. ESTABLISHMENT NO. 8	4. NAME OF COUNTRY Uruguay
	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	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.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: March 31, 2014 Est #: 8 Canelones, [S] (Uruguay)

38 The presence of a fly was detected in the slaughter room. Corrective action was taken by the establishment and inspection officials by removing the flying insect from the premises.

39/51 Space under the door connecting the door with outside premises to hall and eventually to the slaughter was observed. This deficiency was corrected the same day by replacing the faulty rubber.

46/51 The rail and conveyor belt was over greased in the deboning room. This situation was creating possible contamination problem with product produced at the time of the observation. No actual contamination was observed. The operation was stopped by the CCA and corrective action was performed. The room was eventually released for production.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 3/31/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Tacuarembó S.A. Route 5& 26 Tacuarembó Uruguay	2. AUDIT DATE 3-26-2014	3. ESTABLISHMENT NO. 12	4. NAME OF COUNTRY Uruguay
	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: March 26, 2014 Est #:12 Tacuarembó S.A. [S/P] (Uruguay)

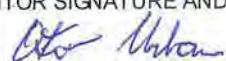
38 The presence of a fly was detected in the slaughter room. Corrective action was taken by the establishment and inspection officials by removing the flying insect from the premises.

39/51 Four rusty screws were observed in the product processing area at the plastic sealing machine but not in product contact area. This deficiency was corrected immediately by the establishment and verified by the inspection service.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

 3/26/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION SIRSIL S.A. (Frigorifico Sarubbi) Coronel Raiz 2764 Montevideo Uruguay	2. AUDIT DATE 4-1-2014	3. ESTABLISHMENT NO. 85	4. NAME OF COUNTRY Uruguay
	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: April 1, 2014 Est #: 85 SIRSIL S.A. Montevideo [S] (Uruguay)

38 The presence of a fly was detected in the slaughter room. Corrective action was taken by the establishment and inspection officials by removing the flying insect from the premises.

39/51 Space under the door connecting the door with outside premises and eventually with the packaging room was observed. This deficiency was scheduled for the correction by the establishment with following verification of the inspection service.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 4/1/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigoyi Bilacor S.A. Ex route 4 Sta Bernardina Durazno Uruguay	2. AUDIT DATE 4-2-2014	3. ESTABLISHMENT NO. 26	4. NAME OF COUNTRY Uruguay
	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
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	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: April 2, 2014 Est #: 26 Frigoyi Bilacor S.A. Durazno [S] (Uruguay)

10/51 During the pre-operational sanitation, dry meat and fat particles from the previous day of operation was observed at few plastic holder support in the deboning room. This deficiency was corrected immediately by the establishment and verified by the inspection service.

61. NAME OF AUDITOR

Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 4/2/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Breeder's and Packer's Uruguay S.A. Route 14 km 170 Durazno Uruguay	2. AUDIT DATE 4-3-2014	3. ESTABLISHMENT NO. 310	4. NAME OF COUNTRY Uruguay
	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: April 3, 2014 Est #: 310 Breeder's and Packer's Uruguay S.A. Durazno [S] (Uruguay)

There are no significant findings to report concerning this establishment and the government oversight verification.

61. NAME OF AUDITOR
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 4/3/2014