USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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Dr. Gustavo Rossi
Director
Animal Industry Division
Ministerio de Ganadería, Agricultura y Pesca
Dirección General De Servicios Ganaderos
Ruta Nacional N° 8 Brigadier Gral. Juan Antonio Lavalleja – Km 17,500
Montevideo, Uruguay

Dear Dr. Rossi,

The Food Safety and Inspection Service (FSIS) conducted an ongoing on-site equivalence verification audit of Uruguay's inspection system governing raw (beef and lamb) and processed (beef, lamb, and pork) meat from June 4 through June 15, 2018. Enclosed is a copy of the final audit report. The comments received from the Government of Uruguay are included as an attachment to the report.

FSIS acknowledges that the General Directorate of Livestock Services (Dirección General de Servicios Ganaderos – DGSG) has provided documentation to address the findings noted during the on-site audit. FSIS is in the process of evaluating your response, and once complete, FSIS will notify you as to whether Uruguay's meat products inspection system remains equivalent to that of the United States.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at InternationalCoordination@fsis.usda.gov.

Sincerely,

for Janell J. Kause

Janell Kause
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

URUGUAY

JUNE 4-15, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW AND PROCESSED
BEEF, LAMB, AND PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

August 29, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from June 4-15, 2018. The purpose of the audit was to determine whether Uruguay's food safety inspection system governing raw (beef and lamb) and processed (beef, lamb, and pork) meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Uruguay currently exports thermally processed, commercially sterile (TPCS) beef; ready-to-eat (RTE) salt-cured beef; RTE fully-cooked beef; RTE dried beef; RTE acidified/ fermented beef (without cooking); raw intact beef; raw intact lamb; and RTE dried pork to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. However, the following findings were identified:

Government Oversight (e.g., Organization and Administration)

- At one of the 11 audited establishments, the establishment employees (not official government inspectors) were assigned to the post-mortem inspection line. This was a temporary arrangement instituted by the Central Competent Authority (CCA) to address a staffing shortage. These individuals were later replaced with official veterinary assistants during the course of the FSIS audit. Nevertheless, the use of establishment employees to conduct post-mortem activities was not submitted to FSIS for equivalence review prior to actual implementation.

Government HACCP System

- HACCP recordkeeping requirements were not met at seven of the 11 audited establishments. At six establishments, records documenting ongoing verification activities did not record the time when the specific event occurred. At one establishment, documentation of corrective actions taken in response to deviations from the critical limit associated with the critical control point for feces, ingesta, and milk (i.e., zero tolerance) was incomplete.
- At the single audited establishment producing post-lethality-exposed RTE product, the written program for the control of *Listeria monocytogenes* (*Lm*) did not specify that product coming into direct contact with a food-contact surface (FCS) that tested positive for *Lm* would be considered adulterated. However, there have been no positives for *Lm* identified in both the establishment and government FCS sampling results in recent history.

Government Microbiological Testing Programs

- The government laboratory did not maintain a written official procedure for the handling of inconclusive Shiga toxin-producing *Escherichia coli* (STEC) sample results.
- The government laboratory was not documenting critical parameters associated with its microbiological testing methods (e.g., documentation of times associated with incubation steps).

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

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Uruguay's food safety system from June 4-15, 2018. The audit began with an entrance meeting held on June 4, 2018, in Montevideo, Uruguay, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the General Directorate of Livestock Services (Dirección General de Servicios Ganaderos – DGSG) of the Ministry of Livestock, Agriculture and Fisheries (Ministerio de Ganaderia, Agricultura y Pesca – MGAP).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety inspection system governing raw (beef and lamb) and processed (beef, lamb, and pork) meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Uruguay currently exports thermally processed, commercially sterile (TPCS) beef; ready-to-eat (RTE) salt-cured beef; RTE fully-cooked beef; RTE dried beef; RTE acidified/fermented beef (without cooking); raw intact beef; raw intact lamb; and RTE dried pork to the United States.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Uruguay as "negligible risk" for bovine spongiform encephalopathy (BSE) and free of rinderpest. Uruguay is not recognized free of foot-and-mouth disease (FMD), but permitted to export fresh (chilled or frozen) beef and ovine meat under specific conditions. Uruguay is eligible to export raw (beef, lamb) and processed (beef, lamb, and pork) meat to the United States.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

Representatives from the CCA accompanied the FSIS auditors throughout the entire audit. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters and 11 local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 11 establishments was selected from a total of 28 establishments certified to export to the United States. This included seven slaughter establishments exporting raw intact beef; three slaughter establishments exporting raw beef or lamb; and one bovine slaughter and processing establishment that produces RTE salt-cured beef, RTE fully-cooked beef, RTE dried beef, and raw intact beef.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) § 327.2.

Additionally, two government laboratories for microbiology and chemical residue were audited to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• DGSG headquarters, Montevideo
Laboratories		2	• División Laboratorios Veterinarios (DILAVE) National Chemical Residue Control Laboratory, Montevideo (Government Laboratory) • DILAVE National Microbiology Laboratory, Montevideo (Government Laboratory)
Cattle slaughter establishments		7	• Establishment 2, Establecimientos Colonia S.A., Canelones • Establishment 8, Frigorífico Canelones S.A., Canelones • Establishment 224, Frigorífico Lorsinal, Canelones • Establishment 245, Copayan S.A., Rocha • Establishment 310, Breeders & Packers Uruguay S.A., Durazno • Establishment 394, Frigorífico La Caballada (Cledinor S.A.), Salto • Establishment 439, Frigorífico Matadero Pando (Ontilcor S.A.), Canelones
Cattle and lamb slaughter establishments		3	• Establishment 3, Frigorífico Carrasco S.A., Canelones • Establishment 344, Frigorífico San Jacinto (Nirea S.A.), Canelones • Establishment 379, Frigorífico Las Piedras S.A., Canelones
Cattle slaughter and processing establishment		1	• Establishment 12, Frigorífico Tacuarembó S.A., Tacuarembó

FSIS performed the audit to verify the system met requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- The Meat Inspection Regulations (9 CFR § 301 to the end).

The audit standards applied during the review of Uruguay's food safety inspection system for raw (beef and lamb) and processed (beef, lamb, and pork) meat included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*.

III. BACKGROUND

From March 26, 2016 to January 31, 2018, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 171,882,209 pounds of meat from Uruguay. This included 11,711,472 pounds of TPCS beef; 97,323 pounds of RTE salt-cured beef; 8,997 pounds of RTE fully-cooked beef; 3,138,761 pounds of RTE dried beef; 9,506 pounds of RTE acidified/fermented beef (without cooking); 156,866,657 pounds of raw intact beef; 33,148 pounds of raw intact lamb; and 16,345 pounds of RTE dried pork exported by Uruguay to the United States. Of these amounts, additional types of inspection were performed on 39,634,896 pounds of meat, including testing for chemical residues and microbiological pathogens: Shiga toxin-producing *Escherichia coli* (STEC) O157:H7, O26, O45, O103, O111, O121, and O145 in beef; and *Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products. As a result of these additional inspection activities, FSIS rejected 2,642,040 pounds of beef imported from Uruguay.

The primary reasons for rejection related to public health included the identification of the organophosphate insecticide ethion (504,462 pounds) or abscesses (766,180 pounds) in reinspected product. FSIS also identified one lot of product containing extraneous material (60,272 pounds), four lots of product presenting contamination with fecal material (39,600 pounds) or ingesta (120,600 pounds), and two positive test results for STEC O103 (30,600 pounds) during this time period. The remaining rejections (1,120,326 pounds) were for reasons not directly related to public health, including failure to meet APHIS animal health requirements, whereby FSIS identified the presence of excessive bruises, blood clots, or bone fragments during reinspection. APHIS regulation 9 CFR § 94.29 requires that all bone, visually identifiable blood clots, and lymphoid tissue be removed from lamb and beef imported from Uruguay.

The FSIS auditors visited nine establishments implicated in the above-referenced POE violations, and focused on establishments presenting three or more critical violations for the specified timeframe. The FSIS auditors concluded that DGSG's implementation of corrective actions accurately reflected commitments made in response to FSIS initial notification, follow-up, and close-out activities for each specific violation. Additional information regarding these POE violations are included in relevant sections of this report.

The previous FSIS audit conducted in 2016 included visits to the central headquarters, two laboratories (microbiology and chemical residue), four bovine slaughter establishments, and two

bovine processing establishments. The results of the audit indicated that that Uruguay's meat inspection system remained equivalent. No systemic findings were identified.

The current evaluation of all six equivalence components included a review and analysis of documentation previously submitted by DGSG as support for the responses provided in the SRT. The FSIS on-site audit included record reviews, interviews, and observations made by the FSIS auditors.

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

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

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

The DGSG of the MGAP continues to serve as the CCA for activities related to the export of meat products to the United States. DGSG consists of four divisions: the Animal Industry Division (División Industria Animal – DIA), the Veterinary Laboratories Division (División Laboratorios Veterinarios – DILAVE), the Animal Health Division (División Salud Animal – DSA), and the Livestock Control Division (División de Contralor de Semovientes – DICOSE). At the time of the audit, DGSG was in the process of merging DSA and DICOSE into a single division.

DGSG is responsible for official control of slaughter and processing establishments including those facilities that are eligible to export to the United States. DGSG has the legal authority and the responsibility to issue, implement, and enforce requirements. Uruguay's *Law N^{o}. 18.996 (2012)* grants DGSG the authority to suspend establishments certified to export to the United States that are suspected of not complying with relevant laws and regulations. The Department of Legal Services within MGAP is tasked with applying penalties such as warnings, fines, product seizure, and suspension of operations.

Uruguay's meat inspection system is directed from the central headquarters in Montevideo. Slaughter and processing establishments are organized geographically into three areas, each with an assigned DIA Area Supervisor, who is responsible for conducting periodic supervisory reviews. Veterinary Inspectors (Inspector Veterinaria Oficials – IVOs) and non-veterinary official inspectors (veterinary assistants) are assigned to each establishment.

While on-site, the FSIS auditors verified that inspection personnel possessed the appropriate educational credentials, training, and experience to carry out their inspection tasks. All IVOs must have a Doctor of Veterinary Medicine or equivalent degree, and the non-veterinary official inspectors have specialized experience or education that allows them to perform their assigned duties. The FSIS auditors also verified through monthly payroll documents (*Recibo de Sueldo*) that, for the most part, personnel assigned to establishments certified to export to the United States are government employees paid directly by the Uruguayan government. The FSIS auditors identified the following finding:

- At one of the 11 audited establishments, the FSIS auditors identified a situation where establishment employees (not government inspectors) were assigned to the post-mortem inspection line. These individuals were assigned to the viscera and final carcass inspection stations. Assigned duties included identification of pathological conditions requiring additional veterinary review (including those related to zoonotic diseases, such as tuberculosis) and verification of a zero tolerance standard for feces, ingesta, or milk. Historically, FSIS has not considered inspection by establishment employees to provide a level of public health protection equivalent to that provided by the United States system. This was a temporary arrangement instituted by DGSG to address a particular staffing shortage within the country's food safety system for which these individuals were later replaced with official veterinary assistants during the course of the FSIS audit. Nevertheless, the use of establishment employees to conduct post-mortem activities was not submitted to FSIS for equivalence review prior to actual implementation.

The authority to enforce inspection laws is granted in the Uruguayan *Decree Nº. 369/983, Decree Nº. 238/00, DIA Resolution Nº. 13.01,* and *Departmental Procedure for Slaughter Establishments Nº. 13.01*. DGSG verifies each exporting establishment's compliance with *Decree Nº. 369/983*, which defines adulterated and misbranded meat products. In accordance with *DIA Order 01.05.2017,* all establishments certified to export to the United States are required to develop product recall procedures. The FSIS auditors noted that each audited establishment maintained these procedures, as well as records sufficient to conduct traceback activities if adulterated product were exported to the United States. No product recalls have occurred in recent history.

All activities related to meat products are under the authority of the IVO, and are subject to technical standards outlined in Article 1 of *Decree Nº. 369/983*. In addition, Articles 3 to 9 of *Decree Nº. 369/983* contain requirements for approval, extension, and modification of slaughter and processing establishments certified as eligible to export to the United States. When the provisions of the these technical standards are violated, the IVO may withdraw inspection, suspend all or part of the activities of the establishment, and seize meat, by-products, derivatives and meat products, including live animals. Withdrawal of the IVO from the establishment premises requires the immediate cessation of activity by the establishment.

While on-site, the FSIS auditors reviewed documents specifically associated with the approval process for the newly-certified Establishment 245. The FSIS auditors also noted that no elevated enforcement actions had been taken at those establishments certified to export to the United States.

Requirements for the export of meat products are provided in *Decree Nº. 369/983*, Chapter VI (Articles 107 through 114). Section XI of *Decree Nº. 369/983* describes the labeling requirements for products (Articles 309 to 344). While on-site, the FSIS auditors verified the labels of products destined for export to the United States, for which no concerns were identified. The FSIS auditors also noted that inspection personnel ensure that raw materials originate only from establishments certified to export to the United States. This was verifiable on-site by cross-referencing the export certificates with the bills of lading and additional certifications (e.g., health certificates, transfer certificates) that accompany each shipment of source materials. The process for receipt of raw materials is outlined in DGSG's *Funciones Del Ayudante De La Inspección Veterinaria Oficial De Control De Embarques*.

During the audit of DGSG headquarters, the FSIS auditors reviewed records indicating that inspectors had successfully completed a 15-month induction training program. All new employees complete training on meat inspection regulations, inspection and verification activities, and country-specific export requirements. Successful completion of training is the fundamental requirement for personnel to be assigned to perform inspection and verification procedures. Veterinary and non-veterinary personnel receive on-the-job training when they are first assigned to establishments certified to export to the United States. Within its *Circular 2: Communication,* DGSG has developed a procedure to ensure that relevant Uruguayan and FSIS import requirements reach the IVO in each certified establishment eligible to export meat products to the United States. This procedure includes documented acknowledgement from the IVO upon receipt of the information.

The FSIS auditors noted that DGSG also provides ongoing training to inspectors at least once a year. Titles of courses offered to inspection personnel since the last FSIS audit included: Animal Welfare; BSE; Epidemiological Surveillance Programs on Antimicrobial Use and Resistance; Food Processing and Human Disease; Tick Control in the Field; HACCP Verification and Validation; Introduction to Food Safety Management; Microbiological Sampling of Pork; National Emergency Response Capabilities Against Exotic Diseases: FMD and Avian Influenza; Validation of Thermal Processes and HACCP Plan Implementation; Ante-mortem and Post-mortem Inspection; and Veterinary Drugs and Maximum Residue Levels.

The FSIS auditors verified through interviews and records review that DGSG ensures its meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website in addition to FSIS' product eligibility chart for individual countries, which also considers current APHIS restrictions. Electronic export certificates (*Certificado Oficial de Transferencia de Exportación* – COTEs) issued by the IVO for a given country are species and commodity specific. In this manner, only those products that have been previously identified by DGSG as meeting both FSIS and APHIS requirements can be certified for export to the United States. Prior to issuing the COTE, the exporting establishment is required to provide the IVO with the HACCP pre-shipment review; results of applicable chemical and microbiological testing; and documentation to indicate that the shipping container has been appropriately sanitized to meet APHIS requirements.

The FSIS auditors verified that laboratories conducting analyses of meat exported to the United States comply with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025. The primary laboratories used in conjunction with export to the United States are found within DILAVE (chemical residue and microbiological departments). These laboratories are ISO/IEC 17025 accredited by the Organismo Uruguayo de Acreditación (OUA), and subject to yearly audits by the accrediting body.

All methods of analysis are scientifically validated. DILAVE has a Laboratory Authorization Unit (Unidad de Habilitación de Laboratorios – UHL) which authorizes private laboratories to perform certain microbiological analyses. This includes all private laboratories used by those establishments certified to export to the United States, as part of their internal testing programs. DILAVE also has contracts with the Macrobiotics Analysis Laboratories in São Paulo, Brazil and Laboratorio Xenobióticos in Buenos Aires, Argentina, to perform certain chemical residue analyses. Members of the UHL audit these private and contracted laboratories annually. While on-site, FSIS reviewed the audit reports associated with the OUA accreditation as well as the activities performed by the UHL, for which no concerns were identified.

The CCA maintains many of the administrative and technical elements to operate its food safety inspection system. However, the practice of using establishment-paid employees to conduct post-mortem activities related to food safety in the absence of an equivalence determination does not meet FSIS' statutory requirements. While this practice was limited in scope and subsequently resolved, FSIS requests that DGSG submit any further changes in inspection coverage for equivalence review prior to actual implementation should they be necessary.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; inspection on the line during all slaughter operations; controls over condemned materials; controls over establishment construction, facilities, and equipment; inspection at least once per shift during processing and on-line inspection during slaughter operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified that DGSG maintains its statutory authority and regulatory requirements as outlined in the official documents including resolutions and circulars issued in accordance with Uruguay's *Law Nº. 3606* and *Decree Nº. 369/983.* These documents outline Uruguay's regulatory requirements to protect public and animal health in both live animals and animal products. There are no other regulatory changes associated with the export of meat products to the United States since the last audit that would have required changes by Uruguay.

The FSIS auditors verified that an in-plant IVO conducts ante-mortem inspection on the day of slaughter by reviewing the incoming registration and identification documents including the *Guía de propiedad y tránsito* (movement permit) and *Certificado oficial de embarque a faena* (animal health certificate). In Uruguay, livestock is identified with one visual and one radio-frequency tag, each with a unique number. In accordance with DGSG's ante-mortem requirements, the IVO observes all animals at rest and in motion from both sides in designated holding pens in order to determine whether they are fit for slaughter. Each establishment presented a designated observation pen for further examination of suspect animals.

The FSIS auditors observed and verified that all animals have access to water in all holding pens (including the pens used for suspect animals), and that if animals are held overnight, feed and water are provided. The FSIS auditors also reviewed documentation demonstrating that the IVO conducts comprehensive humane handling and slaughter (animal welfare) verification audits every six months, and evaluation of the stunning and sticking activities on a daily basis. The Area Supervisor also verifies and documents the proper implementation of this requirement during their monthly supervisory reviews.

The FSIS auditors concluded through on-site record review, interviews, and observations that DGSG's requirements concerning ante-mortem inspection examination (*Decree Nº. 369/983*) and humane handling/slaughter of livestock (*DIA Order Nº. 11.23, Manual Procedure Nº. 03.28,* and *Law Nº. 18.834*) were being implemented and properly documented in all audited slaughter establishments. Within its *DIA Resolution Nº. 1301,* DGSG has adopted a zero tolerance policy against the slaughter of non-ambulatory disabled cattle. The FSIS auditors reviewed *Informe de Necropsia* reports, which indicated that IVOs performed necropsies on all animals condemned at ante-mortem, and in the case on non-ambulatory cattle, the relevant portion of the brain (obex) was sent for official BSE testing.

The CCA's staffing requirements requires at least two IVOs and five veterinary assistants in order to provide inspection on the line during all slaughter operations. The FSIS auditors correlated the number of these individuals conducting post-mortem inspection activities in each audited establishment with the maximum slaughter rate, and concluded that the CCA had provided a sufficient number of inspection personnel for the existing production volume and slaughter line speed, in a manner consistent with 9 CFR § 310.1 (i.e., the FSIS regulation for post-mortem staffing standards).

The FSIS auditors assessed the proper implementation of post-mortem inspection examinations through reviews of inspection records, interviews, and observations of post-mortem inspection examinations in all 11 establishments conducting slaughter activities. The FSIS auditors observed and verified that proper presentation, identification, examination, and disposition of each and every carcass and accompanying viscera are being implemented. Both in-plant veterinary and non-veterinary inspectors are adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditors observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes are made in accordance with DGSG's requirements (*Decree Nº. 369/983*). The FSIS auditors noted that the results of post-mortem inspection activities and related condemnation of heads, viscera, and carcasses (or portions

thereof) were summarized on the *Inspección Veterinaria Control de Decomisios Parciales* report.

The FSIS auditors observed that the appropriate APHIS requirements for the control of FMD were being met at all audited slaughter establishments. An in-plant inspection personnel examines the coronary band for each foot as well as the lips and snout of each individual animal slaughtered. In addition, the FSIS auditors noted that establishment employees measured the pH for each half carcass after it had gone through the maturation chamber in accordance with the DGSG requirements.

The FSIS auditors also reviewed IVO documentation to support that inspection verification activities occurred at least once during each processing shift that product was prepared for export to the United States. Documented verification activities included direct observation and review of establishment records, including HACCP, sanitation standard operating procedures (sanitation SOPs), sanitation performance standards (SPS), and microbiological sampling programs.

The CCA requirements to ensure control over condemned animals and inedible material are found in Article 50 of *Decree Nº. 369/983*. Condemned animals and inedible material are to be excluded from human consumption. During the audit, the FSIS auditors verified that the relevant portions of these requirements were applied, including appropriate identification in accordance with the categories described therein; segregation in specially-marked or otherwise secure containers; and final disposal of these materials at nearby rendering facilities. The FSIS auditors noted that specific quantities of materials sent for disposal are documented by inspection personnel on a form entitled *Pase Sanitario Interno*, and subsequently reconciled with receipts provided by the rendering facilities.

The FSIS auditors accompanied and observed the function of the Area Supervisors who are responsible for conducting the periodic (monthly) supervisory reviews. During the periodic supervisory reviews, the Area Supervisors verify requirements for ante-mortem inspection; humane handling and slaughter; post-mortem inspection; microbiological sampling programs; sanitation; and HACCP verification activities including the review of critical control points (CCPs). The Area Supervisors document their monthly supervisory review on the form entitled *Auditoria De Supervisión,* in accordance with DGSG requirements. During the on-site audit of the 11 establishments certified to export to the United States, the FSIS auditors determined that official Area Supervisors conducted these reviews at the intended frequencies.

The FSIS auditors also conducted follow-up of corrective actions taken in response to the POE violations related to the presence of abscesses in product. DGSG attributed these violations to the administration of vaccines to livestock prior to arriving at the slaughter facilities. Actions taken by Uruguay on a national basis included the following elements, for which the FSIS auditors identified no additional concerns:

1. Replacement of the intra-muscular vaccine with a subcutaneous vaccine, to be applied in the upper middle third of the neck;
2. Standardization of vaccine doses (at a concentration of 2 ml);

3. Modification in the composition of the vaccines, including the maximum permissible concentration of adjuvants (i.e., compounds added to the vaccine to help stimulate the immune response and overall effectiveness); and
4. Implementation of a statistically-based program for reinspection of finished product by exporting establishments, with verification by inspection personnel. The FSIS auditors noted that official verification activities typically occurred every 30 minutes and were documented on the *Carne Deshuesada* worksheet.

FSIS has noted a decline in similar POE violations since the implementation of these changes. The FSIS auditors concluded that Uruguay's food safety inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

The FSIS auditors noted that the CCA has adopted FSIS' sanitation regulatory requirements consistent with 9 CFR § 416. The FSIS auditors verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or adulteration. Each program included maintenance and improvement of sanitary conditions through routine assessment of the establishment's hygienic practices. The FSIS auditors confirmed that the in-plant inspection personnel conduct daily verification procedures of the implementation of each establishment's sanitation program. Inspection verification activities consist of a combination of document reviews and hands-on inspections.

The FSIS auditors reviewed the implementation of the pre-operational inspection verification by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification inspection. The in-plant inspection personnel conducted this activity daily and in accordance with DGSG's instructions outlined in the *Manual de Procedimientos de la División Industria Animal*. The in-plant inspection personnel's hands-on verification procedures begin after the establishment personnel conduct their pre-operational sanitation and determine that the facility is ready for in-plant inspector pre-operational sanitation verification activities.

The FSIS auditors reviewed official verification documentation of operational sanitation procedures at all audited establishments. Official verification activities include direct observation of operations and review of establishment records, for which the results are recorded daily on the *Formulario de Verificación de Procesos*. The FSIS auditors also reviewed the establishment's sanitation monitoring and the corresponding verification records and noted that the inspection and establishment records correspond with the actual sanitary conditions of the establishment. All establishments conducted monitoring of sanitary slaughter practices, including proper skinning; tying of the esophagus and bung; and evisceration several times during the production shift. These establishments maintained sanitation records sufficient to

document the implementation and monitoring of the sanitation SOPs and any corrective actions taken. Establishment employees specified as being responsible for the implementation and monitoring of the sanitation SOP procedures correctly authenticated these records with initials or signatures and the date.

Isolated findings related to the verification of SPS are noted on the establishment checklists attached to this report (Appendix A). The analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs and the CCA continues to maintain sanitation requirements.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

Within its *DIA Circular 2: Implementación HACCP (1999)*, DGSG has adopted HACCP requirements which are consistent with 9 CFR § 417. These requirements are further supplemented by the *Manual of Procedures for Verification of the HACCP Plan*, which provides inspection personnel with instructions for conducting daily verification activities. The in-plant inspection verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The official daily HACCP verification activities also include direct observation or record review of CCPs for all production shifts, with results of verification being entered in the associated inspection records.

The FSIS auditors conducted an on-site observation and document review of CCPs in all the audited establishments including the zero tolerance (feces, ingesta, and milk) CCP control records generated in the 11 audited slaughter establishments. At each slaughter establishment, the FSIS auditors together with the in-plant inspection personnel observed the establishment's employee conducting hands-on HACCP monitoring and verification activities for the zero tolerance CCP in accordance with DGSG's *Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Post-Mortem Inspection*. The FSIS auditors also reviewed the establishment and the in-plant inspections' zero tolerance records. Both establishment (monitoring, verification, and corrective action) and the in-plant inspection (verification) records documented a few deviations from the critical limits and related corrective actions taken by the establishment. Furthermore, the FSIS auditors confirmed that the physical CCP location for inspection verification activities was before the final carcass wash in all audited slaughter establishments.

The FSIS auditors verified that establishments certified to export to the United States had addressed contamination of carcasses with STEC (O157:H7, O26, O45, O103, O111, O121, and O145) within the context of their HACCP systems. This typically included the use of a validated organic acid spray, as well as additional controls to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens. The FSIS auditors' review

of microbiological sampling programs and testing results for carcasses (generic *E. coli*) and beef trimmings (STEC) further supported the conclusions reached in their hazard analyses.

- During the on-site document reviews, the FSIS auditors identified the following findings related to HACCP recordkeeping requirements at seven of the 11 audited establishments:
  - At six establishments, records documenting ongoing verification activities (i.e., direct observation of monitoring, calibration of process-monitoring instruments, or review of records) did not record the time when the specific event occurred.
  - At one establishment, documentation of corrective actions taken in response to deviations from the critical limit associated with the CCP for feces, ingesta, and milk (i.e., zero tolerance) on carcasses was general in nature. This establishment was using a series of codes such as "1. Retrained employee," rather than including specific details as to what was discussed or what other actions were taken for each particular event.

At the one establishment producing RTE products, the FSIS auditors reviewed the HACCP programs for these processes with a special emphasis on lethality for *Salmonella* and other relevant pathogens. For the heat-treated, shelf stable product (beef jerky), the establishment's HACCP system included appropriate measures to address lethality by adhering to the lethality and stabilization performance standards outlined in Appendices A and B of the *FSIS Compliance Guidelines for Cooking/Cooling Meat and Poultry Products*, in addition to monitoring relative humidity within the cooking cycle, cooking temperature, and water activity. For the not-heat-treated, shelf stable beef products (tasajo and bresaola), the FSIS auditors reviewed the supporting documentation and a validation study, which demonstrated lethality for *Salmonella*, in addition to the negative certificates of analysis for O157 and non-O157 STEC in each lot of source material.

The FSIS audit included a review of establishment sampling and testing programs and results for *Lm* and *Salmonella* for finished products and *Lm* for food-contact surfaces (FCSs) and environmental surfaces, however the following finding was identified:

- At the single audited establishment producing post-lethality-exposed RTE product, the written program for the control of *Lm* did not include a provision to reflect the policy outlined in DGSG's *Programa Control Ambiental Listeria Monocytogenes*, that product coming into direct contact with an FCS that tested positive for *Lm* is considered adulterated. However, there have been no positives for *Lm* identified in both the establishment and government sampling results for FCS in recent history.

The FSIS auditors visited 11 establishments conducting slaughter of cattle to observe and verify actual operations concerning removal, segregation, and disposal of specified risk material in accordance with *Decrees Nº. 238/004* and *51/004*. In particular, the FSIS auditors verified the implementation of DGSG's requirements through record reviews, interviews, and direct observations made during both ante-mortem and post-mortem inspection examinations.

Except for the findings above, the analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain a HACCP system for each processing category.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. FSIS based its verification of Uruguay's residue control program on information contained in the National Biological Residues Program (Program Nacional de Residuos Biológicos – PNRB) sampling plan and previous years' (2016-2017) testing results, for which updated versions were provided to FSIS prior to the audit.

While on-site, FSIS verified through interviews and records review that personnel from DGSG, in cooperation with DILAVE, develop and implement the annual residue monitoring plan. DILAVE prepares the sampling schedules and instructions for random collection of samples of specific matrices within a defined period. IVOs receive monthly sampling plans, select the herds to be sampled, collect and prepare samples, and send samples to the designated laboratory in accordance with DGSG instructions. The Area Supervisors ensure that IVOs comply with PNRB procedures and sampling timeframes.

If violative results are identified, the DIA is notified to destroy associated carcasses and offal. Carcasses suspected to be affected by drug residues shall be disposed of per *Decree Nº. 369/983*, Section X. For violative results the DSA will notify the source farm and perform an investigation to identify the root cause. In addition, the farm will be included on the *List of Observed Suppliers.* Identified farms must pass two consecutive sample series (i.e., all livestock in a particular herd) prior to being removed from this list.

FSIS conducted an on-site audit of the chemical laboratory within DILAVE, the principal laboratory providing technical support to Uruguay's food safety inspection system. The documents reviewed at the laboratory demonstrated technical and organizational functions were periodically evaluated by the laboratory quality control manager and audited by a third-party accrediting institution (i.e., OUA). Findings reported during accreditation audits were promptly addressed and documented as required by the ISO/IES 17025 standard. Analysts assigned to the chemical residue laboratory have completed academic work and specialized training that qualify them to conduct the analytical methods for detection and quantification of chemical residues in their scope of accreditation.

A review of the sampling records maintained at the local inspection office of the audited slaughter establishments indicated that the 2018 sampling program was being adhered to as scheduled. Monitoring residue samples are collected by the IVO and are shipped under inspection seal. Samples are shipped to the laboratory in accordance with protocols issued by DILAVE. DILAVE tracks the samples and provides feedback to the in-plant IVO concerning adequacy of sample shipping and results of analysis.

During the audit of ante-mortem inspection at the 11 establishments with slaughter activities, the FSIS auditors observed that an IVO verifies that all lots of animals are accompanied by documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. DGSG has adopted a hold and test procedure within its PNRB to ensure product is not exported to the United States until acceptable results are obtained, for which the FSIS auditors were presented with sufficient audit evidence while on-site (e.g., review of inspection records, presence of "veterinary retained" cages) to demonstrate that this policy was being effectively implemented.

The FSIS auditors also conducted follow-up of corrective actions taken in response to the POE violations related to the presence of ethion in product. The cause of these violations was attributed to an improper use of this compound to treat cattle for parasites (e.g., ticks) prior to arriving to slaughter. The specific actions taken by the government of Uruguay include the following, for which no concerns were identified:

1. Issuance of *Ministerial Resolutions Nºs 183* and *645,* to regulate the use of ethion in the field.
2. Enforcement of the new maximum residue level (MRL) for ethion, which was reduced from 2,500 parts per billion (ppb) to 10 ppb.
3. Installation of new equipment within DILAVE, and development of a validated method to meet this reduced MRL. The implementation of this equipment and validation of the method was verified by FSIS while on-site.

FSIS has noted a decline in POE violations for ethion since the implementation of these changes, and considers this matter resolved. The result of the on-site audit activities indicate that Uruguay continues to maintain the legal authority to regulate, plan, and execute activities of the food safety inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in meat products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

DGSG implements a *Salmonella* official sampling and testing program for chilled livestock carcasses that is consistent with the FSIS *Salmonella* performance standards in 9 CFR § 310.25(b). An establishment failing its first *Salmonella* set must take immediate corrective action after which a second set of samples is collected within 60 days. If the establishment fails to meet the performance standard on the second sample set, then the establishment must take corrective actions and reassess its HACCP system, and another sample set is collected within 30 days. If an establishment fails three consecutive sample sets, it is removed from the list of establishments eligible to export to the United States.

DGSG uses the FSIS Microbiology Laboratory Guidebook (MLG) method 4.08 for official analysis of *Salmonella* in beef. DGSG also conducts verification activities to monitor a slaughter establishment's generic *E. coli* testing program in chilled livestock carcasses. The FSIS auditors' review of records associated with establishments' generic *E. coli* testing and inspection's *Salmonella* verification testing program did not raise any concerns. There have been no *Salmonella* set failures in recent history.

DGSG has identified *E. coli* O157:H7 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. DGSG requires in-plant inspection personnel to review and verify establishments' documents including sampling methodology and testing results. Establishments certified to export to the United States are required to conduct routine sampling of beef manufacturing trimmings in accordance with N60 methodology. In-plant inspection personnel also conduct independent N60 official verification sampling that includes both daily (lot-based) and weekly (herd-based) sampling. The program specifically designates DILAVE as the only laboratory that performs confirmation analyses of official samples. DILAVE uses the FSIS methods for official analysis of *E. coli* O157:H7 (MLG 5A.04) and non-O157 STEC (MLG 5B.05) in raw beef.

DGSG requires RTE processing establishments that produce post-lethality-exposed product to control *Lm* by adopting one of the three alternatives in a manner consistent with 9 CFR § 430.4(b). As per DGSG's *Programa Control Ambiental Listeria Monocytogenes,* an RTE product is considered to be contaminated when the product comes in direct contact with an FCS contaminated with *Lm*. The FSIS auditors also verified through interviews and records review that DGSG has implemented official ongoing verification sampling to test for product, FCS, and environmental surfaces as outlined in *Resolution Nº 98/2016* and *Regulatory Norm Nº 1/2013*. Official government personnel collect samples, and DGSG uses the FSIS MLG methods and test portions for *Lm* and *Salmonella* testing. Establishments are required to hold the product until sampling results are received. If the RTE product tests positive for either *Lm* or *Salmonella,* it is not eligible for export to the United States.

During the audit of DILAVE, FSIS reviewed documentation of analysts' proficiency evaluations, inter-laboratory proficiency testing results, and records of evaluations of corrective actions taken in response to audit findings. The audit also verified that the laboratory maintained appropriate discard criteria to ensure the integrity of the sample and testing results. This included written standard operating procedures to ensure that samples arrive under government seal within specified timeframes and required temperatures, as well as outlining specific follow-up activities to be undertaken when these requirements are not met. Follow-up procedures are in place to notify the IVO and the DGSG headquarters. DGSG receives laboratory results directly from DILAVE. The FSIS review of microbiological testing procedures indicated that the appropriate MLG methods were generally implemented as prescribed. However, the following deficiencies were identified:

- The laboratory did not maintain a written official procedure for the handling of inconclusive STEC sample results. Inconclusive test results include O157 STEC isolates that are determined to be O157+ and stx- and presence of H7 antigen is undetermined; and non-O157

STEC isolate that are confirmatory polymerase chain reaction positive but biochemically negative. While the likelihood of encountering inconclusive results is relatively rare, a written procedure to address this potential situation is consistent with the expectations for a robust testing system.

- The laboratory was not documenting critical parameters associated with its microbiological testing methods. Examples included no documentation of times (i.e., time in, time out) associated with incubation steps; and no documentation of the addition of iodine to the tetrathionate broth on the day of analysis (*Salmonella* testing).

Additional activities performed by DILAVE include species verification testing and examination of heat processed, hermetically sealed (canned) meat products. Species verification sampling is performed at a frequency of once per month at all establishments certified to export to the United States. Establishments producing TPCS are required to submit a sample to DILAVE every 15 days, with the purpose of verifying that the food safety requirements outlined in Section 7, Chapter 3 of *Decree Nº. 369/983* (Articles 220 through 248) for these products are met. DILAVE uses a procedure based on the FSIS MLG method 10 for testing of TPCS products. The FSIS auditors concluded that these additional activities were performed as intended.

The FSIS audit also included a follow-up visit to an establishment with two POE violations for non-O157 STEC during 2016, during which the FSIS auditors gathered sufficient evidence to demonstrate official notification of the positive testing results to the establishment and request for corrective action; segregation of product, with a focus on microbiological independence; reassessment of the establishment's HACCP system (including addition of a control point for a lactic acid rinse); and follow-up government testing with compliant results.

The result of the on-site audit activities indicate that Uruguay continues to maintain the legal authority to regulate, plan, and execute activities of the food safety inspection system aimed at controlling the presence of microbiological pathogens in beef products exported to the United States.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on June 15, 2018, in Montevideo, Uruguay, with DGSG. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The following findings were identified:

Government Oversight (e.g., Organization and Administration)

- At one of the 11 audited establishments, the establishment employees (not official government inspectors) were assigned to the post-mortem inspection line. This was a temporary arrangement instituted by the CCA to address a staffing shortage. These individuals were later replaced with official veterinary assistants during the course of the FSIS audit. Nevertheless, the use of establishment employees to conduct post-mortem activities was not submitted to FSIS for equivalence review prior to actual implementation.

Government HACCP System

- HACCP recordkeeping requirements were not met at seven of the 11 audited establishments. At six establishments, records documenting ongoing verification activities did not record the time when the specific event occurred. At one establishment, documentation of corrective actions taken in response to deviations from the critical limit associated with the critical control point for feces, ingesta, and milk (i.e., zero tolerance) was incomplete.
- At the single audited establishment producing post-lethality-exposed RTE product, the written program for the control of *Lm* did not specify that product coming into direct contact with an FCS that tested positive for *Lm* would be considered adulterated. However, there have been no positives for *Lm* identified in both the establishment and government FCS sampling results in recent history.

Government Microbiological Testing Programs.

- The government laboratory did not maintain a written official procedure for the handling of inconclusive STEC sample results.
- The government laboratory was not documenting critical parameters associated with its microbiological testing methods (e.g., documentation of times associated with incubation steps).

During the audit exit meeting, DGSG committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of DGSG's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Establecimientos Colonia S.A. Ruta 22 Km. 30 Tarariras Colonia	06/11/2018	2	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Uruguay's inspection officials during the establishment review:

10/51. Condensation was observed in the carcass cooler above exposed carcasses. No product adulteration was observed and carcasses were not destined for export to the United States.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/11/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Carrasco S.A. . Cno. Carrasco Nº 5 Paso Carrasco - Canelones, CP 14002	06/13/2018	3	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
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.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

The following non-compliances were not identified by Uruguay's inspection officials during the establishment review:

22/51. The establishment’s verification records documenting direct observation of monitoring activities did not accurately reflect the time the direct observation occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/13/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Canelones S.A. Pando s/n y Ameglio Canelones	06/13/2018	8	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/13/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Tacuarembo S.A. Rutas 5 y 26 Tacuarembo	06/06/2018	12	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Uruguay's inspection officials during the establishment review:

14/51. The establishment's written program for the control *Listeria monocytogenes* did not indicate that product which comes into contact with a food contact surface which has tested positive for *Listeria monocytogenes* to be adulterated.

14/51. The establishment did not identify any chemical or physical hazards related to a processing step where an oxygen-absorbing pack was added during final product packaging.

22/51. The establishment's verification records documenting direct observation of monitoring activities did not accurately reflect the time the direct observation occurred.

41/51. The veterinary-retained area presented frozen condensate to an extent that resulted in the creation of an insanitary condition which could ultimately lead to the adulteration of stored product (no direct product contamination observed).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/06/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Lorsinal Camino Melilla 10270 Canelones	06/06/2018	224	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

22/51. The establishment HACCP verification records for a) direct observation of monitoring; and b) review of records did not include the time when the specific event occurred. The time was also not included in the monitoring records for carcass temperature.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/06/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Copayan SA . Ruta 9 Km. 210 Rocha - CP 27000	06/12/2018	245	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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 .	X	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	X
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

The following non-compliances were not identified by Uruguay's inspection officials during the establishment review:

14/51. The establishment's hazard analysis did not identify the addition of chlorine as a chemical hazard at the process step for carcass washing.

55. The CCA’s use of company-paid individuals to conduct verification activities related to food safety does not meet the requirements for government inspection. Company-paid individuals were assigned viscera (green offal), responsible for identification of pathological conditions related to zoonotic diseases (such as tuberculosis); and the final carcass (lower inspection rail) station, responsible for verification of a zero-tolerance standard for feces, ingesta, or milk.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/12/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Breeders & Packers Uruguay S.A. Ruta 14, km. 170 Durazno	06/05/2018	310	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Uruguay's inspection officials during the establishment review:

22/51. The establishment’s verification records documenting direct observation of monitoring activities did not accurately reflect the time the direct observation occurred.

35. The veterinary-retained area containing product held for residue analysis was not secured with the required seal.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/05/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico San Jacinto (Nirea S.A.) Ruta 7, km. 59.500 Canelones	06/11/2018	344	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

22/51. The establishment HACCP verification records for the calibration of thermometers did not include the time when the specific event occurred.

22/51 Documentation of corrective actions taken in response to deviations from the critical limit associated with the critical control point (CCP) for feces, ingesta, and milk (i.e., “zero tolerance”) on carcasses was general in nature. This establishment was using a series of codes such as “1. Retrained employee,” rather than including specific details as to what was discussed or what other actions were taken for each particular event.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/11/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Las Piedras S.A. Ruta 36, km. 26.100 Canelones	06/05/2018	379	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

22/51. The establishment HACCP ongoing verification records did not document the time when calibration of thermometers occurred. These thermometers were used in conjunction with the monitoring of the critical control point (CCP) for carcass temperature.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/05/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico La Caballada (Cledinor S.A.) Tomas Berretta y Harriague Salto CP 50000	06/07/2018	394	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Uruguay's inspection officials during the establishment review:

38/51. Two doors communicating with exterior areas of the facility were not maintained in a manner sufficient to prevent the entrance of vermin, such as flies, rats, and mice.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/07/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Matadero Pando (Ontilcor S.A.) Ruta 75, Km. 34 Canelones	06/08/2018	439	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

22/51. The establishment HACCP verification records for a) direct observation of monitoring; b) review of records; and c) and calibration of process-monitoring instruments did not include the time when the specific event occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/08/2018

Appendix B: Foreign Country Response to the Draft Final Audit Report

MINISTERIO DE GANADERÍA, AGRICULTURA Y PESCA
DGSG Dirección General de SERVICIOS GANADEROS
DIVISIÓN INDUSTRIA ANIMAL

August 28, 2018

Ms. JANELL KAUSE
ACTING INTERNATIONAL COORDINATION EXECUTIVE
OFFICE OF INTERNATIONAL COORDINATION
USDA/FSIS
WASHINGTON, DC

Dear Ms. Kause,

I am writing to you in reference to your note dated on 08/07/2018, in relation to the draft final report of the last on-site audit of Uruguay's inspection system, conducted from June 4 through June 15, 2018.

In that sense, I would like to inform you that we have no comments regarding the information included in the audit report.

On the other hand, I am pleased to detail to you the following corrective actions taken by Uruguay:

- The employees (not official government inspectors) assigned to the post-mortem inspection line in one establishment, was solved immediately and communicated to the auditors. The General Directorate of Livestock Services (DGSG) issued on 6/13/2018 the Resolution Nº 188/018 (enclosed), amending the Resolution Nº 52T/2018 empowering the Animal Industry Division (DIA) to take measures to cover vacant positions with official personnel. The Slaughter Establishment Department resolved that two official assistants who completed tasks in other establishments should be assigned to establishment # 245 (enclosed).

- Government Microbiological Testing Programs:

  - The Official Veterinary Laboratory (DILAVE) follows internal procedure PR-MIC-15 for E. coli O157:H7 and E. coli non O157 STECs analysis. This procedure is based on USDA MLG 5.09 and MLG 5B.05 methodologies except for VITEK step, which is replaced by traditional biochemistry (enterotubes).
    In the eventuality that we find samples with isolated colonies positive to O157 by PCR and biochemistry, negative to stx and undetermined to H7, samples will be considered positive.

In case of samples analyzed for E. coli non O157 (STECs) with positive results to serotype O, positive results to stx/eae by PCR but negative to biochemistry, result will be considered positive. A new procedure “PR-MIC-15” is enclosed.

- DILAVE works with additional labels on 100% of its samples before incubation in stoves. Additional labels include the time when incubation begins. On this way, all analysts know incubation period for each sample. According to this observation, the laboratory will incorporate new registers for incubation time and iodine addition to the tetrathionate broth, initially manual records as attached (F-MIC-045 and F-MIC046) and further will be automatized.

- Individual establishment audit findings and their corrective actions are detailed in Appendix A and the supporting documents are attached.

Looking forward to hearing from you at your earliest convenience, I remain yours faithfully,

DR. GUSTAVO ROSSI
DIRECTOR

APPENDIX A: INDIVIDUAL ESTABLISHMENT NON-COMPLIANCE / CORRECTIVE ACTIONS			
Est. Nr.	Name	Non-compliance	Corrective Actions
2	Establecimientos Colonia S.A.	10/51. Condensation was observed in the carcass cooler above exposed carcasses. No product adulteration was observed and carcasses were not destined for export to the United States.	File: "2 - Colonia 10/51"
3	Frigorífico Matadero Carrasco S.A.	22/51. The establishment's verification records documenting direct observation of monitoring activities did not accurately reflect the time the direct observation occurred.	File: "3 - Carrasco 22/51"
8	Frigorífico Canelones S.A.	There were no significant findings to report after consideration of the nature, degree, and extent of all observations.	n/a
12	Frigorífico Tacuarembó S.A.	14/51. The establishment's written program for the control *Listeria monocytogenes* did not indicate that product which comes into contact with a food contact surface which has tested positive for *Listeria monocytogenes* to be adulterated.	File: "12 - Tacuarembó 14/51 22/51 41/51"
		14/51. The establishment did not identify any chemical or physical hazards related to a processing step where an oxygen-absorbing pack was added during final product packaging.	
		22/51. The establishment's verification records documenting direct observation of monitoring activities did not accurately reflect the time the direct observation occurred.	
		41/51. The veterinary-retained area presented frozen condensate to an extent that resulted in the creation of an insanitary condition which could ultimately lead to the adulteration of stored product (no direct product contamination observed).	
224	Lorsinal S.A.	22/51. The establishment HACCP verification records for a) direct observation of monitoring; and b) review of records did not include the time when the specific event occurred. The time was also not included in the monitoring records for carcass temperature	File: "224 - Lorsinal 22/51"
245	Copayan S.A.	14/51. The establishment's hazard analysis did not identify the addition of chlorine as a chemical hazard at the process step for carcass washing.	File: "245 - Copayan 14/51"
		55. The CCA's use of company-paid individuals to conduct verification activities related to food safety does not meet the requirements for government inspection. Company-paid individuals were assigned viscera (green offal), responsible for identification of pathological conditions related to zoonotic diseases (such as tuberculosis); and the final carcass (lower inspection rail) station, responsible for verification of a zero-tolerance standard for feces, ingesta, or milk.	Non-compliance was solved immediately and communicated to the auditors. The General Directorate of Livestock Services (DGSG) issued on 6/13/2018 the Resolution Nº 188/018 (enclosed), amending the Resolution Nº 52T/2018 empowering the Animal Industry Division (DIA) to take measures to cover vacant positions with official personnel. The Slaughter Establishment Department resolved that two official assistants who completed tasks in other establishments should be assigned to establishment # 245 (enclosed). File: "245 - Copayan 55"

310	Breeders & Packers Uruguay S.A.	22/51. The establishment's verification records documenting direct observation of monitoring activities did not accurately reflect the time the direct observation occurred.	File: "310 - BPU 22/51"
		35. The veterinary-retained area containing product held for residue analysis was not secured with the required seal.	File: "310 - BPU 35"
344	Frigorífico San Jacinto (Nirea S.A.)	22/51. The establishment HACCP verification records for the calibration of thermometers did not include the time when the specific event occurred.	344 - San Jacinto 22/51
		22/51 Documentation of corrective actions taken in response to deviations from the critical limit associated with the critical control point (CCP) for feces, ingesta, and milk (i.e., "zero tolerance") on carcasses was general in nature. This establishment was using a series of codes such as "1. Retrained employee," rather than including specific details as to what was discussed or what other actions were taken for each particular event.	
379	Frigorífico Las Piedras S.A.	22/51. The establishment HACCP ongoing verification records did not document the time when calibration of thermometers occurred. These thermometers were used in conjunction with the monitoring of the critical control point (CCP) for carcass temperature.	File: "379 - LasPiedras 22/51"
394	Frigorífico La Caballada (Cledinor S.A.)	38/51. Two doors communicating with exterior areas of the facility were not maintained in a manner sufficient to prevent the entrance of vermin, such as flies, rats, and mice.	File: "394 - La Caballada 38/51"
439	Frigorífico Matadero Pando (Ontilcor S.A.)	22/51. The establishment HACCP verification records for a) direct observation of monitoring; b) review of records; and c) and calibration of process-monitoring instruments did not include the time when the specific event occurred.	File: "439 - Pando 22/51"