USDA

United States Department of Agriculture

Food Safety and
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Montevideo, Uruguay

Dear Dr. Rossi,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of the Uruguay's meat inspection system from December 2 through December 13, 2019. 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.

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

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN URUGUAY

DECEMBER 2 – 13, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING RAW AND PROCESSED BEEF AND LAMB PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

March 19, 2020

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 December 2 – 13, 2019. The purpose of the audit was to determine whether Uruguay's food safety inspection system governing raw and processed meat (i.e., beef and lamb) products remains equivalent to that of the United States, with the ability to export meat products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Uruguay currently exports thermally processed, commercially sterile beef, ready-to-eat (RTE) salt-cured beef; RTE beef fully-cooked without subsequent exposure to the environment; RTE fully-cooked beef; RTE dried beef; RTE acidified/fermented beef (without cooking); raw intact beef; and raw intact lamb 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors concluded that Uruguay's meat food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Central Competent Authority (CCA) has implemented sanitary operating procedures and a HACCP system to ensure controls of the food safety inspection system for raw and processed beef and lamb. In addition, the CCA has implemented microbiological and chemical residue testing programs that are organized and administered by the national government to verify Uruguay's food safety inspection system. An analysis of the findings within each component did not identify any systemic findings representing an immediate threat to public health.

Although there were no systemic findings, during the audit exit meeting on December 13, 2019, the CCA committed to address the preliminary isolated findings in the checklists in Appendix A. 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 inspection system from December 2 – 13, 2019. The audit began with an entrance meeting held on December 2, 2019, 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 Ganadería, Agricultura y Pesca – MGAP). During the audit exit meeting on December 13, 2019, DGSG committed to address the preliminary isolated findings. Representatives from DGSG accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing raw and processed meat (i.e., beef and lamb) 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 does not have any certified establishments that are eligible to export pork products to the United States. No pork products from Uruguay have been exported to the United States within the last 10 years. Uruguay is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw – Non-Intact	Raw ground, comminuted, or otherwise non-intact beef	Beef patty product; bench trim from non-intact; formed steaks; ground beef; hamburger; non-intact cuts; other non-intact; sausage; and trimmings from non-intact.
Raw – Non-Intact	Raw ground, comminuted, or otherwise non-intact other (goat, lamb, and mutton)	Ground product; other non-intact; and sausage.
Raw – Intact	Raw intact beef	Boneless manufacturing trimmings; edible offal; other intact; and primals and subprimals.

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States. For processed meat products, meat includes the following species: beef, goat, lamb, and mutton.

Process Category	Product Category	Eligible Products[1]
Raw – Intact	Raw intact meat-other (goat, lamb, and mutton)	Boneless manufacturing trimmings; carcass (including carcass halves or quarters); cuts (including bone in and boneless meats); edible offal; other intact; and primals and subprimals.
Thermally Processed, Commercially Sterile (TPCS)	Thermally processed, commercially sterile	Corned (species); ham; other; sausage; and soups.
Not Heat Treated – Shelf Stable	Ready-to-eat (RTE) acidified/fermented meat (without cooking)	Other – not sliced; other – sliced; sausage/salami – not sliced; and sausage/salami – sliced.
Not Heat Treated – Shelf Stable	RTE dried meat	Ham – not sliced; ham – sliced; jerky; other – not sliced; and other – sliced.
Not Heat Treated – Shelf Stable	RTE salt-cured meat	Not sliced; and sliced.
Heat Treated – Shelf Stable	Not ready-to-eat otherwise processed meat	Bacon; meals/dinners/entrees; other; pies/pot pies; rendered fats, oils; sandwiches/filled rolls/wraps; sauces; smoked parts; and soups.
Heat Treated – Shelf Stable	RTE acidified/fermented meat (without cooking)	Other – not sliced; other – sliced; sausage/salami – not sliced; and sausage/salami – sliced.
Heat Treated – Shelf Stable	RTE dried meat	Ham – not sliced; ham – sliced; jerky; other – not sliced; and other – sliced.
Fully Cooked – Not Shelf Stable	RTE fully cooked meat	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.
Fully Cooked – Not Shelf Stable	RTE meat fully-cooked without subsequent exposure to the environment	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.
Product with Secondary Inhibitors – Not Shelf Stable	RTE salt-cured meat	Not sliced; and sliced.

The USDA's Animal and Plant Health Inspection Service (APHIS) currently recognizes Uruguay as "negligible risk" for bovine spongiform encephalopathy (BSE). 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 and heat-treated or otherwise processed meat (i.e., beef and lamb) to the United States.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Uruguay's self-reporting tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Uruguay's food safety inspection system governing raw and processed meat (i.e., beef and lamb) is being implemented as documented in the country's SRT responses and supporting documentation.

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 SRT.

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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at the CCA headquarters and 10 local inspection offices within the establishments. 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.

The FSIS auditors visited a sample of 10 establishments from a total of 27 establishments certified as eligible to export to the United States. This included one beef and lamb processing and cold storage establishment, two beef and lamb slaughter establishments, and seven beef slaughter and processing establishments. The products these establishments produce and export to the United States include RTE salt-cured beef; RTE beef fully-cooked without subsequent exposure to the environment; RTE fully-cooked beef; RTE dried beef; RTE acidified/fermented beef (without cooking); raw intact beef; and raw intact lamb meat.

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, FSIS visited the microbiology and chemical residue units at the División Laboratorios Veterinarios (DILAVE) 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	• DILAVE National Chemical Residue Control Laboratory, Montevideo (government laboratory) • DILAVE National Microbiology Laboratory, Montevideo (government laboratory)
Beef slaughter and processing establishments		7	• Establishment No. 3, Frigorífico Carrasco S.A., Canelones • Establishment No. 7, Pul (Pulsa S.A.), Cerro Largo • Establishment No. 12, Frigorífico Tacuarembó S.A., Tacuarembó • Establishment No. 58, Frigorífico Casa Blanca S.A., Paysandú • Establishment No. 104, Frigorífico Las Moras (Chiadel S.A.), Canelones • Establishment No. 310, Breeders & Packers Uruguay S.A. Durazno • Establishment No. 439, Frigorífico Matadero Pando (Ontilcor S.A.), Canelones
Beef and lamb slaughter and processing establishments		2	• Establishment No. 55, Inaler S.A., San José • Establishment No. 379, Frigorífico Las Piedras, Canelones
Beef and lamb processing and cold storage facility		1	• Establishment No. 158, Dinolar S.A., Canelones

FSIS performed the audit to verify Uruguay's food safety inspection 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.] Section 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR 301 to the end).

The audit standards applied during the review of Uruguay's meat food safety inspection system for raw and processed meat (i.e., beef and lamb) 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 August 1, 2016 to July 31, 2019, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 284,136,374 pounds of meat products from Uruguay. This included 17,527,008 pounds of TPCS beef; 742,233 pounds of ready-to-eat (RTE) salt-cured beef; 454 pounds of RTE beef fully-cooked without subsequent exposure to the environment; 20,759 pounds of RTE fully-cooked beef; 5,431,158 pounds of RTE dried beef; 9,506 pounds of RTE acidified/fermented beef (i.e., without cooking); 259,876,462 pounds of raw intact beef; and 528,794 pounds of raw intact lamb exported by Uruguay to the United States. Of these amounts, additional types of inspection were performed on 46,283,457 pounds of meat products, 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 441,277 pounds of raw beef products and 24 pounds of raw lamb products.

The primary reason for the rejections related to public health included product off condition (32,160 pounds of raw beef products and 24 pounds of raw lamb products). The remaining rejections (409,117 pounds) were not of public health significance and included shipping damage (37 pounds) and failure to meet APHIS animal health requirements (409,080 pounds), whereby FSIS identified the presence of excessive bruises, blood clots, abscesses 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.

This audit included a visit to seven of the establishments implicated in the above-referenced POE violations with a focus on establishments with two or more critical failures 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 POE violation.

The previous audit in 2018 identified the following findings:

Summary of Findings from the 2018 FSIS Audit of Uruguay
Component One: Government Oversight (e.g., Organization and Administration)
• At one of the 11 visited 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 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.
Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System
• HACCP recordkeeping requirements were not met at seven of the 11 visited 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 (CCP) for feces, ingesta, and milk (i.e., zero tolerance) was incomplete. • At the single visited 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 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.
Component 6: 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).

The FSIS auditors verified that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The FSIS final audit reports for Uruguay's food safety inspection system are available on the FSIS website at: https://www.fsis.usda.gov/foreign-audit-reports.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditor 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.

DGSG is Uruguay's CCA responsible for all activities related to the export of meat products to the United States. DGSG consists of three divisions: The Animal Industry Division (División Industria Animal – DIA), the Veterinary Laboratories Division (División Laboratorios Veterinarios – DILAVE), and the Animal Health Division (División Salud Animal – DSA). The FSIS auditors noted that the former Livestock Control Division (División de Contralor de Semovientes – DICOSE) was dissolved into the DSA to form 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 Nº. 18.996* 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 food safety inspection system is directed from the central headquarters in Montevideo. Slaughter and processing establishments are organized geographically into three areas, each with an assigned Area Supervisor, who is responsible for conducting periodic supervisory reviews. Official Veterinary Inspectors (OVI) and non-veterinary official inspectors (veterinary assistants) are assigned to each establishment.

The FSIS auditors verified that inspection personnel possessed the appropriate educational credentials, training, and experience to carry out their inspection tasks. All OVIs 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 and government-issued identity cards that all inspection personnel assigned to establishments certified to export to the United States are government employees paid directly by the national government.

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 DGSG requirements, all establishments certified as eligible to export to the United States are required to develop product recall procedures. The FSIS auditors noted that each visited 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 recently.

All activities related to meat products are under the authority of the OVI 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 technical standards are violated, the OVI 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 OVI from the establishment premises requires the immediate cessation of activity by the establishment. 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). The FSIS auditors verified the labels of products destined for export to the United States and found them compliant with FSIS' regulatory requirements. Through interviews and records review, the FSIS auditors also noted that inspection personnel ensure that raw materials originate only from establishments certified to export to the United States, as outlined in DGSG's Manuals of Export Procedures for Official Veterinary and Non-Veterinary Official Inspectors.

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 must 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 DGSG and FSIS import requirements reach the OVI in each certified establishment eligible to export meat products to the United States. This procedure includes documented acknowledgement from the OVI 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; 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* – COTE) issued by the OVI 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 OVI 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, *General requirements for the competence of testing and calibration laboratories*. 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 Uruguayan Accreditation Organization (Organismo Uruguayo de Acreditación - OUA), and subject to yearly audits by OUA.

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 as eligible to export to the United States, as part of their internal testing programs. Members of the UHL audit these private and contracted laboratories annually. FSIS reviewed the audit reports associated with the OUA accreditation as well as the activities performed by the UHL and found no concerns.

The FSIS auditors concluded that Uruguay's meat food safety inspection system continues to organize, administer, and enforce its meat food safety inspection system in a manner that meets the core requirements for this component.

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 in-plant inspection personnel are required to conduct ante-mortem inspection in accordance with DGSG's requirements. The FSIS auditors confirmed that an in-plant OVI conducts ante-mortem inspection on the day of slaughter by: (1) reviewing the incoming registration and identification documents including the movement permit and animal health certificate, and (2) observing all animals at rest and in motion from both sides in designated holding pens in order to determine whether they are fit for slaughter.

The FSIS auditors observed that each visited slaughter establishment provides a separate holding pen designated for observation and further examination of suspect animals. The FSIS auditors observed and verified that all animals have access to water in all holding pens, and feed is available if animals are held longer than 24 hours.

The FSIS auditors observed that OVIs conduct humane handling and slaughter (animal welfare) verification activities including evaluation of the stunning and sticking procedures in accordance with DGSG requirements. The Area Supervisors also verifies and documents the proper implementation of this requirement during their monthly supervisory reviews.

The FSIS auditors reviewed the implementation of post-mortem inspection examinations through review of inspection records, interviews, and observations of post-mortem inspection activities in the nine visited slaughter establishments. The FSIS auditors observed and verified that proper presentation, identification, examination, and disposition of each carcass and accompanying viscera are being implemented. The in-plant inspection personnel 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.

The FSIS auditors visited nine slaughter and processing establishments. The FSIS auditors correlated the number of in-plant inspection personnel conducting post-mortem inspection activities in each visited establishment with the line speed (i.e., maximum slaughter rate), and concluded that DGSG has provided a sufficient number of inspection personnel for the existing production volume and slaughter line speed, in a manner consistent with FSIS requirements. The FSIS auditors also reviewed the OVI's documentation to support inspection verification activities occurred continuously during slaughter operations and at least once during each processing shift at one visited RTE processing establishment.

The FSIS auditors verified that the appropriate APHIS requirements for the control of FMD were being implemented at all visited slaughter establishments. In-plant inspection personnel examine 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 control of condemned materials is accomplished through the application of Article 50 of *Decree Nº. 369/983*. The FSIS auditors verified that the relevant portions of this document were applied, including: (1) appropriate identification of inedible or condemned materials; (2) segregation in specially marked or otherwise secure containers; and (3) documentation of final disposal of these materials at rendering facilities.

The FSIS auditors accompanied Area Supervisors responsible for conducting the periodic (monthly) supervisory reviews and observed their functions. During these reviews, the Area Supervisors verify the proper implementation of requirements for ante-mortem inspection; humane handling and slaughter requirements; post-mortem inspection; *Salmonella,* generic *E. coli, E. coli* O157:H7, and non-O157 STEC sample collection; economic and labeling procedures; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities, including the CCP verification in the slaughter establishment. These reviews were recorded on a standard form that includes a follow-up section regarding the previous supervisory review findings. The FSIS auditors concluded that the Area Supervisors conducted these reviews in accordance with DGSG requirements.

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 standard operating procedures (sanitation SOP) to prevent direct product contamination or insanitary conditions.

The FSIS auditors confirmed that DGSG has adopted FSIS' sanitation regulatory requirements consistent with 9 CFR 416. DGSG requires certified establishments eligible to export to the United States to develop and implement sanitation SOPs. The FSIS auditors verified that each visited establishment maintains a written sanitation program to prevent direct product contamination or adulteration. Each establishment's sanitation SOPs included maintenance and improvement of sanitary conditions through ongoing evaluation of the establishment's hygienic practices. The FSIS auditors confirmed that 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, observations, and hands-on inspection verification.

The FSIS auditors assessed the adequacy of the pre-operational inspection verification by observing in-plant inspection personnel conducting pre-operational sanitation verification inspection in one of the visited establishments. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation procedures and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification inspection. The in-plant inspection personnel conduct pre-operational sanitation verification in accordance with DGSG's established procedures.

The FSIS auditors observed in-plant inspection personnel performing actual operational sanitation verification at all visited establishments. The FSIS auditors confirmed that the inspection verification activities included direct observation of the actual operations and review of the establishments' associated records. The FSIS auditors compared their overall observation of the sanitary conditions of the establishments with the in-plant inspection verification records. The FSIS auditors' records review included both the establishments' sanitation monitoring and corrective action records, in addition to the in-plant inspection records documenting inspection verification results, noncompliances, and monthly supervisory follow up reviews of establishments. The FSIS auditors' review of records generated by in-plant inspection personnel (including noncompliance and verification records) showed that in-plant inspection personnel have identified and documented sanitation findings in their daily verification or periodic supervisory review records.

The FSIS auditors noted that DGSG requires sanitary dressing of livestock throughout the slaughter process at visited slaughter establishments. As a result, slaughter establishments

have implemented monitoring procedures to prevent potential carcass contamination. These included sanitary practices to prevent: potential carcass contamination during hide removal, direct contact between carcasses during dressing procedures, and carcass contamination with gastrointestinal contents during evisceration, including tying the bung and esophagus. The visited establishments maintained sanitation records sufficient to document the implementation and monitoring of the sanitation SOPs and any corrective actions taken. Establishment personnel responsible for the implementation and monitoring of the sanitation SOPs correctly authenticated these records with initials or signatures and the date.

Isolated noncompliances related to the verification of sanitation requirements, including the observation of establishment construction and equipment, are noted in the individual establishment checklist provided in Appendix A of this report. The FSIS analysis and on-site verification activities indicate that DGSG requires operators of official establishments to develop, implement, and maintain sanitation programs. FSIS concludes that DGSG continues to meet the core requirements for this component.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (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.

The FSIS auditors confirmed that DGSG has adopted FSIS' HACCP regulatory requirements consistent with 9 CFR 417. DGSG requires certified establishments eligible to export to the United States to develop, implement, and maintain a HACCP program. The FSIS auditors verified that the establishments' HACCP programs include written hazard analysis, flow charts, and HACCP plans to identify, evaluate, and prevent or control food safety hazards in their production processes. The HACCP plans included activities designed to validate adequacy of controls, to conduct monitoring and verification procedures, and to document the results of monitoring and verification activities as well as implementation of corrective actions if needed. The in-plant inspection personnel's daily verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel performing monitoring, verification, corrective actions, and recordkeeping activities. The inspection HACCP verification activities also include direct observation or records review of CCPs for all production shifts, with the 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 visited establishments including the zero tolerance (for feces, ingesta, and milk contamination) CCP monitoring and verification records generated in the visited slaughter establishments. At each slaughter establishment, the FSIS auditors observed the establishment personnel conducting hands-on HACCP monitoring and verification activities for the zero tolerance CCP. The FSIS auditors also reviewed the establishment and the in-plant inspections' zero tolerance records. Both establishment (monitoring, verification, and corrective action) records and in-plant

inspection verification records documented a few deviations from the zero tolerance critical limits.

The FSIS auditors reviewed records and verified that the establishments took appropriate corrective actions in response to any deviations from their critical limits. Furthermore, the FSIS auditors confirmed that the physical location of the zero tolerance CCP verification for both the establishment personnel and in-plant inspection personnel is before the final carcass wash in all visited slaughter establishments.

The FSIS auditors confirmed that beef slaughter establishments certified as eligible to export to the United States had addressed contamination of beef carcasses with STECs as a hazard reasonably likely to occur within the context of their HACCP system. This included the use of a validated intervention organic acid spray and a zero tolerance CCP for the presence of feces, ingesta, and milk. In addition, each establishment had controls in place to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens. Furthermore, the visited establishments have implemented microbiological sampling and testing programs for carcasses (generic *E. coli*) and beef trimmings (STECs) to support their hazard analysis. The FSIS auditors' interviews and document reviews of both establishment microbiological sampling/testing programs and inspection verification procedures in relation to the implementation of establishment generic *E. coli* and STECs microbiological testing programs did not identify any concerns.

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 (i.e., 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 *E. coli* O157:H7 and non-O157 STEC in each lot of source material. The FSIS auditors verified that DGSG considers an RTE product to be adulterated when the product either comes in direct contact with equipment or FCS contaminated with *Lm.* The FSIS auditors' review of the establishments' and government's verification testing programs and results for *Salmonella* in finished products and *Lm* in products, on FCSs, and on environmental surfaces did not raise any concerns.

The FSIS auditors verified that all visited slaughter establishments have procedures in place for identification, removal, segregation, and disposal of specified risk materials (SRM) in accordance with DGSG requirements. The FSIS auditors reviewed the establishments' monitoring and inspection verification records concerning control and disposal of SRMs. In addition, the FSIS auditors observed the implementation of these requirements during the slaughter operation including the use of the dedicated equipment and safeguarding the disposed

materials. The FSIS auditors concluded that the program is being implemented properly in all visited establishments.

The FSIS auditors identified isolated noncompliances related to the inspection verification of HACCP record-keeping requirements. These findings are noted in the individual establishment checklists provided in Appendix A of this report. The FSIS analysis and on-site verification activities indicate that DGSG requires operators of official establishments to develop, implement, and maintain a HACCP system for each processing category. FSIS concludes that DGSG continues to meet the core requirements for this component.

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.

Prior to the on-site visit, FSIS' residue experts reviewed Uruguay's National Biological Residues Program (Programa Nacional de Residuos Biológicos – PNRB of 2019), associated methods of analysis, and additional SRT responses outlining the structure of Uruguay's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit conducted in 2018.

Uruguay's PNRB is based on European Commission (EC) Directive *No. 96/23/EC,* which prescribes measures to monitor certain substances and residues in live animals and animal products and describes provisions for the prohibition or authorization of substances and residues as well as their distribution and marketing. DGSG in collaboration with DILAVE, has the overall legal authority and responsibility to develop, implement, and coordinate a national residue program aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The FSIS auditors verified through interviews and records review that personnel from DGSG, through DILAVE, have developed and implemented the annual residue monitoring plan that prevents and controls all veterinary drugs, pesticides and environmental contaminants. The residue plan describes the number of samples, matrix (tissue) analyzed, analytical methods used, and action levels. In addition, DILAVE is responsible for preparing the sample schedules and determining the number of random samples to be collected for specific matrices within a defined period. Through records review at the visited establishments, the FSIS auditors verified that Uruguay tests urine, muscle, liver, kidney, fat, and thyroid. OVIs 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. In addition to the monthly plan, OVIs collect target residue samples of suspected animals and herds as specified in *PNRB 04.*

The FSIS auditors also verified through interviews and observations that OVIs were retaining carcasses and offals sampled for chemical residues until laboratory results were received, as required by *PR-PNRB 18* and *23*. If violative results are identified, the DIA is notified to destroy associated carcasses and offal. Carcasses suspected to be affected by drug residues are to be disposed of as per *Decree Nº. 369/983*, Section X. In the event of violative results, the DSA is to notify the source farm and perform an investigation to identify the root cause; then the farm will be included in the List of Observed Farms. Observed farms must pass two consecutive sample series (i.e., all livestock in a particular herd) prior to being removed from this list. Additionally, *PR-PNRB 12* through *15* require that, when an observed farm brings a herd of beef or sheep for slaughter, inspection personnel are to sample the entire herd.

A review of the sampling records maintained at the nine local inspection offices of the visited slaughter establishments indicated that the 2019 sampling program was being adhered to as scheduled. Monitoring residue samples are collected by the OVIs and shipped under inspection seal. Samples are shipped to the laboratory in accordance with protocols issued by DILAVE. DILAVE tracks the samples and electronically provides feedback to the in-plant OVI concerning the adequacy of sample shipping and the results of analysis. The Area Supervisors ensure that OVIs comply with PNRB procedures and sampling timeframes.

During the audit of ante-mortem inspection at the nine establishments with slaughter activities, the FSIS auditors observed that an OVI verifies that all lots of animals are accompanied by documentation which discloses the origin of the animals and includes a signed declaration to attest that owners have adhered to veterinary pharmaceutical withdrawal periods. DGSG has adopted a hold and test procedure within its PNRB to ensure that no sampled carcass is exported to the United States until acceptable results are obtained. Through inspection verification records and observation of "veterinary retained" cages at the establishments, the FSIS auditors verified that DGSG's test and hold policy was being implemented as designed.

The FSIS auditors 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). OUA last audited the DILAVE laboratory on September 13, 2019. Findings reported during accreditation audits were promptly addressed and documented as required by the ISO/IES 17025 standard.

The FSIS auditors verified through interviews and records review that 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.

The FSIS auditors also reviewed intra- and inter-laboratory proficiency testing associated with the methods and found the results to be acceptable. The FSIS auditors verified that the visited laboratory ensured traceability throughout sample receipt, analysis, and reporting per the laboratory Quality Control Manual, and that the laboratory performs a timely analysis of samples

and reports the number of analyzed samples and the results to DGSG in a timely manner. No concerns arose from these observations and reviews.

The FSIS auditors verified that Uruguay's food safety inspection system continues to maintain a chemical residue testing program, organized and administered by the national government. The CCA maintains 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 beef and lamb products destined for export to the United States. FSIS has not identified any POE violations related to this component since the last FSIS audit in 2018.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection 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. The FSIS auditors verified Uruguay's microbiological sampling and testing programs through direct observation, document review, and interviews of DGSG personnel at the local inspection offices within the visited slaughter and processing establishments as well as microbiological laboratory personnel.

Uruguay adopted FSIS' regulatory requirements for *E. coli* sampling and testing programs that are stipulated in 9 CFR 310.25 (a). *Resolutions of December 20, 1996* and *December 20, 2002* set the requirements for sampling and testing of bovine and ovine carcasses for indicators of fecal contamination. Furthermore, Sections 4.1 and 4.5 of the *Manual for Generic E. coli Testing Program* requires that certified establishments develop written sampling procedures for generic *E. coli*, identify the employees responsible for sample collection, identify the locations of sampling (three-site sponge sample from bovine and ovine carcasses from the flank, brisket, and rump), and identify how randomness is achieved as well as measures to ensure sample integrity. While the testing is conducted by the establishments, OVIs are responsible for verifying that the standards are being met.

The FSIS auditors confirmed that government inspection personnel conduct verification activities that verify written generic *E. coli* testing programs meet requirements including the location of sampling, randomness of sampling, and sample integrity. The FSIS auditors noted that inspection personnel were verifying establishment sampling collection methodology for indicator organisms through direct observation of establishment sampling and its secure submission of each sample to the microbiological laboratory for analysis. Government inspection personnel use the test results to verify establishment slaughter dressing controls for fecal contamination. Furthermore, government inspection personnel verify that each establishment documents and correctly evaluates test results and takes appropriate corrective actions if the upper control limits are exceeded.

At the visited establishments, the FSIS auditors confirmed through records review and interviews that the OVIs were verifying that establishments collect generic *E. coli* samples at the required frequency of one sample per 300 carcasses and recording the test results onto a process control chart showing at least the 13 most recent results (moving windows) in accordance with FSIS requirements. No concerns were identified.

Uruguay's *Program of Pathogen Reduction/Analysis for Salmonella in Fresh Meat* dated May 26, 2010 is based on *DIA Resolution of September 1, 2011*. 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). Sampling sets are established annually, and the start dates of sampling are communicated to the OVI at the certified establishment. After that, the OVI notifies the establishment of the start date to ensures the samples are collected and sent to the laboratory.

The FSIS auditors verified through observations, interviews, and records review that OVIs were collecting one sample on each production day until the number of samples designated for each set (82 samples for steers and heifers and 58 samples for cows and bulls) has been reached. The FSIS auditors also verified that OVIs were receiving the results of the *Salmonella* samples electronically and by mail.

An establishment that fails its first *Salmonella* set must take immediate corrective action, after which a second set of samples is collected. 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. If an establishment fails three consecutive sample sets, it is removed from the list of establishments eligible to export to the United States.

DILAVE uses the FSIS Microbiology Laboratory Guidebook (MLG) method for official analysis of *Salmonella* in beef, but modifies the method by using a different agar, consistent with an FSIS equivalence determination issued previously. There have been no *Salmonella* set failures in recent history.

DGSG has identified *E. coli* O157:H7 and six additional non-O157 STECs 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 official government sampling program specifically designates DILAVE as the only laboratory that performs confirmation analyses of official samples. DILAVE uses the previous FSIS MLG methods for official analysis of *E. coli* O157:H7 (MLG 5.09) and non-O157 STEC (MLG 5B.05) in raw beef, which is equivalent.

DGSG's *Procedure for the Monitoring Program of Listeria monocytogenes in the Environment in Establishments which are Authorized to Export to the United States* requires establishments certified for export to the United States to control *Lm* in RTE meat products by adopting one of the three alternatives specified in 9 CFR 430.4, regardless of post-lethality status. Products contaminated with or that have passed over surfaces contaminated with *Lm* are adulterated and must be destroyed or reprocessed. The FSIS auditors verified that through interviews and records review that DGSG has implemented official ongoing verification sampling to test product, FCSs, 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 DILAVE visit, 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 OVI and the DGSG headquarters. DGSG receives laboratory results directly from DILAVE. The FSIS review of microbiological testing procedures indicated that the applicable MLG methods were implemented as documented.

The FSIS auditors verified the implementation of the DGSG proposed corrective actions in response to 2018 audit findings consisting of: (a) the government laboratory not maintaining a written official procedure for the handling of inconclusive STEC sample results, and (b) not documenting critical parameters associated with its microbiological testing methods (e.g., documentation of times associated with incubation steps). The FSIS auditors verified that DILAVE continues to implement its established procedures should an STEC sample result be inconclusive. The procedure considers as positive all samples with isolated colonies positive for O157 by polymerase chain reaction and biochemistry but negative for STECs and undetermined for *E. coli* O157:H7. Additionally, the FSIS auditors verified through records review that DILAVE has revised its incubation records in order to include the incubation time and iodine addition to the tetrathionate broth. The auditors concluded that the corrective actions were implemented as communicated to FSIS.

The FSIS auditors verified that Uruguay's food safety inspection system 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 and lamb products exported to the United States, and ensures that those beef and lamb products are unadulterated, safe, and wholesome in accordance with FSIS requirements. The CCA's meat food safety inspection system continues to meet the FSIS requirements for this component. There have not been any POE violations related to microbiological testing conducted by FSIS at POE since the last FSIS audit in 2018.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on December 13, 2019, in Montevideo, Uruguay, with DGSG. At this meeting, the FSIS auditors presented the preliminary isolated findings from the audit.

The FSIS auditors concluded that Uruguay's food safety inspection system governing raw and processed meat (i.e., beef and lamb) products is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has implemented sanitary operating procedures and a HACCP system to ensure controls of the food safety inspection system governing raw and processed meat products. In addition, the CCA has implemented microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety inspection system. An analysis of the findings within each component did not identify any systemic findings representing an immediate threat to public health.

Although there were no systemic findings, during the audit exit meeting, the CCA committed to address the preliminary isolated findings in the checklists in Appendix A. FSIS will evaluate the adequacy of the CCA'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
Frigorifico Carrasco S.A. Camino Carrasco No. 5 Canelones	12/09/2019	3	Uruguay
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals).

60. Observation of the Establishment

22: The establishment's HACCP verification record for calibration of process-monitoring instruments did not include the time of the verification activities.

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/09/2019

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
Pul (Pulsa S.A.) Ruta 8, km. 389 Cerro Largo	12/05/2019	7	Uruguay
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals).

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 Branch (IAB)	12/05/2019

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	12/04/2019	12	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals); RTE acidified / fermented beef (without cooking) (other - not sliced); RTE dried beef (jerky, other - not sliced, and other - sliced); RTE fully-cooked beef (nuggets, other fully cooked not sliced product, and other fully cooked sliced product); RTE beef fully-cooked without subsequent exposure to the environment (other fully cooked not sliced product); and RTE salt-cured beef (not-sliced, and sliced).

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 Branch (IAB)	11/08/2019

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
Inaler S.A. Paraje Banado San Jose	12/11/2019	55	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef/Lamb slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, primals and subprimals)

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 Branch (IAB)	12/11/2019

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 Casa Blanca S.A. Localidad Casa Blanca Paysandu	12/05/2019	58	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (beef manufacturing trimmings, cuts, primals and subprimals).

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 Branch (IAB)	12/05/2019

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 Moras (Chiadel S.A.) Camino Aldabalde s/n Canelones	12/10/2019	104	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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.	X
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.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals).

60. Observation of the Establishment

8. The FSIS auditor observed black grease smudges on conveyor belt carrying exposed products. Seventy kilos of products were condemned and conveyer belt was cleaned and sanitized. Products were not destined for export to the United States.

19. The frequency of record review was not listed as part of the ongoing verification activities for CCP1 and CCP2.

39. A) One conveyer belt carrying packaged products was observed with large cracks on it.
B) Five overhead cooling units had rusty fan guards and motors
C) Numerous cracks were observed on the floor near the freezers

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/10/2019

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
Dinolar S.A. Ruta 8, km. 28.300 Canelones	12/04/2019	158	Uruguay
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	O
Part E - Other Requirements	
36. Export	X
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. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Beef/Lamb processing and cold storage
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals).

60. Observation of the Establishment

36. The FSIS auditor found that in one of the freezers, United States-eligible beef products were commingled with (stacked on the same pallets as) non-United States-eligible beef products.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/04/2019

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	12/10/2019	310	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals).

60. Observation of the Establishment

46:
A) There was not adequate space between some of the eviscerated/split beef carcasses on the main slaughter line before final rail inspection, therefore, beef carcasses with potential pathology or dressing defects could touch each other.
B) The carcass splitting saw's wiring system was occasionally touching the back side of the passing carcasses on the main slaughter line. This may create insanitary condition or a potential for cross-contamination between carcasses and equipment.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/10/2019

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	12/03/2019	379	Uruguay
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	X	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.	X	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.	X	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. Periodic Supervisory Reviews	
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.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef/Veal/Lamb slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, primals and subprimals); Raw intact lamb (cuts, carcass halves and quarters)

60. Observation of the Establishment

7. The FSIS auditor found that the SSOP program was not signed by an individual with overall authority on-site at the establishment.

13. The FSIS auditor found that the establishment has not documented pre-operational and operational sanitation activities on November 13, 14, 15, and 16, 2019.

19. The FSIS auditor found that:
A) The frequency of thermometer calibration was not listed as part of the ongoing verification activities in the HACCP plan.
B) The establishment did not conduct record review as part of the ongoing verification activities but rather in the event of a deviation from a critical limit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/03/2019

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	12/11/2019	439	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[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	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals).

60. Observation of the Establishment

38: The FSIS auditor observed a deteriorated seal under an exterior shipping door that did not provide a tight seal when the door was closed. This could create insanitary condition and facilitate the entrance of vermin to the production areas.

39: The FSIS auditor observed several gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products in the production areas. No direct product contamination observed by the FSIS auditor at this time. However, this condition may create an insanitary condition.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	12/11/2019

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

Ministerio
de Ganadería,
Agricultura y Pesca

Dirección General de Servicios Ganaderos
División Industria Animal

March 17, 2020

Dr. MICHELLE CATLIN, PHD
INTERNATIONAL COORDINATION EXECUTIVE
OFFICE OF INTERNATIONAL COORDINATION
USDA/FSIS
WASHINGTON, DC

Dear Dr. Catlin,

I am writing to you in reference to your note dated on February 12, 2020, enclosing a copy of the draft final report of the verification audit conducted in Uruguay from December 2 – 13, 2019.

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

In addition, we are sending attached in successive e-mails, the files including the reports referring to the corrective actions taken by the Uruguayan establishments and verified by the services of Official Veterinary Inspection (IVO).

Any additional information that you deem necessary, do not hesitate to request it.

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

DR. GUSTAVO ROSSI
DIRECTOR