United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
20250

8/16/2024

Dr. Pablo Nadal, Director
Animal Industry Division
Ministerio de Ganadería, Agricultura y Pesca (MGAP)
Dirección General De Servicios Ganaderos
Montevideo, Uruguay

Dear Dr. Nadal,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Uruguay's inspection system March 4–20, 2024. 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.

Sincerely,

BRYCE CARSON
Digitally signed by BRYCE CARSON
Date: 2024.08.16 13:21:21 -06'00'

On behalf of:
Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

URUGUAY

MARCH 4–20, 2024

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

RAW AND PROCESSED BEEF AND RAW LAMB AND MUTTON PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

August 13, 2024

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Uruguay conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) March 4–20, 2024. The purpose of the audit was to verify whether Uruguay's food safety inspection system governing raw and processed beef, and raw lamb and mutton products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Uruguay currently exports thermally processed, commercially sterile beef; ready-to-eat beef; 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.

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

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- The government laboratory does not routinely include all positive and negative controls required by the analytical method used for detecting *Listeria monocytogenes*.

GOVERNMENT CHEMICAL RESIDUES TESTING PROGRAMS

- The Central Competent Authority, the General Directorate of Livestock Services (Dirección General de Servicios Ganaderos (DGSG)), does not apply a zero-tolerance policy when evaluating results of samples tested for pesticides or veterinary drugs for products intended for export to the United States when there is no established tolerance for the compound in the United States. In the United States, if there is no tolerance set for a specific pesticide or veterinary drug residue, FSIS considers the product adulterated if any level is detected in accordance with 80 Federal Register 81272, National Residue Program: Monitoring Chemical Hazards

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Uruguay's food safety inspection system March 4–20, 2024. The audit began with an entrance meeting March 4, 2024, 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)). Representatives from DGSG accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference March 20, 2024.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing raw and processed beef, and raw lamb and mutton products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Uruguay is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw - Intact	Raw Intact Beef	Beef - All Products Eligible except Cheek Meat, Head Meat, Heart Meat, and Weasand Meat
Raw - Intact	Raw Intact Meat-Other (Sheep, Goat)	Lamb and Mutton - All Products Eligible
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	Beef - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Acidified/Fermented Meat (without cooking)	Beef - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Beef - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Beef - All Products Eligible
Heat Treated - Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Beef - All Products Eligible
Heat Treated - Shelf Stable	RTE Acidified / Fermented Meat (without cooking)	Beef - All Products Eligible
Heat Treated - Shelf Stable	RTE Dried Meat	Beef - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Beef - All Products Eligible

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Process Category	Product Category	Eligible Products[1]
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Beef - All Products Eligible
Products with Secondary Inhibitors - Not Shelf Stable	RTE Salt-Cured Meat	Beef - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) subjects beef imported from Uruguay to bovine spongiform encephalopathy requirements specified in Title 9 of the U.S. Code of Federal Regulations (9 CFR) 94.18 or 9 CFR 94.19 and to foot-and-mouth disease (FMD) requirements specified in 9 CFR 94.29 or 9 CFR 94.4.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Uruguay's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify whether Uruguay's food safety inspection system governing raw and processed beef, and raw lamb and mutton products 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 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 3-year period, in addition to information obtained directly from DGSG 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 DGSG headquarters, and 11 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 documented in the country's SRT responses and supporting documentation.

A sample of 11 establishments was selected from a total of 31 establishments certified to export to the United States. This included seven beef slaughter and processing establishments; two lamb and beef slaughter and processing establishments; and two beef processing establishments. The products these establishments produce and export to the United States

include RTE salt-cured beef; RTE fully-cooked beef; RTE dried beef; TPCS beef: raw intact beef; and raw intact lamb.

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 DGSG's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

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

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Dirección General de Servicios Ganaderos (DGSG), Montevideo
Laboratories		2	• División Laboratorios Veterinarios (DILAVE) National Chemical Residue Control Laboratory, Montevideo (Government Laboratory) • DILAVE National Microbiology Laboratory, Montevideo (Government Laboratory)
Beef slaughter and processing establishments		7	• Establishment No. 2, Establecimientos Colonia S.A., Colonia • Establishment No. 7, Frigorífico Pul (Pulsa S.A.), Cerro Largo • Establishment No. 12, Frigorífico Tacuarembó S.A., Tacuarembó • Establishment No. 55, Inaler S.A., San José • Establishment No. 58, Frigorífico Casa Blanca S.A., Casablanca • Establishment No. 394, Frigorífico La Caballada (Cledinor S.A.), Salto • Establishment No. 439, Frigorífico Matadero Pando (Ontilcor S.A.), Canelones
Lamb and beef slaughter and processing establishments		2	• Establishment No. 344, Frigorífico San Jacinto (Nirea S.A.), Canelones • Establishment No. 379, Frigorífico Las Piedras S.A., Canelones
Beef processing establishments		2	• Establishment No. 30, Establecimientos Colonia S.A., Rio Negro • Establishment No. 327, Establecimientos Juan Sarubbi S.A., Montevideo

FSIS performed the audit to verify that the food safety inspection system meets 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 Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR parts 301 to the end).

The audit standards applied during the review of Uruguay's inspection system for raw and processed beef, and raw lamb and mutton products 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 November 1, 2020 to October 31, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 327,766,364 pounds of beef and lamb products from Uruguay. This included 18,237,073 pounds of TPCS beef; 807,779 pounds of RTE salt-cured beef; 68,405 pounds of RTE fully-cooked beef; 5,807,396 pounds of RTE dried beef; 468 pounds of raw intact beef - other; 300,010,812 pounds of raw intact beef; and 2,834,431 pounds of raw intact lamb exported by Uruguay to the United States. Of these amounts, additional types of inspection were performed on 27,747,970 pounds of beef and lamb products (1,405,368 pounds of TPCS beef; 74,891 pounds of RTE salt-cured beef; 68,405 pounds of RTE fully-cooked beef; 730,957 pounds of RTE dried beef; 25,253,819 pounds of raw intact beef; and 214,530 pounds of raw intact lamb).

These additional types of inspection included physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (i.e., *Salmonella* and Shiga toxin-producing *Escherichia coli* (STEC) serogroups O26, O45, O103, O111, O121, O145, and O157 in beef; and *Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products). As a result of this additional testing, 88,698 pounds of beef products were rejected for issues related to public health, including off-condition product and presence of ingesta. An additional 1,540,455 pounds of beef products, and 1,368 pounds of lamb products were refused for other issues not related to public health, including shipping damage, labeling, or other miscellaneous issues.

The previous FSIS audit in 2022 identified the following finding:

Summary of Findings from the 2022 FSIS Remote Audit of Uruguay
Component 1: Government Oversight (e.g., Organization and Administration)
• The Central Competent Authority (CCA) had not provided written instructions to ensure that products with violative chemical residue results that are retested at the establishment's request are not certified for export to the United States.

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

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

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

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

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 Veterinary Laboratories Division (División Laboratorios Veterinarios (DILAVE)), the Animal Health Division (División Salud Animal), and the Animal Industry Division (División Industria Animal (DIA)). DIA includes the following five field departments:

1. Department of Slaughter Establishments (DEF) – responsible for verifying compliance of official Uruguayan guidelines, resolutions, and instructions in establishments certified to export to the United States.
2. Department of Processing Establishments – responsible for establishments processing edible and inedible meat products and byproducts.
3. Department of International Trade Control – responsible for issuing export certificates and oversight of cold-storage facilities.
4. Technical Department – responsible for approving slaughter and processing establishments (domestic and export markets) and coordination of the microbiology and chemical residue sampling programs.
5. Technology Department – responsible for meat grading.

The slaughter and processing establishments under DIA are organized geographically into three regions, each with an assigned regional supervisor (RS) that is responsible for conducting periodic supervisory reviews. In-plant government inspection personnel include both official veterinary inspectors (OVI) and non-veterinary official inspectors (veterinary assistants).

The authority to enforce inspection laws is granted in Uruguayan Decree No. 369/983, Decree No. 238/00, and Resolution of August 12, 2014. 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 confirmed that each visited establishment continues to maintain these procedures, which include records sufficient to conduct traceback activities if adulterated product were exported to the United States. The FSIS auditors also reviewed establishment records related to mock recalls conducted

in accordance with these plans, and the records indicated that establishment procedures were effective. No actual product recalls have occurred at any of the establishments certified to export to the United States since the previous FSIS audit conducted in 2022.

All activities related to inspection of meat products are under the authority of the OVI and are subject to technical standards outlined in Decree No. 369/983. In addition, Decree No. 369/983 contains requirements for approval, extension, and modification of slaughter and processing establishments certified as eligible to export to the United States. 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. The FSIS auditors reviewed records and noted that no elevated enforcement actions had been taken at any establishments certified to export to the United States.

The FSIS auditors verified that DGSG implements its requirements for government inspection personnel to possess the appropriate educational credentials, training, and experience to carry out their inspection tasks. All OVIs must have a doctorate in veterinary medicine or equivalent degree, and the non-veterinary official inspectors must have specialized experience or education that allow 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.

During the audit of DGSG headquarters, the FSIS auditors confirmed that inspectors are required to successfully complete a 15-month training program. These training records were further verified during visits to establishments certified to export to the United States. 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 inspection personnel receive on-the-job training when they are first assigned to establishments certified to export to the United States. Within Circular No. 2/2015, 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 verified that DGSG also provides ongoing training to inspectors at least once a year.

The FSIS auditors reviewed export certificates and accompanying documents associated with shipments of product previously exported to the United States, noting that establishments routinely provide HACCP pre-shipment reviews and results of any product testing conducted as part of HACCP verification procedures to certifying inspection personnel for review. Export certificates issued by the OVI for a given country are species and commodity specific. The FSIS auditors verified that government inspection officials maintained accountable item inventory of all issued certificates in a secure environment. The FSIS auditors' review of records indicated that government inspection personnel routinely confirm acceptable test results of official

microbiological and chemical residue sampling prior to certifying product for export to the United States. Regarding chemical residue testing specifically, Resolution No. 11A of January 19, 2010, requires that maximum residue limits (MRLs) of the United States are to be met when products are certified for export to the United States.

The FSIS auditors confirmed that DGSG ensures that product eligible for export to the United States is not commingled with product intended for the Uruguayan domestic or other foreign markets or with other products that are not eligible for export to the United States. Additionally, the FSIS auditors confirmed that, in accordance with its Manual of Export Procedures for Official Veterinary and Non-Veterinary Official Inspectors, DGSG ensures that source materials used in processing operations originate only from establishments certified to export to the United States.

The FSIS auditors verified that laboratories conducting official analyses of meat exported to the United States implement laboratory standards consistent with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025. DILAVE's chemical residue and microbiological laboratories are the primary official laboratories conducting testing for products intended for export to the United States. These laboratories are accredited and audited yearly by the Uruguayan Accreditation Organization (Organismo Uruguayo de Acreditación (OUA)). DILAVE also has a Laboratory Authorization Unit (Unidad de Habilitación de Laboratorios (UHL)) which authorizes third-party (private) laboratories to perform certain microbiological analyses, including all third-party laboratories used by establishments certified as eligible to export to the United States as part of their internal testing programs. Members of the UHL audit these third-party 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 interviewed personnel at DILAVE regarding implementation of analytical methods for official DGSG verification sampling programs. This laboratory conducts analytical testing, including for *Salmonella*, *Lm*, and STEC, for official verification of products intended for export to the United States. These interviews included review of records for each phase of the analytical testing process, including sample receipt, implementation of test methods, and reporting of results to DGSG.

The FSIS auditors identified the following finding related to the quality control procedures associated with the analysis for *Lm* at DILAVE:

- The government laboratory does not routinely include all positive and negative controls required by the analytical method used for detecting *Listeria monocytogenes*.

With the exception of this finding, the FSIS auditors concluded that Uruguay 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 equivalence component 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; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once-per-shift inspection during processing operations; and periodic supervisory visits to official establishments.

DGSG inspection personnel verify that livestock are humanely treated and slaughtered at certified meat establishments in accordance with Resolution of November 23, 1983, Resolution of June 30, 2004, Resolution of February 1, 2005, and Circular No. 2/2008. DGSG has issued the Procedure for Verification of Humane Handling and Slaughter, which instructs government inspection personnel to conduct daily verification of the establishment's slaughter stunning procedures. Additionally, government inspection personnel are to perform a documented audit every 6 months to ensure that facilities and premises are maintained in a manner to prevent inhumane treatment of animals. The FSIS auditors, through record reviews, observations, and interviews of government inspection personnel, confirmed that humane handling and slaughter of livestock are conducted in accordance with these procedures.

Decree No. 369/983 describes the ante-mortem inspection procedures for livestock prior to slaughter and specifies the inspection tasks that are performed by government inspection personnel. Decree No. 369/983 requires that all livestock receive ante-mortem inspection when the herd arrives at the establishment. The Manual of Procedures of the Functions of the Veterinary Inspection Assistant Functions in Authorized Slaughter and Cycle II Establishments and the Manual of Procedures of the Functions of the Head of Service and Veterinary Inspectors in Authorized Slaughter and Cycle II Establishments describe the ante-mortem and post-mortem inspection procedures conducted by the assistants and veterinarians, respectively. The FSIS auditors verified that DGSG conducts ante-mortem inspection on the day of slaughter in accordance with these requirements by reviewing related ante-mortem records, including incoming registration and identification documents, movement permits, animal health certificates, and final disposition records.

Decree No. 369/983 describes the post-mortem inspection procedures for livestock. Decree No. 369/983 prescribes the facility requirements that establishments certified to export to the United States are to provide for inspection personnel to perform post-mortem inspection. The FSIS auditors verified that each slaughter establishment is staffed with enough on-line government inspectors and that post-mortem inspection of every carcass and its parts is conducted according to the stated requirements. The FSIS auditors' activities included review of supervisory records and observations to verify the implementation of inspection requirements as they relate to proper presentation; identification; examination of heads, viscera, and carcasses; and disposition of affected carcasses and parts.

The FSIS auditors verified that the appropriate APHIS requirements for the control of FMD were being implemented at all audited slaughter establishments. In addition, the FSIS auditors confirmed that all meat products certified for export to the United States are derived from carcasses meeting APHIS requirements for pH and carcass maturation. Carcasses that do not meet APHIS maturation requirements are clearly identified and segregated from the products intended for export to the United States.

Requirements to ensure control over condemned animals and inedible material, including specified risk materials, are described in Decree No. 369/983. Furthermore, the Manual of Procedures of the Functions of the Veterinary Inspection Assistant in Authorized Slaughter and Cycle II Establishments and the Manual of Procedures of the Functions of the Head of Service and Veterinary Inspectors in Authorized Slaughter and Cycle II Establishments describe the verification for proper disposition of these materials. The FSIS auditors observed and reviewed records to verify these requirements were properly implemented, including appropriate identification, segregation in specially marked or otherwise secure containers, and proper documentation of final disposal of the materials.

Decree No. 369/983 sets the general labeling requirements for meat products, byproducts, and derivatives of meat products. Decree No. 369/983 requires the establishments to obtain approval for labels or stickers from DIA before the products enter commerce. Circular No. 4/2003 sets the labeling requirements for products that are exported to the United States, including information that must be printed on the packaging and on the label, such as the generic name of the product, special handling statements (e.g., keep refrigerated or keep frozen), production date, net weight, and the establishment and registry number.

The FSIS auditors verified that DGSG routinely ensures that products exported to the United States are correctly labeled and packaged through review of DGSG's government records related to label submission and approval; allergen control; declaration of retained water; species testing; calibration of production scales; and standards of identity (e.g., moisture/protein ratios for beef jerky products). No concerns were identified.

The Manual of Procedures for Supervision Functions in Authorized Slaughter and Cycle II Establishments describes the periodic supervisory visits conducted at establishments certified to export to the United States. DGSG requires periodic supervisory visits by the RS to each establishment no less than once a month. As part of the monthly supervisory visit to the establishments, the RS also evaluates the performance of government inspection personnel. This evaluation consists of onsite observations to assess government inspection personnel's knowledge of job requirements and their ability to execute inspection controls. All findings are documented on the form titled DEF Formulario Auditoría de Supervisión. The FSIS auditors confirmed that these reviews were performed and documented 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. The FSIS auditors identified an isolated deficiency related to this component, which is described in the individual establishment checklists provided in Appendix A of this report.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation The food safety inspection system is to require that each official establishment develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

The FSIS auditors confirmed that DGSG has adopted sanitation regulatory requirements consistent with FSIS requirements in 9 CFR part 416. Decree No. 369/983 describes the requirements for sanitation and hygienic practices for slaughter establishments, processing establishments, and cold storage facilities. Resolution of February 1, 2005, sets the requirements for establishments to have a manual of good manufacturing practices that includes a written procedure for processing activities. Resolution of December 20, 1996, sets the requirement for certified establishments to develop, implement and maintain Sanitation SOPs. The Manual for the Control and Implementation of Sanitation SOPs provides guidance to government inspection personnel on how to classify findings of noncompliance.

The FSIS auditors confirmed through record reviews, observations, and interviews that government inspection personnel are verifying pre-operational and operational compliance with DGSG's requirements for Sanitation SOPs, including daily verification records (i.e., Chequeo de Mantenimiento Informe Higiénico Sanitario) generated by government inspection personnel assigned to the certified establishment and monthly records associated with the supervisory visits performed by the RS (i.e., DEF Formulario Auditoría Supervisión).

The FSIS auditors also observed in-plant government inspection personnel conducting pre-operational sanitation verification inspection. The in-plant government inspection personnel's hands-on verification procedures to determine that the facility was ready for operations started after the establishment had conducted its pre-operational sanitation procedures. No concerns were identified.

The FSIS auditors confirmed that government inspection personnel routinely verify that the establishment implements sanitary dressing procedures throughout the slaughter process in accordance with requirements in DGSG's Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Post-Mortem Inspection. Additional verification of these procedures occurs during monthly supervisory reviews.

The FSIS auditors' verification activities indicate that DGSG requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs, including requirements for SPS, Sanitation SOP, and sanitary dressing procedures. The FSIS auditors concludes that DGSG continues to meet the core requirements for this component. The FSIS auditors observed isolated deficiencies related to the inspection verification of sanitation requirements, which are described in the individual establishment checklists provided in Appendix A of this report.

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

The fourth equivalence component 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 HACCP requirements consistent with FSIS requirements in 9 CFR part 417. Resolution of November 19, 1997, and Circular No. 2/1998 require establishments certified to export to the United States to develop, implement, and maintain a HACCP plan. Additionally, Resolution No. 104 of July 8, 2013, indicates that establishments certified to export to the United States are required to implement HACCP or equivalent systems. Government inspection personnel follow the Manual of Procedures for HACCP Plan Verification and the Manual of Procedures of the Functions of the Head of Service and Veterinary Inspectors in Authorized Slaughter and Cycle II Establishments to verify that establishments certified to export to the United States are implementing their HACCP system and to verify the effectiveness of the HACCP system in controlling hazards.

The FSIS auditors assessed the implementation and effectiveness of DGSG verification procedures in ensuring that HACCP requirements are effectively and fully implemented in each certified establishment. DGSG requires that bovine slaughter establishments certified to export to the United States consider STEC contamination (including serogroups O157, O26, O45, O103, O111, O121, and O145) of beef carcasses as a hazard reasonably likely to occur in their HACCP system. The FSIS auditors verified that audited establishments had implemented controls for STEC and for the prevention of contamination with fecal material, ingesta, and milk; and to ensure that carcasses are chilled in a manner sufficient to prevent the outgrowth of microbiological pathogens.

For the establishments producing RTE products, the FSIS auditors reviewed the government verification activities with a special emphasis on HACCP records for lethality of *Salmonella* and other relevant pathogens. Establishments producing cooked beef products intended for export to the United States maintained supporting documentation consistent with the FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) and the FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) for lethality and stabilization, respectively.

The FSIS auditors confirmed through the review of inspection records that government inspection personnel conduct ongoing reviews of the establishments' HACCP plans and verify their effectiveness in ensuring wholesome and unadulterated meat products are produced for export to the United States. This included both daily verification records generated by government inspection personnel assigned to the certified establishment (documented on the HACCP Plan Verification Form) and monthly records associated with the supervisory visits performed by the RS (documented on the Formulario Auditoría Supervisión). The FSIS auditors reviewed a sample of noncompliance reports documented by government inspection personnel in all audited establishments, and no concerns were identified.

The FSIS auditor's verification activities indicate that DGSG requires establishments certified to export to the United States to implement DGSG's requirements to develop, implement, and maintain HACCP programs for each processing category. The FSIS auditors identified isolated establishment deficiencies related to basic HACCP requirements, which are described in the individual establishment checklist provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Uruguay's National Biological Residues Program (Programa Nacional de Residuos Biológicos - PNRB) is based on Regulation (EU) 2017/625, which prescribes measures to monitor certain substances and residues in live animals and animal products. The PNRB also 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 chemical residue sampling program aimed at preventing and controlling the presence of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The FSIS auditors verified through interviews and record reviews that DGSG has developed and implemented a chemical residue sampling program for veterinary drugs, pesticides, and environmental contaminants. The PNRB describes the number of samples to be collected, the sample matrix (tissue) analyzed, analytical methods used, and action levels for evaluating the results. 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. 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 procedures. Products tested under the PNRB and intended for export to the United States are held pending receipt of satisfactory results from testing conducted as part of the PNRB. DGSG annually designs a sampling program that includes action levels for all chemical compounds included for testing. These action levels are established by considering international standards (e.g., Codex Alimentarius) and tolerances established by third countries and applying the most restrictive tolerance level for all countries to each compound tested. However, the following finding was identified:

- DGSG does not apply a zero-tolerance policy when evaluating results of samples tested for pesticides or veterinary drugs for products intended for export to the United States when there is no established tolerance for the compound in the United States. In the United States, if there is no tolerance set for a specific pesticide or veterinary drug residue, FSIS considers the product adulterated if any level is detected in accordance with 80 Federal Register 81272, National Residue Program: Monitoring Chemical Hazards.

A review of the sampling records maintained at local inspection offices of the audited slaughter establishments indicated that the 2024 PNRB was being adhered to as scheduled. The FSIS auditors verified through record reviews 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 from suppliers to attest that they have adhered to veterinary pharmaceutical withdrawal periods.

The FSIS auditors interviewed government laboratory personnel from DILAVE to verify its ability to provide adequate technical support to the inspection system. These interviews included a review of records documenting sample receipt, implementation of testing methods, adherence to MRLs, and reporting of results. No concerns arose as a result of interviews held with DILAVE personnel.

With the exception of the identified finding, the FSIS auditors' activities indicate that DGSG continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of veterinary drugs and chemical contaminants in beef, lamb, and mutton products intended for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component 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 beef, lamb, and mutton products prepared for export to the United States are safe and wholesome. This component also addresses requirements for TPCS beef products.

The FSIS auditors verified that DGSG requires that all slaughter establishments certified to export meat products to the United States collect and analyze carcass samples for indicator organisms to verify process control. Resolution of December 20, 1996, sets the requirements for sampling and testing of carcasses for indicators of fecal contamination. The Manual for Generic *E. coli* Testing Program (Bovine) and the Manual of the Detection Program of *E. coli* (Ovine) set the requirements for establishments certified to export to the United States to develop written sampling procedures for generic *E. coli*. The sampling and testing is performed by the establishment and is verified by government inspection personnel to ensure process control is maintained.

DGSG continues to implement *Salmonella* performance standards for beef carcasses consistent with FSIS requirements in 9 CFR 310.25(b). The Resolution of April 11, 2018, and Pathogen Reduction Program/Analysis for *Salmonella* in Fresh Beef set the requirements for sampling and testing of beef carcasses for *Salmonella*. These documents describe the sampling procedures and instructions for government inspection personnel regarding sampling frequency, collection sites on beef carcasses, randomized selection, sampling techniques, submission of samples to the designated laboratory, laboratory testing methods, interpretation of test results, and enforcement

strategies. The FSIS auditors reviewed government sampling results from nine slaughter establishments and concluded that DGSG is verifying that establishment indicator organism and official *Salmonella* carcass testing programs are implemented as documented.

DGSG's requirements for verifying control of STEC is covered in two primary documents: 1) Procedure for Verification of Compliance with the Control Program for the Presence of Shiga Toxin-Producing *E. coli* in Beef (non-O157 STEC); and 2) Control Program for *Escherichia coli* O157:H7 in Beef. Within these documents, DGSG outlines its official government verification sampling program for STEC at beef slaughter and processing facilities eligible to export raw beef to the United States. These documents further specify that all beef products contaminated with STEC are ineligible for export to the United States. In accordance with the requirements outlined therein, the FSIS auditors verified that government inspectors conduct STEC verification sampling of beef products at prescribed frequencies. Samples are randomly selected and collected from every shift the establishment operates (regardless of whether the product is intended for export to the United States) and sent to government-approved laboratories for analysis. Establishments are required to hold or maintain control of sampled raw beef products pending receipt of results reported as negative for STEC. If a confirmed positive result is received, government inspection personnel are to verify that the establishment takes corrective actions and initiate government follow-up sampling. If the establishment continues to demonstrate ineffective corrective actions as demonstrated by additional confirmed positives results, DIA will suspend the establishment's operations.

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 to export to the United States to adopt one of three *Lm* alternatives consistent with those described in 9 CFR 430.4. Products contaminated with or that have passed over surfaces contaminated with *Lm* or *Salmonella* are considered adulterated and must be destroyed or reprocessed to receive an additional lethality treatment (e.g., cooking). Establishments are required to hold or maintain control of the sampled RTE product pending receipt of results reported as negative for *Lm* or *Salmonella*. RTE product testing positive for either *Lm* or *Salmonella* are not eligible for export to the United States. The FSIS auditors verified through interviews and record reviews that DGSG has implemented official verification sampling for RTE product and for environmental surfaces, including food contact and non-food contact surfaces, as described in Resolution No. 98/2016, and Regulatory Norm No. 1/2013. Government inspection personnel collect samples that are sent to DILAVE for analysis using methods consistent with the FSIS Microbiology Laboratory Guidebook methods and test portions for testing RTE products for *Lm* and *Salmonella*.

During the visit to the facility producing TPCS products, the FSIS auditors confirmed that the requirements for these products outlined in Circular No. 1/2014 are routinely verified by in-plant government inspection personnel. Topics reviewed included receipt of raw materials and ingredients; receipt and cleaning of containers and lids; review of process schedules; procedures addressing operations (e.g., posting of processes, retort traffic control, initial temperature) in thermal processing areas; closure of containers; chlorination of retort cooling water; and incubation. No systemic concerns were identified.

The FSIS auditors found that Uruguay's beef, lamb, and mutton inspection system has an official microbiological verification sampling program organized and administered by the national government, and that DGSG has implemented the necessary sampling programs to verify the effectiveness of establishments' production of products intended for export to the United States. The FSIS auditors identified an isolated establishment deficiency related to the interpretation of generic *E. coli* testing results, which is noted on the individual establishment checklist provided in Appendix A of this report.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held March 20, 2024, by videoconference with the DGSG. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- The government laboratory does not routinely include all positive and negative controls required by the analytical method used for detecting *Listeria monocytogenes*.

GOVERNMENT CHEMICAL RESIDUES TESTING PROGRAMS

- DGSG does not apply a zero-tolerance policy when evaluating results of samples tested for pesticides or veterinary drugs for products intended for export to the United States when there is no established tolerance for the compound in the United States. In the United States, if there is no tolerance set for a specific pesticide or veterinary drug residue, FSIS considers the product adulterated if any level is detected in accordance with 80 Federal Register 81272, National Residue Program: Monitoring Chemical Hazards.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Establecimientos Colonia S.A. Ruta 22 Tarariras Colonia	03/07/2024	2	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
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 boneless beef

60. Observation of the Establishment

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

46. A bovine half-carcasses was observed entering the final wash/antimicrobial rinse cabinet with a piece of hide (3cm x 1cm) on the brisket that had not been completely removed during the deskinning process. Inspection officials took immediate action to ensure the observation was corrected.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/07/2024

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	03/13/2024	7	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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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	X
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	X
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

60. Observation of the Establishment

During the audit of DGSG at the site, the following was observed;

28; During review of establishment generic *E. coli* program, it was determined that the establishment used statistical process control to determine values of M/m, as required by the CCA. However, the establishment was using old values for M/m and did not implement the updated values based on the previous year's test results.

52; During observation of the animal pens, a gate with an area of deterioration was observed to have sharp and jagged metal edges with the presence of cattle hair. The CCA took action to ensure corrective measures were taken prior to any additional movement of cattle in the affected area.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/13/2024

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	03/12/2024	12	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
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. Other	X
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Beef; Raw intact, RTE dried, RTE fully-cooked, RTE salt-cured

60. Observation of the Establishment

During the audit of DGSG at the site, the following was observed;

15; Soy and Wheat (product ingredients) were not identified as potential hazards (allergens) within the establishment's hazard analysis. However, further review indicated that the product label was accurate, and the establishment maintained an allergen control (prerequisite) program.

19; Establishment lethality validation study for the process of producing the dried beef product “Tasajo” indicates salt curing to occur in room temperature of 7 degrees C (44.6 F) or less for 5 days with drying to occur at 40 degrees C (104 F) over an approximate 4-day period. The process as implemented is using curing room temperature of 10 degrees C (50 F) or less and a drying room temperature range of 30-45 degrees C (86-113 F) over a 3–4-day period, while lacking technical documentation indicating how the implemented process at a wider range of temperatures and time would still achieves an adequate log reduction of pathogens and prevent any other potential hazards. The CCA indicated additional technical documentation would be required for the process.

45; After pre-operational verification by the CCA in the beef jerky processing and packaging room, the following observations were identified; equipment was not disassembled to the extent necessary to allow for adequate inspection for sanitation purposes, small particles of product residue were visible between metal surface and white plastic conveyor belt guides. Some overlapping surfaces of equipment were not able to be disassembled to allow for adequate inspection for sanitation and could not be easily cleaned as evidenced by slight discoloration of the stainless surfaces. Additionally, rough welds were observed on product contact surfaces at the end of the product conveyor belt which would create difficult to clean surfaces. Also, the product conveyor belt had small areas of deterioration where the underlying fibrous belt material was visible. The CCA took immediate action to control the identified issues and ensure corrective actions occurred.

57: Establishment *Listeria* control program did not include testing of employees ungloved hands who handle post lethality exposed beef jerky product at several locations in the processing and packaging process as part of their listing of eligible and sampled food contact surface test sites to verify adequate control of sanitation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/12/2024

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
Establecemientos Colonia S.A. Ruta Puenta Puerto 2 km. 310,700 Rio Negro	03/14/2024	30	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

15. The critical limit for CCP2 (overlap of double seam) was not clearly defined. While some portions of the HACCP plan stated that a single can (in approximately a 60 minute time frame) with a overlap of less than 45% would constitute a deviation from the critical limit, other sections of the plan indicated that a deviation consisted in two cans not meeting this value.

16. Records documenting the verification procedure for monthly calibration of retort thermometers associated with monitoring of CCP3 (thermal process) did not include then exact time the verification event occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	06/04/2024

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	03/06/2024	55	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
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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.	
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19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
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. Other	X
58.	
59.	

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef

60. Observation of the Establishment

During the audit of DGSG at the site, the following was observed;

46; During observation of sanitary dressing procedures, employees who were skinning hind legs were observed making opening cuts and then additional skinning cuts prior to washing or changing their knives, a practice that could potentially cause contamination of the carcass. Inspection officials took actions as appropriate to ensure disposition of any affected product would occur.

57; During the establishment walkthrough of the outside facility, a closed barrel containing animal byproduct (cooked bile) was observed to have no identification of the contents of the barrel or permitted use (inedible product). Inspection officials took action to ensure the observation was corrected.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/06/2024

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	03/13/2024	58	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. 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

60. Observation of the Establishment

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

12. The establishment written SSOP did not specify that "disposition of product" was to be documented as part of corrective actions taken in response to contamination of product or product contact surfaces.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/13/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Establecimientos Juan Sarubbi S.A. Cno. Coronel Raíz 2902 Montevideo	03/8/2024	327	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
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 processing.
Prepared Products:	RTE fully-cooked beef

60. Observation of the Establishment

During the audit of DGSG at the site, the following was observed;

15; Soy (a product ingredient) was not identified as a potential hazard (allergen) within the establishment's hazard analysis. However, further review indicated that the product label was accurate and the establishment maintained an allergen control (prerequisite) program.

45; During walkthrough of the establishment, the surface chute of the hot dog peeler was observed to have pitted/rough areas due to welding of the brackets, creating a surface which would be difficult to clean and inspect for sanitation. Inspection took immediate action to stop operations and require corrective actions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/13/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico San Jacinto (Nirea S.A.) Ruta 7, km. 59.500 Canelones	03/07/2024	344	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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 & lamb slaughter and processing
Prepared Products:	Raw intact beef, Raw intact lamb

60. Observation of the Establishment

During the audit of DGSG at the site, the following was observed;

46; During observation of sanitary dressing procedures, employee skinning the initial hind leg of animals were observed making an opening cut and then an additional skinning cut prior to washing or changing the knife, a practice that could potentially cause contamination of the carcass. Inspection officials took actions as appropriate to ensure disposition of any affected product would occur.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/05/2024

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	03/05/2024	379	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
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	X
46. Sanitary Operations	X
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. Other	X
58.	
59.	

Establishment Operations:	Beef & lamb slaughter and processing
Prepared Products:	Raw intact beef, Raw intact lamb

60. Observation of the Establishment

During the audit of DGSG at the site, the following was observed;

13; Establishment corrective action records did not include documentation if any product was affected during operational observations of deficiencies involving product contact surfaces.

45; Numerous cutting boards were observed to have frayed edges with plastic pieces which could potentially cause contamination of finished product with extraneous materials. Inspection officials took actions as appropriate to ensure disposition of any affected product would occur.

46; During observation of sanitary dressing procedures, employees who were skinning hind legs were observed making opening cuts and then additional skinning cuts prior to washing or changing their knives, a practice that could potentially cause contamination of the carcass. Inspection officials took actions as appropriate to ensure disposition of any affected product would occur.

57; During the establishment walkthrough, four pallet size containers of chemical substance (with two containers in use) were observed to have no identification of the contents of the skids. Inspection officials took action to ensure the observation was corrected.

57: Carcass spray cabinet and spray nozzles were not functioning correctly to ensure adequate application of the antimicrobial solution (lactic acid).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/05/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico La Caballada (Cledinor S.A.) Tomas Berretta y Harriague Salto	03/12/2024	394	Uruguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	X
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

60. Observation of the Establishment

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

16. HACCP record keeping: 1) Establishment did not document the specific time at which the verification activity of document review for CCP1 (zero tolerance) occurred. 2) The establishment did not document the results of increased (100%) monitoring conducted as part of the corrective actions taken in response to a deviation for the zero tolerance CCP.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/12/2024

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	03/06/2024	439	Uruguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
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	X
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. SRM Control	X
58.	
59.	

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Raw-intact boneless beef

60. Observation of the Establishment

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

10. Flaking paint was noticed on water pipes in the deboning room in the vicinity of raw exposed product. No direct product was observed.

15. The establishment's hazard analysis did not identify chemical hazards for the carcass rinse step during which lactic acid (@ 2-5%).

52. A bent piece of metal (4"x 6" in dimension) was observed in the cattle walkway and positioned in such manner that could cause injury to transiting animals. This problem was immediately corrected.

55. The lighting at the inspection station where veterinary dispositions occurred was not of sufficient intensity (less than 500 lux required by Uruguay's inspection system)

57. The establishment did not institute measures to prevent the leakage of brain tissue from the knock hole of cattle during head washing. While the age of the animals was being determined through the use of electronic records, specific measures were not taken to segregate younger animals from those 30+ months for the purpose of SRM removal. Consequently, all animals were being treated as 30+ months or older. Establishment is not currently exporting head meat to the US.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/06/2024

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

Ministerio de Ganadería, Agricultura y Pesca | Dirección General de Servicios Ganaderos

RESPONSE TO THE FINAL AUDIT REPORT

1 - GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- The government laboratory does not routinely include all positive and negative controls required by the analytical method used for detecting Listeria monocytogenes.

Response

The government laboratory has begun to routinely include positive and negative controls as required by the analytical method used for detecting Listeria monocytogenes.

2 - GOVERNMENT CHEMICAL RESIDUES TESTING PROGRAMS

- DGSG does not apply a zero-tolerance policy when evaluating results of samples tested for pesticides or veterinary drugs for products intended for export to the United States when there is no established tolerance for the compound in the United States. In the United States, if there is no tolerance set for a specific pesticide or veterinary drug residue, FSIS considers the product adulterated if any level is detected in accordance with 80 Federal Register 81272, National Residue Program: Monitoring Chemical Hazards.

Response

The National Biological Residues Program (PNRB) carries out continuous monitoring of residues of veterinary drugs, prohibited substances, pesticides and environmental contaminants in food of animal origin. This monitoring is carried out through the collection of muscle and other tissue samples in bovine and ovine slaughterhouses. The sampling program is official and is always conducted by the Official Veterinary Inspection (IVO) at each slaughterhouse.

The criteria used to design the control plans include the setting of maximum residue limits (MRLs) or action levels, considering different international organizations or agencies as references. For instance, for veterinary drugs, the MRLs set by Codex Alimentarius, the Food and Drug Administration (FDA), and the European Medicines Agency (EMA) are considered.

In order to provide greater guarantees for the export of beef and ovine meat to the United States of America, the DGSG proposes the actions described below.

Considering that the Codex Alimentarius recommends a series of Maximum Residue Limits (MRLs) established through rigorous scientific evaluations by international expert committees, and that both Uruguay and the USA recognize these recommendations as science-based and actively participate in the relevant subcommittees advocating for their adoption, the DGSG requests the incorporation of these MRLs into its monitoring program.

When residues of veterinary drugs or pesticides that do not have an established tolerance in US regulations or Codex Alimentarius are detected, the following procedures will be followed:

1. Upon detection of residues of veterinary drugs or pesticides in samples of bovine or ovine muscle that do not have an established tolerance in US regulations or Codex Alimentarius, the carcass corresponding to the sampled animal will be segregated from the export to the USA.
2. Upon detection of residues of veterinary drugs or pesticides that do not have an established tolerance in US regulations or Codex Alimentarius in samples of tissues or fluids other than bovine or ovine muscle, the corresponding muscle sample from the same animal will be analyzed. If residues are confirmed in the muscle, the corresponding carcass will be segregated from the export to the USA. This criterion is based on the fact that Uruguay is not authorized to export bovine and ovine by-products.

3. Where it is not possible to analyze the muscle sample from an animal in which residues of veterinary drugs or pesticides that do not have a tolerance established in US regulations or Codex Alimentarius are detected in samples of tissues or fluids other than bovine or ovine muscle, the carcass will be segregated from export to the USA.