USDA

United States Department of Agriculture

OCT 14 2022

Food Safety and
Inspection Service

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

Dr. Pablo Nadal
Director
División Industria Animal
Ministerio de Ganadería, Agricultura y Pesca (MGAP)
Dirección General De Servicios Ganaderos
Ruta Nacional N°8 Brigadier Gral. Juan Antonion Lavalleja-Km 17,500
Montevideo, Uruguay

Dear Dr. Nadal,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote verification audit of Uruguay's meat food safety and inspection system May 3–June 14, 2022. Enclosed is a copy of the final audit report. The comments received from the Government of Uruguay are included as an attachment to the report.

For any questions regarding this audit report, please contact the Office of International Coordination at InternationalCoordination@usda.gov.
Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF

URUGUAY

MAY 3 TO JUNE 14, 2022

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

October 14, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Uruguay conducted by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) from May 3 to June 14, 2022. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to verify whether Uruguay's food safety inspection system governing raw and processed beef and lamb 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 (TPCS) beef; ready-to-eat (RTE) 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 audit results within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following finding:

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

- The Central Competent Authority (CCA) has 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.

During the audit exit meeting, the CCA of Uruguay committed to address the preliminary finding as presented. Furthermore, a review of records by FSIS auditors confirmed that no retesting occurred on product shipped to the United States. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Uruguay's food safety system from May 3 to June 14, 2022. The audit began with an entrance meeting held via videoconference on May 3, with 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 participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether the food safety inspection system governing raw and processed beef and lamb 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) currently recognizes Uruguay as "negligible risk" for bovine spongiform encephalopathy (BSE). Uruguay is not recognized free of foot-and-mouth disease (FMD) but is permitted to export fresh (chilled or frozen) beef and ovine meat under specific conditions. Uruguay is eligible to export raw beef, lamb, and mutton, and heat-treated or otherwise processed beef to the United States.

Prior to the remote 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 and reviewed records to determine whether Uruguay's food safety inspection system governing raw and processed beef and lamb 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 (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from 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 records related to administrative functions and oversight from DGSG headquarters, as well as government verification records from three local inspection offices within the establishments. The audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to two meetings each week over a seven-week period. Through records review, the FSIS auditors evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 3 establishments was selected for the remote audit from a total of 31 establishments certified to export to the United States. This included two slaughter and processing establishments producing solely beef, and a slaughter and processing establishment producing

both beef and lamb. The products these establishments produce and export to the United States include RTE salt-cured beef; RTE fully-cooked beef; RTE dried beef; raw intact beef; and raw intact lamb.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. 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 Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2.

The FSIS auditors also remotely audited the government-operated laboratory that conducts chemical residue and microbiological analyses to verify that the laboratory is capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	• Dirección General de Servicios Ganaderos, Montevideo
Laboratory		1	• División Laboratorios Veterinarios (DILAVE), government microbiological and residue laboratory, Montevideo
Beef slaughter and processing establishment		2	• Establishment No. 7, Frigorífico Pul (Pulsa S.A.), Cerro Largo • Establishment No. 12, Frigorífico Tacuarembó S.A., Tacuarembó
Lamb and beef slaughter and processing establishment		1	• Establishment No. 379, Frigorífico Las Piedras S.A., Canelones

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 1901-1906); and
- The Meat Inspection Regulations (9 CFR 301 to the end).

The audit standards applied during the review of Uruguay's inspection system for raw and processed beef and lamb 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 February 1, 2019, to January 31, 2022, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 293,949,928 pounds of meat from Uruguay. This included 14,857,569 pounds of TPCS beef; 1,029,631 pounds of RTE salt-cured beef; 132,817

pounds of RTE fully-cooked beef; 5,076,700 pounds of RTE dried beef; 270,816,275 pounds of raw intact beef; and 2,036,936 pounds of raw intact lamb exported by Uruguay to the United States.

Of these amounts, additional types of inspection were performed on 32,894,249 pounds of meat (1,257,673 pounds of TPCS beef; 177,881 pounds of RTE salt-cured beef; 111,926 pounds of RTE fully-cooked beef; 720,071 pounds of RTE dried beef; 30,420,891 pounds of raw intact beef; and 205,807 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 (Shiga toxin-producing *Escherichia (E.) coli* (STEC) O157:H7, O26, O45, O103, O111, O121, and O145 in beef; and *Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products).

As a result of this additional testing, 367,163 pounds of meat were rejected for issues related to public health, including: 297,300 pounds of beef rejected for STEC-positive results; 39,667 pounds of meat rejected for extraneous material, and 30,196 pounds of meat as being identified as "off-condition."

The previous FSIS audit conducted in 2019 indicated that Uruguay's meat inspection system remained equivalent with no systemic findings identified.

The most recent 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 (DSA)), and the Animal Industry Division (División Industria Animal (DIA)). In turn, the 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 certified establishments.
2. Department of Processing Establishments – responsible for processing plants of 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 residue programs.
5. Technology Department – responsible for grading.

The slaughter and processing establishments under the DIA are organized geographically into three regions, each with an assigned regional supervisor (RS), who 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 the Uruguayan Decree No. 369/983, Decree No. 238/00, Resolution of August 13, 2004, and Resolution of January 13, 2004. 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 with the interviewed government official that each audited establishment continues to maintain these procedures, as well as records sufficient to conduct traceback activities if adulterated product were exported to the United States. The FSIS auditors also reviewed government verification records related to mock recalls conducted in accordance with these plans, indicating that establishment procedures were effective. No actual product recalls have occurred since the previous FSIS audit conducted in 2019.

All activities related to meat products are under the authority of the OVI and are subject to technical standards outlined in Article 1 of Decree No. 369/983. In addition, Articles 3 to 9 of Decree No. 369/983 contain requirements for approval, extension, and modification of slaughter and processing establishments certified as eligible to export to the United States. 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 also noted that no elevated enforcement actions had been taken at those establishments certified to export to the United States.

The FSIS auditors verified that government inspection personnel possessed 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 have specialized experience or education that allows them to perform their assigned duties. The FSIS auditors also verified through monthly payroll documents and government-issued identity cards that all inspection personnel assigned to establishments certified to export to the United States are government employees paid directly by the national government.

During the audit of DGSG headquarters, the FSIS auditors reviewed records indicating that inspectors had successfully completed a 15-month training program. All new employees must complete training on meat inspection regulations, inspection and verification activities, and country-specific export requirements. Successful completion of training is the fundamental requirement for personnel to be assigned to perform inspection and verification procedures. Veterinary and non-veterinary personnel receive on-the-job training when they are first assigned

to establishments certified to export to the United States. Within its Circular 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. Courses offered to government inspection personnel since the previous FSIS audit included: Animal Welfare; Ante-Mortem Inspection; BSE; Epidemiological Surveillance Programs; Good Manufacturing Practices; HACCP Verification and Validation; Sanitation; Microbiological Sampling; National Emergency Response Capabilities Against Exotic Diseases; Post-Mortem Inspection; Veterinary Drugs and Maximum Residue Limits (MRL); and Zoonoses and Zoonotic Agents.

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 certifying inspection personnel with their HACCP pre-shipment reviews, as well as the results of any product testing conducted as part of their HACCP verification procedures. 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, i.e., "hold and test," prior to certifying product for export to the United States. Regarding chemical reside testing specifically, Resolution No. 11A of January 19, 2010, states that the MRLs of the United States are to be met.

The FSIS auditors confirmed that DGSG ensures that product eligible for export to the United States is not commingled with domestic or other products that are not eligible. 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 (ISO)/International Electrotechnical Commission (IEC) Guide 17025, General Requirements for the Competence of Testing and Calibration Laboratories. 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 by the Uruguayan Accreditation Organization (Organismo Uruguayo de Acreditación (OUA)) to ISO/IEC 17025 standards and are audited yearly by 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 identified a finding related to the policy concerning retesting of product samples, as it was noted that the national chemical residue program has provisions in place that allow for chemical residue samples with violative test results to be retested at the producer's request. Furthermore, DGSG has not provided official personnel with written instruction to ensure that products retested under this provision cannot be exported to the United States. However, the FSIS auditors verified that no retesting has occurred on product shipped to the United States in recent history.

- The DGSG has 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.

With the exception of the finding related to the potential for retesting of chemical residue samples, the FSIS auditors concluded that Uruguay's meat food safety inspection system continues to organize, administer, and enforce its meat food safety inspection system in a manner that meets the core requirements for this component.

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

The second 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, that instructs government inspection personnel to conduct daily verification of the establishment's slaughter stunning procedures. For this verification, the government inspection personnel are to randomly select and observe at two different times the establishment's stunning procedure and its effectiveness for five animals, for which results are documented on a specific form (Auditoría del Manejo y Faena Humanitaria). Additionally, the government inspection personnel are to perform a documented audit every six months to ensure that facilities and premises are maintained in a manner to prevent inhumane treatment of animals. The FSIS auditors through record reviews and interviews of government inspection personnel confirmed that humane handling and slaughter of livestock are conducted in accordance with these procedures.

Chapter II, Articles 17-38 of Decree No. 369/983 describe the ante-mortem inspection procedures for livestock prior to slaughter and specifies the tasks that are performed by government inspection personnel. Article 22 of Decree No. 369/983 requires that all livestock

receive ante-mortem inspection when the herd arrives at the establishment and as many times as determined by the government inspection personnel. 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 confirmed 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.

Chapter III, Articles 39-86 of Decree No. 369/983 describe the post-mortem inspection procedures for livestock. Articles 10 and 13 of Decree No. 369/983 prescribe 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 reviewed documentation demonstrating that each slaughter establishment is staffed with enough online government inspectors and that post-mortem inspection of every carcass and its parts is conducted in a manner consistent with FSIS requirements. This included review of supervisory records 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. Government inspection personnel examine the coronary band for each foot as well as the lips and snout of each individual animal slaughtered. In addition, the FSIS auditors confirmed that all meat products derived from animals slaughtered in establishments certified to export to the United States derive from carcasses that have completed the necessary maturation process. Carcasses that do not meet the established pH requirements for maturation are to be 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 the proper disposition of these materials. DGSG provided inspection documentation to demonstrate that relevant portions of these requirements were applied, including appropriate identification in accordance with the categories described therein; segregation in specially marked or otherwise secure containers; and documented final disposal of these materials at nearby rendering facilities.

Section XI, Articles 309-344 of Decree No. 369/983 set the general labeling requirements for meat products, byproducts, and derivatives of meat products. Article 339 of Decree No. 369/983 requires the establishments to obtain approval for labels or stickers by the DIA before the products enter commerce. Circular No. 4/2003 sets the labeling requirements for products that

are exported to the United States. Section 1 of Circular No. 4/2003 describes the information that must be printed on the packaging (including secondary packaging). Section 2 of Circular No. 4/2003 describes the information that must be included 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 required MGAP/DIA/DGSG statement (Establishment Number and Registry Number).

The FSIS auditors verified that DGSG routinely ensures that products exported to the United States are correctly labeled and packaged. This included the review of programs and 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 the government inspection personnel. This evaluation consists of onsite observations to assess the government inspection personnel's knowledge of job requirements and their ability to execute inspection controls. All findings are documented on the DEF Formulario Auditoria Supervision. 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.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOP) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards and sanitary dressing.

The FSIS auditors confirmed that DGSG has adopted FSIS' sanitation regulatory requirements consistent with 9 CFR 416. Chapter III, Articles 135-155 of Decree No. 369/983 indicate the requirements for sanitation and hygienic practices. Additionally, Section VI of Decree No. 369/983 includes the specific requirements 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 (GMP) and such manual is to include a written procedure for processing activities. Resolution of December 20, 1996, sets the requirement for certified meat establishments to develop, implement and maintain Sanitation SOPs. Section 7 of the Manual for the Control and Implementation of Sanitation SOP provides guidance to the government inspection personnel on how to classify findings of noncompliance.

The FSIS auditors confirmed through the review of inspection records that the government inspection personnel are verifying pre-operational and operational Sanitation SOP compliance in accordance with DGSG's requirements. This included both daily verification records (Chequeo de Mantenimiento Informe Higiénico Sanitario) generated by government inspection personnel assigned to the certified establishment as well as monthly records associated with the supervisory visits performed by the RS (DEF Formulario Auditoría Supervision).

The FSIS auditors also reviewed a sample of noncompliance reports (NR) generated by government in-plant inspection personnel to verify that in-plant inspection personnel had identified deficiencies during pre-operational and operational verification activities. The in-plant inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. Based on the FSIS auditors' review of this documentation, the FSIS auditors determined that government inspection personnel adequately described noncompliances and verified the effectiveness of the establishment's corrective actions.

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

DGSG requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs to ensure that the establishment's construction, facilities, and equipment prevent the contamination or adulteration of meat products destined for the United States.

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 certified establishment develop, implement, and maintain a HACCP system.

The FSIS auditors confirmed that DGSG has adopted FSIS' HACCP regulatory requirements consistent with 9 CFR 417. 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 its effectiveness 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. The FSIS auditors reviewed the critical control points and results of official veterinary verification activities to verify compliance. All three slaughter establishments had addressed zero-tolerance contamination with fecal material, ingesta, and milk, as well as additional controls to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens within the scope of their HACCP system.

For the establishment producing RTE products, the FSIS auditors reviewed the government HACCP verification records with a special emphasis on lethality for *Salmonella* and other relevant pathogens. Establishments producing cooked beef products elected to follow the lethality and stabilization performance standards based on Appendices A and B of the FSIS Compliance Guidelines for Cooking and for Cooling Meat and Poultry Products, respectively.

The FSIS auditors confirmed through the review of inspection records that the official 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 (HACCP Plan Verification Form) generated by government inspection personnel assigned to the certified establishment and monthly records associated with the supervisory visits performed by the RS (Formulario Auditoría Supervision). The FSIS auditors reviewed a sample of NRs in three audited establishments for which no concerns were identified.

The FSIS auditors verified the corrective actions for one establishment (No. 7) implicated in the STEC-positive test results referenced in section III (Background) of this report. The inspection records maintained by the local government inspection personnel indicated that enforcement actions in response to this POE violation were acceptable. This included review of a set of 16 negative government follow-up samples, as well as documented verification of the changes instituted by the establishment to their Sanitation SOP, GMP, and HACCP programs.

The audit results show that DGSG verifies that operators of official establishments implement DGSG's requirement to develop, implement, and maintain HACCP programs for each processing category.

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) is based on European Commission (EC) Council Directive 96/23/EC, which prescribes measures to monitor certain substances and residues in live animals and animal products. This program

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 residue program aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The FSIS auditors' verification of this component, while conducted remotely, occurred at all levels of the inspection system and included interviews with officials employed in central and local inspection offices at establishments and DILAVE. The FSIS auditors reviewed documents, interviewed government officials and OVIs, and reviewed the residue testing program to confirm that the types and sizes of samples, sampling methods, methods of analysis, and locations of sample collection of the targeted compounds were consistent with the information included in DGSG's 2022 national residue sampling program.

The FSIS auditors verified through interviews and records review that DGSG has developed and implemented the annual residue monitoring plan that prevents and controls all veterinary drugs, pesticides, and environmental contaminants. The residue plan describes the number of samples, matrix (tissue) analyzed, analytical methods used, and action levels. In addition, DILAVE is responsible for preparing the sample schedules and determining the number of random samples to be collected for specific matrices within a defined period. Through records review of the audited establishments, the FSIS auditors verified that Uruguay tests urine, muscle, liver, kidney, fat, and thyroid. OVIs receive monthly sampling plans, select the herds to be sampled, collect and prepare samples, and send samples to the designated laboratory in accordance with DGSG instructions.

A review of the sampling records maintained at the three local inspection offices of the audited slaughter establishments indicated that the 2022 national residue sampling program was being adhered to as scheduled. The FSIS auditors verified through records review 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 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, application of equivalent testing methods, adherence to MRLs, and reporting of results. No concerns arose as a result of interviews held with laboratory personnel.

The result of the audit activities indicates 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 residues of veterinary drugs and chemical contaminants in beef and lamb 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 meat products prepared for export to the United States are safe and wholesome. This component also addresses requirements for TPCS meat products.

The FSIS auditors verified that DGSG requires all slaughter establishments certified to export product to the United States to collect and analyze carcass samples for indicator organisms. 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 testing is done by the establishments and is verified by government inspection personnel to ensure process control is maintained.

The DGSG continues to implement a *Salmonella* sampling and testing program for performance standards in beef carcasses which is consistent with the requirements outlined 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 three slaughter establishments and concluded that DGSG is verifying that establishment indicator organism and official *Salmonella* carcass testing programs are implemented as documented.

Within both its Program for the Control of *E. coli* O157:H7 in Bovine Meat and the Program for the Control of STEC in Bovine Meat, DGSG outlines its verification testing program for STEC at beef slaughterhouses 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 intended frequencies. Samples are randomly selected and collected from every shift the establishment operates and sent to government-approved laboratories for analysis. Establishments are required to hold and maintain control of sampled raw beef products until results are reported as negative for STEC.

The DGSG document entitled 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 the three alternatives that are consistent with those in 9 CFR 430.4. Products contaminated with or that have passed over surfaces contaminated with *Lm* are adulterated and must be destroyed or reprocessed. Establishments are required to hold the product until sampling results are received. 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 records review that DGSG has implemented official ongoing verification sampling to test product, food-contact surfaces, and environmental surfaces as outlined in Resolution No. 98/2016 and Regulatory Norm No. 1/2013. Official government personnel collect samples, and DILAVE uses the FSIS Microbiology Laboratory Guidebook methods and test portions for *Lm* and *Salmonella* testing.

The FSIS auditors interviewed personnel at DILAVE regarding analytical methods for official DGSG sampling programs. This laboratory conducts analytical testing, including *Salmonella*, *Lm*, and STEC, for official verification of products destined for export to the United States. These interviews included review of records for each phase of the analytical process, including sample receipt, application of equivalent testing methods, and reporting for these pathogens. No concerns were identified.

During interviews with DGSG, the FSIS auditors confirmed the requirements for TPCS products outlined in Circular No. 1/2014 are routinely verified by in-plant government inspection personnel. Topics discussed included receipt of raw materials/ingredients; receipt and cleaning of containers/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 concerns were identified.

The FSIS auditors found that Uruguay's beef and lamb inspection system has a microbiological testing program organized and administered by the national government, and that DGSG has implemented the necessary sampling and testing programs to verify the effectiveness of its system.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held June 14, 2022, by videoconference with DGSG. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the audit results within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following finding:

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

- The DGSG has 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.

During the audit exit meeting, DGSG committed to address the preliminary finding as presented. Furthermore, a review of records by FSIS auditors confirmed that no retesting occurred on product shipped to the United States. FSIS will evaluate the adequacy of the DGSG's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

Appendix: Foreign Country Response to the Draft Final Audit Report

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

División Industria Animal

September 30, 2022

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

Dear Dr. Catlin,

I am writing to you in relation to your note dated August 3, 2022, with reference to the final report of the remote verification audit of Uruguay's meat inspection system conducted by Food Safety and Inspection Service (FSIS) from May 3 to June 14, 2022.

In this regard, we inform that Uruguay has no comments on the information in the audit report.

Please find enclosed the corrective actions taken to address the audit findings (Annex I).

Looking forward to hearing from you, I remain yours sincerely,

DR. PABLO NADAL ARIZAGA
DIRECTOR

ANNEX I – Corrective actions

The FSIS auditors identified the following finding:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION) • The DGSG has 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.

As was informed during the audit, the procedure currently approved by the DGSG does not allow resampling of merchandise whose initial analysis result was non-compliant. The procedure describes that the sample collected from an animal is divided into two equal parts called A and B. Both subsamples are kept under Official control at all times, initially by the Official Veterinary Inspection and later by the Official laboratory.

In particular cases, specifically for some compounds that are prohibited by National regulations, such as hormonal growth promoters (Decree 915/988), if subsample A indicates the presence of these compounds, the Official Laboratory proceeds to verify the result by analyzing subsample B in order to have the greatest guarantees in terms of results, if the livestock producer so requests (never at the request of the slaughterhouse). This procedure does not imply that the merchandise involved is re-sampled.

In order to address the finding identified by the USDA-FSIS auditors, DGSG approved a new procedure, particularly directed to merchandise that may be destined to United States (PR-PNRB-EEUU01).
For these cases, the DGSG, through the Animal Industry Division, will proceed to segregate from the US market the merchandise produced from the carcass of the sampled animal based only on the result of subsample A.

Please find enclosed the "Procedure to determine the acceptability of animals sampled within Code 001 for the USA" (Annex 1A) and its corresponding Resolution DGSG Nº 153/2022 (Annex 1B).

Ministerio de Ganadería, Agricultura y Pesca	Dirección General de Servicios Ganaderos Programa Nacional de Residuos Biológicos	PR-PNRB-EEUU01 Versión 01 02/09/22
Procedimiento para determinar aceptabilidad de animales muestreados dentro del Código 001 para EEUU		

Antecedentes: Observación de la auditoría FSIS/USDA transcurrida entre 3 de mayo y 14 de junio de 2022. No aceptabilidad de análisis de muestra y contramuestra ("retesteo")

Objetivo: Implementar acciones para evitar que animales en los cuales en la muestra A de orina correspondiente al Código 001 se detecten sustancias prohibidas según el Decreto 915/988 [1] sean elegibles para exportar a los EEUU, independientemente de si se procede al análisis de la contramuestra B.

Alcance: animales faenados en establecimientos habilitados por la División Industria Animal (DIA) para exportar a los EEUU.

Responsabilidades:

- Muestreo y segregación: Departamento Establecimientos de Faena a través de Inspección Veterinaria Oficial (IVO).
- Análisis: Departamento Protección de Alimentos - Sección Residuos Biológicos (DILAVE).
- Gestión: Coordinación del PNRB (DGSG).

Descripción:

En aquellos casos donde el análisis de la muestra A de orina determine la presencia sustancias prohibidas según el Decreto 915/988, el Departamento Protección de Alimentos - Sección Residuos Biológicos (DILAVE) procederá a realizar la comunicación a la Coordinación del PNRB.

Independientemente de los procedimientos establecidos en el Manual del PNRB - DIA, Revisión 06 (PR-PNRB 06), la Coordinación del PNRB procederá a

[1] https://www.impo.com.uy/bases/decretos/915-1988

comunicar a la IVO del establecimiento de faena la condición de animal no elegible con destino a la exportación a los EEUU (**NO APTO EEUU**).

La IVO deberá notificar a los responsables del establecimiento de faena, quienes procederán a segregar la mercadería procedente del animal muestreado del mercado de la EEUU, otorgando garantías de trazabilidad.

La IVO mantendrá registro de las actuaciones por un periodo de 2 años.

Documentos asociados:

Formulario de Muestreo: Formulario DILAVE Residuos biológicos, Sección Carnes

Comunicación de la Coordinación del PNRB a la IVO.

Registros de segregación de la mercadería del mercado de los EEUU.

Formulario de Informe de Análisis de Laboratorio: Formulario Informe de Resultados

	Elaborado	Revisado	Aprobado
Firma			
Nombre	Dr. Diego Moreira Borelli	Dr. Pablo Nadal Arizaga	Dr. Diego de Freitas
Cargo	Coordinación PNRB	Dirección de la División Industria Animal	Dirección General de Servicios Ganaderos Presidente del PNRB
Fecha	02/09/22	27/9/2022	27/09/2022

REPUBLICA ORIENTAL DEL URUGUAY
MINISTERIO DE GANADERÍA, AGRICULTURA Y PESCA
DIRECCIÓN GENERAL DE SERVICIOS GANADEROS

Montevideo, 30 de setiembre de 2022

DGSG/Nº153 /2022

VISTO: el resultado de la auditoría realizada USDA/FSIS al sistema de inspección de carne y productos cárnicos de Uruguay entre el 3 de mayo a 14 de junio de 2022;

RESULTANDO: I) del informe final de la auditoria precitada, se observa que esta Dirección General debería proveer instrucciones escritas a efectos de garantizar que aquellos productos con resultados de residuos por encima de los valores de tolerancia en el análisis inicial no sean certificados para la exportación a los EEUU;

II) que el Manual del Programa Nacional de Residuos Biológicos, Capítulo CARNE, Revisión Nº6, aprobado por resolución DGSG N°222/2015 de 23 de octubre de 2015, establece que para compuestos prohibidos por la normativa nacional como son los promotores de crecimiento hormonales (Decreto 915/988 de 28 de diciembre de 1988), frente a la solicitud expresa del productor ganadero el resultado final se emitirá luego que el laboratorio haya procedido a analizar la muestra A y verificado el resultado con el análisis de la muestra B a los efectos de dar las mayores garantías a los administrados;

CONSIDERANDO: I) necesario proporcionar garantías al mercado de los EEUU a los efectos de mantener la equivalencia con la reglamentación de USDA/FSIS;

II) el acta del Comité del Programa Nacional de Residuos Biológicos de fecha 19 de agosto de 2022, que se tiene como parte integrante de esta resolución;

III) de la misma surge la necesidad de mantener el sistema de análisis de muestra A y de muestra B, sin perjuicio de que para aquellos que

deseen exportar a Estados Unidos se tome el resultado del análisis de la muestra A como concluyente

ATENTO: a lo precedentemente expuesto; a lo dispuesto por la ley Nº 3.606 el 13 de abril de 1910 modificativas y concordantes; decreto Nº 369/983 de 7 de octubre de 1983 modificativos y concordantes; decreto Nº 360/003 de 3 de setiembre de 2003;

LA DIRECCIÓN GENERAL DE SERVICIOS GANADEROS
RESUELVE

1. Apruébese el *"Procedimiento para determinar la aceptabilidad de animales muestreados dentro del Código 001 para EEUU"* que se adjunta y se tiene como parte integrante de esta resolución.
2. El incumplimiento con las disposiciones establecidas en la presente resolución, será motivo de la aplicación de sanciones dispuestas en la Sección XII del Decreto 369/983 del 7 de octubre de 1983; artículo 144 de la Ley No. 13.835, de 7 de enero de 1970, en la redacción dada por el Art. 134 de la Ley 18.996, de 7 de noviembre de 2012; art. 285 de la Ley 16.736, de 5 de enero de 1996 en la redacción dada por el art. 87 de la Ley No. 19.535 del 25 de septiembre de 2017 y artículo 131 de la Ley N° 18.996 de fecha 7 de noviembre de 2012 en la redacción dada por el artículo 133 de la Ley 19.670 de fecha 15 de octubre de 2018.
3. Comuníquese a la División Industria Animal y por su intermedio al Departamento Establecimientos de Faena.
4. Dese cuenta a la Coordinación Ejecutiva del Programa Nacional de Residuos Biológicos.
5. Publíquese en el Diario Oficial y en la página Web del MGAP.
6. Cumplido, que sea, archívese

Dr. Jorge Viera Rezende
Adscripto a la Dirección
General de Servicios Ganaderos