United States Department of Agriculture

Food Safety and Inspection Service

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

FEB 15 2022

Ing. Carlos Paz
Presidente
Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA)
Ministerio de Agroindustria
Paseo Colón 367-Piso 9
C1063ACD – Ciudad Autónoma de Buenos Aires, Argentina

Dear Ing. Paz,

The United States Department of Agriculture, Food Safety and Inspection Service remotely conducted an ongoing verification audit of Argentina's meat inspection system July 27 through August 27, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of Argentina are included as an attachment to the final audit 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

ARGENTINA

JULY 27–AUGUST 27, 2021

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 14, 2021

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a routine equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from July 27–August 27, 2021. Due to the global COVID-19 pandemic, FSIS conducted the audit remotely using video conferences to conduct interviews and records review. The purpose of the audit was to determine whether Argentina's food safety inspection system governing beef remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Argentina currently exports raw intact and raw non-intact beef products to the United States.

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

The FSIS auditors concluded that Argentina's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Central Competent Authority (CCA) has required that establishments certified as eligible to export products to the United States implement sanitary operating procedures and a HACCP system designed to ensure the safety of their products. In addition, the CCA has implemented microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Argentina's food safety system from July 27–August 27, 2021. The audit began with an entrance meeting via videoconference on July 27, 2021, with representatives from the Central Competent Authority (CCA)—Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA). Representatives from SENASA 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 beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Argentina 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 - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Beef	Beef - All Products Eligible except Advanced Meat Recovery Product (AMR); Finely Textured Beef (FTB); Low Temperature Rendered Product (LTRP); Other Non-Intact; Partially Defatted Beef Fatty Tissue (PDBFT); and Partially Defatted chipped Beef (PDCB)

The USDA's Animal and Plant Health Inspection Service (APHIS) has declared the region of Patagonia North "B" and Patagonia South in Argentina as free of foot-and-mouth disease (FMD) with special restrictions as specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.1 (a)(1) which lists the regions that APHIS has declared free of FMD and subject to the restrictions specified in 9 CFR 94.11. Fresh (chilled or frozen) beef imported from a region in Argentina located north of Patagonia South and Patagonia North B, referred to as Northern Argentina, is subject to animal health requirements specified 9 CFR 94.29. In addition, Argentina is subject to Bovine Spongiform Encephalopathy (BSE) requirements specified in 9 CFR 94.18 or 9 CFR 94.19.

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

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed Argentina's self-reporting tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether Argentina's food safety inspection system governing meat is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included analyses 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 three-year period, in addition to information obtained directly from SENASA 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 the SENASA headquarters, and three regional offices, as well as government verification records from three local inspection offices located within the certified establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled three meetings each week over a five-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 three establishments was selected for the remote audit from a total of twenty-one establishments certified to export to the United States. This included three beef slaughter establishments. The products these establishments produce and export to the United States include raw intact and raw non-intact beef.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. The FSIS auditors assessed the SENASA's ability to provide oversight through supervisory reviews conducted in accordance with the FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also remotely audited one microbiological laboratory and one residue laboratory to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	• SENASA, Buenos Aires
	Regional	3	• SENASA, Santa Fe Regional Center • SENASA, Metropolitan Regional Center • SENASA, Entre Rios Regional Center
Laboratories		2	• Litoral SA Laboratory, (private residue), Santa Fe • National Reference Laboratory, (government microbiological), Martinez
Beef slaughter establishments		3	• Establishment No. 13, Swift Argentina SA, Rosario • Establishment No. 1920, Frigorífico Rioplatense SAICIF, General Pacheco • Establishment No. 2595, Frigorífico Alberdi S.A., Oro Verde

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 Livestock Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

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

III. BACKGROUND

From March 1, 2018 to February 28, 2021, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 51,776,224 pounds of meat from Argentina. Of these amounts, additional types of inspection were performed on 7,072,125 pounds of meat, including physical examination, chemical residue analysis, and testing for microbiological pathogens. As a result of these additional inspections, FSIS refused 106,117 pounds of meat products for Shiga toxin-producing *Escherichia coli* (STEC) positives and detection of chemical residues, including violations for ethion and diazinon. An additional 150,317 pounds of meat products were refused entry for various issues including leaking vacuum packages, shipping damage, export certification, or labeling verification failures. The current audit included remote audits of the three establishments with point of entry violations (POEV) to assess SENASA's verification of controls for STECs and chemical residues.

The last routine FSIS audit in February-March of 2019 identified the following findings:

Summary of Findings from the February-March of 2019 FSIS Audit of Argentina
Component One: Government Oversight (e.g., Organization and Administration)
• The Central Competent Authority (CCA) uses designated establishment personnel (non-government employees) to conduct post-mortem inspection examination. These personnel are assigned by the establishment to work under the direct supervision of a government veterinary inspector, but the designated personnel are establishment employees whose salaries are paid by the establishment. The number of government employees is determined by how many government employees are available to work. If the government has enough staff, they will staff with government inspectors. If they do not have enough government inspectors, they will use the designated establishment employees for the vacant positions.
Component Five: Government Chemical Residue Testing Programs
• The CCA's national chemical residue plan has provisions in place that allow chemical residue samples with confirmed violative or unacceptable test results to be re-analyzed to negate previous confirmed violative or unacceptable test results.

The FSIS auditors verified through interviews and review of records that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The most recent FSIS final audit reports for Argentina's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/inspection/import-export/international-reports/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.

The SENASA is the CCA of Argentina's meat inspection system through Regulatory Decree No. 4238/68 which provides for overall responsibility for the food safety regulation of meat production activities related to the export of products to the United States. SENASA ensures direct oversight of the production of beef products and certifies shipments of products for export to the United States. The FSIS auditors confirmed through interviews that there have been no major changes to the organizational structure with the exception of an increase in Regional Competent Authority (RCA) offices.

SENASA indicated that since the last FSIS audit, they have increased the number of RCA offices from seven to fourteen. Official controls in certified establishments are administrated through each RCA office and the Veterinary Inspection Service (VIS) offices which are located within each individual certified establishment. The official control system ensures adequate staffing

levels and provides for monthly supervisory reviews by the RCA supervisor, daily completion of program verification tasks basis by VIS personnel on a shift-by-shift basis, and completion of official sampling tasks as assigned through the RCA. The FSIS auditors verified through review of programs and records that SENASA has procedures in place to ensure an effective level of oversight is maintained within certified establishments, and inspection activities are required to be conducted continuously during slaughter operations and at least once per shift during processing. The FSIS auditors also verified through interview and review of credentials that inspection personnel are employed and paid by the government of Argentina.

The FSIS auditors verified through interviews and record reviews the process for certification of an establishment as eligible to export beef products to the United States. An establishment which intends to export beef product must officially apply to SENASA for certification. SENASA reviews the establishment's written food safety system and, if acceptable, performs an onsite audit of the establishment's facilities and food safety systems in operation for compliance with SENASA requirements in addition to specific export requirements for the United States. Upon acceptable onsite audit results, which would include verification of corrective measures taken in response to any findings, SENASA will certify the establishment and request that FSIS list it as eligible to export to the United States.

SENASA conducts audits in each certified establishment once every two-years. Audit scheduling is based on several factors including export data, microbiological and residue testing results, results of supervisory reviews, and results of VIS verification procedures. SENASA auditors document the results of each audit and provide a report of findings to certified establishments. The establishments are required to respond to any findings with written corrective action plans that are reviewed for acceptability. Enforcement action such as suspension or delisting of the establishment as eligible to export beef products to the United States can also occur if observations warrant such action.

SENASA Circular Letter No. 4243A requires beef products for export to the United States be derived from animals that were born, reared, and slaughtered in Argentina. Beef from other countries is not permitted for use as source material. The circular also requires the segregation of products intended for export to the United States from those intended for other destinations, and for the clear identification of all products that are eligible for export to the United States.

SENASA's export certification process starts when an establishment indicates they wish to export product to the United States and enters all required information into the electronic export certification system. After an establishment requests export certification, the VIS will verify all aspects of the paperwork which the establishment is required to include with the initial request for export. The VIS also verifies the product meets all export requirements, including origin of materials, labeling and shipping marks, and all testing results are acceptable. After verification procedures are performed by the VIS at the establishment, a provisional export certificate is issued which allows the product to be moved to the exit port location for loading in a shipping container. At the exit port location, SENASA personnel further verify the loading of the product with the provisional export certificate and the container identification number loaded. The SENASA personnel provide a physical SENASA seal for the container, after which the official signed export certificate can then be issued allowing the product to leave for the United States.

Certified establishments are required to maintain traceability of all beef products beginning with the source of animals for slaughter through the entire production process and ending with the shipment of products as listed on an official export certificate. The VIS personnel verify that certified establishments have written traceability and recall procedures according to the SENASA requirements. The VIS personnel verify traceability documents as part of the export verification process, and review establishment programs as part of their routine scheduled daily verification procedures. SENASA has a mechanism in place to notify FSIS of the shipment of adulterated product. There have been no recalls of beef products exported from Argentina since the last FSIS audit.

The FSIS auditors verified through interview and document reviews that SENASA has the legal authority and responsibility to authorize laboratories to analyze samples as part of a national network of testing and diagnostic laboratories according to Resolution No. 736/2006. SENASA only authorizes laboratories accredited by the Argentinian Accreditation Body (Organismo Argentino de Acreditación (OAA)) to meet standards consistent with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 for technical competence of testing and calibration laboratories. During the audit, FSIS auditors verified through records review and interviews that laboratories performing analysis of official samples are in good standing with OAA.

SENASA Resolution 532/2014 provides a description of positions, job duties and activities, and educational requirements for all employees specific to their assignment. The FSIS auditors verified through interviews and review of records that SENASA has an annual training plan in place and conducts initial training of employees upon hiring as well as continual ongoing and refresher training of all employees. Employees are trained based on their specific job duties including ante-mortem, post-mortem, humane handling, export certification, sanitation, and sampling techniques. Employees are also provided training about specific FSIS requirements including labeling, test and hold, and pre-shipment review.

The auditors verified that Argentina's meat inspection system is organized and administered by the national government, and that SENASA inspection officials are assigned to enforce the laws and regulations governing meat products.

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 each carcass and part; 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 establishments certified to export to the United States.

The FSIS auditors verified through interviews and record reviews that SENASA requires a VIS veterinarian to perform ante-mortem inspection of each animal prior to slaughter. The ante-mortem procedure begins with arrival of transport trucks carrying the animals. An electronic transport document must arrive with the animals providing the seal number on the truck, number of animals, herd and supplier origin, and general animal health information. The VIS veterinarian then observes the unloading of animals from the transport truck, after which the animals are moved to a pen for further observation. All animals are observed by the VIS veterinarian from both sides while walking in order to identify any abnormalities which require the separation of the animal and identification for further examination in a separate suspect animal pen. The FSIS auditors verified through review of documents that records of ante-mortem inspection are maintained at each certified establishment.

The VIS veterinarian ensures any animals injured during transport or within the pens at the certified establishment are identified, as the veterinarian is present during unloading of transports and observes animals in the pens throughout the day, including each pen just prior to animals being moved to slaughter. Any animals which become injured are segregated and not permitted for use in production intended for export to the United States. Animals are evaluated for signs of BSE, segregated and condemned with samples taken for analysis from those animals which exhibit clinical signs or are suspect for BSE. The veterinarian also verifies that animals are provided water at all times and feed if held overnight. Conditions of the pens and movement of animals are also observed by the VIS veterinarian to verify humane handling requirements are met at all times. The FSIS auditors also verified that a VIS veterinarian performs a verification of stunning effectiveness and humane handling at the point of slaughter. The FSIS auditors verified through interviews and review of records that VIS veterinarians follow Circular Letter No. 4301A and document results of any actions taken as a result of their humane handling verification activities on Annex II and their verification of stunning effectiveness on Annex VI.

SENASA has procedures to ensure APHIS requirements for the control of FMD are met, including examination of feet, lips, and snout of each individual animal, as well as pH for each half carcass after maturation in the cooling chambers. The chief VIS veterinarian at each audited establishment reviewed with the FSIS auditors the procedures followed for post-mortem inspection of each carcass, viscera, head, and parts of animals slaughtered. The VIS personnel have authority to slow or stop the slaughter line as needed based on their observations during the inspection process. The VIS veterinarians verify certified establishments follow requirements of Circular Letter No. 4246A for the identification, segregation, and removal of Specified Risk Materials (SRMs) for BSE.

The FSIS auditors verified through interviews and review of documents that the VIS follows the SENASA Circular Letter No. 4301A protocols for record keeping and documentation of their daily activities including humane handling, stunning effectiveness, and facilities verification. The VIS veterinarian ensures certified establishments follow the SENASA requirements for the control of SRMs for BSE, in addition to inedible and condemned materials for which daily observation and controls by the VIS are in place. Additionally, the VIS personnel document nonconformances and non-compliances on Annex II according to Circular Letter No. 4301A based on the types of observations identified. A non-compliance is a finding that does not pose a

risk to product, whereas a nonconformance is a finding that may pose a risk to product. The VIS may also determine a finding to be a nonconformance if there are repetitive findings of non-compliance.

Supervisors from the RCA perform a monthly supervisory visit in accordance with provisions in Circular Letter No. 4362. During this monthly visit, the supervisors review and verify the functions of the VIS staff as well as the certified establishments' compliance with SENASA and FSIS export requirements. After each monthly visit, the supervisor documents the results of their verification procedures with actions required in response to any findings. Certified establishments are required to respond to findings in writing with corrective actions, the VIS personnel verify establishment actions, and the RCA supervisor also verifies corrective actions during the next supervisory visit.

The FSIS analysis and remote verification activities indicate that SENASA maintains the legal authority and a regulatory framework that is consistent with the provisions for this component and therefore continues to meet the core requirements.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

SENASA Decree No. 4238/68 requires that all establishments where animals are slaughtered or foods are stored or processed must comply with SPS, Good Manufacturing Practices or operational SOPs, and Sanitation SOPs. The FSIS auditors verified that certified establishments are required to develop, implement, monitor, document, and maintain procedures effective in ensuring slaughter, processing, handling, and storage of beef products occur in sanitary facilities and under conditions that control risks to the consumer of the products they produce.

The VIS personnel verify compliance with sanitation requirements in accordance with instructions in Circular Letter No. 4301A. The FSIS auditors verified through document reviews and interviews that VIS staff perform a daily pre-operational inspection after establishment personnel indicate the facility is ready for operations. The VIS veterinarian verifies equipment and facilities are clean and maintained in acceptable working condition during this pre-operational inspection. The VIS staff also perform monitoring of operational SOPs by reviewing the facility and conditions during operations. The VIS veterinarian documents the result of all sanitation inspections including determinations of nonconformance or noncompliance and any VIS actions taken on the Annex II form in Circular Letter No. 4301A. The VIS veterinarian reviews and observes establishment personnel responses and corrective actions taken as a result of any findings of nonconformance or noncompliance.

The SENASA Circular Letter No. 4301A also requires establishments to ensure sanitary dressing of carcasses throughout the slaughter process. The VIS veterinarian performs twice daily

verification of dressing procedures to ensure establishment personnel follow programs including adequate separation of carcasses to prevent cross contamination; cleaning and sterilization of equipment and utensils; handling of hides of carcasses during the de-hiding process; and washing of hands, arms, and aprons which may contact carcasses or parts of the animal. The VIS veterinarian also documents the result of twice daily sanitary dressing verification, including determinations of nonconformance or noncompliance and any VIS actions taken, on the form of Annex II in Circular Letter No. 4301A.

The FSIS auditors verified that the SENASA requires the VIS veterinarians to ensure certified establishments follow zero-tolerance requirements for fecal, ingesta, and milk as required by Circular Letter No. 4301A. The VIS staff ensures during post-mortem inspection that visual contamination is removed from carcasses and parts. If the VIS inspector observes feces, ingesta, or milk, the slaughter rail is stopped for trimming or the carcass is segregated to a separate rail to allow establishment personnel to remove the visibly affected carcass and tissue areas. Carcasses separated from the slaughter line cannot be returned until the VIS veterinarian re-inspects and approves their movement back onto the main slaughter line. The VIS veterinarian also conducts zero-tolerance verification checks of carcasses twice daily prior to any final wash cabinet the carcass may pass through. The VIS veterinarian documents the result of zero-tolerance inspections, including determinations of nonconformance or noncompliance and any VIS actions taken, on the form of Annex III in Circular Letter No. 4301A.

The FSIS analysis and remote verification activities indicate that the SENASA requires operators of certified establishments to develop, implement, and maintain sanitation programs, including requirements for SPS, sanitation SOPs, and sanitary dressing procedures. FSIS concludes that SENASA continues to meet the core requirements for this component.

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.

SENASA Resolution No. 205/2014 mandated and incorporated HACCP requirements as part of Decree No. 4238/68. This Decree requires all establishments where animals are slaughtered or where foods are stored or processed to comply with HACCP requirements. Circular Letter No. 4299 provides instructions to VIS personnel on how to conduct Official HACCP Verification Activities (OHVA) which is a comprehensive review conducted on at least a yearly basis. When the VIS or regional supervisor perform an OHVA, they verify a complete HACCP program, including the flow chart, hazard analysis, supporting documentation for critical control points (CCPs) and critical limits, supporting documentation for hazard analysis decisions, and documentation of validation and reassessments as required.

The VIS verifies the development and implementation of the establishment's HACCP food safety system and the regulatory requirements of monitoring, corrective measures, verification, record keeping, and reassessment on a daily basis according to instructions in Circular Letter No.

4301A. The VIS veterinarian may verify the CCPs through direct observation of monitoring, record review, or direct measure by performing the monitoring procedure themselves. The VIS veterinarian will also verify calibration of process monitoring instruments, corrective measures if needed, records, and that pre-shipment review is documented by the establishment. The VIS veterinarian documents the verification results, including determinations of nonconformance or noncompliance and any VIS actions taken, on the form of Annex II in Circular Letter No. 4301A.

The FSIS auditors reviewed documents confirming that SENASA verifies CCPs in each certified establishment on a daily basis. Documents included in-plant inspection records of zero tolerance checks and daily CCP verification reviews. The VIS veterinarian would document findings if deviations from critical limits were observed, take action to identify and retain any affected product, notify the certified establishment through documentation of the finding, and then review the establishment's corrective actions and responses to ensure all HACCP requirements were satisfactorily met. The FSIS auditors verified that the VIS inspectors documented findings of their verification procedures on the Circular Letter No. 4301A Annex II form.

The FSIS analysis and remote verification activities indicate that SENASA requires operators of certified establishments to develop, implement, and maintain a HACCP system for each processing category. FSIS concludes that SENASA continues to meet the core requirements for this component.

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 include a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Prior to the remote audit as part of the SRT review and ongoing equivalence determination, FSIS' residue experts reviewed the Argentina 2020 chemical residue plan (*Plan Nacional de Control de Residuos e Higiene de los Alimentos* (CREHA plan)), associated methods of analysis, reported results of the testing program, and additional SRT responses outlining the structure of Argentina's chemical residue testing program. The FSIS auditors noted that there have been POEVs for chemical residue violations for ethion and diazinon since the last FSIS audit.

The FSIS auditors verified that the CREHA plan is developed and administered by SENASA to plan and manage the testing of live animals, carcasses, and parts for residues and contaminants in beef products. The CREHA plan is developed annually based on the prior year's test results, changes in scientific criterion and methodology, and inputs from international scientific organizations and is created with an overall focus on ensuring proportionality of sampling based on regional production volumes. The SENASA headquarters is responsible for sending sampling schedules to the RCA who then submits sample schedules to the VIS chief at each regulated establishment.

The FSIS auditors verified through interviews with the VIS veterinarians that routine residue sample schedules are received, and the chief VIS veterinarian will then select a random date, time, and herd from which to collect tissues for analysis. The sample tissues are collected and packaged in a container with official forms indicating the required analysis and are sealed by the VIS veterinarian to ensure integrity of the sample and sampling forms. The sealed and packaged sample is then sent by the certified establishment to a residue lab of their choice within the SENASA authorized network. The VIS veterinarian indicated during interviews that the sampled carcass is held pending acceptable test results, and that Circular Letter No. 4011/2012 now clearly indicates that in the case of product intended for export to the United States, a violative test result is considered final and there can be no request to analyze any other sample.

The SENASA Resolution No. 125/98 provides for the management of a noncompliant or violative test result and ensures the supplier of the live animal is placed on the Establecimiento con Antecedentes de Residuos (EAR) residue violation list. The SENASA Resolution No. 14/2020 created an additional residue violation list called the Establecimiento con Antecedentes de Residuos—Destino (EARD), which now includes animal suppliers who are not eligible to supply animals for slaughter based on the intended export market of the beef products. SENASA Resolution No. 467/2012 provides that certified establishments cannot receive animals from a farm listed on the EAR or EARD Lists if product is intended for export to the United States, and that the VIS veterinarian at the establishment is to verify this requirement prior to receiving live animals from transport trucks. The FSIS auditors verified that SENASA initiates an official investigation into the cause of a violative result, conducts traceback activities to the supplier, and schedules targeted follow-up samples of the EAR or EARD List farms. SENASA maintains a listing of the maximum residue limits permitted for carcasses intended for export to the United States.

The FSIS auditors confirmed through record review and interview of personnel of the Litoral SA Laboratory that SENASA conducts an audit of private authorized National Network laboratories once every two years. The laboratory is also routinely audited by the Argentine accrediting body of OAA to ensure their competency. The FSIS auditors interviewed staff and reviewed documents from Litoral SA Laboratory to verify adequate controls for package integrity at receiving, use of recognized and approved analysis methods, and results are reported according to the SENASA procedures and systems. The FSIS auditor also verified how laboratory staff evaluate residue analysis results to determine an occurrence of a violative test result based on United States residue limit requirements. The FSIS auditors also reviewed internal employee training and proficiency requirements and the results of the most recent OAA, SENASA and internal audits.

The FSIS analysis and remote verification activities indicate that SENASA has overall authority of a chemical residue testing program which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in beef products destined for human consumption. SENASA followed their action plans for violative results of ethion and diazinon according to their resolutions in response to reported FSIS POEVs for residues. FSIS concludes that SENASA continues to meet the core requirements for this component.

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 verify that raw beef products prepared for export to the United States are safe and wholesome.

Since the last FSIS audit in 2019, SENASA has not made any major changes to microbiological verification testing programs or requirements. The FSIS auditors noted that there have been POEVs for positive microbiological testing results for STECs since the last FSIS audit.

The FSIS auditors verified through interview that VIS ensures establishments follow SENASA Circular Letter No. 3259 revision 2/2020 regarding process hygiene testing and analysis for carcasses. This circular instructs the VIS to verify establishments develop written programs which identify who will collect samples, location of sampling, how sampling is performed, randomness of carcass selection, and how the integrity of the results are maintained. Establishments must test for generic *E. coli* at the rate of 1 test for 300 carcasses, with a minimum sample of once per week of operation. Results of testing must be recorded on a process control chart showing the most recent 13 test results. The establishment must evaluate the data using standards developed according to SENASA regulatory tables provided in the circular letter which set a lower limit (m) and upper limit (M) and indicate the maximum number of samples permitted in the marginal range. The VIS staff is to verify the establishment takes action to reestablish control of the slaughter process if sample results indicate a loss of process control.

SENASA Circular Letter No. 4245A identifies requirements for official verification sampling of *Salmonella* in raw beef. The VIS is responsible for collecting and preparing the sample for shipment in a sealed package which is then sent to an authorized SENASA national network laboratory for analysis. The VIS veterinarian samples carcasses of the predominant class of animals slaughtered at the establishment on consecutive days of production. A sample set is completed, based on the class of animal, according to the number of samples and number of allowable positives identified in Annex I of Circular Letter No. 4245A. Annex IV of the same circular letter identifies actions to be taken by the VIS based on positive *Salmonella* test results including follow-up testing, actions to be taken by the certified establishment, and enforcement actions to be taken by SENASA for repeated failure to meet the *Salmonella* standard.

The FSIS auditors verified through interviews and document reviews that, in accordance with Circular Letter No. 4210B, SENASA requires certified establishments to identify and determine the risks of STECs in their hazard analysis. Certified establishments must define production lots and be able to trace beef products from source animals through final packaging for export. SENASA requires certified establishments to develop an STEC sampling plan for beef products exported to the United States as part of their HACCP procedures. The FSIS auditors verified through interview that the VIS personnel review establishment STEC testing data and any corrective actions required due to a positive test result.

SENASA Circular Letter No. 4210B also mandates the VIS veterinarian perform official government sampling of beef products for STEC using N60 methodology. Sampling frequency is based on the production volume of each certified establishment. The Circular Letter No. 4210B identifies VIS actions to be taken in response to a positive STEC test result on an official sample including documentation of non-compliance, perform verification activities of establishment corrective actions, and collection of follow-up samples. The FSIS auditors verified through interview that VIS personnel are knowledgeable on actions to take in response to a positive test result in accordance with Annex IV and Annex VII of the same circular letter.

The National Reference Microbiology Laboratory, which is a government operated facility, currently performs analyses of all official *Salmonella* and STEC samples taken by the VIS. The FSIS auditors confirmed through interview and review of records that the laboratory currently uses the most recent FSIS Microbiology Laboratory Guidebook test methods for STECs and *Salmonella*, and reports results according to the SENASA system requirements. The FSIS auditors confirmed the laboratory is routinely audited by the Argentine accrediting body of OAA and reviewed the results of the most recent OAA, and internal audits. The FSIS auditors also verified that the laboratory has appropriate programs in place and maintains records for all procedures and steps official samples undergo, including receiving of the sample to ensure package integrity, tracking and documenting each step of the analysis process, calibrating equipment, internal employee training programs, and proficiency requirements specific to the analyses performed.

The FSIS analysis and remote verification activities indicate that SENASA has overall authority and implements its microbiological sampling and testing programs to verify that meat products are safe and wholesome. SENASA followed their action plans for positive STEC results according to their circulars in response to reported FSIS POEVs for STEC. FSIS concludes that SENASA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held remotely on August 27, 2021, with SENASA. The FSIS auditors concluded that Argentina’s meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. SENASA has required that establishments certified as eligible to export products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, SENASA has implemented microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

Appendix: Foreign Country Response to the Draft Final Audit Report

República Argentina - Poder Ejecutivo Nacional
Las Malvinas son argentinas

Nota

Número: NO-2022-12825266-APN-PRES#SENASA

CIUDAD DE BUENOS AIRES
Miércoles 9 de Febrero de 2022

Referencia: ESTADOS UNIDOS - Exportación de carne bovina / Comentarios al Informe Borrador de auditoria

A: Jose Domingo Molina (DNRRII#MAGYP), Consejero Rachel Bickford (EMBAJADA DE ESTADOS UNIDOS),

Con Copia A: Melisa Galvano Quiroga (DNRRII#MAGYP), Santiago Bonifacio (DNRRII#MAGYP), Silvina Ines Rivero (DNRRII#MAGYP), Juan Maximiliano Moreno (DNRRII#MAGYP), Gustavo Alberto Martino (DREAN#MRE), Alicia Irene Falkowski (DREAN#MRE), Antonella Carminati Woll (DREAN#MRE), Gabriel Hernan Rivera (SECCYPE#MRE), Alejandra Belén Bomben (DREAN#MRE), Maria Florencia Venticinque (PRES#SENASA), Hernan Galarza (PRES#SENASA), María Paula Kupferberg (PRES#SENASA),

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De mi mayor consideración:

Tengo el agrado de dirigirme a usted en respuesta a la Nota del FSIS/USDA mediante la cual se remite el Informe Borrador de la auditoria virtual llevada a cabo entre el 27 de julio y 27 de agosto de 2021, a fin de evaluar el sistema de control oficial a la producción de carne bovina que se exporta con destino a los Estados Unidos.

Al respecto, este Servicio Nacional considera necesario realizar una aclaración en lo declarado en el siguiente componente:

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

"*SENASA Circular Letter No. 4245A identifies requirements for official verification sampling of Salmonella in raw beef. The VIS is responsible for collecting and preparing the sample for shipment in a sealed package which is then sent to the SENASA National Reference Laboratory for analysis*."

Resulta oportuno aclarar que el ensayo de Detección de *Salmonella* en carne cruda correspondiente a la Circular

4245 A, se realiza en la actualidad en los laboratorios pertenecientes a la Red Nacional de Laboratorios del SENASA autorizados para dicho ensayo.

En este sentido, se agradecerá tener a bien remitir los mencionados comentarios a las Autoridades Norteamericanas, para su conocimiento y a los efectos que estimen corresponder.

Sin otro particular saluda atte.

Miguel Donatelli
Técnico Profesional
Presidencia
Servicio Nacional de Sanidad y Calidad Agroalimentaria

Unofficial translation of SENASA response

QUOTE.

We are writing to you in response to FSIS/USDA letter attaching the Draft Final Audit Report of the audit carried out on July 27-August 27, 2021, to evaluate the official inspection system for beef that is exported to the United States.

On that respect, this National Service would like to make a clarification on the following component:

IX. COMPONENT SIX. GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

"SENASA Circular Letter No. 4245A identifies requirements for official verification sampling of Salmonella in raw beef. The VIS is responsible for collecting and preparing the sample for shipment in a sealed package which is then sent to the SENASA National Reference Laboratory for analysis."

It is appropriate to clarify that the detection test for Salmonella in raw meat related to Circular 4245 A is currently being carried out at laboratories that belong to SENASA National Laboratory Network, which are authorized for that test.

We would greatly appreciate your forwarding the above comments to U.S. authorities for their knowledge and use.

UNQUOTE.