FINAL REPORT OF AN AUDIT CONDUCTED OF COSTA RICA

NOVEMBER 6–22, 2023

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

RAW BEEF PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

May 6, 2024

Food Safety and Inspection Service
U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Costa Rica conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) November 6–22, 2023. The purpose of the audit was to verify whether Costa Rica's food safety inspection system governing raw beef 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. Costa Rica currently exports raw intact and raw non-intact beef to the United States.

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

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

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

- The Central Competent Authority, the National Service of Animal Health (SENASA), currently authorizes both government-employed and contracted veterinarians to certify products exported to the United States. This is not consistent with SENASA's written export certification procedure and is outside the scope of the alternative procedures found equivalent by FSIS for the use of contracted employees to conduct inspection activities in establishments certified to export products to the United States.

- The official government microbiological laboratory, National Laboratory of Veterinary Services (Laboratorio Nacional de Servicios Veterinarios), was not properly documenting the sample analysis procedure for detection of *Salmonella* and Shiga toxin-producing *Escherichia coli* (STEC) in raw beef products in accordance with International Organization for Standardization/International Electrotechnical Commission 17025 standards for traceability. The incubation start time was recorded but the incubation end time was not recorded.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Costa Rica's food safety inspection system November 6–22, 2023. The audit began with an entrance meeting November 6, 2023, in San Jose, Costa Rica, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – National Service of Animal Health (Servicio Nacional de Salud Animal [SENASA]) within the Ministry of Agriculture and Livestock (Ministerio de Agricultura y Ganadería [MAG]). Representatives from SENASA accompanied the FSIS auditor throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference November 22, 2023.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing raw beef 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. Costa Rica is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw – Non Intact	Raw Ground, Comminuted, or Otherwise Non-Intact Beef	Beef - All Products Eligible except Advanced Meat Recovery Product (AMR); Beef Patty Product; Ground Beef; Hamburger; Low Temperature Rendered Product (LTRP); Partially Defatted Beef Fatty Tissue (PDBFT); Partially Defatted Chopped Beef (PDCB); and Finely Textured Beef (FTB)
Raw – Intact	Raw Intact Beef	Beef - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) subjects the beef imported from Costa Rica to bovine spongiform encephalopathy (BSE) requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.18 or 9 CFR 94.19.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Costa Rica's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to verify whether Costa Rica's food safety inspection system governing raw beef products is being implemented as documented in the country's SRT responses and supporting documentation.

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

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a 3-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 auditor reviewed administrative functions at SENASA headquarters and six local inspection offices within certified establishments. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the country's SRT responses and supporting documentation.

A sample of six establishments was selected from a total of seven establishments certified to export to the United States. This included three beef slaughter and processing establishments, and three cold storage facilities.

During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor assessed SENASA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditor also visited one government laboratory conducting both microbiological and chemical residue testing to verify its ability to provide technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• SENASA, Heredia
Laboratory		1	• National Laboratory of Veterinary Services (Laboratorio Nacional de Servicios Veterinarios, LANASEVE), Heredia – Microbiological Division – Chemical Residue Division
Beef slaughter and processing establishments		3	• Establishment No. 8, Coopemontecillos R.L, Alajuela

		• Establishment No. 9, Ganaderos Industriales de Costa Rica S.A, Alajuela • Establishment No. 12, El Arreo, S.A., Heredia
Cold storage facilities	3	• Establishment No. 502, Visión Comercial S.A., Alajuela • Establishment No. 503, FRIONET, Alajuela • Establishment No. 201102199, Centro Logístico TICAL, Alajuela

FSIS performed the audit to verify that the food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR parts 301 to the end).

The audit standards applied during the review of Costa Rica's inspection system for raw beef 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 July 1, 2020, to June 30, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 47,716,087 pounds of meat from Costa Rica. This included 47,500,503 pounds of raw intact beef and 215,584 pounds of raw non-intact beef exported by Costa Rica to the United States.

Of these amounts, additional types of inspection were performed on 6,307,032 pounds of raw beef. These additional types of inspection included physical examination, chemical residue analysis, and testing for microbiological pathogens (i.e., *Salmonella* and Shiga toxin-producing *Escherichia coli* [STEC] serogroups O157, O26, O45, O103, O111, O121, and O145). As a result of this additional testing, one lot of boneless manufacturing trimmings (46,247 pounds) was rejected due to adulteration by a chemical residue. FSIS evaluated SENASA's corrective action responses, found them sufficient, and closed the POE violation. An additional 212 pounds of raw intact beef were refused for other issues not related to public health including shipping damage, labeling, or other miscellaneous issues.

FSIS conducted the previous audit of Costa Rica remotely March 8–April 6, 2022, and did not identify any systemic findings representing an immediate threat to public health. The most recent FSIS final audit reports for Costa Rica'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 auditor reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The national government of Costa Rica organizes and manages the food safety inspection system. SENASA is the CCA of Costa Rica's meat inspection system in accordance with Law No. 8495, General Law on the National Service of Animal Health (Ley General del Servicio Nacional de Salud Animal). This law provides for overall responsibility for regulating meat inspection and production activities related to the export of raw beef products to the United States. The FSIS auditor confirmed through interviews and record reviews that there have been no major changes in SENASA's organizational structure since the previous FSIS audit in 2022. SENASA's Directorate for Food Safety in Products of Animal Origin (Dirección de Inocuidad de Productos de Origen Animal [DIPOA]) oversees the implementation of regulatory requirements pertaining to the production of meat products.

DIPOA's meat inspection system consists of two levels: central and establishment. At the central level, DIPOA is responsible for regulating food safety and sanitary measures in all stages of meat inspection and production in accordance with national legislation and FSIS import requirements. Additionally, DIPOA has the authority to provide direct supervision over government inspection personnel at establishments certified to export raw beef products to the United States. At the establishment level, each beef slaughter and processing establishment is staffed by at least one veterinary medical inspector (médico veterinario inspector [MVI]) and several auxiliary inspectors (inspectores auxiliares) who conduct inspection verification tasks in accordance with SENASA documented procedures and frequencies.

The FSIS auditor verified through interviews and record reviews that all government inspection personnel, except for contracted inspectors, are hired and paid by the national government. SENASA has established a cooperative agreement with an independent contracting organization, the Regional International Organization on Animal and Plant Health (Organismo Internacional Regional de Sanidad Agropecuaria [OIRSA]), to supply contracted inspectors to establishments certified to export to the United States. OIRSA is responsible for providing administrative functions, including hiring and payment of the salaries of these contracted inspectors, while SENASA is responsible for providing direct supervision, performance evaluations, and training. The FSIS auditor confirmed through interviews and record reviews that SENASA maintains ultimate control and supervisory oversight over its inspection personnel, including contracted inspectors. The FSIS auditor reviewed inspection records associated with government inspection personnel educational credentials, performance evaluations, initial and ongoing trainings, and payment of salaries. No concerns arose regarding these reviews.

Law No. 8495 provides SENASA with the legal authority and responsibility to take enforcement actions as needed when an establishment does not meet the importing country or Costa Rica's regulatory requirements. At the establishment level, regulatory control actions by government inspection personnel include detaining products, rejecting equipment or facilities, or stopping or slowing the line speed. The FSIS auditor verified through interviews and record reviews that SENASA has provided instructions to its inspection personnel to identify and document any noncompliance findings on the Establishment Inspection and Control System (Sistema de Inspección y Control de Establecimientos [SICE]).

SICE is SENASA's web-based system that is used to generate inspection verification tasks, set task frequencies, and document inspection verification results, including official microbiological and official chemical residue sampling results. SICE allows government inspection personnel to obtain and analyze real-time data concerning SENASA's food safety inspection system. The FSIS auditor confirmed that government inspection personnel had identified, documented, and verified the adequacy of the establishment's preventive measures or corrective actions in response to noncompliance findings in accordance with SENASA requirements. SENASA has not implemented any elevated enforcement actions including closure of the establishment, suspension of inspection, or partial withdrawal of inspection in any of the establishments certified to export to the United States since the previous FSIS audit in 2022.

SENASA Decree No. 29588-MAG-S, Sanitary Regulation and Veterinary Inspection of Bovine Slaughter, Carcass Production and Processing Establishments (Reglamento Sanitario y de Inspección Veterinaria de Mataderos, Producción y Procesamiento de Carnes), defines adulterated product as meat that has been thoroughly inspected and condemned, or officially determined in some other way, as unsuitable for human consumption, thus requiring destruction. Decree No. 40006-MEIC-MAG Costa Rican Technical Regulation (RTCR) 400:2006: Labeling for Raw Meat, Ground Meat, Marinated, Marinated with Adobo, Tenderized and Viscera (Reglamento Técnico Costarricense (RTCR) 400:2006: Etiquetado de la Carne Cruda, Molida, Marinada, Adobada, Tenderizada y Vísceras) requires that the label should not describe or present false, wrong, or misleading information, or create in any way a misconception about the meat product. Government inspection personnel are required to verify that exported meat products are labeled in compliance with the national legislation and as indicated by the importing country's requirements as part of the inspection tasks generated by SICE.

SENASA requires that all establishments certified to export to the United States have written recall and traceback procedures, as required by Law No. 8495. SENASA provides notification to FSIS for any exported products affected by a recall. The FSIS auditor confirmed that in-plant government inspection personnel review and verify the implementation of this requirement at the establishments certified to export to the United States in accordance with SENASA requirements. There have been no product recalls in products exported to the United States since the previous FSIS audit in 2022.

SENASA has the legal authority and responsibility to enforce the laws and regulations governing meat inspection, and to approve or reject an establishment certification for export in accordance with Article 167 of Decree No. 29588-MAG-S. This decree states that establishments approved for exports must comply with the laws and regulations of importing countries and with the

technical standards of Costa Rica's sanitary inspection in accordance with the national laws and regulations.

SENASA only allows raw beef products produced in establishments certified as meeting FSIS requirements to be exported to the United States. The FSIS auditor verified through interviews and record reviews that establishments certified to export to the United States only slaughter cattle that were born and raised in Costa Rica and were not receiving any raw materials from other establishments or other countries for use in products intended for export to the United States.

MVIs are responsible for reviewing and signing export health certificates of beef products intended for export to the United States. MVIs conduct a pre-shipment verification task that includes reviewing all associated traceability documents and food safety records for each lot, observing the staged products, and verifying the weight declaration, shipping marks, and labels prior to applying the official export's stamp and signature on the export health certificate. In addition, MVIs also verify that all official verification samples and establishment monitoring samples are negative for tested microbiological pathogens and chemical residues prior to signing an export health certificate.

The FSIS auditor confirmed through interviews and record reviews that MVIs maintain the pertinent verification documents for each production lot intended for export to the United States. At the time of the audit, all interviewed MVIs certifying product for export to the United States were SENASA (government), rather than OIRSA (contracted), employees. However, during discussions held with SENASA officials, it was indicated that OIRSA employees were also authorized by SENASA to certify product for export to the United States. This is not consistent with SENASA requirements described in DIPOA-PG-001, which indicates that the export health certificate is issued by a SENASA veterinarian. Additionally, while FSIS has found equivalent the use of contracted employees by SENASA for some inspection activities, use of contracted employees for export certification activities is outside the scope of that equivalence determination. Consequently, the following finding was identified related to export certification:

- The Central Competent Authority, the National Service of Animal Health (SENASA), currently authorizes both government-employed and contracted veterinarians to certify products exported to the United States. This is not consistent with SENASA's written export certification procedure and is outside the scope of the alternative procedures found equivalent by FSIS for the use of contracted employees to conduct inspection activities in establishments certified to export products to the United States.

SENASA has the legal authority and responsibility to designate government and private laboratories to conduct analytical testing of beef products intended for export to the United States. The FSIS auditor verified through interviews and record reviews that SENASA provides administrative and technical support to LANASEVE, the national government reference laboratory. The Costa Rican Central Accreditation Entity (Ente Costarricense de Acreditación [ECA]) has the authority for accrediting laboratories in Costa Rica in accordance with International Organization for Standardization (ISO)/International Electrotechnical Commission

(IEC) 17025 standards. The FSIS auditor reviewed the ECA accreditation certificates and scope of accreditation for LANASEVE.

The FSIS auditor's record reviews included documents associated with sample receipt, timely analysis, analytical methodologies, analytical controls, analyst qualifications, proficiency testing, and reporting of results. The FSIS auditor verified that LANASEVE, on behalf of SENASA, also conducts annual reviews of any authorized third-party (private) laboratories that perform analyses of official government samples of raw beef products intended for export to the United States. The FSIS auditor verified that annual audits and related follow-up reviews have been conducted in accordance with SENASA requirements. No concerns arose regarding these reviews.

The FSIS auditor verified through interviews and record reviews that analysts assigned to LANASEVE possess academic credentials and specialized training that qualify them to conduct the analytical methods for chemical residues and microbiological pathogens in their scope of accreditation. The FSIS auditor also confirmed that LANASEVE performs timely analysis of samples and reports the results to SENASA headquarters in a timely manner.

The FSIS auditor interviewed personnel at LANASEVE regarding analytical methods for official SENASA sampling programs. This laboratory conducts analytical testing, including *Salmonella* and STEC, for official verification of products intended for export to the United States. These interviews included review of records for each phase of the analytical process, including sample receipt, application of equivalent testing methods, and reporting of results for these pathogens. The FSIS auditor reviewed the laboratory's implementation of the approved procedures and identified the following finding:

- The official government microbiological laboratory, National Laboratory of Veterinary Services (Laboratorio Nacional de Servicios Veterinarios), was not properly documenting the sample analysis procedure for detection of *Salmonella* and Shiga toxin-producing *Escherichia coli* (STEC) in raw beef products in accordance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards for traceability. The incubation start time was recorded but the incubation end time was not recorded.

DIPOA-PG-006, Management of Laboratory Results Outside the Established Parameters (Manejo de Resultados de Análisis de Laboratorio Fuera de los Parámetros Establecidos) states that the establishments' management, MVIs, and area coordinators (ACs) are notified immediately of noncompliant microbiological or chemical residue laboratory results. The FSIS auditor reviewed recent noncompliant cases and associated records to verify the proper implementation of inspection verification and reporting activities were performed in accordance with SENASA requirements. Furthermore, a review of records by FSIS auditor confirmed that no retesting occurred on product shipped to the United States.

FSIS determined that SENASA organizes and administers its food safety inspection system and that government inspection personnel enforce laws and regulations governing production and

export of raw beef at establishments certified to export to the United States. However, findings related to product certification and sample traceability were identified.

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 auditor 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.

In-plant government inspection personnel are required to conduct humane handling and slaughter procedures in accordance with SENASA requirements in Animal Welfare Laws No. 7451 and No. 9458. SENASA requirements include inspection verification of proper repair and maintenance of holding pens and alleyways, verification of proper handling of livestock prior to slaughter, and evaluation of the proper stunning and sticking procedures. The FSIS auditor' verified that humane handling and slaughter of livestock are conducted in accordance with SENASA requirements.

All cattle presented for slaughter undergo ante-mortem inspection by in-plant inspection personnel in accordance with SENASA requirements in Decree No. 29588-MAG-S on Bovine Ante-mortem and Post-mortem Inspection (Inspección Ante y Post Mortem en Bovinos). The FSIS auditor reviewed inspection documentation within SICE demonstrating that in-plant government inspection personnel conduct daily ante-mortem inspection tasks prior to slaughter of livestock. In-plant government inspection personnel use SENASA's Official Bovine/Buffalo Livestock Movement Guide (Guía Oficial de Movilización de Ganado Bovino/Bufalino) when evaluating livestock health status prior to slaughter and to verify traceability of animals from farm to slaughterhouse. SENASA also has in place instructions for in-plant government inspection personnel regarding handling of suspect animals, including identification of reportable and condemnable disease conditions. Non-ambulatory disabled cattle and those showing signs of central nervous system disorders are condemned during ante-mortem inspection, and brain tissue samples are tested for BSE by the official government laboratory. No concerns arose regarding SENASA ante-mortem inspection procedures.

SENASA keeps informed of animal health restrictions for raw beef products intended for export to the United States by subscribing to APHIS notifications. Export health certificates issued by SENASA indicate any APHIS requirements associated with animal health restrictions. Only those raw beef products that have been previously identified by SENASA as meeting both FSIS and APHIS requirements are certified for export to the United States.

The FSIS auditor verified that each audited establishment is staffed with a sufficient number of government inspection personnel to conduct post-mortem inspection activities in accordance

with SENASA requirements in Decree No. 29588-MAG-S, including verification of proper presentation and identification of carcasses and parts; examination of heads, viscera, and carcasses; and disposition of affected carcasses and parts. In addition, DIPOA-PG-003-IN-001(B), Description of Pathological Process and Technical Criteria for Bovine Product Seizures (Descripción de Procesos Patológicos y Criterios Técnicos para el Decomiso en Bovinos), describes pathological conditions that must be addressed prior to applying the mark of inspection. The FSIS auditor confirmed that post-mortem inspection is conducted continuously during all slaughter operations in accordance with SENASA requirements.

SENASA labeling requirements for products eligible for export to the United States are described in Law No. 8495 and Decree No. 40006-MEIC-MAG. Additionally, tasks within SICE direct government inspection personnel to verify that establishments comply with labeling requirements of importing countries. The export health certificate for beef products intended for export to the United States includes certification that meat products are processed, stored, and transported in a manner to preclude them from being commingled with products ineligible for export to the United States. The FSIS auditor verified that in-plant government inspection personnel conduct labeling verification tasks for products intended for export to the United States at least weekly to ensure that the information on the product labels is complete, accurate, and meets FSIS labeling requirements. The results of the labeling verification tasks are documented in SICE.

SENASA's authority to control condemned animals or inedible materials is implemented through Decree No. 29588-MAG-S. SENASA provided inspection documentation to demonstrate that relevant portions of this decree were applied, including: (a) appropriate identification, (b) segregation in specially-marked containers, (c) storage in separate areas from edible products, and (d) documented final disposal of these materials. The FSIS auditor verified through interviews and record reviews that in-plant government inspection personnel verify requirements as described in DIPOA-PG-013-IN-004, Identification, Removal, Segregation and Disposal of Specified Risk Materials (Identificación, Remoción, Segregación y Desecho de Materiales Específicos de Riesgo) for the control of specified risk materials (SRM). SENASA defines SRMs consistent with FSIS requirements in 9 CFR 310.22. In-plant inspection verification activities include review of establishment SRM control records, observation of establishment SRM monitoring procedures, and direct observation of beef carcasses to verify that the establishment's procedures comply with SENASA requirements for control of SRMs. The FSIS auditor observed that the audited establishments implement controls for all cattle slaughtered as though the animals are 30 months or older regardless of the animal's age, and review of in-plant inspection verification records concerning removal, segregation, and disposal of condemned animals, inedible materials, and SRM controls did not identify any concerns.

Decrees No. 29588-MAG-S and No. 37057 require that facilities and equipment be constructed in a manner that prevents direct product contamination or the creation of insanitary conditions; are maintained in good condition; are installed such that product does not come into direct contact with the floor or walls; and are constructed with materials that facilitate thorough cleaning and disinfection. The FSIS auditor verified through interviews, observations, and record reviews that in-plant government inspection personnel verify the sanitary condition of

establishments' construction, facilities, and equipment during pre-operational and operational inspections in accordance with SENASA requirements.

ACs are responsible for conducting quarterly supervisory reviews. During these quarterly reviews, ACs evaluate the performance of MVIs regarding proper implementation and verification of regulatory requirements in accordance with SENASA requirements in DIPOA-PG-002. Performance review of inspection verification tasks includes: humane handling and slaughter requirements; ante-mortem inspection; post-mortem inspection; microbiological and chemical residue sample collection; labeling procedures; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities. The FSIS auditor reviewed several periodic supervisory review records for each visited establishment and verified that ACs conducted these reviews in accordance with SENASA requirements.

Performance evaluations are also conducted by MVIs of subordinate inspection personnel with a minimum frequency of two performance evaluations per year. These evaluations consist of record reviews and onsite observations of in-plant government inspection personnel to assess their knowledge, skills, and abilities in conducting their assigned inspection verification activities. The FSIS auditor's review of MVI performance evaluation did not identify any concerns.

FSIS audit verification activities indicate that SENASA has the legal authority and a regulatory framework to operate its food safety inspection system. FSIS concludes that SENASA continues to meet the core requirements for this component. The FSIS auditor identified an isolated deficiency related to post-mortem inspection at one facility, which is described in the individual establishment checklist provided in Appendix A of this report.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

Decrees No. 29588-MAG-S and No. 37057 require slaughter and processing establishments to develop, implement, and maintain written Sanitation SOPs, SPS, and implement sanitary dressing procedures to prevent direct product contamination or the creation of insanitary conditions. The establishments must have written procedures to require that food contact surfaces are cleaned prior to the start of operations and to maintain sanitary conditions during operations to prevent product adulteration.

The FSIS auditor confirmed through record reviews, observations, and interviews that government inspection personnel are verifying implementation of pre-operational and operational Sanitation SOPs in accordance with SENASA requirements. Inspection verification activities include document reviews, observations, and hands-on inspections. The FSIS auditor also reviewed a sample of noncompliance reports generated by government inspection personnel

where deficiencies were identified during pre-operational or operational verification activities. In these instances, government inspection personnel closed noncompliance reports after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures, in accordance with SENASA requirements.

The FSIS auditor also observed in-plant government inspection personnel conducting pre-operational sanitation verification inspection. The in-plant government inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation procedures and determined that the facility was ready for operations.

SENASA Decree No. 29588-MAG-S requires establishments to ensure sanitary dressing of carcasses throughout the slaughter process and mandates that any contamination with gastrointestinal contents, purulent material, urine, or other contaminants on carcasses be removed by cutting the affected tissue. The in-plant government inspection personnel conduct daily verification of dressing procedures to ensure establishments comply with sanitary dressing requirements. These inspection activities include verification of the establishment's sanitary practices to prevent potential carcass contamination during hide removal, prevention of direct contact between carcasses during dressing procedures, and prevention of carcass contamination with gastrointestinal contents during evisceration. The FSIS auditor reviewed the daily verification records of these requirements within SICE and found no concerns.

The FSIS auditor's audit verification activities indicate that SENASA requires establishments certified to export to the United States 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. The FSIS auditor observed isolated noncompliances related to the inspection verification of sanitation requirements, which are noted in the individual establishment checklists provided in Appendix A of this report.

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

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

SENASA requires slaughter and processing establishments certified to export to the United States to design, implement, and maintain HACCP systems in accordance with Decree No. 26559-MAG-S, which is consistent with FSIS requirements in 9 CFR part 417. Each establishment's HACCP program must include hazard analysis; flow charts; supporting documentation for hazard analysis decisions and critical limits, monitoring, and verification activities for CCPs; documentation of validation and reassessments; and records supporting the implementation of the HACCP system.

In-plant government inspection personnel verify compliance with the HACCP requirements, including monitoring, verification, recordkeeping, and adequacy of corrective actions taken in

response to a deviation from a CCP, in accordance with instructions in Decree No. 26559-MAG-S. The FSIS auditor verified through interviews and record reviews that in-plant government inspection personnel conduct daily and weekly verification activities in accordance with SENASA requirements.

SENASA requires that slaughter and processing establishments certified to export to the United States consider contamination of beef carcasses with STEC (including serogroups O157, O26, O45, O103, O111, O121, and O145) as a hazard reasonably likely to occur in their HACCP system. The FSIS auditor verified that audited establishments had implemented controls for prevention of contamination with fecal material, ingesta, and milk; and to ensure that carcasses are chilled in a manner sufficient to prevent the outgrowth of microbiological pathogens.

The FSIS auditor reviewed documentation of CCPs in all the audited establishments, including zero tolerance (for feces, ingesta, and milk contamination) records. The FSIS auditor also observed establishment personnel at each audited slaughter establishment conducting hands-on HACCP monitoring and verification activities for the zero tolerance CCP. Furthermore, the FSIS auditor reviewed records and verified that the establishments implemented appropriate corrective actions, when necessary, in response to any deviations from established critical limits. Lastly, the FSIS auditor confirmed at all audited establishments that the physical location of the zero tolerance CCP verification for both establishment and in-plant government inspection personnel is after the final post-mortem inspection station and prior to the final wash, in accordance with SENASA requirements.

The FSIS auditor's verification activities indicate that SENASA requires establishments certified to export to the United States to develop, implement, and maintain a HACCP system. FSIS concludes that SENASA continues to meet the core requirements for this component. The FSIS auditor identified isolated establishment noncompliances related to the basic HACCP requirements, which are noted in the individual establishment checklist provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditor 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.

SENASA has the legal authority and responsibility to regulate, plan, and execute its National Residue Program (NRP) as described in Law No. 8495. SENASA generates an annual official sample schedule (Cronograma Oficial de Muestreo) for each certified establishment that includes the sample collection dates, types of analysis, species, and required tissue matrices. The FSIS auditor verified through interviews and record reviews that in-plant government inspection personnel follow SENASA procedures as described in DIPOA-PG-004, Sampling in Establishments with Products, By-Products and Derivatives of Animal Origin intended for

Human Consumption (Muestreo en Establecimientos de Productos, Sub Productos y Derivados de Origen Animal para Consumo Humano). DIPOA-PG-004 provides instructions for random selection of animals, tissue sample collection methodology, proper handling of samples, and secure transportation of samples to the designated laboratories. At the establishment level, MVIs are responsible for ensuring the proper implementation of the program in accordance with SENASA requirements.

SENASA implements a hold and test policy for its NRP as described in Section 7.5.4 of DIPOAPG-004 to ensure that no sampled carcass or its parts are exported to the United States pending receipt and review of acceptable results. SENASA maximum residue limits are set to be consistent with the Codex Alimentarius, European Union, and United States requirements. The FSIS auditor reviewed in-plant inspection verification records to confirm that SENASA's hold and test policy was being implemented as described in DIPOA-PG-004.

The FSIS auditor's verification activities indicate that SENASA has the regulatory requirements for an official chemical residue testing program that is organized and administered by the national government to prevent and control the presence of veterinary drugs and contaminants in beef products intended for export to the United States. 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 auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat prepared for export to the United States is safe and wholesome.

SENASA requires that establishments certified to export to the United States develop written sampling procedures for monitoring process control through indicator organism testing of cattle carcasses. These requirements for generic *Escherichia coli* (*E. coli*) testing of cattle carcasses are described in DIPOA-PG-004, which includes sample collection procedures, required frequencies, statistical process control criteria for establishing upper and lower limits, and requirements for establishments to take actions to reestablish process control of the slaughter operation if sample results indicate a loss of process control.

SENASA implements an official government verification sampling program for *Salmonella* in cattle carcasses that is consistent with the FSIS *Salmonella* performance standards in 9 CFR 310.25(b). *Salmonella* verification samples are collected and sealed by government inspection personnel prior to submission to LANASEVE. The FSIS auditor reviewed official *Salmonella* verification sampling records, including test results, and found no concerns.

SENASA considers seven STEC serogroups identified as adulterants by FSIS (O157, O26, O45, O103, O111, O121, and O145) to be adulterants in all raw non-intact beef and raw intact beef intended for use in raw non-intact products. In-plant government inspection personnel conduct N60 official verification sampling with a minimum frequency of one sample per week on a

production lot of beef manufacturing trimmings and one sample per week on a production lot of other raw ground beef components in accordance with the requirements of DIPOA-PG-004. SENASA requires certified establishments to hold the production lot associated with STEC testing as part of the establishment's self-monitoring or official verification sampling until receipt and review of negative results. The FSIS auditor reviewed in-plant government inspection personnel sampling records for STEC testing, including test results and implementation of hold and test policy, and found no concerns.

SENASA describes its enforcement strategies in DIPOA-PG-006 to address disposition of affected products and actions taken when STEC positive test results are received from either the establishment's self-monitoring or official government verification testing programs. The enforcement strategies for confirmed positive test results obtained through the official verification testing program include conducting Sanitation SOPs and HACCP verification activities, verifying the proper implementation of the establishment's corrective actions, conducting follow-up sampling activities, and suspension of export certification, if warranted. The FSIS auditor reviewed official verification sampling results, noting that there were no positive STEC results in recent history at any of the audited establishments.

The FSIS auditor's verification activities indicate that SENASA has overall authority and implements its official microbiological sampling and testing programs to verify that raw beef products are safe and wholesome. The FSIS auditor identified an isolated establishment noncompliance related to the sampling methodology for generic *E. coli*. This is noted on the individual establishment checklist provided in Appendix A of this report. FSIS concludes that SENASA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held November 22, 2023, by videoconference with SENASA. At this meeting, the FSIS auditor presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following findings:

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

- The Central Competent Authority, the National Service of Animal Health (SENASA), currently authorizes both government-employed and contracted veterinarians to certify products exported to the United States. This is not consistent with SENASA's written export certification procedure and is outside the scope of the alternative procedures found equivalent by FSIS for the use of contracted employees to conduct inspection activities in establishments certified to export products to the United States.

- The official government microbiological laboratory, National Laboratory of Veterinary Services (Laboratorio Nacional de Servicios Veterinarios), was not properly documenting the sample analysis procedure for detection of Salmonella and Shiga toxin-producing Escherichia coli (STEC) in raw beef products in accordance with ISO/IEC 17025 standards

for traceability. The incubation start time was recorded but the incubation end time was not recorded.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Coopemontecillos R.L. Contiguo al plantel del MOPT Motecillos Alajuela	11/10/2023	8	Costa Rica
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw Intact and Non-intact Beef

60. Observation of the Establishment

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

20. The establishment's written corrective actions associated with the critical control point (CCP) for carcass chilling were incomplete in that they did not include specific measures to ensure that "No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce." However, no deviations related to the CCP were identified by the FSIS auditor in recent history.

28. While observing the sampling of a carcass for generic *E. coli*, the FSIS auditor noted that the establishment employee did not swab the entirety of the area defined by the template (10 cm x 10 cm) used for taking the sample. Most of the swabbing occurred in the center of the template, with little or no swabbing occurring in the upper and lower boundaries.

39. Presence of defective rubber stripping under an exterior shipping door that did not provide a tight seal when closed and could facilitate the entrance of vermin into production areas

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/10/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Ganaderos Industriales de Costa Rica S.A. 2 Km west of Juan Santamaria Airport San Antonio del Tejar Alajuela	11/09/2023	9	Costa Rica
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw Intact and Non-Intact Beef

60. Observation of the Establishment

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

10. During verification of pre-operational sanitation procedures in the deboning area, the FSIS auditor identified: a) presence of flaking paint on the handle of a small circular saw used on product; b) presence of frayed plastic edges on some cutting boards; and c) remnants of frayed adhesive stickers on tables and equipment, all three of which represent a potential for the contamination of product during operations.

20. The establishment’s written corrective actions associated with the critical control point (CCP) for carcass chilling were incomplete in that they did not include specific measures to ensure that “No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.” However, no deviations related to the CCP were identified by the FSIS auditor in recent history.

22. Establishment records documenting the calibration of thermometers associated with the monitoring of the CCP for carcass chilling did not include the time that the actual event occurred.

In addition, FSIS identified the following findings related to the implementation of Costa Rica's inspection system:

The SENASA inspection official responsible for conducting post-mortem inspection did not observe the dorsal surface of the head. Only the ventral surface of the head was inspected (including slicing of the appropriate lymph nodes). Observation of the dorsal surface of the head is important in identifying disease conditions such as icterus, or bovine ocular squamous cell carcinoma (“cancer eye”).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/09/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
El Arreo S.A. Apdo. 6072-1000 La Ribera de Belen	11/13/2023	12	Costa Rica
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw Intact Beef

60. Observation of the Establishment

39. Two doors in the dispatch area presented gaps communicating with the outside which could facilitate the entrance of insects or other pests.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/13/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Vision Comercial S.A. .	11/14/2023	502	Costa Rica
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Cold storage facility.
Prepared Products:	NA

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/14/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frionet	11/15/2023	503	Costa Rica
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Cold storage facility.
Prepared Products:	NA

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/15/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Centro Logistico TICAL .	11/16/2023	201-102199	Costa Rica
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Cold storage facility.
Prepared Products:	NA

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/16/2023

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

March 15, 2024
SENASA-DIPOA-0183-2024

Mrs.
Margaret Burn Rath, JD, MPH
Acting International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
United States

Dear Margaret:

In follow-up to the letter dated January 23, 2024, by which the report of the audit carried out in Costa Rica during the period from November 6 to 22, 2023 is notified, we proceed to lay out the following action plan:

1. Government Oversight Component

    a. The Central Competent Authority, the National Service of Animal Health (SENASA), currently authorizes both government-employed and contracted veterinarians to certify products exported to the United States. This is not consistent with SENASA's written export certification procedure and is outside the scope of the alternative procedures found equivalent by FSIS for the use of contracted employees to conduct inspection activities in establishments certified to export products to the United States.

Response

It is important to clarify that SENASA grants official figure to those personnel who are hired through the official payroll, under the guidelines of the General Directorate of Civil Service, or through the officialization of people, as provided for by SENASA's law No. 8495.

In accordance with the recognition of equivalence communicated by the FSIS in the letter sent in September 2020, SENASA Costa Rica proceeded to carry out a review of and change of wording in the DIPOA-PG-001 procedure, to avoid possible confusions and clarify that veterinary doctors hired under the figure of officialization of people, are authorized to sign export health certificates.

The changes made in the wording of said procedure are detailed below:

- ✓ Section 3. Responsibility: Defines the Official Veterinary Inspector [MVIO] or Official Safety Inspector [IIO] as those who are hired by the state, through the General Directorate of Civil Service, or hired under the figure of officialization of people.

- ✓ Point 7.6.1.2 indicates: The printing of all required certificates must be done on security paper, and certificates must be signed only by the MVIO.

- ✓ Point 7.6.1.5 indicates: The Export Health Certificate is the document that certifies the sanitary condition of the commodities, issued by a MVIO.

Find below the link to the latest version of the DIPOA-PG-001 procedure. You will also find the document attached to this letter.

https://www.senasa.go.cr/informacion/centro-de-informacion/informacion/sgc/dipoa/dipoa-pg-001-exportacion-de-productos-subproductos-y-derivados-de-origen-animal-para-consumo-humano/1931-dipoa-pg-001-v02-exportacion-de-productos-subproductos-y-derivados-de-origen-animal-para-consumo-humano/file

It can also be accessed through the e-Authentication platform.

b. The official government microbiological laboratory, National Laboratory of Veterinary Services (Laboratorio Nacional de Servicios Veterinarios), was not properly documenting the sample analysis procedure for detection of *Salmonella* and Shiga toxin-producing *Escherichia coli* (STEC) in raw beef products, in accordance with International Organization for Standardization / International Electrotechnical Commission (ISO/IEC) 17025 standards for traceability. The incubation start time was recorded, but the incubation end time was not recorded.

Response

The response issued by the National Laboratory of Veterinary Services LANASEVE is attached.

2. Regarding the finding related to the implementation of Costa Rica's inspection system, indicated in the Individual Foreign Establishment Audit Checklists, identified at the GICO establishment.

   The SENASA inspection official responsible for conducting post-mortem inspection did not observe the dorsal surface of the head. Only the ventral surface of the head was inspected

(including slicing of the appropriate lymph nodes). Observation of the dorsal surface of the head is important in identifying disease conditions such as icterus, or bovine ocular squamous cell carcinoma ("cancer eye").

Response

The Official Safety Inspectors [IIO] are continually supervised by both the Official Veterinary Inspector [MVIO] based at the establishment and the area coordinator. There is evidence of the supervisions carried out by both official figures during the year 2023. During the supervision carried out by the MVIO to the IIO to whom the finding was detected, no non-compliance was identified in the execution of the post-mortem inspection. However, due to non-compliance, the following actions were taken:

Once the finding was identified, a follow-up on compliance with the steps described in section 7.2 about post-mortem inspection, of the *Inspección ante y post mortem en bovinos* (DIPOA-PG-003 (B), version 03), was immediately carried out.

The finding was communicated to the inspection team working at the GICO establishment. A review of all the steps contemplated in said section 7.2 was carried out. The importance of the steps contemplated in section 7.2.1, Head Inspection, were emphasized, highlighting the following: "We proceed to perform a visual inspection of the external part of the head, eyes, ears and frontal turbinate to rule out any contamination or abnormality present".

A review of section 1, Head diseases, of the procedure *Descripción de procesos patológicos y criterios técnicos para el decomiso en bovinos* (DIPOA-PG-003-IN-001 (B), version 05) was carried out.

Pathologies that can be identified by observing the dorsal part of the head (jaundice, cyanosis, infectious diseases) were also indicated.

The procedures above-mentioned can be found at the following link: https://www.senasa.go.cr/informacion/centro-de-informacion/informacion/sgc/dipoa/dipoa-pg-003-inspeccion-ante-y-post-mortem-ovinos/4928-dipoa-pg-003-b-v01-inspeccion-ante-y-post-mortem-en-bovinos/file

https://www.senasa.go.cr/informacion/centro-de-informacion/informacion/sgc/dipoa/dipoa-pg-003-inspeccion-ante-y-post-mortem-ovinos/4927-dipoa-pg-003-in-001-b-v04-descripcion-de-procesos-patologicos-y-criterios-tecnicos-para-el-decomiso-en-bovinos/file

During the first semester of 2024, the results of the monitoring activities contemplated in section 15, Post mortem inspections, will be documented in the SICE audit form, Staff audit report. These monitoring activities will be applied by the MVIO to each IIO based at the GICO establishment. In addition, the area coordinator will audit the section mentioned above with the objective of cross-checking the measures applied.

The personnel audit report that includes section 15, Post-mortem inspections, is attached.

Evidence of meeting minutes and training attendance records are included.

3. The corresponding action plans regarding the findings detected in the establishments are attached.

Should you need additional information, do not hesitate to contact me.

Sincerely,

Dr. Olivet Cruz Vásquez
Director of Safety of Products of Animal Origin

CD. Dr. Warren Hidalgo Jara, Head of Audit Aepartment
Dra. Karla Esquivel Rodríguez, Head of Regulatory Department
Dra. Lilliam Chaves Rodríguez, Registration Department Head
Dra. Laura Villalobos Chaves, Bovine Area Coordinator