



United States Department of Agriculture

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Food Safety and
Inspection Service

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Ministerio de Agricultura y Ganadería (MAG)
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Dear Dr. Rojas,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote verification audit of Costa Rica's inspection system from March 8 to April 6, 2022. Enclosed please find a copy of the final audit report. The comments received from the Government of Costa Rica are included as an attachment to the report.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michelle Catlin".

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF
COSTA RICA

MARCH 8 TO APRIL 6, 2022

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

June 24, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Costa Rica conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from March 8 to April 6, 2022. Due to the global COVID-19 pandemic the audit was conducted remotely using video conferences to conduct interviews and record reviews. 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 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 auditor concluded that Costa Rica's meat inspection system for raw beef is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. Costa Rica's Central Competent Authority (CCA) has required that establishments certified to export raw beef products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their exported products. In addition, the CCA has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety inspection system. An analysis of each component did not identify any findings that represented 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 Costa Rica's food safety inspection system from March 8 to April 6, 2022. The audit began with an entrance meeting via videoconference on March 8, 2022, 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 participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether the food safety inspection system governing raw 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 Products¹
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; 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) recognizes Costa Rica as free of foot-and-mouth disease and with negligible risk for bovine spongiform encephalopathy (BSE).

Prior to the remote 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 remote audit, the FSIS auditor conducted interviews and reviewed records to determine 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.

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,

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

point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from 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 records related to administrative functions and oversight from SENASA headquarters and three local inspection offices within the establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled three meetings each week over a five-week period. Through interviews and record reviews, the FSIS auditor evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditor selected a sample of three establishments from a total of seven establishments certified to export to the United States. This included two beef slaughter and processing (cutting) establishments and one cold storage facility.

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

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

Remote Audit Scope		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> • SENASA, Heredia
Laboratory		1	<ul style="list-style-type: none"> • National Government Reference Laboratory, Heredia - Microbiological Division - Chemical Residue Division
Beef slaughter and processing establishments		2	<ul style="list-style-type: none"> • Establishment No. 8, Coopemontecillos R.L, Alajuela • Establishment No. 12, El Arreo, S.A., Heredia

Cold storage facility	1	<ul style="list-style-type: none"> Establishment No. 401120657, Red Frigorífica Nacional (PIMA), Heredia
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FSIS performed the audit to verify that Costa Rica’s 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.] 601 et seq.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); 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 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 February 1, 2019, to January 31, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 56,438,570 pounds of raw beef exported by Costa Rica to the United States. Of this volume, FSIS also performed reinspection on 7,324,825 pounds at POE for additional types of inspection, including testing for chemical residues and microbiological pathogens (Shiga toxin-producing *Escherichia coli* [STEC] O157:H7, O26, O45, O103, O111, O121, and O145 in beef). As a result of this additional testing, FSIS identified STEC O111 as a POE violation and rejected 42,006 pounds of raw intact beef. FSIS evaluated SENASA’s corrective action responses and closed the POE violation on August 22, 2019.

The last FSIS audit in 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of Costa Rica
<p>Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)</p> <ul style="list-style-type: none"> • The government inspection personnel did not verify that slaughter establishments identified all specified risk materials (SRM) listed in Circular SENASA-DIPOA-1485-2019 in their SRM control programs. However, the FSIS auditors verified that all required SRMs were condemned and sent to inedible rendering. • The government inspection personnel did not verify that products certified to export to the United States were stored separately by time or space from products for other markets.
<p>Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System</p> <ul style="list-style-type: none"> • The government inspection personnel did not verify that the antimicrobial intervention was validated. This finding was also documented in the FSIS 2017 audit report; however,

<p>the corrective actions provided to FSIS were not implemented.</p> <ul style="list-style-type: none"> • The government inspection personnel did not verify that the HACCP plans included all the required HACCP ongoing verification activities. • The government inspection personnel did not verify that the critical control point (CCP) monitoring and verification records included all the HACCP record requirements. This finding was also documented in the FSIS 2017 audit report; however, the corrective actions provided to FSIS were not implemented. • The government inspection personnel did not verify that the CCP corrective actions identified the cause of the deviations.
<p>Component 6: Government Microbiological Testing Programs</p> <ul style="list-style-type: none"> • The CCA did not enforce their requirement that establishments certified to export to the United States sample each production lot of beef manufacturing trimmings and other raw intact beef products that are destined to be a source of ground beef for non-O157 Shiga toxin-producing <i>Escherichia coli</i>.

During the current audit, the FSIS auditor 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 Costa Rica'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 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), which 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 last FSIS audit conducted in 2019. 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 [IA]) who conduct inspection verification tasks in accordance with SENASA's prescribed procedures and frequencies.

The FSIS auditor verified through interviews and record reviews that all inspection personnel, except for contracted inspectors, are hired and paid by the national government. On September 17, 2020, FSIS determined that SENASA's use of contracted inspectors provides an equivalent level of public health protection to that of the FSIS inspection system. 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 the certified establishments. 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 trainings. The FSIS auditor noted that only two contracted inspectors, designated by SENASA as official IAs, are conducting post-mortem inspection examination in one of the three audited establishments. The FSIS auditor confirmed through interviews and record reviews that SENASA maintains ultimate control and supervisory oversight over its inspection personnel including the contracted inspectors in accordance with FSIS equivalence criteria for government inspectors. The FSIS auditor reviewed inspection records associated with 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 appropriate when an establishment does not meet the importing country or Costa Rica's regulatory requirements. At the establishment level, inspection personnel regulatory control actions 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 National Residue Plan (NRP) sampling results. SICE allows inspection personnel to obtain and analyze real time data concerning SENASA's food safety inspection system. The FSIS auditor confirmed that 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's 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 last FSIS audit in 2019.

SENASA has provided regulatory definitions for adulterated and misbranded products that meet FSIS requirements. 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 and must be destroyed. 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), states that the label should not describe or present false, wrong, or misleading information, or create in any way a wrong conception about meat's nature. SENASA's 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 requirements described in DIPOA-PG-001, Exportation of Products and By-products of Animal Origin for Human Consumption (Exportación de Productos, Subproductos y Derivados de Origen Animal para Consumo Humano).

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's requirements. There have been no product recalls in exported products to the United States since the last FSIS audit in 2019.

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. The FSIS auditor reviewed a newly certified establishment's approval process which included inspection personnel's evaluation of establishment written programs and onsite follow-up audits to determine the establishment's compliance with SENASA requirements. The FSIS auditor verified through interviews and record reviews that inspection personnel followed SENASA's approval process and made their determination based on the outcome of the record reviews and onsite inspection verification. No concerns arose regarding implementation of this process.

SENASA only allows raw beef products produced in certified establishments to be exported to the United States. The FSIS auditor verified through interviews and record reviews that certified

establishments only slaughter cattle that were born and raised in Costa Rica and they were not receiving any raw materials from other establishments or other countries for use in products exported to the United States. The MVIs are responsible for reviewing and signing export health certificates of beef products destined for export to the United States. The 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, the MVIs also verify that all official verification samples and establishment monitoring samples are negative for microbial 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.

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 the National Laboratory of Veterinary Services (Laboratorio Nacional de Servicios Veterinarios [LANASEVE]) as the national government reference laboratory. LANASEVE conducts all microbiological testing of official verification samples for products that are destined for export to the United States. Chemical residue testing of official verification samples for products that are destined for export to the United States are conducted by the following laboratories: LANASEVE; two private laboratories in Costa Rica, AGQ Lambda Chemical Laboratory (Laboratorio Químico Lambda), and Laboratory Research Center in Atomic, Nuclear, and Molecular Sciences (Laboratorio Centro de Investigación en Ciencias Atómicas, Nucleares y Moleculares [CICANUM]); and one private foreign laboratory, Eurofins WEJ Contaminants in Germany.

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) Guide 17025:2017. The FSIS auditor reviewed the accreditation certificates and scope of accreditation to ISO 17025:2017 standards for LANASEVE. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support SENASA's inspection program. The FSIS auditor 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 noted that LANASEVE laboratory audit team conducts annual reviews of contracted private laboratories in Costa Rica and Germany as part of government oversight functions over private laboratories that perform analyses of official government samples of 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 detection and quantification of chemical residues and microbiological pathogens in their scope of accreditation. The FSIS auditor verified that LANASEVE ensures traceability throughout sample receipt, analysis, and reporting per their laboratory quality control manual. The FSIS auditor also confirmed that LANASEVE performs timely analysis of samples and reports the results to SENASA headquarters in a timely manner. No concerns arose from the records reviewed.

FSIS analysis and remote verification activities indicate that SENASA has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements. FSIS concludes that SENASA continues to meet the core requirements for this component.

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

The second equivalence component the FSIS 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; continuous inspection during slaughter and at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditor verified through interviews and record reviews that in-plant inspection personnel are required to conduct humane handling and slaughter procedures in accordance with 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's remote audit activities confirmed that humane handling and slaughter of livestock are conducted in accordance with SENASA requirements.

The FSIS auditor verified through interviews and record reviews that all cattle presented for slaughter receive ante-mortem inspection in accordance with Decree No. 29588-MAG-S and DIPOA-PG-003(B) Bovine Ante-mortem and Post-mortem Inspection (Inspección Ante y Post Mortem en Bovinos). SENASA provided inspection documentation to show that in-plant inspection personnel conduct ante-mortem inspection daily and prior to slaughter of livestock. This included Official Bovine/Buffalo Livestock Movement Guide (Guía Oficial de Movilización de Ganado Bovino/Bufalino) to demonstrate livestock health status prior to slaughter and traceability of animals from farm to slaughterhouse. SENASA also provided instructions to its inspection personnel for 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 with their brain tissue samples collected for BSE testing in the government laboratory. No concerns arose regarding SENASA's ante-mortem inspection procedures.

SENASA requires that raw beef products destined for export to the United States are not subject to animal health restrictions by subscribing to APHIS notifications. The export health certificates issued by SENASA also include APHIS requirements. Only those raw beef products that have been previously identified by SENASA as meeting both FSIS and APHIS requirements can be certified to export to the United States.

The FSIS auditor verified through interviews and record reviews that each audited establishment is staffed with a sufficient number of government inspection personnel to conduct post-mortem inspection activities. This included in-plant inspection verification of proper presentation and identification of carcasses and parts; examination of heads, viscera, and carcasses; and disposition of affected carcasses and parts in accordance with Decree No. 29588-MAG-S and DIPOA-PG-003(B). 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) provides descriptions of 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 slaughter operations in accordance with SENASA requirements.

SENASA's labeling requirements for products eligible for export to the United States are described in Law No. 8495 and Decree No. 40006-MEIC-MAG. Additionally, DIPOA-PG-001 requires certified establishments comply with the labeling requirements of importing countries. The export health certificate for beef products destined for export to the United States requires meat products be processed, stored, and transported in a manner to preclude them from being commingled with non-United States eligible meat products. The government inspection personnel verify that products certified to export to the United States are stored separately by time or space from products for other markets. The FSIS auditor was informed that in-plant inspection personnel conduct (at a minimum) a weekly labeling verification of products destined for export to the United States to ensure that the information on the product labels is complete, accurate, and meets FSIS labeling requirements.

SENASA's authority to control condemned animals or inedible materials is accomplished through the application of 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 inspection personnel follow DIPOA-PG-013-IN-004, Identification, Removal, Segregation and Disposal of Specified Risk Materials (Identificación, Remoción, Segregación y Desecho de Materiales Específicos de Riesgo) requirements for the control of SRMs. The FSIS auditor noted that SENASA maintains a definition of SRMs, which is consistent with that outlined in 9 CFR

310.22. The in-plant inspection verification activities include reviewing of establishment's SRM control records, observing establishment's SRMs monitoring procedures, and direct observation of beef carcasses to ensure whether the establishment's procedures comply with SENASA's SRM control requirements. The FSIS auditor's 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; maintained in good conditions; installed in such a way that product does not come into direct contact with the floor or walls; and constructed with materials that facilitate thorough cleaning and disinfection. The FSIS auditor verified through interviews and record reviews that in-plant inspection personnel confirm the sanitary condition of establishments' construction, facilities, and equipment during pre-operational and operational inspections in accordance with SENASA requirements.

The area coordinators (AC) are responsible for conducting the periodic supervisory reviews. During these quarterly reviews, the ACs evaluate the performance of the MVIs concerning proper implementation and verification of regulatory requirements in accordance with DIPOA-PG-002, including: humane handling and slaughter requirements; ante-mortem inspection; post-mortem inspection; microbiology and chemical residue sample collection; labeling procedures; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities, including the critical control point (CCP) verification in the certified slaughter and processing establishments. The FSIS auditor reviewed several periodic supervisory review records for each audited establishment and noted that ACs conducted these reviews in accordance with SENASA requirements. The FSIS auditor also reviewed MVIs' performance evaluations of the 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 inspection personnel to assess their knowledge, skills, and abilities in conducting their assigned inspection verification activities. The FSIS auditor's review of periodic supervisory reviews and performance evaluation reports did not identify any concerns.

FSIS analysis and remote 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.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

Decreets 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 verified through interviews and record reviews that in-plant inspection personnel conduct daily verification of the establishment's sanitary procedures in accordance with SENASA requirements. Inspection verification activities consist of a combination of document reviews, observations, and hands-on inspection verification.

The FSIS auditor verified that in-plant inspection personnel perform daily pre-operational inspection after the establishment had conducted its pre-operational sanitation procedures and determined that the facility was ready for production. The in-plant inspection personnel also perform daily operational sanitation verification by reviewing establishment's sanitary conditions during operations.

The FSIS auditor confirmed through the review of inspection records that the inspection personnel are verifying pre-operational and operational Sanitation SOPs, SPS, and establishment procedures to control contamination throughout the slaughter and dressing operation in accordance with SENASA's requirements. This review included the in-plant inspection personnel verification of corrective actions in response to documented noncompliances. The FSIS auditor verified that inspection personnel took official regulatory control actions sufficient to restore sanitary conditions and prevent the recurrence of direct contamination or adulteration of products when noncompliances occurred.

SENASA's Decree No. 29588-MAG-S requires establishments to ensure sanitary dressing of carcasses throughout the slaughter process. It also 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 inspection personnel conduct daily verification of dressing procedures to ensure establishments comply with sanitary dressing requirements. This included inspection verification of establishment's sanitary practices to prevent potential carcass contamination during hide removal, prevent direct contact between carcasses during dressing procedures, and prevent carcass contamination with gastrointestinal contents during evisceration, including tying of the bung and esophagus. The FSIS auditor reviewed the in-plant inspection daily verification records and found no concerns.

FSIS analysis and remote 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.

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 and Codex Alimentarius Commission's Recommended International Code of Practice - General Principles of Food Hygiene. These require that each establishment's HACCP program 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.

SENASA provided instructions to in-plant inspection personnel on how to verify compliance with the HACCP requirements, including monitoring, verification, recordkeeping, and adequacy of corrective actions taken in response to a deviation from a CCP. The FSIS auditor verified through interviews and record reviews that in-plant inspection personnel conduct daily and weekly verification activities in accordance with SENASA requirements.

SENASA stated that slaughter and processing establishments certified to export to the United States had addressed contamination of beef carcasses with STEC (O157:H7, O26, O45, O103, O111, O121, and O145) as a hazard reasonably likely to occur in their HACCP system. The FSIS auditor noted that audited establishments have implemented controls including the use of a validated intervention (organic acid spray); a zero tolerance CCP to control the presence of fecal material, ingesta, and milk; and additional controls to ensure that carcasses are chilled in a manner sufficient to prevent the outgrowth of microbial pathogens. The FSIS auditor verified that inspection verification methodology includes such activities as evaluating the establishment's written HACCP programs and associated HACCP records, and direct observation of establishments' employees performing HACCP monitoring, verification, corrective actions, and recordkeeping activities. The FSIS auditor's review of HACCP verification records generated by inspection personnel including periodic supervisory reviews did not raise any concerns.

DIPOA-PG-003 (B) describes inspection personnel verification procedures for hands-on verification of cattle carcasses for visible fecal material, ingesta, and milk. The FSIS auditor verified that in-plant inspection personnel perform daily verification of zero tolerance CCPs before the final carcass wash. The inspection verification is conducted based on the number of cattle slaughtered: two carcasses are selected if 100 cattle or less are slaughtered, four carcasses are selected if 101 to 250 cattle are slaughtered, and eight carcasses are selected if 251 to 500 cattle are slaughtered. The FSIS auditor also conducted reviews of inspection generated noncompliance records associated with all CCPs, including antimicrobial intervention and zero tolerance CCPs. The FSIS auditor confirmed that in-plant inspection personnel adequately documented and verified the adequacy of the establishment's corrective actions.

FSIS analysis and remote 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.

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 inspection authorities or by FSIS as potential contaminants.

Costa Rica's 2021 NRP specified the analytes included in the testing program, the methods of analysis to be used, the matrices to be collected, and the total number of samples to be collected and tested.

SENASA has the legal authority and responsibility to regulate, plan, and execute its NRP in accordance with 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 tissues matrices. The FSIS auditor compared in-plant inspection records of chemical residue samples collected in 2021 to SENASA's 2021 Official Sample Schedule and confirmed that in-plant inspection personnel collected all samples as required. The FSIS auditor verified through interviews and record reviews that in-plant inspection personnel follow the procedures 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's requirements.

SENASA implements a hold and test policy for its NRP as described in Section 7.5.4 of DIPOA-PG-004 to ensure that no sampled carcass or part is exported to the United States until acceptable results are obtained. SENASA's maximum residue limits are set to be consistent with the Codex Alimentarius, as well as 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. No concerns arose from these reviews.

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 ACs are notified immediately of noncompliant chemical residue laboratory results. The FSIS auditor reviewed a recent noncompliant case and

associated records to verify the proper implementation of inspection verification and reporting activities were performed in accordance with SENASA requirements. No concerns arose from these reviews.

FSIS analysis and remote 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 destined for human consumption. FSIS concludes that SENASA continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth 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 raw beef products prepared for export to the United States are safe and wholesome.

The FSIS auditor confirmed there have not been any major changes to SENASA's official microbiological verification testing programs or requirements regarding raw beef exported to the United States since the last FSIS audit conducted in 2019.

DIPOA-PG-004 requires that certified establishments develop written sampling procedures for generic *Escherichia coli* (*E. coli*), set the required frequency (one sample per 300 carcasses), identify the locations of sampling (three-site sponge sample from the flank, rump, and brisket for a total of 300 cm²), apply statistical process control to determine lower (m) and upper (M) limits, and take actions to reestablish process control of the slaughter operation if sample results indicate a loss of process control. The FSIS auditor reviewed the in-plant inspection verification records of generic *E. coli* sampling results and found no concerns.

SENASA implements a *Salmonella* testing program that is consistent with the FSIS *Salmonella* performance standards cited in 9 CFR Part 310.25(b). DIPOA-PG-004 provides instruction to inspection personnel concerning the sample collection technique and methodology. Cattle carcasses are selected randomly. The in-plant inspection personnel collect 100 cm² sponge samples from the flank, rump, and brisket for a total of 300 cm² of chilled carcass surface for *Salmonella* testing. The FSIS auditor confirmed that in-plant inspection personnel are required to collect one sample per 300 carcasses. SENASA's *Salmonella* performance standards consist of a collection of 58 samples from slaughtered and chilled cow and bull carcasses, for which no more than two positive samples are permitted. *Salmonella* samples are collected and sealed by inspection personnel prior to submission to LANASEVE. The FSIS auditor reviewed *Salmonella* official sampling records including testing results and found no concerns.

The FSIS auditor verified through interviews and record reviews that SENASA has identified *E. coli* O157:H7 and non-O157 STEC serogroups O26, O45, O103, O111, O121, and O145 as

adulterants in all raw non-intact beef and raw intact beef intended for use in raw non-intact products. In-plant 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 ground beef components in accordance with the requirements of Section 7.5.3. of DIPOA-PG-004 (Sampling for *E. coli* O157:H7 and non-O157 STEC in raw beef in establishments that export to the USA). SENASA requires certified establishments to hold the production lot associated with the establishment's self-monitoring samples or official verification samples for *E. coli* O157:H7 and non-O157 STEC until negative test results have been obtained. The FSIS auditor reviewed in-plant inspection personnel N60 sampling records including testing results and implementation of hold and test policy and found no concerns.

SENASA describes its enforcement strategies in Section 7.2.1.1 of DIPOA-PG-006 (Deviation from *E. coli* O157:H7 and non-O157 STEC resulting from the N60 sampling methodology and aseptic sampling method in establishments that export to the USA) 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 and based on additional findings. SENASA implements its follow-up sampling without waiting for the establishment to start its corrective actions. SENASA's follow-up samples are collected as a 16-sample set and will continue until 16 consecutive negative samples have been collected. The FSIS auditor reviewed official verification sampling results including in-plant inspection follow-up sampling results in response to previous positive results for *E. coli* O157:H7 and non-O157 STEC in audited establishments. The FSIS auditor also reviewed periodic supervisory records and in-plant inspection personnel records associated with SENASA's enforcement activities and found no concerns.

The FSIS auditor verified through interviews and record reviews that LANASEVE conducts all microbiological testing of government verification samples for products that are destined for export to the United States. LANASEVE uses FSIS Microbiology Laboratory Guidebook (MLG) method 4C.07 (*Salmonella* screening) and FSIS MLG method 4.11 (*Salmonella* confirmation). LANASEVE uses the BAX® System Real-Time PCR Assay for *E. coli* O157:H7 (screening) and DuPont™ BAX® System Real-Time PCR Assay STEC Suite for non-O157 STEC (screening). Confirmation for *E. coli* O157:H7 and non-O157 STEC is carried out using the FSIS MLG method 5C.02. The FSIS auditor reviewed the laboratory's implementation of the approved procedures and found no concerns.

FSIS analysis and remote 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. 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 April 6, 2022, with representatives from SENASA. FSIS concluded that Costa Rica's meat inspection system for raw beef products is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. SENASA has required that establishments certified to export beef products to the United States implement sanitation and a HACCP system designed to improve the safety of their exported products. In addition, SENASA has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety inspection system. An analysis of each component did not identify any findings that represented an immediate threat to public health.

Appendix: Foreign Country Response to the Draft Final Audit Report

Heredia, 21 de junio del 2022
SENASA-DG-0614-2022

Señor
Victor González
Especialista Agrícola (USDA/FAS)
San José
Costa Rica

Estimado Señor:

El Servicio Nacional de Salud Animal (SENASA), no tiene observaciones o comentarios para el siguiente documento: Costa Rica FY 2022 Draft Final Audit Report 061122 FINAL. Adicionalmente queremos resaltar y agradecer la transparencia y el profesionalismo expuesto durante todo el proceso de auditoría.

Atentamente,



Dr. German Rojas Hidalgo
Director General
Servicio Nacional de Salud Animal



- CD. Dr. Olivet Cruz Vásquez, Director DIPOA
Dr. Luis Matamoros Cortés, Jefe del Departamento de Auditoría DIPOA
Dra. Laura Villalobos, Coordinador de Área DIPOA

Unofficial translation of SENASA's response:

Dear Sir:

The National Animal Health Service (SENASA), has no observations or comments regarding the following document: Costa Rica FY 2022 Draft Final Audit Report 061122 FINAL. In addition, we would like to highlight and express our gratitude for the transparency and professionalism shown during the entire audit process.

Sincerely,

Dr. German Rojas, Director General, National Animal Health Service.