United States Department of Agriculture

Food Safety and
Inspection Service

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Washington, D.C.
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FEB 12 2020

Dr. Bernardo Jaén Hernandez
Director General, Servicio Nacional de Salud Animal (SENASA)
Ministerio de Agricultura y Ganadería (MAG)
Barreal de Heredia, Jardines de Recuerdo
1 Km to West Campus Benjamin Nunez
Heredia, Costa Rica

Dear Dr. Jaén,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Costa Rica's inspection system from August 19 through August 29, 2019. FSIS provided Costa Rica with a draft audit report, and Costa Rica provided responses to that draft report. FSIS is evaluating your response, including Costa Rica's corrective actions, and will be evaluating those actions to determine whether Costa Rica is maintaining a meat inspection system equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Costa Rica are included as an attachment to the report.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at: InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

COSTA RICA

AUGUST 19 - 29, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW BEEF PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 6, 2020

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) on August 19 - 29, 2019. The purpose of the audit was to determine 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 correctly labeled and packaged. Costa Rica currently exports raw intact beef products to the United States.

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

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

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

- The government inspection personnel did not verify that slaughter establishments identified all specified risk materials (SRMs) 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.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- 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, the corrective actions provided to FSIS were not implemented.
- 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.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The central competent authority (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 *Escherichia coli*.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA'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 United States Department of Agriculture (USDA) conducted an on-site audit of Costa Rica's food safety inspection system August 19 - August 29, 2019. The audit began with an entrance meeting on August 19, 2019 in Heredia, Costa Rica, during which the FSIS auditors 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 Ganaderia* [MAG]). During the exit meeting on August 29, 2019, SENASA officials committed to address the preliminary findings. Representatives from SENASA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. 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 correctly 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– Intact	Raw intact beef	Boneless manufacturing trimmings; carcass (including halves or quarters); cheek meat; cuts (including bone in and boneless meats); edible offal; head meat; heart meat; other intact; primals and subprimals; and weasand meat.
Raw – Non-Intact	Raw ground, comminuted, or otherwise non-intact beef	Beef patty products; bench trim from non-intact; formed steaks; ground beef; hamburgers; non-intact cuts; other non-intact; sausages, and trimmings from non-intact.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Costa Rica as free of foot-and-mouth disease (FMD) and with negligible risk for bovine spongiform encephalopathy (BSE).

[1] All source beef 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 three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (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.

Administrative functions were reviewed at CCA headquarters and five local inspection offices at each establishment. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of five establishments was selected from a total of six establishments certified to export to the United States. This included three slaughter and processing establishments and two cold storage facilities. These establishments produce and export raw - intact beef and raw - non-intact beef products to the United States. The third cold storage facility was audited during the last FSIS audit in 2017.

During the establishment visits, the FSIS auditors paid attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threaten food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2.

Additionally, one government microbiological laboratory and one government residue laboratory were audited to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• National Service of Animal Health, Heredia
Laboratories		2	• National Laboratory of Veterinary Services, Microbiological Division (government), Heredia • National Laboratory of Veterinary Services, Residue Division (government), Heredia

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	2	• Establishment No. 201-102199, Centro Logístico TICAL, Alajuela • Establishment No. 502, Visión Comercial S.A., Alajuela

FSIS performed the audit to verify the food safety inspection system met 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 301 to the end).

The audit standards applied during the review of Costa Rica's inspection system for beef 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 May 1, 2016 to April 30, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 55,092,065 pounds of raw intact beef exported by Costa Rica to the United States. FSIS also performed reinspection on 5,593,934 pounds at POE for additional types of inspection, including testing for chemical residues and microbiological pathogens (Shiga toxin-producing *Escherichia coli* [*E. coli*] O157:H7, O26, O45, O103, O111, O121, and O145 in beef). As a result of this additional testing, 42,006 pounds of raw intact beef – boneless beef manufacturing trimmings were rejected for testing positive for Shiga toxin-producing *E. coli* (STEC) O111.

The previous audit in 2017 identified the following findings:

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- In the audited establishments, the HACCP monitoring (two slaughter establishments) and verification records (three slaughter establishments) did not include the time the monitoring activity occurred.

- In two of the three audited slaughter establishments, the HACCP plan did not provide sufficient supporting documentation for validation of the antimicrobial intervention.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- Costa Rica's routine monitoring program does not require the holding of product prior to receiving test results, as required by FSIS and outlined in Federal Register Vol. 77, No. 237.

Through records review, observation, and interviews of government inspection personnel, the FSIS auditors determined that the CCA did not verify the implementation of the corrective actions associated with the Government HACCP System component. However, the FSIS auditors confirmed that the CCA verified the implementation and effectiveness of the finding related to the Government Chemical Residue Testing component

The FSIS auditors reviewed and analyzed Costa Rica's SRT responses and supporting documentation. During the onsite audit, the FSIS auditors conducted interviews, reviewed records, and made observations 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.

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

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

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

The FSIS auditors verified that there have been no major changes in the CCA's organizational structure since the last FSIS audit conducted in 2017. The national government of Costa Rica organizes and manages the meat inspection system. The CCA is the SENASA within the MAG. SENASA has overall responsibility for animal health, residues, veterinary control of zoonotic diseases, traceability, safety of food of animal origin, animal feed, veterinary medicines, animal genetic material and implementation of international agreements as established in Law No. 8495, *General Law on the National Service of Animal Health (Ley General del Servicio Nacional de Salud Animal)*. SENASA is comprised of directorates, including the Directorate for Food Safety of Products of Animal Origin (*Dirección de Inocuidad de Productos de Origen Animal*

[DIPOA]) and the National Laboratory of Veterinary Services (*Laboratorio Nacional de Servicios Veterinarios* [LANASEVE]).

DIPOA is responsible for the implementation of regulatory requirements pertaining to the production of meat products destined for export to the United States. DIPOA's meat inspection system has two levels: central and establishment. At the central level, DIPOA's headquarters provides direct supervision over establishments certified to export to the United States in accordance with national legislation and FSIS import requirements. At the establishment level, the Veterinary Medical Inspectors (*Médico Veterinario Inspectores* [MVIs]) are responsible for performing inspection and verification procedures as well as oversight of Auxiliary Inspectors (*Inspectores Auxiliares* [IAs]). The government inspection personnel conduct inspection verification tasks, including sampling in accordance with the CCA's prescribed frequency, take and document enforcement actions when necessary, and report verification task results through the chain of command. The CCA has the authority and responsibility to take enforcement actions in accordance with Law No. 8495. The CCA has not implemented any enforcement actions at establishments certified to export to the United States since the last FSIS audit in 2017.

The FSIS auditors verified that the CCA has a definition for adulterated and misbranded products that meets FSIS requirements. Regulation No. 29588-MAG-Ministerio de Salud (S)., *Veterinary Inspection and Sanitary Production and Processing of Meats Regulation (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. 33744-MEIC, *Labeling of Raw, Ground, Marinated, Tenderized Meat and Viscera (Etiquetado de la Carne Cruda, Molida, Marinada, Adobada, Tenderizada y Vísceras),* states that the label to identify meat should not describe or present false, wrong, or misleading information, or create in any way a wrong perception about its nature. The government inspection personnel are required to verify that products to be exported are approved by the importing country and labeled in compliance with the national legislation of the importing country and as indicated by the trading partner as 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)*.

The FSIS auditors verified through documentation, that all establishments certified to export to the United States had written recall and traceback procedures, as required by DIPOA-PG-002-IN-001 (REPO), *Sanitary Requirements for Establishments that Slaughter and Process Ruminants, Horses, Swine and Others (Requisitos Sanitarios para Establecimientos de Sacrificio y Procesadores de Rumiantes, Equinos, Porcinos y Otros)* and Law No. 8495, *General Law on the National Service of Animal Health (Ley General del Servicio Nacional de Salud Animal)*. The CCA will notify the United States of any exported products affected by a recall. The FSIS auditors confirmed that government inspection personnel review and verify the implementation of this requirement at the establishments certified to export to the United States, in accordance with the CCA's requirements. There have been no product recalls related to exported products to the United States since the last FSIS audit in 2017.

The MVIs are responsible for export certification of products to the United States. The CCA provides MVIs with paper export certificates and seals with unique serial numbers for products exported to the United States. The FSIS auditors verified that export certificates, stamps, and seals were securely stored in the local inspection office at each establishment. The MVIs conduct a preshipment 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 stamp and signature on the export certificate. In addition, the MVIs also verify that all government and establishment samples are negative for microbial pathogens and residues prior to signing an export certificate. The FSIS auditors verified through document review, that the MVIs maintained the pertinent documents for each production lot intended for export to the United States.

The CCA ensures that source meat products used in processing operations originate from eligible countries and establishments certified to export to the United States. Through document reviews and interviews, the FSIS auditors verified that establishments certified to export to the United States only slaughter cattle that were born and raised in Costa Rica and they were not receiving raw materials from other establishments or other countries.

SENASA maintains a single set of laws, regulations, and procedures applicable to the establishments certified to export to the United States. SENASA annually develops DIPOA-PG-002-RE-001, *Verification Schedule for Third Party Audits (Cronograma de Verificación para Auditoría de Tercera Parte),* for official controls. The schedule includes verification of sanitation, HACCP, and all other requirements for establishments certified to export to the United States. The FSIS auditors confirmed through document review that the government inspection personnel were conducting the verification tasks at the frequency established in DIPOA-PG-002-RE-001.

SENASA headquarters personnel are notified of FSIS regulatory and policy matters and receive FSIS correspondence through e-mail, then distribute all significant information, including revisions to policy and requirements, to government inspection personnel via e-mail. The FSIS auditors reviewed e-mail from SENASA headquarters to government inspection personnel regarding changes in FSIS policy as well as changes to SENASA policy in response to previous FSIS audit findings.

All SENASA employees are required to commit to independence and impartiality by signing the form SENASA-PG-005-RE-001, *Staff Commitment* (*Compromiso del Personal*) and they are to report any incidents of conflict of interest or commercial, financial, or political pressure by completing form DIPOA-MC-RE-002 *Conflict Statement for Commercial Pressure* (*Declaración de Conflicto por Presión Comercial*). DIPOA's Area Coordinator (AC) conducts supervisory reviews at least quarterly in accordance with SENASA's requirements. During the periodic supervisory reviews, the AC verifies that the government inspection personnel behave in an independent and impartial manner and they are aware of the procedures for reporting conflicts of interest. All SENASA personnel at slaughter and processing establishments that are certified to export to the United States are employed by the government of Costa Rica.

The FSIS auditors verified that government inspection personnel assigned to slaughter and processing establishments certified to export to the United States receive payment from SENASA by reviewing electronic copies of pay stubs. SENASA has 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 an official inspector to a cold storage facility that does not conduct export certification of products destined to the United States. Products are stored at this cold storage facility and returned to the producing establishment for export certification. OIRSA performs the administrative functions related to the official inspector, but SENASA is responsible for the inspector's training, supervising, and appraisals.

SENASA assigns government inspection personnel to establishments certified to export to the United States, and ensures that they have appropriate educational credentials, training, and experience to carry out their inspection tasks. The IAs are required to complete six to nine months of food safety training at the National Training Institute. The MVIs are graduates of government-approved universities and members of the National College of Veterinarians. Prior to assuming their official responsibilities, the MVIs receive on-the-job training on veterinary inspection requirements to supplement their academic qualifications. The FSIS auditors verified through records that government inspection personnel were evaluated for their competence before being assigned to the establishments certified to export to the United States and receive ongoing training as needed to perform their assigned duties. The FSIS auditors reviewed the training records and verified that both inspection and laboratory personnel have attended the ongoing training.

The CCA maintains the legal authority to certify and de-certify establishments that export to the United States. The FSIS auditors verified that the CCA's document DIPOA-PG-001 provides requirements for exporting establishments and instructions for verification of initial and annual certification for export of meat products to the United States by DIPOA. The requirements include that (a) each establishment present, along with their applications for certification, a current operating permit from the Ministry of Health, (b) a prerequisite program that includes the general principles described in the Codex Alimentarius Commission's *Recommended International Code of Practice - General Principles of Food Hygiene;* (c) a HACCP program; and (d) a copy of the veterinary operation certificate issued by SENASA.

The FSIS auditors verified that DIPOA reviews the required documents submitted by each exporting establishment, conducts an on-site audit of the establishment, and evaluates the establishment's ability to meet the CCA's regulatory requirements prior to granting renewal of certification to export meat products to the United States. During the audit, the FSIS auditors reviewed and verified the process of issuing an inspection license at a recently approved cold storage facility that conducts certification of products to export to the United States. No concerns arose regarding the CCA's implementation of this process.

The FSIS auditors verified that the CCA provides administrative and technical support to LANASEVE, which is the national government reference laboratory for the testing of official verification samples collected from products that are destined for export to the United States. 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) 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*. The CCA is responsible for designating official laboratories and conducts audits every three years of the designated laboratories in order to verify that the ISO 17025:2005 standards are being met and accreditation of methods and designation requirements are being achieved. LANASEVE conducts all microbiological testing and analysis of government verification samples for products that are destined for export to the United States.

Residue testing of government verification samples for products that are destined for export to the United States is conducted by the following laboratories: LANASEVE; two private laboratories in Costa Rica, 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 two private foreign laboratories, Eurofins WEJ Contaminants in Germany and ALS Laboratory Group in the United States. The FSIS auditors reviewed the accreditation certificates and scope of accreditation to ISO 17025:2005 standards for LANASEVE and the four private laboratories. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support the CCA's inspection program.

The FSIS auditors verified that LANASEVE's internal quality management system carries out annual proficiency testing on its laboratory personnel. The FSIS auditors verified the CCA reviews intra-lab and inter-lab proficiency testing to ensure that each analyst possesses the required competencies necessary to conduct the analyses. The FSIS auditors also reviewed the inter-lab proficiency tests results from 2018 for the laboratory technicians at LANASEVE and confirmed that all the test results were satisfactory for raw beef samples. The FSIS auditors reviewed the CCA's oversight activities, including the CCA's audit reports for LANASEVE, Lambda Chemical Laboratory, CICANUM, and Eurofins WEJ Contaminants. No concerns arose as the result of these reviews.

The FSIS auditors verified that the CCA's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component. However, FSIS auditors describe in Component 6 (below) a failure by the CCA to enforce the CCA's requirement for establishments sampling of each production lot of beef manufacturing trimmings and other raw ground beef components for non-O157 Shiga toxin-producing *Escherichia coli*.

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 of six equivalence components the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem (AM) inspection of animals; post-mortem (PM) inspection of each and every carcass and 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 auditors verified that MVIs, with the assistance of IAs, are required to conduct AM inspection daily, prior to slaughter, in accordance with DIPOA-PG-018(B), *Ante-Mortem Inspection of Bovines (Inspección Ante Mortem en Bovinos)*. The AM inspection task includes verification of animal health, welfare, and origin. Each establishment is required to have a platform and adequate lighting for AM inspection and designate an isolation pen for further examination of suspect animals, as required by Regulation No. 29588-MAG-S. MVIs observe all animals at rest and in motion from both sides. Only animals that pass AM inspection and have been properly documented on the AM inspection card are eligible for slaughter. In addition, MVIs verify that animals are transported in a manner to minimize the risk of injury, stocked in a roofed pen that is constructed in a way to prevent injuries, have access to water, and are moved without sharp instruments or objects. SENASA has provided instructions describing disease conditions warranting condemnation of animals at AM inspection. Non-ambulatory disabled cattle, as well as cattle showing neurological symptoms, are to be humanely slaughtered and samples are collected from their brain tissues for BSE testing, and then the carcass is either buried with lime or burned.

Furthermore, animals are stunned before slaughter to avoid unnecessary suffering. The MVIs receive specific training on verifying stunning effectiveness. The MVIs confirm once a week that stunning is quick and effective. Through interviews and direct observation, the FSIS auditors verified that stunning was effective and that the animals were rendered insensible to pain before shackling, hoisting, and cutting. The FSIS auditors did not identify any areas of concern during the interviews or with direct observations. Law No. 7451, *Animal Welfare Law (Ley de Bienestar de los Animales),* outlines the administrative sanctions that SENASA would impose in the event of inhumane handling of animals at the slaughter establishments. After observing MVIs performing AM inspection verification and reviewing the records associated with their verification activities, the FSIS auditors concluded that MVIs were conducting AM inspection and humane handling verification in a manner that is consistent with FSIS requirements.

The FSIS auditors verified that government inspection personnel perform official controls and inspection activities continuously during slaughter operations and once per shift during

processing. The FSIS auditors observed and verified that proper presentation, identification, examination, and disposition of each and every carcass, parts, and accompanying viscera were being implemented. The FSIS auditors observed that establishment personnel stamp the carcasses and corresponding heads and viscera with the same identification numbers. The FSIS auditors observed the performance of government inspection personnel examining the heads, viscera, and carcasses. The FSIS auditors verified that government inspection personnel were conducting online PM inspection of every carcass to ensure they were free from pathological conditions in accordance with DIPOA-PG-013-IN-002, *Technical Criteria for Condemnation of Pathological Conditions in Cattle (Criterios Técnicos para el Decomiso de los Estados Patológicos en Bovinos)*, or any contamination prior to applying the mark of inspection. The FSIS auditors verified through records that government inspection personnel documented results of PM inspection, including any retained or condemned carcass.

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

DIPOA-PG-013-IN-004, *Identification, Removal, Segregation and Disposal of Specified Risk Materials (Identificación, Remoción, Segregación y Desecho de Materiales Específicos de Riesgo),* provides requirements for domestic and export beef slaughter establishments regarding the handling of SRMs to ensure they do not enter the human or animal food chain. However, this document does not identify skulls and trigeminal ganglia as SRMs; therefore, SENASA issued *Circular SENASA-DIPOA-1485-2019* for establishments certified to export to the United States. The circular requires establishments to have a procedure for segregation of the following SRMs: brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), dorsal root ganglia, distal ileum of the small intestine, and the tonsils of all cattle.

When penetrating stunners are used, SENASA requires additional measures to keep the brain inside the skull during processing. The FSIS auditors visually verified that the two slaughter establishments that used penetrating stunners sealed the hole in the frontal bone with a plug. SENASA does not permit the separation of muscular tissue from the skull and the vertebral column to be conducted by methods that utilize high pressure, such as advanced meat recovery systems. SENASA requires establishments to have containers that are designed to ensure SRMs can be collected and stored to prevent cross-contamination with other products. SENASA requires SRM containers to be identified with the Spanish acronyms for SRM or BSE.

The FSIS auditors verified that the tonsils, distal ileum, brain, eyes, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglion were collected in containers identified with the Spanish acronyms for SRM or BSE, however, the skull and trigeminal ganglia were collected in containers marked “inedible” without the Spanish acronyms for SRM or BSE. The

FSIS auditors reviewed the SRM control program at the beef slaughter establishments certified to export to the United States and found the following:

- The government inspection personnel did not verify that slaughter establishments identified all SRMs 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 CCA requires that establishments segregate and store inedible products in a separate area from edible products. Containers used for collecting inedible products must be marked and distinguished from other containers. The FSIS auditors verified that government inspection personnel are responsible for confirming that products that do not comply with regulations are withheld, withdrawn from trade or circulation, confiscated, denatured, and destroyed. The FSIS auditors observed the disposal process of condemned and inedible materials at each audited establishment and found no concerns.

The periodic supervisory reviews include an evaluation of AM and PM inspection, export certification, sanitation verification, HACCP verification, sampling, and recordkeeping in accordance with DIPOA-PG-002-IN-002, *First Party Audit for Personnel Supervision (Auditoría de Primera Parte para Supervisión del Personal)*. The FSIS auditors reviewed supervisory records maintained at SENASA headquarters and local inspection offices for each visited establishment. Through interviews and record reviews, the FSIS auditors verified that DIPOA's area coordinators (ACs) conducted periodic supervisory visits to each establishment certified to export to the United States at the required frequency. The AC appraised the performance of the MVIs while the MVIs assessed the performance of the IAs under their supervision.

DIPOA-PG-001 requires that establishments approved to export their products to the United States comply with the labeling requirements of 9 CFR 317.2. DIPOA-PG-002-IN-001 (REPO) requires government inspection personnel to verify that products to be exported meet all requirements (including labeling requirements) of the importing country. The export certificate for products destined for the United States requires that United States eligible meat products to be processed, stored, and transported in a manner to preclude them from being commingled with non-United States eligible meat products. The FSIS auditors identified isolated problems related to the verification of export label requirements that are documented on the individual establishment checklists attached to this report (Appendix A). The FSIS auditors observed the following systemic finding related to government inspection personnel verification of export requirements:

- 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.

Despite the above-mentioned isolated and systemic findings, the FSIS auditors concluded that Costa Rica's raw beef inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (sanitation SOPs) to prevent direct product contamination or insanitary conditions.

Regulation No. 29588-MAG-S requires slaughter establishments to develop, implement, and maintain written sanitation SOPs and implement sanitary dressing procedures in order to prevent direct product contamination or the creation of insanitary conditions. Establishments are also required to have a written program of cleaning and disinfection and address pre-operational, operational, and post-operational activities. Government inspection personnel verify compliance with sanitation requirements daily by direct observation and review of records as described in DIPOA-PG-002-IN-001 (REPO). The document provides instructions to government inspection personnel for verifying that the establishments have adequately implemented prerequisite programs such as good manufacturing practices, sanitation SOPs, and sanitation performance standards. If insanitary conditions or product contamination are found, Regulation No. 29588-MAG-S gives government inspection personnel the authority to reduce line speed or suspend operations until the establishment implements corrective actions.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs in all the visited establishments. The FSIS auditors observed government inspection personnel performing pre-operational sanitation SOP verification at one beef slaughter establishment and observed them thoroughly inspecting equipment and food contact surfaces and taking regulatory control actions in response to identified noncompliance. The FSIS auditors also observed government inspection personnel's verification of operational sanitation SOPs and compared their overall sanitary conditions to the inspection verification documentation.

Government inspection personnel activities included direct observation of operations and review of the establishment's records. Through records review, the FSIS auditors confirmed that government inspection personnel were reviewing the results of any sampling programs the establishment uses to monitor or assess the effectiveness of their sanitation SOPs. The FSIS auditors reviewed SENASA's documentation of sanitation noncompliance, including those documented during the current FSIS audit. The FSIS auditors did not have any concerns with the documentation of sanitation noncompliance or the verification of the establishment's corrective actions.

The establishments are required to take necessary measures to prevent direct product contamination or creation of insanitary conditions. Regulation No. 29588-MAG-S requires establishments to remove the hide prior to evisceration, bag and tie the esophagus and rectum, and take other measures to prevent carcass contamination with gastrointestinal contents. Establishments are required to keep carcasses separated from one another to avoid contact during dressing to minimize risk of cross contamination. Regulation No. 29588-MAG-S mandates that

any contamination with gastrointestinal contents, purulent material, urine, or other contaminants on carcasses be removed by cutting the affected tissue. Through observation, the FSIS auditors verified the establishments' procedures to ensure that carcasses were not contaminated with fecal material, ingesta, or milk prior to the final carcass wash, and that head, cheek, and weasand meat were not contaminated with fecal material, ingesta, or milk at the completion of the harvesting process. Through observation, interviews, and records review, the FSIS auditors confirmed that government inspection personnel were verifying sanitary dressing at the beef slaughter establishments. No concerns arose as the results of these observations, interviews, or record reviews.

DIPOA-PG-002-IN-001(REPO) provides instructions to government inspection personnel for the official controls of establishment construction, facilities, and equipment. SENASA requires that facilities and equipment be constructed in a manner that prevents direct product contamination or the creation of insanitary conditions; be maintained in good condition; be installed in such a way that product does not come into direct contact with the floor or walls; and be constructed with materials that facilitate thorough cleaning and disinfection. The FSIS auditors verified through documentation that SENASA provides inspection instructions to their personnel to confirm the establishment's construction, facilities, and equipment during pre-operational and operational verification of sanitary conditions.

The FSIS auditors observed offline government inspection personnel conducting hands-on verification of the establishment's zero tolerance critical control point (CCP), to verify the critical limit of zero visible fecal material, milk, or ingesta on livestock carcasses, before the final wash. The FSIS auditors confirmed though records review and interviews that offline government inspection personnel verify zero tolerance daily as part of their HACCP verification tasks and document any identified deficiencies, however, the FSIS auditors observed inconsistencies in the number of carcasses selected and the method of carcass selection between establishments.

The FSIS auditors verified that inspection and establishment records mirrored the actual sanitary conditions of the establishments, although the FSIS auditors identified isolated deficiencies documented on the individual establishment checklists attached to this report (Appendix A). SENASA's food safety inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

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

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

SENASA requires slaughter and processing establishments certified to export to the United States to design, implement, and maintain HACCP systems according to the Codex Alimentarius

Commission's *Recommended International Code of Practice - General Principles of Food Hygiene.* This includes a flow diagram, hazard analysis, HACCP plan for hazards identified as likely to occur, intended use of product, monitoring and verification activities, corrective actions, reassessment, and records supporting the implementation of the HACCP system. In addition, the establishment's documents must support the decisions made in the hazard analysis and HACCP plan, including the validation of the HACCP system.

The FSIS auditors reviewed the supporting documentation for the slaughter establishments' HACCP systems. The FSIS auditors found that one establishment did not have scientific data to support their antimicrobial intervention, one establishment did not monitor the critical operational parameters included in the scientific support for their antimicrobial intervention, and neither establishment collected validation data for their antimicrobial interventions. Through records review, the FSIS auditors evaluated the design of the establishments' HACCP plans. At two establishments, the ongoing verification activities did not include calibration of process monitoring equipment and one establishment did not conduct direct observation of monitoring. The FSIS auditors identified the following findings:

- The government inspection personnel did not verify that the antimicrobial intervention was validated. This finding was also documented in the 2017 audit report. Therefore, the corrective actions provided to FSIS in response to the FSIS 2017 audit finding were not implemented.
- The government inspection personnel did not verify that the HACCP plans included all the required HACCP ongoing verification activities.

Instructions for additional HACCP regulatory requirements in establishments certified to export to the United States are documented in DIPOA-PG-005, *Verification and Sampling Activities for the Determination of* E. coli O157:H7 and non-O157 STEC *(Actividades de Verificación y Toma de Muestras para la Determinación de Escherichia coli O157:H7 y Otras E. coli Productoras de Shiga Toxina [STEC] en Carne de Res Cruda),* which requires establishments certified to export to the United States to identify *E. coli* O157:H7 and non-O157 STEC as hazards and to specify they have an intervention for *E. coli* O157:H7 and non-O157 STEC. SENASA also requires establishments certified to export to the United States to have a zero tolerance CCP for the presence of fecal matter, ingesta, and milk in their HACCP plans. Through records review, the FSIS auditors verified that all slaughter establishments certified to export to the United States identified *E. coli* O157:H7 and non-O157 STEC as hazards and applied antimicrobial solutions to carcasses.

The FSIS auditors verified that the establishments certified to export to the United States identified microbiological hazards associated with fecal matter, ingesta, and milk as reasonably likely to occur and established zero tolerance CCPs and conducted 100 percent monitoring of beef carcasses for the presence of fecal matter, ingesta, and milk. The FSIS auditors reviewed the establishments' CCP monitoring, verification, and corrective action records and observed the establishment conduct monitoring and verification activities. The FSIS auditors identified that the monitoring records for the zero tolerance CCPs did not include the time the event occurred.

Additionally, there were numerous errors on the CCP monitoring and verification records including missing initials/signatures, missing times, missing dates, and errors corrected by writing over the incorrectly recorded value. Finally, the corrective actions in response to the deviations did not correctly identify the cause of the deviations. The FSIS auditors identified the following findings:

- The government inspection personnel did not verify that the CCP monitoring and verification records included all the HACCP record requirements. This finding was also documented in the 2017 audit report. Therefore, the corrective actions provided to FSIS in response to the FSIS 2017 audit finding were not implemented.
- The government inspection personnel did not verify that the CCP corrective actions identified the cause of the deviations.

DIPOA-PG-002-IN-001 (REPO) provides an overview of HACCP inspection verification activities. The government inspection personnel review the results of the establishments' microbiological testing programs once a week and conduct daily verification activities for HACCP requirements. The government inspection personnel are responsible for verification of the establishment's flow chart, hazard analysis, HACCP plan, and all other HACCP requirements through direct observation, hands-on activities, and review of records. The FSIS auditors verified through interviews and review of inspection records that government inspection personnel conduct daily HACCP verification activities. Except for the HACCP findings above, SENASA continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes government inspectors' random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

The 2017 FSIS audit identified that Costa Rica's government inspection personnel were not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate. The FSIS auditors confirmed SENASA's response that this finding was resolved by observing carcasses and parts intended for export to the United States being retained under official control in the coolers pending acceptable residue results. The FSIS auditors reviewed records of product retention and release once acceptable residue results were received.

Prior to the on-site visit, FSIS residue experts reviewed the 2019 Residue Plan for Bovines, associated methods of analysis, and additional SRT responses outlining the structure of Costa

Rica's chemical residue testing program. There have not been any POE violations related to this component since the 2017 FSIS audit.

Law No. 8495 gives SENASA the legal authority to administer; plan; direct; and take veterinary or sanitary measures on the control, security, and safety of products and by-products of animal origin, regarding food additives, veterinary medicine residues, pesticides, and other chemical, biological, or biotechnological origin contaminants. Costa Rica's National Residue Program (NRP) specifies the analytes to be detected, the method of analysis to be used, the species, the matrix to be collected, the tolerance, the action level, and the total number of samples to be collected. A residue program coordinator, who reports directly to SENASA's general director, coordinates with representatives from SENASA's directorates to execute the NRP. SENASA creates an *Official Sample Schedule (Cronograma Oficial de Muestreo)* for each establishment that includes the date for collection, type of analysis, species, and tissues matrix.

At the establishment level, the government inspection personnel follow the procedures in DIPOA-PG-004, *Sampling in Establishments of Products, By-Products and Derivatives of Animal Origin for Human Consumption (Muestreo en Establecimientos de Productos, Sub Productos y Derivados de Origen Animal para Consumo Humano),* regarding collecting, handling, and transporting the samples collected for delivery to the official laboratories. The government inspection personnel conduct the sampling according to the establishment-specific document *Official Sample Schedule*. The government inspection personnel are authorized to carry out additional sampling on suspicion of contamination of the products. The FSIS auditors compared the documentation of the samples collected in 2019 to the establishment specific *Official Sample Schedule* and confirmed the samples were collected as required. The FSIS auditors also reviewed the residue results for the 2019 submitted samples and did not identify any results that exceeded the permitted levels.

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 head of the registration department at DIPOA receives notifications of noncompliant results from the official laboratories. The head of the registration department electronically notifies the establishment and copies the DIPOA AC and the MVI. SENASA requires and verifies that establishments take corrective measures in response to results that exceed the permitted levels. In the case of violative results of veterinary drugs, the Veterinary Medicines Directorate is also notified, and they initiate an investigation to include research, collection of evidence, and a farm visit. A hard copy report of negative residue results is sent to the DIPOA AC, the MVI, and the establishment.

The FSIS auditors visited the LANASEVE residue laboratory and interviewed the LANASEVE analysts to assess their technical competency, training, and knowledge of the analytical methods used to detect chemical residues. The FSIS auditors' document reviews included an evaluation of management system documents, sample handling and frequencies, timely analyses, data reporting, tissue matrices for analysis, and minimum detection levels. The FSIS auditors observed LANASEVE's web-based system for tracking and reporting of all samples received to

ensure accuracy. The FSIS audit of the laboratory's technical competency, training, and analysis used to detect chemical residues did not identify any areas of concern. The FSIS auditors concluded that the CCA's meat inspection system has the regulatory requirements for a chemical residue testing program that is organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

DIPOA-PG-006 states that the head of the registration department at DIPOA receives notifications of noncompliant microbiological results from the official laboratories. The head of the registration department electronically notifies the establishment and copies the DIPOA AC and the MVI. A hard copy report of negative microbiological results is sent to the DIPOA AC, the MVI, and the establishment. The MVIs review the results of the establishments' microbiological testing programs once a week.

Establishments are required to conduct generic *E. coli* testing on carcasses in accordance with the procedures described in DIPOA-PG-004 in order to verify process control sufficient to prevent fecal contamination. SENASA does not have a requirement for the frequency of generic *E. coli* testing. The FSIS auditors reviewed the written generic *E. coli* sampling and testing programs at the slaughter establishments certified to export to the United States and found that they have elected to collect samples for generic *E. coli* analysis at a frequency of one per 300 carcasses. Each establishment uses statistical process control to determine the lower control limit, upper control limit, and marginal range for generic *E. coli* results according to their historical data. SENASA has recently changed the permitted number of samples testing positive in the marginal range from 3 out of 13 consecutive samples to 2 out of 13 consecutive samples. SENASA is in the process of updating their written procedures to reflect this change. The FSIS auditors reviewed the establishments' generic *E. coli* test results and found that there were no samples exceeding the established upper control limits.

SENASA conducts sampling of the carcass surface for analysis of *Salmonella* on 1 out of every 300 carcasses according to DIPOA-PG-004. SENASA conducts *Salmonella* testing on by-products produced at establishments certified to export to the United States four times a year according to the establishment-specific *Official Sampling Schedule*. DIPOA-PG-006 states that the maximum number of positives allowed for carcasses is 2 out of 58. SENASA has not defined a maximum number of positives allowed in by-products. The FSIS auditors observed the government inspection personnel at one slaughter establishment collecting a sponge sample of the carcass surface for official *Salmonella* testing. The government inspection personnel followed the sampling methodology described in Section 7.2.3 of DIPOA-PG-004. The FSIS auditors reviewed official inspection records at the visited slaughter establishments and

concluded that the *Salmonella* process control sampling programs were implemented as described. The FSIS auditors reviewed the official *Salmonella* sample results from 2019 and found that they did not exceed the permitted number of positive samples.

At establishments certified to export to the United States, SENASA conducts sampling for *E. coli* O157:H7 and non-O157 STEC once a week on a production lot of beef manufacturing trimmings and once a week on a production lot of other ground beef components in accordance with the requirements of DIPOA-PG-005. The slaughter establishments consider a production lot to be the entire day's production volume. The government inspection personnel randomly select the day of the week to collect the sample and select products from the first case, the last case, and throughout production. The FSIS auditors observed government inspection personnel collecting beef manufacturing trimmings using the N60 methodology and collecting other ground beef components for *E. coli* O157:H7 and non-O157 STEC testing. The final weight for the beef manufacturing trimmings and the other ground beef components must be 325 ± 32.5 grams. If the sample is outside of this weight range, it will be rejected by LANASEVE. The government inspection personnel inform the establishment to keep the production lot associated with official samples for *E. coli* O157:H7 and non-O157 STEC under control until negative results have been obtained.

The FSIS auditors verified that SENASA follows their official sampling procedure for sampling beef manufacturing trimmings and other ground beef components for *E. coli* O157:H7 and non-O157 STEC. The FSIS auditors reviewed the official sample results for *E. coli* O157:H7 and non-O157 STEC and identified that during the 16-sample set, performed by SENASA, in response to an FSIS POE violation for STEC in beef manufacturing trimmings, there was an *E. coli* O157:H7 positive result from a sample that was collected. The FSIS auditors verified that SENASA retained the affected product and required the establishment to implement corrective actions. After the positive result, SENASA re-started the 16-sample set. The FSIS auditors verified that the 16 samples, following the *E. coli* O157:H7 positive result, were all negative.

DIPOA-PG-005 requires that establishments certified to export to the United States sample each production lot of beef manufacturing trimmings and other raw ground beef components for *E. coli* O157:H7 and non-O157 STEC. The FSIS auditors verified that establishments certified to export to the United States were sampling every lot of beef trimmings and other raw ground beef components for *E. coli* O157:H7 only but the establishments were not sampling every lot for non-O157 STEC. The FSIS auditors identified the following finding:

- 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 *Escherichia coli*.

The FSIS auditors visited LANASEVE, the national government reference laboratory for microbiological analyses. LANASEVE conducts all microbiological testing of government verification samples for products that are destined for export to the United States. For

Salmonella testing, LANASEVE follows the enrichment protocol described in Microbiology Laboratory Guidebook (MLG) method 4.06, *Isolation and Identification of Salmonella from Meat, Poultry, Pasteurized Egg and Catfish Products*. LANASEVE uses the Dupont BAX System Polymerase chain reaction (PCR) assay for *Salmonella* screening and follows the confirmation procedure in MLG 4.09, *Isolation and Identification of Salmonella from Meat, Poultry, Pasteurized Eggs, and Siluriformes (Fish) Products and Carcass and Environmental Sponges*. LANASEVE uses the Dupont BAX System PCR assay for screening for *E. coli* O157:H7 and non-O157 STEC. LANASEVE follows MLG 5C, *Detection, Isolation and Identification of Top Seven Shiga Toxin-Producing Escherichia coli (STEC) from Meat Products and Carcass and Environmental Sponges* for confirmation testing with the modification of using the BAX System assay in place of the Bio-Rad iQ-Check.

During the LANASEVE audit, the FSIS auditors observed their sample receipt and handling procedures. To ensure the chain of custody of the samples, a security bag is used to protect the contents and prevent tampering, and the samples arrive in a locked cooler. The technicians verified that the samples arrived at the appropriate temperature and within the permitted timeframe, complied with the weight requirement, and came with complete and accurate paperwork. The FSIS auditors observed the laboratory technician reject a sample that arrived without the MVI's signature.

The FSIS auditors reviewed the most recent audit report issued by ECA for LANASEVE. The FSIS auditors also verified that LANASEVE also performs its internal audits according to the Quality Assurance Manual. The FSIS auditors' observation of the laboratory processes and review of the laboratory documents including the annual audit reports and corresponding follow-up reports found no concerns within the CCA's documentation of its laboratory oversight activity.

Except for the finding above related to SENASA's verification of establishments' failure to test for non-O157 STEC in beef manufacturing trimmings and ground beef components, FSIS concludes that SENASA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held with SENASA officials on August 29, 2019, in Heredia, Costa Rica. The on-site audit did not identify any findings that represented an immediate threat to public health. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

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

- The government inspection personnel did not verify that slaughter establishments identified all SRMs 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.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- 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, the corrective actions provided to FSIS were not implemented.
- 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 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.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- 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 *Escherichia coli*.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

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

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 Montecillos, Alajuela Costa Rica	8/21/2019	8	Costa Rica
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	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	O
35. Residue	
Part E - Other Requirements	
36. Export	X
37. Import	O
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.	

60. Observation of the Establishment

SSOP – Ongoing Requirements

10. *Implementation of SSOPs, including monitoring of implementation*

- During pre-operational Sanitation SOP verification, the government inspection personnel did not identify fat particles, too numerous to count, from the previous production day on the overhead structures near the Viscera Inspection station.

HACCP Systems – Basic Requirements

15. *Content of HACCP Plan*

- For critical control point (CCP) 3, Beef Carcass Temperature, of the Beef Slaughter HACCP plan, the frequency of the calibration of the thermometers was not listed as a verification activity. The government inspection personnel did not verify the HACCP plans included all the required HACCP ongoing verification activities.

HACCP Systems – Ongoing Requirements

19. *Verification and Validation of HACCP Plan*

- The establishment was using FSIS Directive 7120, *Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products*, as scientific support for their antimicrobial concentration and the establishment did not collect validation data for their antimicrobial intervention. The government inspection personnel did not verify the validation of the antimicrobial intervention. This finding was also documented in the 2017 audit report. Therefore, the Central Competent Authority (CCA) did not verify the implementation of the corrective actions provided to FSIS in response to the FSIS 2017 audit finding.

22. *Records documenting: the written HACCP plan, monitoring of the CCPs, dates and times of specific event occurrences*

- The zero tolerance HACCP monitoring records for beef carcasses did not include the time the event occurred. This finding was also documented in the 2017 audit report. Therefore, the CCA did not verify the implementation of the corrective actions provided to FSIS in response to the FSIS 2017 finding.
- Multiple zero tolerance HACCP monitoring records did not include the result of the verification activity. The government inspection personnel did not verify the establishment's HACCP monitoring records complied with the HACCP record requirements.
- The corrective actions taken after a deviation from the CCP2, antimicrobial concentration, did not include the identification of the cause of the deviation. The government inspection personnel did not verify the actions taken by the establishment after a deviation to a critical limit complied with the HACCP corrective action requirements.
- The preshipment review did not review records associated with the production of the product included in the shipment but reviewed records at the end of each day for that day's production and it did not include a review of sample results. The government inspection personnel did not verify that prior to shipping product, the establishment reviewed the records associated with the production of that product.

Other Requirements

36. *Export*

- In the cold storage rooms (freezers and tunnels), United States-eligible beef products were commingled with (stacked on the same pallets as) non-United States-eligible beef products. 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, in the freezers, tunnels, and staging areas.

39. *Establishment Construction/Maintenance*

- Extensive rust buildup was observed on overhead structures in the loading dock. The government inspection personnel did not verify the establishment's structures were kept in good repair.

Inspection Requirements

55. *Post-Mortem Inspection*

- The establishment's Specified Risk Material (SRM) control program does not list the skull as an SRM. The government inspection personnel did not verify the establishment identified all SRMs listed in *Circular SENASA-DIPOA-1485-2019* in their SRM Control Programs. However, FSIS auditors verified that all SRMs, including the skulls, were condemned and sent to inedible rendering.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	8/21/2019

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 2 Kilometros Oeste del Aeropuerto International Juan Santamaria Alajuela - Costa Rica	8/22/2019	9	Costa Rica
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	X
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	O
35. Residue	
Part E - Other Requirements	
36. Export	X
37. Import	O
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
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60. Observation of the Establishment

HACCP Systems -- Ongoing Requirements

19. *Verification and Validation of HACCP Plan*

- The establishment did not monitor the critical operating parameters identified in their supporting documentation for their antimicrobial intervention and they did not collect validation data for their antimicrobial intervention. The government inspection personnel did not verify the validation of the establishment's antimicrobial intervention. This finding was also documented in the 2017 audit report. Therefore, the Central Competent Authority (CCA) did not verify the implementation of the corrective actions provided to FSIS in response to the FSIS 2017 audit finding.

22. *Records documenting: the written HACCP plan, monitoring of the CCPs, dates and times of specific event occurrences*

- The zero tolerance HACCP monitoring records, critical control point (CCP) 1, for beef carcasses did not include the time the event occurred. This finding was also documented in the 2017 audit report. Therefore, the CCA did not verify the implementation of the corrective actions provided to FSIS in response to the FSIS 2017 audit findings.
- The corrective actions taken after a deviation from the zero tolerance critical limit for beef edible offals did not identify the cause of the deviation. The government inspection personnel did not verify the actions taken by the establishment after a deviation to a critical limit complied with the HACCP corrective action requirements.
- The corrective actions taken after a deviation from the zero tolerance critical limit for the beef carcasses did not include measures to prevent recurrence; instead only listed regular routine activities. The government inspection personnel did not verify the actions taken by the establishment after a deviation to a critical limit complied with the HACCP corrective action requirements.
- The records associated with the monitoring of CCP3, Beef carcass temperature, were not authenticated. The government inspection personnel did not verify the establishment's HACCP monitoring records complied with the HACCP record requirements.

Economic/Wholesomeness

25. *General Labeling*

- The FSIS-approved label for "Beef Scalded Burnt Smoked Skin" required the removal of the words "Burnt Smoked" as part of the name of the product; however, the establishment is still shipping the product under the name of "Beef Scalded Burnt Smoked Skin." The government inspection personnel did not verify the labels complied with the label approval.
- "Beef Face" is not a permitted product description. The government inspection personnel did not verify the establishment's labels used approved product descriptions.

Other Requirements

36. *Export*

- In the cold storage rooms (freezers and tunnels) and staging area, United States-eligible products were commingled with (stacked on the same pallets as) non-United States-eligible products. 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, in the freezers, tunnels, and staging areas.

39. *Establishment Construction/Maintenance*

- Rust buildup was observed on a coil above the shipping dock door and on overhead structures in the production area. The government inspection personnel did not verify the establishment's structures were kept in good repair.
- A broken overhead water pipe was observed dripping in the bleeding area. The government inspection personnel did not verify the establishment's structures were kept in good repair.

Inspection Requirements

55. *Post-Mortem Inspection*

- The establishment's Specified Risk Material (SRM) control program does not include skulls, trigeminal ganglia, and dorsal root ganglia. The government inspection personnel did not verify the establishment identified all SRMs listed in *Circular SENASA-DIPOA-1485-2019* in their SRM Control Programs. However, FSIS auditors verified that all SRMs, including the skulls, trigeminal ganglia, and dorsal root ganglia, were condemned and sent to inedible rendering.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	8/22/2019

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. 1.5 Kilometros Oeste de la Firestone, Contiguo a Intel Heredia, Costa Rica	8/20/2019	12	Costa Rica
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	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	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	O
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

60. Observation of the Establishment

HACCP Systems – Basic Requirements

15. *Content of HACCP Plan*

- For critical control point (CCP) 3, Chilling, of the Beef Slaughter HACCP plan, the calibration of the thermometers was not listed as a verification activity. The government inspection personnel did not verify the HACCP plans included all the required HACCP ongoing verification activities.

22. *Records documenting: the written HACCP plan, monitoring of the CCPs, dates and times of specific event occurrences*

- The zero tolerance HACCP monitoring records for beef carcasses did not include the time the events occurred. This finding was also documented in the 2017 audit report. Therefore, the Central Competent Authority (CCA) did not verify the implementation of the corrective actions provided to FSIS in response to the FSIS 2017 audit finding.
- Multiple HACCP monitoring and verification records showed errors corrected by writing over the incorrectly recorded value, they were missing the initial or the signature of the person conducting the monitoring or verification and were missing the times of monitoring or verification activity. The government inspection personnel did not verify the establishment's HACCP monitoring records complied with the HACCP record requirements.
- The HACCP corrective actions after a deviation for CCP1 (Zero tolerance for fecal matter, milk and ingesta) and CCP2 (antimicrobial concentration) of the Beef Slaughter HACCP plan, did not include the identification and elimination of the cause of the deviation. The government inspection personnel did not verify the actions taken by the establishment after a deviation to a critical limit complied with the HACCP corrective action requirements.

Other Requirements

39. *Establishment Construction/Maintenance*

- Extensive rust buildup was observed on overhead structures in the loading dock. The government inspection personnel did not verify the establishment's structures were kept in good repair.

Inspection Requirements

55. *Post-Mortem Inspection*

- The establishment's Specified Risk Material (SRM) control program does not identify skulls and dorsal root ganglion as SRMs. The government inspection personnel did not verify the establishment identified all SRMs listed in *Circular SENASA-DIPOA-1485-2019* in their SRM Control Program. However, FSIS auditors verified that all SRMs, including the skulls and dorsal root ganglion, were condemned and sent to inedible rendering.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	8/20/2019

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. Contiguo a las Instalaciones de la Zona Franca Saret, Rio Segundo Alajuela - Costa Rica	8/27/2019	502	Costa Rica
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

HACCP Systems – Basic Requirements

15. *Content of the HACCP Plan*

- The HACCP plan did not include ongoing verification activities (calibration of the thermometers, direct observation of the monitoring activities, and records review). The government inspection personnel did not verify the HACCP plans included all the required HACCP ongoing verification activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	8/27/2019

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 800 Metros Oeste de Riteve Cayal de Alajuela Alajuela, Costa Rica	8/27/2019	201102199	Costa Rica
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	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)	
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	O
37. Import	O
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.	

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 Branch (IAB)	8/27/2019

Heredia 15 de enero 2020
SENASA-DG-0074-2020

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
FSIS
United States of America

Dear Mrs. Catlin

With the purpose of giving an official response to the findings reported in the audit of Costa Rica's meat inspection system from August 19 to 29, 2019, we are including the proposal of corrective actions of SENASA:

As a general measure, in the order to increase the controls and strengthen the supervisory activities regarding the processes and products that are destined to be exported to USA, SENASA has determined the need to modify the official verification guide (DIPOA-PG-002-IN-001 (REPO), including a new section called FSIS Specific Requirements, which will tackle specific issues addressed below.

Furthermore, our Supervisory Tool *"Auditoría de primera parte para supervisión del personal DIPOA-PG-002-IN-002"* will be modified with the purpose of guaranteeing that all FSIS requirements be evaluated with the frequency and extension that it requires, so that compliance is fully ensured at all times.

1-The Government Inspection officials did not verify that slaughter establishments identified all SRMs listed in Official Notification 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.

It is important to clarify, that even though an official memorandum SENASA-DIPOA-1485-2019 was formally issued stating that all official inspectors assigned to establishments must abide by specific guides regarding SRM, this official memorandum is primarily focused on preventing the export of organs and tissues considered as specific risk materials by the FSIS.

Another important aspect that is necessary to emphasize -as indicating in the auditor's report- is the fact that all organs and tissues considered by the FSIS as risk materials, are adequately separated, and SENASA has effective controls to prevent such specific risk materials from being introduced into the food chain of products exported to US.

As acknowledged by the sanitary authorities of the USA, Costa Rica is recognized by the OIE as a country with negligible risk.

It is for this reason that we formally request the FSIS to recognize Official Notification SENASA-DG-1286-2019 regarding this issue. Document enclosed.

2-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.

Regarding this issue, it is important to indicate that SENASA's inspectors regularly verify that products to be exported to the USA are effectively separated in the refrigeration chambers. However, in order to strengthen the existing controls and based on the finding detected in this audit, this specific point will be incorporated into the official verification guide (DIPOA-PG-002-IN-001 (REPO) under the section of specific markets requirements.

Furthermore, all official inspectors will properly follow up on the corrective actions carried out by the establishment, which will be based on proper identification of the pallets in the cold chambers.

3- 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, the corrective actions provided to FSIS were not implemented

With the purpose of complying and correcting the findings regarding this issue, SENASA will include the validation requirements - as established by the FSIS- under the specific markets requirements section of the REPO.

Also, the establishments have submitted to SENASA an action plan that contemplates among other issues, the development of their CCP 2 validations.

4- The government inspection personnel did not verify that the HACCP plans included all the required HACCP ongoing verification activities.

SENASA has proceeded to provide instructions to all official inspectors in order to fully ensure that all types of verifications (record review, observation, physical measurements) as established in the master sheets, are also evidenced in the CCP records.

In addition, the verification guide (REPO) will be modified to include all types of verification.

5- The government inspection personnel did not verify that the 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.

Within the findings regarding this issue, we can indicate that:

- Some records do not include a timestamp when the event occurred
- The cause of the deviation is not reported
- Measures to prevent recurrence are not included
- Thermometer calibration is not included in verification activities
- There are HACCP records that do not include verification results
- Some records have erasures, or have been overwritten.

In order to properly address these non-conformances, the official verification guide (DIPOA-PG-002-IN-001 (REPO) will effectively include these items allowing inspectors to have a detailed guide.

In addition, the inspection team will be evaluated via a first-party auditing supervisory tool DIPOA-PG-002-IN-002 for supervision officials, so that compliance can be adequately monitored.

6- Government inspection officials did not verify that CCP corrective actions identified the cause of the deviations.

In order to properly address these non-conformances, the official verification guide (DIPOA-PG-002-IN-001 (REPO) will effectively include these items allowing inspectors to have a detailed guide.

In addition, the inspection team will be evaluated via a first-party auditing supervisory tool DIPOA-PG-002-IN-002 for supervision officials, so that compliance can be adequately monitored.

7- 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 Escherichia coli.

In regards to this finding, SENASA is requiring for establishments, STEC-group monitoring plan for all lots, as established in DIPOA-PG005, starting in February 2020.

Sincerely,

SERVICIO NACIONAL DE SALUD ANIMAL - COSTA RICA - DIRECCIÓN GENERAL

Dr. Bernardo Jaén Hernández
General Director SENASA

Attachment 1: Notification SENASA-DG-1286-2019

CD: Dr. Olivet Cruz DIPOA