United States Department of Agriculture

Food Safety and
Inspection Service

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

Dear Dr. Hernández,

The Food Safety and Inspection Service (FSIS) conducted an onsite audit of Costa Rica's meat inspection system from May 15 through May 26, 2017. 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 Kristen Hendricks in the Office of International Coordination at Kristen.hendricks@fsis.usda.gov.

Sincerely,

Mary H. Stanley
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

COSTA RICA
May 15 – 26, 2017

EVALUATING THE FOOD SAFETY SYSTEMS

GOVERNING MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

November 30, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from May 15-26, 2017. The purpose of the audit was to determine whether Costa Rica's food safety system governing raw intact 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. Currently, Costa Rica is eligible to export 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, 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors identified the following systemic findings for Government HACCP System and Government Chemical Residue Testing Programs. However, these systemic findings did not represent an immediate threat to public health.

Government Hazard Analysis and Critical Control Points (HACCP) System

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

During the audit exit meeting, the Central Competent Authority (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 onsite audit of Costa Rica's food safety system from May 15 - 26, 2017. The audit began with an entrance meeting held on May 15, 2017, in Heredia, Costa Rica with the participation of representatives from the Central Competent Authority (CCA) – The National Animal Health Service (SENASA) and two FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing raw intact 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. The scope of this audit included all aspects of Costa Rica's meat inspection system for producing and exporting raw intact beef products to the United States. Currently, Costa Rica is eligible to export raw intact beef products 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) 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 a self-reporting tool (SRT).

Representatives from the CCA and local inspection offices accompanied the FSIS auditors throughout the entire audit. 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, 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at the CCA headquarters and four local inspection offices located within the audited establishments. The FSIS auditors evaluated the implementation of control systems in place that ensures the national system of meat inspection, verification, and enforcement is being implemented as intended.

FSIS audited all four United States-certified establishments currently eligible to export raw intact beef products to the United States, including a cold storage facility. During the establishment visits, the FSIS auditors paid particular attention to the extent to which the meat industry and government officials interacted to control hazards and prevent noncompliances that threaten food safety. The FSIS auditors focused on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR § 327.2), the FSIS regulations addressing equivalence determination for

foreign country inspection systems for meat. In addition, the FSIS auditors conducted an onsite verification of the CCA's corrective actions in response to the audit findings reported during the previous FSIS audit in Fiscal Year (FY) 2015. The FSIS auditors verified that the CCA has effectively implemented its proposed corrective actions.

The FSIS auditors also visited the Laboratorio Nacional De Servicios Veterinarios (LANASEVE), a government laboratory conducting microbiological and chemical residue analyses to verify its ability to provide adequate technical support to the inspection system and assess the CCA's oversight of laboratory functions.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• CCA - SENASA, Heredia
Laboratories		1	• LANASEVE, Heredia o Microbiological Division o Chemical Residue Division
Meat slaughter and processing (boning) establishments		3	• Est. 8 / Coopemontecillos R.L., Alajuela • Est. 12 / El Arreo S.A., La Ribera de Belen • Est. 9 / Ganaderos Industriales de Costa Rica S.A., Alajuela
Cold storage facility		1	• Est. 503 / Frionet, Coyol de Alejuela

The audit was undertaken 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, *et seq.*); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR §327).

The audit standards applied during the review of Costa Rica's meat inspection system 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 Sanitary/Phytosanitary Agreement.

III. BACKGROUND

Currently, Costa Rica is eligible to export raw intact beef products to the United States. USDA's Animal and Plant Health Inspection Service (APHIS), which regulates the importation of animals and animal products into the United States, considers Costa Rica as a controlled risk for Bovine Spongiform Encephalopathy (BSE). APHIS has no other disease restrictions in place for Costa Rica regarding the export of raw intact beef products.

From January 1, 2014, to May 15, 2017, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 70,995,199 pounds of raw intact beef products exported by Costa Rica to the United States. No products were rejected for public health safety-related issues. FSIS also performed reinspection on 6,722,366 pounds at POE for additional types of inspection, of which a total of 4,722 pounds was rejected for certificate issues, shipping damage, and label defects.

The FSIS final audit reports for Costa Rica's food safety system are available on the FSIS web site at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/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. The national government of the foreign country must design and administer an inspection system with standards equivalent to those of the United States.

The evaluation of all the components included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT. The FSIS onsite audit component included record reviews, interviews, and observations made by the FSIS auditors. The audited facilities included five government inspection offices, one government laboratory, and four establishments that include one cold storage facility currently certified as eligible to export to the United States.

The FSIS auditors noted that there have been no major changes in the CCA's organizational structure since the last FSIS audit conducted in FY 2015. FSIS recognizes SENASA as Costa Rica's CCA in accordance with Law No. 8495, General Law on the National Service of Animal Health (GLNSAH); Ministry of Agriculture and Animal Husbandry (MAG) Regulation No. 37917-MAG, Organizational Structure of National Animal Health Service (OSNAHS), and MAG Regulation No. 29588-MAG, Veterinary Inspection and Sanitary Production and Processing of Meats Regulations (VISPPMR). The CCA has the legal authority and responsibility to control and ensure the safety of meat products for human consumption and to establish sanitary controls in all slaughter and processing establishments. The OSNAHS designates the LANASEVE as the section of the CCA that oversees the functions of the chemical residue and microbiological laboratories that provide administrative and technical support.

The CCA oversees the functions of the Directorate for Food Safety in Products of Animal Origin (DIPOA). DIPOA is in charge of the implementation of regulatory requirements pertaining to the production of meat products destined for export to the United States. The CCA's meat inspection system has two levels: central and establishment. At the central level, DIPOA's headquarters located in Heredia provides direct supervisory authority over the United States-certified establishments in accordance with national legislation and FSIS' import requirements. At the establishment level, the inspection personnel conduct inspection verification tasks, including sampling in accordance with the CCA's prescribed frequency; take and document enforcement actions when necessary; assess the effectiveness of the establishment's corrective action plans submitted in response to identified noncompliances; and communicate inspection personnel's verification task results through the chain of command.

The CCA also has the authority and responsibility to take enforcement actions in accordance with Law No. 8495. The FSIS auditors reviewed documented enforcement actions at the CCA's headquarters and the audited establishments. This included review of inspection-generated

noncompliance reports and follow up enforcement actions. In addition, the FSIS auditors verified that the CCA has a definition for adulterated products that meets FSIS requirements. A review of the inspection-generated records did not raise any concerns regarding the enforcement of the inspection requirements or proper implementation of the establishment's corrective actions in accordance with the CCA's requirements.

The FSIS auditors noted that in accordance with Law No. 8495 and the CCA's document, DIPOA-PG-002-IN-001-REPO, establishments are required to have a written procedure for trace back and recall. The CCA will provide notification to the United States for any exported products affected by a recall. The FSIS auditors verified that the inspection personnel review and verify the implementation of this requirement at the United States-certified establishments in accordance with the CCA's requirements.

The CCA maintains the legal authority to certify and de-certify establishments eligible for export to the United States. The FSIS auditors verified that the CCA's document, DIPOA-PG-006, provides requirements for exporting establishments and instruction for verification of initial and annual certification for export of meat products to the United States by the Department of Audit. The requirements include that each establishment present, along with their applications for certification, a current SENASA license to operate, written Sanitation Standard Operating Procedures (SSOP), a HACCP program, and SENASA's Certification of Supplier of Raw Materials of Animal Origin. The FSIS auditors verified that the Department of Audit reviews the required documents submitted by each exporting establishment, conducts an onsite 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 issuance of the inspection licenses at a newly certified establishment for export to the United States. No concerns arose regarding the CCA's implementation of this process.

The FSIS auditors verified through document reviews and interviews that the CCA has implemented a single standard of laws and regulations in all United States-certified establishments. The CCA's document, DIPOA-PG-002-IN-001-REPO, provides inspection instructions to DIPOA's National Supervisor, who is responsible for conducting periodic supervisory reviews at least quarterly in accordance with the CCA's requirements. The periodic supervisory reviews include an evaluation of inspection personnel conducting ante-mortem inspection; post-mortem inspection; humane handling verification; SSOP, Sanitation Performance Standard (SPS) and HACCP verification; labeling verification; official verification sampling programs; export certification; and official controls over condemned material.

At the establishment level, the Médico Veterinario Inspector (MVI) is in charge of supervising inspection personnel who conduct daily inspection verification activities. These verification activities include direct observation of establishment operations and review of the establishment's records. The FSIS auditors' review of daily inspection verification records and quarterly periodic supervisory reviews did not raise any concerns. The FSIS auditors noted that the Chief of the Regulatory Department in DIPOA utilizes email for all correspondence related to changes in inspection methods or requirements as well as any new and revised FSIS requirements.

Currently, Costa Rica has three United States-certified beef slaughter establishments and one cold storage facility. The FSIS auditors verified through document reviews and interviews that these establishments only slaughter cattle that were born and raised in Costa Rica. In addition, these establishments are not receiving any raw materials from any other establishment. The cold storage facility has a system in place to identify and segregate the United States-certified establishment products from other non-certified products.

The FSIS auditors verified that all DIPOA personnel are full time government-paid employees of the national government. The document review at the CCA headquarters and local inspection offices, located within the audited establishments, showed that the CCA requires the presence of the inspection personnel during all hours of operations in all the United States-certified slaughter establishments. During the onsite audit of each slaughter establishment, the FSIS auditors interviewed MVIs and reviewed daily inspection records to verify that the CCA has provided the required government inspection personnel to conduct daily inspection activities including ante-mortem and carcass-by-carcass post-mortem inspection of carcasses and parts for all operating shifts. The CCA employs the MVIs, who are graduates of government-approved universities and members of the National College of Veterinarians. Prior to assuming their official responsibilities, all MVIs receive on-the-job training on veterinary inspection requirements to supplement their academic qualifications. Non-veterinary food inspectors also receive required training when they first join the inspection task force and additional training as needed to perform their assigned duties in United States-certified establishments. The FSIS auditors noted that all inspection personnel were evaluated for their competence before being assigned to the United States-certified establishments, with the outcomes of these evaluations documented in accordance with the CCA's requirements.

The FSIS auditors verified that the CCA has provided ongoing training programs to inspection personnel assigned in the United States-certified establishments since the last FSIS audit conducted in FY 2015. The FSIS auditors reviewed the training records and verified that both inspection and laboratory personnel have attended the ongoing training. The FSIS auditors also interviewed a number of the inspection and laboratory personnel to assess their knowledge, skills, and abilities. Furthermore, the FSIS auditors observed inspection and laboratory personnel while they were conducting their assigned activities. No concerns arose as the results of these reviews or observations.

The FSIS auditors noted that the CCA provides administrative and technical support to the 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 (ECA) has the authority for accrediting laboratories in accordance with International Organization for Standardization (ISO) 17025:2005. The CCA has approved and uses two ISO certified private laboratories, Lambda Laboratories (heavy metals) and GeneSeek Laboratory (confirmatory testing for Shiga toxin-producing *Escherichia coli* (STEC)), for analytical testing of the products destined for export to the United States.

The FSIS auditors verified that LANASEVE's internal quality management system carries out annual proficiency testing on its laboratory technicians. The laboratory maintained training

records supporting that each technician had been qualified for their assigned duties. The FSIS auditors also verified that the CCA's reviews of intra-lab and inter-lab proficiency testing ensure that each analyst possesses the required competencies necessary to conduct the analyses. The FSIS auditors reviewed the CCA's oversight activities including the CCA's audit reports for LANASEVE and GeneSeek laboratories. No concerns arose as the result of these reviews.

The FSIS auditors concluded that the CCA's meat inspection system has organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY, 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 that the FSIS auditors reviewed was Government Statutory Authority, Food Safety, and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock, ante-mortem inspection of animals, post-mortem inspection of carcasses and parts; controls over condemned materials, controls over establishment construction, facilities, and equipment; daily inspection, and periodic supervisory visits to official establishments.

The FSIS auditors assessed humane handling, ante-mortem, and post-mortem inspection examinations through onsite record reviews, including a review and analysis of the information provided by the CCA in the updated SRT, interviews, and observations of in-plant inspection personnel performing these examinations in all three audited beef slaughter establishments.

The FSIS auditors verified that in-plant inspection personnel are required to conduct ante-mortem inspection in accordance with the CCA's requirements. The MVIs, with the assistance of food inspectors, conduct ante-mortem inspection on the day of slaughter by observing all animals at rest and in motion from both sides in designated holding pens. Inspection personnel document the results of ante-mortem inspection daily. The FSIS auditors noted that each audited slaughter establishment provides a holding pen designated for observation and further examination of suspect animals.

The CCA has provided instructions describing disease conditions warranting condemnation of animals at ante-mortem inspection. The MVIs identify and condemn any animal that shows signs of central nervous system disorders including non-ambulatory cattle during the ante-mortem inspection. The CCA mandates that inspection personnel collect required tissue samples from any animal with signs of neurological disorders, document their ante-mortem observations on suspect animals, and dispose of the entire carcass of these animals in accordance with the CCA's requirements. The FSIS auditors reviewed inspection records and observed execution of ante-mortem procedures that demonstrate proper implementation of the CCA's requirements. The FSIS auditors also observed implementation of the humane handling programs in all three audited beef slaughter establishments. This included the inspection personnel's hands-on verification of the maintenance and conditions of the holding pens, movement of animals, and proper stunning of animals. Additionally, the FSIS auditors reviewed the inspection-generated

humane handling verification records documenting the results of their verification activities. The FSIS auditors did not identify any areas of concern during the review of records and direct observations.

The FSIS auditors verified that in-plant inspection personnel perform post-mortem inspection at the time of slaughter in accordance with the CCA's requirements. Inspection personnel are required to document post-mortem inspection results, including any retained or condemned carcasses. The FSIS auditors observed the implementation of the CCA's requirements by inspection personnel during post-mortem inspection presentation, identification, examination, and disposition of beef carcasses and parts. The FSIS auditors also observed the performance of in-plant inspection personnel examining the heads, viscera, and carcasses to assess whether the proper incision, observation, and palpation of required organs and lymph nodes is conducted in accordance with the CCA's requirements. The FSIS auditors verified that inspection personnel are conducting carcass-by-carcass post-mortem inspection examination to ensure carcasses are free from pathological conditions or any contamination prior to applying the mark of inspection.

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

The CCA's document,DIPOA-PG-013, defines specified risk materials (SRMs) as the skull, brain, eyes, spinal cord, trigeminal ganglion, and spine of slaughtered bovine animals that are older than 30 months of age and the tonsils and the distal ileum of animals of all ages. The FSIS auditors noted that all three audited beef slaughter establishments considered all slaughtered cattle as older than 30 months in their operations. The CCA's document, DIPOA-PG-013-IN-004, provides instructions to establishments for the identification, removal, segregation, and disposal of SRMs, and instructions to inspection personnel to verify that establishments have carried these out. The FSIS auditors reviewed the establishment's monitoring and inspection verification records concerning control and disposal of SRMs. In addition, the FSIS auditors observed the implementation of these requirements during the slaughter operation including the use of the dedicated equipment and safeguarding the disposed materials.

The CCA requires that establishments segregate and store inedible products in a separate area from edible products. In addition, containers used for collecting inedible products must be marked and distinguished from other containers. The FSIS auditors noted that the inspection personnel have the authority and responsibility to detain, denature, and destroy inedible products in accordance with the CCA's regulatory requirements. The FSIS auditors reviewed both inspection and establishment generated records, and observed the disposal process of condemned and inedible materials at each audited establishment and found no concerns.

The FSIS auditors concluded that the CCA's meat inspection system has the legal authority and a documented regulatory framework to implement the CCA's regulatory requirements for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT, interviews, and observations made during the onsite audit.

The FSIS auditors verified that the CCA requires each certified establishment to develop, implement, and maintain written sanitation programs to prevent direct product contamination or the creation of insanitary conditions. The establishment's sanitary procedures must include the required frequency and a list of the establishment's personnel accountable for conducting sanitary procedures. The establishments are required to take necessary measures to prevent direct product contamination or creation of insanitary conditions. The CCA's document, DIPOA-PG-002-IN-001-REPO, provides instructions to the inspection personnel for verifying that the establishments have adequately implemented prerequisite programs such as Good Manufacturing Practices (GMP), SSOPs, and SPS.

The FSIS auditors reviewed sanitation plans and records related to the design and implementation of sanitation programs in all of the audited establishments. In one of the audited beef slaughter establishments, the FSIS auditors also verified the actual pre-operational inspection verification by shadowing and observing in-plant inspection personnel conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the establishment was ready for the in-plant inspector's pre-operational sanitation verification inspection. Inspection personnel conduct and document this activity daily and in accordance with the CCA's established procedures.

- In one of the three beef slaughter establishments audited, the FSIS auditors identified isolated SPS findings during the pre-operational inspection verification. There was no product involved at the time of the audit. However, these SPS findings may create an insanitary condition and the potential for direct product contamination. The inspection personnel took regulatory enforcement action by tagging the area and equipment. The establishment took immediate corrective action with verification done by inspection personnel on the day of the audit. SPS findings are noted in the individual establishment checklist provided in Appendix A of this report.

The FSIS auditors also observed in-plant inspection verification of operational sanitation procedures in all audited establishments and compared their overall sanitary conditions to the inspection verification documentation. Inspection personnel activities included direct observation of operations and review of the establishment's records. The FSIS auditors noted that the CCA requires sanitary dressing of livestock at slaughter establishments. As a result, each audited slaughter establishment has implemented sanitary procedures to prevent potential

carcass contamination throughout the process. These included sanitary procedures to prevent carcass contamination during hide removal; prevent direct contact between carcasses during dressing procedures; and prevent carcass contamination with gastrointestinal contents during evisceration including tying the bung and weasand. All three audited establishments utilized sanitary dressing procedures for each step in the process and monitored the implementation daily.

The FSIS auditors' observations and record reviews including the establishment's sanitation monitoring and corrective action records as well as those of inspection personnel documenting in-plant inspection verification results or periodic supervisory reviews did not raise any concerns. Except for isolated sanitation findings above, the CCA's meat 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 POINTS (HACCP) SYSTEM

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

The CCA's document, Decree No. 26559 MAG, requires each United States-certified establishment to develop, implement, and maintain a HACCP system. The FSIS auditors noted that the United States-certified establishments are required to meet all regulatory requirements identical to FSIS' HACCP requirements under 9 CFR §417. This includes a flow diagram, hazard analysis, HACCP plan for hazards identified as likely to occur, monitoring and verification activities, corrective action, reassessment, validation, and records keeping requirements 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. This supporting documentation includes the validation of the HACCP system. The FSIS auditors noted that the Auditing Unit (AU) of DIPOA evaluates the design and implementation of the HACCP system in each United States-certified establishment yearly and prior to granting of certification renewal.

The FSIS auditors visited three beef slaughter establishments to determine whether the CCA maintained adequate government oversight for the implementation of HACCP requirements. In addition, FSIS assessed the adequacy of HACCP program verification activities conducted by inspection personnel and establishment employees at these audited establishments. The CCA mandates that all United States-certified beef slaughter establishments identify STEC as a hazard reasonably likely to occur; have at least one intervention Critical Control Point (CCP) for control of STEC; and have a zero tolerance CCP for the presence of fecal matter, ingesta, and milk. Furthermore, establishments must have a STEC sampling and testing program for products intended for further processing into non-intact products.

The FSIS auditors noted that all three audited beef slaughter establishments have elected to conduct 100 percent monitoring of beef carcasses for the zero tolerance CCP for presence of

fecal matter, ingesta, and milk. The FSIS review of the establishment's monitoring and corrective actions records in response to the few observed deviations from the zero tolerance critical limit showed that the establishment took appropriate corrective actions addressing all four parts of the corrective action regulation. The FSIS auditors also reviewed the inspection verification records and observed the in-plant inspection personnel's hands-on verification activities for the zero tolerance and antimicrobial intervention CCPs. The FSIS auditors noted that inspection personnel conduct daily verification of the CCPs in accordance with the CCA's requirements. The physical zero tolerance CCP monitoring and verification location for both the establishment's employees and in-plant inspection personnel is before the final wash in all three audited beef slaughter establishments.

The FSIS auditors' HACCP verification activities also included interviews with establishment and inspection personnel and review of the establishment's records that provided supporting documents as part of the decision making process for the HACCP system. During this activity, the FSIS auditors identified the following HACCP record keeping and validation findings in the audited establishments:

- In all three beef slaughter establishments, the critical limit monitoring record for the zero tolerance CCP did not include the time the event occurred.
- In two beef slaughter establishments, the verification records for CCPs did not include the time the event occurred.
- In two beef slaughter establishments, the HACCP plan did not provide sufficient supporting documentation for validation of the antimicrobial intervention.

Except for the HACCP findings above, the CCA's meat inspection system continues to meet the core requirements for this component. The CCA committed to provide FSIS with corrective action plans which would be verified once they are implemented.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

The CCA has Law No. 8495, GLNSAH; MAG Regulation No. 29588-MAG, VISPPMR; and Costa Rica's Annual Residue Control Plan, which demonstrates that the CCA has legal authority and responsibility to regulate, plan, and execute its national residue plan. The national residue plan is used to prevent and control the presence of residues of veterinary drugs and contaminants in the tissues of animals slaughtered for meat and meat products for human consumption. The CCA has assembled a regulatory task force with representatives from DIPOA, National Residue Program, Operations Directorate, Veterinary Medication Directorate, Animal Quarantine Directorate, Animal Feed Directorate, LANASEVE, and General Directorate.

The task force designs the National Residue Control Program (NRCP) under the coordination of the Residue Program Manager (RPM) who reports directly to the CCA's Executive Office. The CCA's document, DIPOA-PG-015, provides instructions to inspection personnel assigned in the slaughter establishments for random selection of animals, tissue sample collection, proper handling of samples, and secure transportation of samples to the designated laboratories. At the establishment level, the MVIs are responsible for ensuring the proper implementation of the program in accordance with the CCA's requirements. The FSIS auditors' review of the inspection documentation in all three audited beef slaughter establishments indicated that in-plant inspection personnel have collected the required residue samples in accordance with the CCA's prescribed sample collection schedule.

The FSIS auditors identified the following:

- Costa Rica's current 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. FSIS requires holding or maintaining inspection control of livestock carcasses selected for residue sampling until the official test results are reported as acceptable.

The FSIS auditors verified that the CCA has established control measures for noncompliant results that include follow-up sampling. For follow-up sampling, inspection personnel sample animals from the next 10 deliveries from the violative farm, except for macrocyclic lactones, which requires sampling from the next 15 deliveries.

The FSIS auditors also visited the LANASEVE residue laboratory. LANASEVE is the official government laboratory that conducts all chemical residues testing, except for the testing of heavy metals (lead, arsenic, and mercury). The Lambda Laboratory, an approved private laboratory, conducts the analytical testing of heavy metals on behalf of the CCA. These two laboratories are ISO 17025:2005 accredited by ECA. The FSIS auditors 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; equipment operation and printouts; minimum detection levels; recovery frequency; percent recoveries; and corrective action. The FSIS auditors noted that LANASEVE maintains a web-based system to ensure accurate tracking and reporting of all samples received. The FSIS audit of the laboratory 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 regulatory requirements for a chemical residue-testing program that is organized and administered by the national government. However, FSIS identified the finding above concerning the CCA routine monitoring program. The CCA committed to provide FSIS with corrective actions that would be verified once they are implemented.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. The inspection system is to implement certain sampling and

testing programs to ensure that meat produced for export to the United States are safe and wholesome.

The FSIS auditors reviewed each audited establishment's written generic *Escherichia coli* (*E. coli)* sampling and testing programs as well as the records of analytical testing results. In one of the audited establishments, the FSIS auditors observed the establishment's employee collecting samples that was consistent with FSIS regulatory requirements (9 CFR §310.25(a)). The establishment's employees did collect the samples from chilled beef carcasses using the aseptic sampling techniques. The FSIS auditors noted that in-plant inspection personnel also collect generic *E. coli* official verification samples (weekly) to compare and verify the results of establishment's daily testing program.

The CCA has adopted the FSIS *Salmonella* performance standards outlined in 9 CFR §310.25(b). In another audited establishment, the FSIS auditors observed that the in-plant inspection personnel's *Salmonella* sample collection methodology was in accordance with the CCA's requirements. LANASEVE analyzes samples using a validated method. The FSIS auditors verified that the CCA provides instructions to its inspection personnel to verify the establishment's corrective measures when the establishment does not meet the performance standards. This included the establishment's re-evaluation of the dressing and sanitary procedures and additional follow-up sampling. In addition, the CCA requires further serotyping of the positive *Salmonella* samples.

The CCA requires that the United States-certified establishments implement a sampling program for STEC (*E. coli* O157:H7, O26, O45, O103, O111, O121, and O145) based on N60 methodology for each lot of products. In addition, the establishments are required to have procedures in place to hold the product pending test results. Products subject to sampling are raw ground beef (including beef patties), ground beef components (head meat, cheek meat, weasand meat, heart meat, and partially defatted meat fatty tissue), beef patties, and beef trim. Currently, Costa Rica does not ship any ground beef or ground beef patties to the United States. The FSIS auditors verified that the CCA has implemented official verification sampling (weekly) for STEC as part of its oversight verification activity.

At one of the audited slaughter establishments, the FSIS auditors observed in-plant inspection personnel application of N60 sampling methodology when collecting official verification samples of beef trimmings. In all three audited beef slaughter establishments, the FSIS auditors reviewed inspection-generated verification sampling records and interviewed the MVIs regarding the STEC sampling programs. The in-plant inspection personnel were taking samples at the designated frequencies and in accordance with the CCA's requirements. The FSIS auditors noted that there have not been any positive results for the CCA's verification sampling in any of these establishments since the last FSIS audit. No concerns arose as the results of this verification activity.

The FSIS auditors visited the LANASEVE microbiology residue laboratory. LANASEVE is the official government microbiology laboratory conducting microbiological analyses of government's verification samples. The FSIS auditors noted that the CCA uses a private laboratory, GeneSeek Laboratory, only for confirmation of potential positive non-O157 STEC

screening results. The FSIS auditors verified that ECA has accredited LANASEVE based on the ISO 17025:2005 requirements. 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.

During the LANASEVE audit, the FSIS auditors observed and verified sample receipt and handling procedures, testing methodology, timely analysis of samples, data reporting, equipment operation, technical training, and intra-lab competencies. In addition, the FSIS auditors reviewed the most recent audit report issued by ECA. The FSIS auditors also noted 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.

The FSIS auditors concluded that the CCA's meat inspection system has a microbiological testing program that is organized and administered by the national government and that the CCA has implemented sampling and testing programs to verify its system.

CONCLUSIONS AND NEXT STEPS

An exit meeting was held on May 26, 2017, in Heredia, Costa Rica, with the CCA. The onsite audit did not identify any significant findings that represented an immediate threat to public health. At this meeting, the FSIS auditors presented the following preliminary audit findings:

Government Hazard Analysis and Critical Control Points (HACCP) System

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

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 Checklist

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. . Montecillo Alajuela	05/18/2017	8	Costa Rica
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

22/51
The establishment's HACCP verification records did not include the time the event occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	May 18, 2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Ganaderos Industriales de Costa Rica S.A. San Antonio del Tejar	05/23/2017	9	Costa Rica
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	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	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

39/51
The FSIS auditors observed the following during the pre-operational inspection verification:
- A stainless steel table (direct food contact surface) had uneven and interrupted weld on its edges making it hard to clean.
- The bovine carcass entryway from the cooler to the boning room had peeling paint on the ceiling above exposed products.

19/51
The establishment's HACCP plan did not provide sufficient supporting documentation for validation of the antimicrobial intervention.

22/51
The establishment's HACCP monitoring and verification records did not include the time the event occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	May 23, 2017

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 La Ribera de Belen	05/19/2017	12	Costa Rica
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	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	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

19/51
The establishment's HACCP plan did not provide sufficient supporting documentation for validation of the antimicrobial intervention.

22/51
The establishment's HACCP monitoring and verification records did not include the time the event occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	May 19, 2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frionet Coyol de Alejuela	05/24/2017	503	Costa Rica
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
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	
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.		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. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	May 24, 2017

Appendix B: Foreign Country Response to Final Audit Report

Heredia, August 18, 2017
SENASA-DG-1114-2017

Jane H. Doherty
International Coordination Executive
Office of International Coordination
FSIS-USDA
United States of America

Dear Mrs Doherty:

In SENASA-DIPOA, all efforts are directed in search of continuous improvement and successfully meet all no complies identified in the audit conducted by FSIS in May 15-16 2017 and the findings detected, SENASA-DIPOA has developed an action plan:

Government Hazard Analysis and Critical Control Point (HACCP) System

- In the audited establishments, the HACCP monitoring and verification records did not include the time the event occurred

SENASA-DIPOA response

The three of the establishment audit makes modification of the HACCP records now all the monitoring and verification documents include the exactly hour that events occurred.

SENASA-DIPOA is going to verify these changes in the plant records according with DIPOA-PG-002-IN-001 (REPO) Official verification guide. This verification activity made by SENASA-DIPOA occurs one time in the mouth.

- Two of the three audited slaughter establishment, the HACCP plan did not provide sufficient supporting documentation for validation of the antimicrobial intervention

SENASA-DIPOA response

The establishments using FSIS Compliance Guide Validation for reference to complement and support of the antimicrobial intervention, this validation are ongoing in the plants, and they are include variables like water pressure, temperature, time of application of the antimicrobial chemist.

SENASA-DIPOA is going to verify the validation documents and the implementation of these new variables in the process the official verification is according with DIPOA-PG-002-IN-001 (REPO) Official verification guide. DIPOA-PG-002-IN-001 (REPO) Official verification guide.

Government Chemical Residue Testing Programs

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

SENASA-DIPOA in the official document DIPOA-PG-004 (Sampling in Establishments of Products, Byproducts and Derivatives of Animal Origin for Human Consumption) and in the national residue plan for the next year will include in the holding of the product which includes retention of the product to be officially sampled.

Sincerely,

Dr. Alexis Sandi Muñoz
General Director SENASA

Heredia, November 1, 2017
SENASA-DG-1395-2017

Jane H. Doherty
International Coordination Executive
Office of International Coordination
FSIS-USDA
United States of America

Dear Mrs Doherty:

In SENASA-DIPOA, all efforts are directed in search of continuous improvement and successfully meet all no complies identified in the audit conducted by FSIS in May 2017 and the findings detected, SENASA-DIPOA has developed an action plan:

- Item 1 – HACCP monitoring and verification records did not include the time the event occurred – SENASA's response indicates that in those three establishments, monitoring and verification documents include the time that events occurred and that SENASA verifies this according to document DIPOA-PG-002-IN-001 (REPO). FSIS reviewed this document and found that it indicates that SENASA's inspection personnel verify that establishments have a documented monitoring procedure of the CCP's critical limits which defines the frequency of monitoring. However, the document doesn't indicate explicitly that the time must be recorded. Can SENASA please clarify this issue?

- SENASA emitted an official notification (SENASA-DIPOA-2057-17, Attachment 1) to the three audited establishments by FSIS, to include the time the PCC´s monitoring and verification when occurred in the establishment.

In the same way, SENASA modified the item 1.28.37 of the DIPOA-PG-002-IN-001 (REPO) to include the verification of the above requirement:

Ministerio de Agricultura y Ganadería • Servicio Nacional de Salud Animal
Tel: (506) 2587-1696•2262-0221
Fax: (506) 2260-8301
www.senasa.go.cr

"The control documents for the CCPs, are signed by the respective personal in charge of monitoring and verification of each CCP, and include the hour when the event occur" (Attachment 2).

- Item 2 – HACCP plan did not provide sufficient supporting documentation for validation of the antimicrobial intervention – SENASA's response indicates that establishments are using the FSIS Validation compliance guide for reference to complement and support the use of antimicrobial interventions, and that SENASA will verify validation in accordance with DIPOA-PG-002-IN-001 (REPO). While this document for SENASA's inspection personnel does address validation (specifically referencing scientific and technical information), this is already a requirement. Can SENASA please provide additional clarification on the additional supervisory oversight has been implemented to ensure that inspection personnel do assess validation in all establishments, in accordance with existing requirements?

SENASA emitted an official notification (SENASA-DIPOA-2057-17, Attachment 1) to the three audited establishments by FSIS, to provide the validation documentation of the antimicrobial intervention CCP, required in the next HACCP reassessment. SENASA will verify this requirement based on the item 1.28.33 of the DIPOA-PG-002-IN-001 (REPO): "the critical limits are based in scientific data and are validated"

- Item 3 – the chemical residue program does not require holding of product prior to receiving test results – SENASA's response appears to indicate that in document DIPOA-PG-004 (instructions for inspection personnel on sampling of products) that holding of sampled product is addressed. This document was submitted to FSIS in April in response to another inquiry; however, the document is 46 pages in length, and only the relevant section was translated, which doesn't address test and hold requirements. FSIS attempted to translate the document with Google Translate, but we were unable to

obtain a full translation. Can SENASA please provide an English version of the entire document so FSIS can review the test and hold procedures? Or can SENASA indicate which section this information may be found, so that FSIS can obtain a translation of that specific section? Also, SENASA indicates that in next year's residue

We are attach part of the new include in the version 3 of the procedure DIPOA-PG-004 (instructions for inspection personnel on sampling of products) (Attachment 2).

Includes page 24

"Retention of sampled product

For the Establishments approved to export to the United States the sampling of drug residues and environmental contaminants for the animal subject to official sampling will be identified and retained by the official personnel of DIPOA in the establishment, their meat, viscera and by-products will be released until the official laboratory result indicates negative for the analyte sampled".

The application of this modification applies from this month.

Sincerely,

Dr. Bernardo Jaén Hernández
General Director SENASA

Heredia, November 20, 2017
SENASA-DG-1463-2017

Jane H. Doherty
International Coordination Executive
Office of International Coordination
FSIS-USDA
United States of America

Dear Mrs Doherty:

In the official response, send to FSIS the las 2 November 2017 we want to clarify the information and provide the evidence:

1. We are attaching the official document and specify the items translate and page that you can find the information:
   a. In the official document attach (REPO) Código:DIPOA-PG-002-IN-001 (REPO) version 4 " in the page 20 says

      Ítem 1.28.33 El personal oficial verifica que los límites críticos se basan en datos científicos y están validados**. The official staff verifies that the critical limits are based on scientific data and are validated. (Anex 1)**

      Ítem 1.28.37 El personal oficial verificara que Los documentos de control para los PCC, están firmados por el personal de control de calidad del establecimiento respectivo a cargo de la supervisión y verificación de cada PCC, que incluyen la hora en que ocurre el evento. **The official staff will verify that the control documents for the CCPs are signed by the quality control personnel of the respective establishment in charge of the supervision and verification of each CCP, including the time at which the event occurs. (Anex 1)**

      In the document this paragraph is colored in green to facilities the visualization.
   b. In the oficial document (Muestreo en Establecimientos de Productos, Sub Productos y Derivados de Origen Animal para Consumo Humano) in the page 24: says **(Anex 2)** Retención de producto muestreado.

Para los Establecimiento aprobados para exportar a los Estados Unidos se realizará el muestreo de residuos de medicamentos y contaminantes ambientales de forma que el animal sujeto a muestreo oficial será identificado y retenido por el personal oficial de DIPOA en el establecimiento, su carne, vísceras y subproductos NO serán liberados hasta que el resultado oficial de laboratorio indique negativo para el analito muestreado. **For the Establishments approved to export to the United States, the sampling of residues of medicines and environmental contaminants will be carried out so that the animal subject to official sampling will be identified and retained by the official personnel of DIPOA in the establishment, its meat, viscera and by-products. They will NOT be released until the official laboratory result indicates negative for the analyte sampled.**

In the document this paragraph is colored in green to facilities the visualization.

2. In the response send to FSIS the las november, 2017 we forgot to not the final document SENASA-DIPOA-2057-2017). In this new document, we are attaching the final document. **(Anex 3)**
3. In the point 3 according with the offcial document (Muestreo en Establecimientos de Productos, Sub Productos y Derivados de Origen Animal para Consumo Humano) in the page 24: says (Anex 2) we want to clarify that will **NOT released any product** until laboratory result indicates negative for the analyte sampled.

In the document the paragraph is colored in green to facilities the visualization:

We hope to complete with all the question if the necessary more information please contact with me.

Sincerely,

Dr. Bernardo Jaén Hernández
General Director SENASA