



SEP 25 2013

Dr. German Rojas Hidalgo, General Director
Servicio Nacional de Salud Animal-Sector Agro Alimentario
Ministerio de Agricultura y Ganadería
Barreal de Heredia, Jardines del Recuerdo
1 Km to West Campus Benjamín Nuñez
Heredia, Costa Rica

Dear Dr. Rojas:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Costa Rica's meat inspection system from March 26 through April 3, 2012. FSIS received your comments to the report and included them, as an attachment to the enclosed copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at international.audit@fsis.usda.gov.

Sincerely,

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit

Enclosure

SEP 25 2013

FINAL REPORT OF AN AUDIT CONDUCTED IN
COSTA RICA
MARCH 26- APRIL 3, 2012

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
THE PRODUCTION OF MEAT
PRODUCTS INTENDED FOR EXPORT TO
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 26 through April 3, 2012 to determine if Costa Rica's food safety system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products which are safe, unadulterated, and properly labeled. The audit outcome made evident that the CCA is able to meet the principal requirements for Statutory Authority and Food Safety Regulations, Sanitation, HACCP, Chemical Residue and Microbiological Testing Programs components. However, the CCA must improve government oversight to several components of its meat inspection system to ensure ongoing equivalence with FSIS. .

The focus of the audit was on the ability of the Central Competent Authority (CCA), SENASA, to regulate meat products production. FSIS reviewed and verified the information provided by the CCA in the Self Reporting Tool (SRT). The audit scope included one central and two local government offices; two slaughter and one processing establishments; and the official chemical residues and microbiology laboratories. Determinations concerning the effectiveness of Costa Rica's meat inspection system focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points Systems, (5) Chemical Residue Control Programs and (6) Microbiological Testing Programs.

The findings of the audit that demonstrate a need for improvement of government oversight are summarized below, with the detailed findings documented in the body of the report:

- Government Oversight Component
 - FSIS observed that at two of the three establishments audited, government oversight was not adequately implemented. Inspection officials were not ensuring full regulatory compliance of establishments with the regulations of the system for construction, design and maintenance of facilities, design of HACCP programs and post mortem inspection.
- Statutory Authority and Food Safety Regulations
 - Periodic supervisory reviews did not recognize opportunities for improvement of in-plant regulatory activities, failing to act upon and resolve regulatory enforcement deficiencies related to post mortem inspection, sanitation and HACCP requirements
- Sanitation Component
 - In-plant officials were not evaluating adequately and consistently the sanitation programs implemented by slaughter and RTE processing establishments to ensure that they remain in compliance with the regulations of the system
- HACCP Component
 - The official review process of establishments' written HACCP programs did not identify flaws in the design of their hazard analyses and HACCP plans.

CCA representatives addressed the above described findings by implementing acceptable, immediate corrective actions and proposed to follow-up with implementation of long term corrective measures. Furthermore, the CCA has provided in the comments for this report, assurances indicating that all long term corrective actions will be adequately implemented and also indicated that the CCA delisted the RTE processing establishment.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

| | |
|-------------------|--|
| AI | Auxiliary Inspector |
| CCA | Central Competent Authority (Servicio Nacional de Salud Animal) |
| CVO | Chief Veterinary Officer |
| DIPOA | Dirección de Inocuidad de Productos de Origen Animal (Directorate for Safety of Products of Animal Origin) |
| <i>E. coli</i> | <i>Escherichia coli</i> |
| FSIS | Food Safety and Inspection Service |
| GLNSAH | General Law on the National Service of Animal Health |
| IIO | In-plant Inspection Official |
| LANASEVE | Laboratorio Nacional de Servicios Veterinarios (National Laboratory for Veterinary Services, Chemical Residues and Microbiological laboratories) |
| MAG | Ministerio de Agricultura y Ganadería (Ministry of Agriculture and Livestock) |
| MIS | Meat Inspection System |
| MVI | Medico Veterinario Inspector (Veterinary Medical Inspector) |
| <i>Salmonella</i> | <i>Salmonella</i> species |
| SENASA | Servicio Nacional de Salud Animal (National Animal Health Service) |
| SPS | Sanitation Performance Standards |
| SRM | Specified Risk Materials |
| SSOP | Sanitation Standard Operating Procedures |
| USDA | United States Department of Agriculture |
| VISPPMR | Veterinary Inspection and Sanitary Production and Processing of Meats Regulations |

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Costa Rica's meat inspection system (MIS) from March 26 through April 3, 2012.

The audit began with an entrance meeting held on March 26, 2012, in Barreal, Heredia with the participation of representatives from the Central Competent Authority (CCA) – National Animal Health Service (SENASA), the Directorate for Safety of Products of Animal Origin (DIPOA), the National Chemical Residues and Microbiological Laboratories (LANASEVE), and the FSIS's Office of International Affairs (OIA)- International Audit Staff (IAS).

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to verify that Costa Rica's food safety system governing the production of meat continues to be equivalent to that of the United States of America (U.S.), with the resultant capacity to produce products which are safe, unadulterated, and properly labeled.

In pursuit of this objective and prior to conducting this audit, FSIS conducted an analysis of information provided by Costa Rica in the FSIS document entitled Self Reporting Tool (SRT Version 2009), U.S.'s port-of-entry (POE) testing results, other data collected by FSIS, and findings reported from onsite audits conducted in the last three years.

The FSIS auditor was accompanied throughout the entire audit by representatives from SENASA and the DIPOA.

Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residues Control programs, and (6) Microbiological Testing Programs.

Administrative functions of the system were reviewed at CCA headquarters and at two local inspection offices, where the auditor evaluated the management control systems in place, which ensure that the national system of inspection, verification, and enforcement is implemented as intended.

A sample of three establishments was selected from a total of six, currently certified to export meat products to the U.S. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's

ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

Additionally, the two laboratories that conduct official microbiological and chemical residues analyses were audited to verify their ability to provide adequate technical support to the inspection system and the oversight that the CCA provides to their functions.

| Sectors Visited During the Audit | | No. Sites | Locations |
|----------------------------------|---------|-----------|---|
| Competent Authority Offices | Central | 1 | Heredia |
| | Local | 2 | Alajuela and Heredia |
| Laboratories | | 2 | Heredia |
| Slaughter Establishments | | 2 | <ul style="list-style-type: none"> • Est. 9, Ganaderos Industriales de Costa Rica, S. A. (bovine) • Est. 12, El Arreo, S. A. (bovine) |
| Processing Establishments | | 1 | <ul style="list-style-type: none"> • Est. 9J, Ganaderos Industriales de Costa Rica, S. A. |

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

The audit was undertaken under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations

The audit standards included all applicable legislation and procedures originally determined by FSIS as equivalent as part of the initial review process, and any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Costa Rica has equivalence determinations in place for the following:

- National program for *E. coli* O157:H7
- Alternative program for ready-to-eat (RTE) products

4. BACKGROUND

Costa Rica is eligible to export beef products to the U.S. and in fiscal year 2011, it exported 15,710,904 pounds of raw-not ground beef products. FSIS re-inspected 4,398,153 pounds of that volume and rejected 874 pounds at POE due to findings that were not of public health significance.

FSIS audited Costa Rica's MIS last in 2009 and reported findings that pertained to the Sanitation and HACCP components of the system. DIPOA personnel verified and documented the adequacy of the corrective actions that the establishments implemented.

During this audit, the FSIS auditor verified that the 2009 audit findings had been adequately corrected.

The FSIS final audit reports for Costa Rica's MIS are available on the FSIS' website at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>

5. GOVERNMENT OVERSIGHT

The first of the six equivalence components of the MIS of Costa Rica that FSIS reviewed was Government Oversight. The evaluation of this component included a review and analysis of documents submitted by the CCA as support for the responses provided in the SRT (2009 Version) and onsite observations made by the FSIS auditor at certified establishments, government offices and laboratories of the system. Results of the evaluation showed that in-plant inspection officials (IIO) were not ensuring full compliance of establishments with the rules of the system.

In accordance with Costa Rica's Law No. 8495, General Law on the National Service of Animal Health (GLNSAH); Ministry of Agriculture and Livestock (MAG) Regulation No. 34319, Organizational Structure of National Animal Health Service (OSNAHS) and MAG Regulation No. 29588, Veterinary Inspection and Sanitary Production and Processing of Meats Regulations (VISPPMR); and MAG Regulation No. 26559, Hazard Analysis and Critical Control Points (HACCP); SENASA is the agency of the government of Costa Rica that serves as the CCA to administer the Costa Rican meat products inspection system. The OSNAHS also designate the Directorate for Veterinary Services Laboratories (LANASEVE) as the section of the CCA that oversees the functions of the Chemical Residue and Microbiological laboratories that provide technical support to the Costa Rican MIS.

FSIS verified onsite that SENASA is the agency of the Costa Rican government that ensures the safety of products placed in domestic and international markets. SENASA oversees the functions of the DIPOA, its subordinate agency in charge of regulating the meat industry and certifying establishments to export meat products to the U.S. DIPOA-certified establishments undergo initial and continued eligibility evaluations to determine their ability to meet U.S. requirements related to the safe production of beef products. The FSIS auditor reviewed DIPOA-PG-006, Procedure to Obtain Initial and Annual Certification to Export Meat Products and verified that DIPOA officials require that establishments present along their applications for certification, a current SENASA license to operate, written Sanitation Standard Operating Procedures (SSOPs), HACCP Program, and SENASA's Certification of Supplier of Raw Materials of Animal Origin. Additionally, the FSIS auditor verified that that in accordance with DIPOA-PG-006, MIS officials had reviewed the documents submitted by the establishments, audited the facilities and evaluated their ability to meet regulatory requirements that apply to construction and maintenance of facilities, food safety controls and sanitary requirements, prior to granting renewal of certification to export meat to the U.S.

All individuals who work for the Costa Rican MIS, from the CCA down to in-plant officials, and laboratory personnel are employees of the Government of Costa Rica (GOCR), who are subject to administrative policies that apply to all government officials.

FSIS assessed the hierarchical organization of the DIPOA by interviewing CCA officials at headquarters, field personnel and by reviewing regulatory documents. FSIS verified that DIPOA is staffed with government employees who accomplish administrative and regulatory functions under the coordination of the Director of DIPOA (DD) by reviewing personnel records maintained by supervisory officials. The DD, reports to the General Director of SENASA and supervises the in-plant veterinary medical inspectors (MVI). The DD is assisted by an Area Coordinator (CA), who serves as field supervisor covering certified establishments. MVIs serve as veterinarians in charge stationed at the six certified establishments of the system where they supervise the performance of teams of in-plant auxiliary government inspectors (IA) who conduct ante and post mortem inspection, and verification activities.

The central office of the DIPOA makes available to its inspection officials, written operational procedures, directives and notifications that assist them to uniformly deliver regulatory oversight at certified establishments. Internet service is available in the locations where certified establishments operate. Thus, the system customarily maintains transmission of agency issuances electronically. FSIS observed in-plant officials as they navigated within SENASA's website and verified that they knew how to locate pertinent regulatory issuances.

The MIS of Costa Rica recruits veterinarians, who are graduates from government approved universities and members of the National College of Veterinarians. Prior to assuming their official responsibilities, all MVIs receive additional on the job training on veterinary inspection at certified establishments to supplement their academic qualifications. Additionally, MVIs receive training offered by other SENASA agencies, regional government organizations, USDA, and DIPOA on enforcement of U.S. export requirements, food safety, humane handling of livestock and professional development. Non-veterinary personnel are also provided with training when they first join DIPOA and receive additional training as needed to perform their assigned duties.

FSIS assessed the ability of the CCA to ensure the assignment of competent qualified inspectors to the certified establishments and laboratories by reviewing training records, performance evaluations and by observing the functions of official personnel at work.

The assessment conducted at the laboratories made evident that analysts have successfully acquired greater expertise on analytical methodology. Records reviewed at the laboratories show that analysts have completed training and have successfully passed intra and inter-laboratory proficiency evaluations to gradually expand the scope of their analytical qualifications. Results of evaluations of their performance conducted by supervisory personnel are recorded and further analyzed to remedy deficiencies and generate improvements. FSIS observed that work being performed by the analysts at both laboratories was in conformance with quality standards imposed by the

LANASEVE and verified by laboratory supervisors, all practices being consistent with guidelines provided by ISO 17025.

At the establishments, FSIS reviewed records of training completed by veterinary and non-veterinary in-plant personnel. Documents reviewed indicated that inspection personnel had successfully completed training on slaughter inspection, sampling methodology, Hazard Analysis and Critical Control Points (HACCP), Sanitation Standard Operating Procedures (SSOP), food microbiology, meat technology, meat inspection, and handling of specified risk materials (SRM). In-plant inspection officials (IIO) also receive compilations of the regulations of the system, which provide clear descriptions of the sanitary measures that establishments must implement and the regulatory actions that government officials are to take to ensure compliance. However, the FSIS auditor observed that at two of the three establishments audited, IIOs were not ensuring full compliance of establishments with the regulations of the system that apply to: 1. Construction, design and maintenance of facilities; 2. Design of HACCP programs; and 3. Post mortem inspection. This finding makes evident that the CCA must improve the manner in which it assesses the performance of IIOs. Furthermore, the CCA must ensure that DIPOA officials possess the knowledge, skill and abilities (KSAs) required to adequately enforce the regulations of the system. More information related to these three areas of concern is found in the sections of this report that discuss Sanitation, HACCP and Statutory Authority and Food Safety Regulations components.

In conclusion, the Costa Rican MIS is organized and administered by the national government and provides standards equivalent to those of the federal system of meat inspection of the United States. However, FSIS found that IIOs were not ensuring full compliance of establishments with the rules of the system. This indicates that the manner in which the CCA maintains government oversight of the establishments is inadequate. Accordingly, the CCA must effectively verify that IIOs possess and utilize the KSAs to ensure full regulatory compliance of certified establishments with the regulations of the system.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework utilized by the CCA to impose upon producers, requirements equivalent to those governing the system of meat inspection of the U.S.

The evaluation of this component included an analysis of information provided by the CCA in the SRT (2009 Version) and observations gathered during the onsite audit of the system. FSIS verified that the MIS of Costa Rica has statutory authority to deliver inspection to all establishments certified to slaughter and process meat products as described in Costa Rica's Law No. 8495, GLNSAH; MAG 34319, OSNAHS; MAG 29588, VISPPMR and MAG 26559, HACCP. The above listed documents constitute the legal framework upon which the Costa Rican MIS bases its decisions to require that

establishments produce safe, wholesome, and properly labeled and packaged meat products for domestic and international markets. The regulations of the system apply to sanitary design, construction, and maintenance of facilities and equipment; sanitation programs; production activities conducted in slaughter and processing rooms; HACCP systems; and other consumer protection requirements; as well as, control of inedible and condemned materials. In addition, the CCA has legal authority to impose administrative controls, and to initiate civil and criminal prosecution of parties involved in violations of the statutory requirements of the system. The system also provides requirements for daily inspection as well as official periodic supervisory reviews of certified establishments.

FSIS conducted onsite observations and reviewed official records to verify that official inspection and verification activities followed the established regulatory framework to ensure establishments' regulatory compliance. The FSIS auditor observed that during ante-mortem inspection, IIO verify identification and origin of arriving cattle and inspect all animals at rest and in motion, in accordance with established regulatory procedures. IIOs ensure that only animals that pass ante-mortem inspection continue to slaughter and also verify that operators comply with humane handling requirements imposed by the Costa Rican government. Dispositions of suspects during ante-mortem and post-mortem, and verification of acceptability of the final product is the responsibility of the resident MVIs, who prepare daily post-mortem disposition reports to document their official control actions. The MVIs have legal authority to condemn carcasses and adjust production rates in accordance with the incidence of pathology and other characteristics of the livestock being inspected that they observe.

The regulations of the Costa Rican MIS also prescribe the procedures which IIOs must follow to conduct post-mortem inspection of heads, viscera and carcasses. FSIS observed their performance and verified that at the head inspection station, the IIO sliced lymph nodes and observed the cut surfaces, sliced head muscles, palpated tongues and made dispositions on the acceptability of the inspected parts for human consumption. At the viscera inspection table, the IIO palpated lymph nodes, palpated lungs and liver, incised and explored the bile duct, and observed and palpated the kidneys. However, at one of the two slaughter establishments audited, the FSIS auditor observed a government inspector not following the regulatory procedure to inspect carcasses. The inspector stood in a fixed position at floor level and from that position could not inspect areas of the carcass that were beyond his reach, namely, the caudal surfaces of the posterior quarters. Consequently, carcass inspection was not consistent with the official procedure stipulated in MAG Regulation 29588, Chapter XX, Article 136 that requires government inspectors to visually examine the entire carcass and palpate lymph nodes located in the anterior, posterior and lateral areas of carcasses. Furthermore, the establishment was not in compliance with MAG 29588, Chapter VII, Article 33, Item b; that requires establishments to provide equipment needed by inspection personnel to perform inspection duties. The FSIS auditor further observed that notwithstanding the inadequacies of official carcass inspection, the establishment adequately compensated for that deficiency. Quality Assurance (QA) and production personnel stationed adjacent to the government's carcass inspection station, inspected and trimmed carcasses' defects

prior to the final QA carcass inspection station where carcasses were again assessed to ensure their acceptability prior to being allowed to continue to the chilling room.

DIPOA officials promptly addressed the above described finding. As an immediate corrective measure, DIPOA officials reduced line speed and required that the establishment modified the inspection station to permit the IIO to inspect the entire carcass. In addition, the IIO-carcass inspector received additional supervisory guidance followed by an evaluation of his competence to properly conduct inspection of carcasses. As a long term corrective measure, DIPOA officials indicated that they would coordinate with plant management to decide on the permanent location and design of the IIO's carcass inspection station.

Periodic supervisory reviews of certified establishments that consist of evaluations of adequacy of establishments' food safety systems and delivery of official inspection and verification services are conducted by the DIPOA Director, the Chief of the Auditing Department and the Area Coordinator. During this audit, FSIS reviewed supervisory reports and verified that supervisory personnel had documented outcomes of periodic reviews of the performance of IIOs and establishments. Supervisory officials and CCA experts had evaluated design and maintenance of the facilities, sanitary conditions, monitoring of food safety systems, verification and inspection activities and technical competence of IIOs. Additionally, FSIS conducted onsite observations of supervisory officials as they evaluated design and maintenance of the facilities, sanitary conditions, monitoring of food safety systems, official verification activities and technical competence of in-plant officials. The assessment of supervisory records that contain results of evaluations and observations made onsite, revealed that supervisors: a) periodically assess the functions of officials and establishment operators, b) document findings, c) verify adequacy of corrective actions and d) provide guidance to IIOs to correct deficiencies and develop their competence. However, FSIS's audit findings described in several sections of this report, that relate to government oversight, sanitation, and HACCP components of the system, in addition to the findings described above for post-mortem inspection, indicate that the CCA must improve the manner in which DIPOA officials conduct supervisory periodic reviews to ensure a more accurate assessment of the performance of IIOs.

In conclusion, the CCA of the MIS of Costa Rica has legal authority which it has used to develop a regulatory framework to impose requirements upon the sectors of the system that are equivalent to those governing the system of meat inspection organized and maintained by the United States. However, FSIS found that supervisory reviews inadequately assessed the ability of IIOs to fully enforce the regulatory requirements of the meat inspection system that apply to post mortem inspection, HACCP and sanitation verification. Conclusively, it is necessary for the CCA to assess the knowledge and/or the execution of duties performed by supervisory personnel to ensure that during periodic reviews, opportunities for improvement of regulatory services are appropriately recognized, acted upon and resolved.

7. SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures.

The evaluation of this component included a desk review and analysis of the responses provided by the CCA in the Sanitation component portions of the SRT (2009 Version) covering Sanitation Performance Standards and Sanitation Standard Operating Procedures (SSOPs). References to the responses provided included Law No. 8495, GNSAH; MAG 29588, VISPPMR; MAG 26559, HACCP and government records reporting results of verification and monitoring of sanitation programs.

FSIS verified that the CCA uses its legal authority to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. Furthermore, FSIS verified that inspection personnel exercise their official authority as prescribed by the regulations of the system and follow guidance provided by DIPOA-PG-002-IN-001, General Instructions for Auditing HACCP Systems (GIAHS), to verify that the establishments adequately implement pre-requisite programs such as SSOPs, good manufacturing practices and sanitation performance standards. However, at two of the three audited establishments, FSIS detected that DIPOA officials had not identified the following sanitary deficiencies related to the construction and maintenance of establishments' facilities:

- During verification of the preoperational sanitation program at the only establishment that the CCA has certified to export for ready-to-eat (RTE) products to the U.S., FSIS observed that direct and indirect product contact surfaces of equipment and other structures in the post lethality environment could not be easily cleaned and sanitized. The RTE production facilities had been recently built and the structures in the room did not show signs of chronic lack of maintenance. However, organic residue had started to accumulate on rough surfaces of pieces of equipment, surfaces of deteriorating caulking material, and the surfaces of bundled long electric cords. Conveyor belts and conduit lines also had multiple crevices that made cleaning and sanitizing of their surfaces difficult. Supervisory DIPOA officials immediately provided guidance to the inspector in charge (IIC) on the sanitary standards to be enforced in RTE production areas and instructed the IIC to evaluate and document non-compliances found in the entire RTE production area.
- At one of the two slaughter establishments audited, FSIS observed that repairs to several areas of the ceiling of the debone production room, had created multiple surfaces where caulking material was not smooth and could not be easily cleaned and sanitized. FSIS also observed rough welding and accumulation of corrosion on the surfaces of overhead rails in a carcass chilling room. DIPOA officials had identified similar non-compliances in one section of the establishment and plant management had planned to correct the problems. However, there were

inadequately maintained overhead structures in other areas of the plant that inspection personnel had not identified for abatement.

These findings indicate that the CCA was not adequately enforcing the regulatory requirements that apply to sanitation programs. Specifically, regulatory requirements contained in three separate chapters of MAG 29588, VISPPMR that are described below:

1. Chapter VI, Article 28 item b, that requires establishment structures that are solidly built, adequately maintained, and designed to allow easy cleaning and sanitizing of its surfaces
2. Chapter XXVII, Article 174, item d, that calls for smooth, impermeable ceilings that can be easily cleaned
3. Chapter XXVIII, Article 182, that calls for equipment and machines built and installed in a manner that facilitates their cleaning and sanitizing

At the RTE establishment, DIPOA officials immediately initiated a comprehensive evaluation of the adequacy of the sanitation program of the establishment and identified additional sanitary non-compliance that were documented and presented to the establishment managers with a request for corrective actions. At the slaughter establishment, DIPOA representatives indicated to the FSIS auditor that following the implementation of immediate corrective actions, the establishment would make major structural renovations that will improve the facilities in the near term. The FSIS auditor did not observe evidence of direct product contamination in the production areas where the above described deficiencies were identified. In the case of the RTE establishment, the facilities were newly constructed and results of sampling of product and environmental surfaces in the post lethality environment conducted by DIPOA and the establishment have yielded negative results for the presence of *Listeria monocytogenes*. However, these deficiencies in construction, and maintenance of the establishment's facilities, even when they don't represent an immediate risk to the safety of the meat products, must be corrected to prevent the creation of insanitary conditions which could cause adulteration of product. Accordingly, the CCA must ensure that in plant inspection personnel adequately and consistently execute verification activities that result in the identification and correction of deficiencies of sanitation programs within the establishments. Furthermore, FSIS requests that the CCA verify and document the adequacy of implementation of the long term corrective measures proposed by the establishments, and send to FSIS the results of the verification activities with its comments to this report.

DIPOA officials incorporated into the corrective actions plan, training of in-plant inspection personnel and proceeded to organize ad-hoc training that was delivered by subject matter experts in April 2012. The FSIS auditor received documentation that describes delivery of training on food microbiology and evaluation of sanitation programs to in-plant inspection personnel.

In conclusion, the results of the assessment of the sanitation programs conducted by FSIS, demonstrates that the Costa Rican MIS provides requirements equivalent to those of the U.S. system for sanitation performance standards, sanitary handling of products, and for the development and implementation of sanitation standard operating procedures

that prevent direct product contamination. However, the CCA must ensure that in-plant officials improve their ability to consistently and adequately evaluate the sanitation programs implemented by the establishments to ensure that they remain in compliance with the regulations of the system. Furthermore, FSIS requests that the CCA verify and document the adequacy of implementation of the long term corrective measures proposed by the slaughter establishment, and send to FSIS the results of the verification activities with its comments to this report.

The comments to this report that FSIS received from the CCA, contain assurances of its commitment to implement all corrective actions and to train inspection personnel periodically to ensure continuity of their proficiency. Furthermore, the CCA has delisted the RTE processing establishment due to its inability to meet the requirements of the Costa Rican MIS.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require that each official establishment develop, implement and maintain a HACCP program.

The evaluation of this component included a review and analysis of information provided by the CCA in the HACCP portion of the SRT (2009 Version) and documents submitted as support for the responses given including Costa Rica's Law No. 8495, GLNSAH; MAG 34319, OSNAHS; MAG 29588, VISPPMR and MAG 26559, HACCP and DIPOA-PG-002-I-01, General Instructions for Auditing HACCP Systems (GIAHS). Additionally, FSIS conducted onsite observations to assess the operations of the establishments and local government offices of the system.

The FSIS auditor verified that the CCA has issued regulations that require that establishments that operate under the Costa Rican MIS, develop, implement, and maintain HACCP programs that the CCA must approve. The Auditing Unit (AU) of DIPOA manages the HACCP program reviews and auditing activities. The AU evaluates the design and implementation of all certified establishments' HACCP programs yearly, prior to granting of certification renewal.

The approval process includes the review of all aspects of the written HACCP programs and it is conducted by auditors from the AU, who follow procedure DIPOA-PG-002-I-01, GIAHS to accomplish that task. The AU auditors review HACCP program documentation to verify that the design of the program meets regulatory requirements. In accordance with the GIAHS, the auditors verify that establishments include in their written program, the individuals who form the HACCP team; a description of products, including their shelf life; accurate flow charts describing processing steps and flow of product; hazard analyses for each step in the process; and the HACCP plans prepared to control identified hazards. The evaluation also assesses the design of critical control points (CCPs), their validation, and the scientific knowledge that supports the decisions made by the establishments to select the critical limits (CL).

The responsibilities of in-plant personnel are limited to daily verification activities that include reviews of monitoring records and hands-on procedures to assess the adequacy of implementation of HACCP plans on the part of the establishments. The MVIs receive weekly assignments that direct them to conduct specific HACCP program verification tasks and prepare daily reports of findings and actions taken. In addition, the MVIs file monthly reports describing the results of their verification activities with the DIPOA headquarters.

FSIS evaluated onsite, the design and execution of HACCP programs at three certified slaughter establishments. Documentation reviewed by the FSIS auditor made evident that CCA representatives conduct regular verifications of the adequacy of the HACCP programs used by the certified establishments. Review of records maintained by IIOs and onsite observations conducted by FSIS demonstrate that in-plant officials conduct daily verification of the adequacy of implementation of the HACCP programs. IIOs conduct daily reviews of monitoring records, hands on measurements at the CCPs' stations and verify adequacy of corrective actions. The FSIS auditor reviewed a sample of monitoring records associated with establishments' HACCP plans for raw and RTE meat products that included temperature controls during fabrication of raw meat products and product temperature controls during the lethality, stabilization and drying steps in the processing of RTE meat products. Technicians documented results of measurements of temperature critical limits at the frequency specified by the HACCP plans and documented corrective actions. In the case of raw products production, FSIS verified that when product's temperature deviated from the critical limit (CL), the products were segregated, the cause of the deficiency was identified, the safety of the product assessed, and all actions taken were documented. In the case of RTE, no deviations from the critical limits had been reported. The records also contained entries that showed that government inspectors regularly verified adequacy of CCP monitoring activities.

The overall verification conducted by FSIS demonstrated that the CCA exerts its legal authority to require that operators comply with the HACCP System rules. Additionally, IIOs maintain daily verification of implementation of HACCP programs and HACCP auditors from the AU have identified and documented non-compliances in the design of written HACCP programs, which establishments have promptly corrected. However, FSIS found that the design of the written HACCP programs still had flaws as described below:

- The hazard analysis conducted at one establishment identified microbial contamination rather than microbial growth as the hazard to be controlled by adequate chilling of product. Similarly, the hazard analysis conducted for the stabilization step of the RTE beef production process did not identify spore forming organisms as the biological hazards of concern. In both situations, prerequisite programs and good manufacturing practices effectively ensure food safety of the beef products. Quality assurance personnel continuously control temperature of product and production rooms. Monitoring records show that raw product is adequately chilled to reach a temperature below 45° F to control microbial growth and cooked product, in accordance with the manufacturing

process, is immediately chilled after cooking to prevent germination of spore forming pathogens.

The above findings make evident that the AU and DIPOA officials that review written HACCP programs as part of the approval process for recertification, need to improve the knowledge, skills and abilities required to adequately perform their duties

DIPOA officials documented the above described findings in non-compliance records issued to the establishments. The CVO indicated that the corrective actions would include immediate review and revisions of the design of the non-conforming portions of the HACCP programs identified during the audit on the part of the establishment. Also as part of the corrective actions, DIPOA stated that SENASA would conduct comprehensive audits of the HACCP programs of all certified establishments to ensure that they meet the requirements of the system. Consequently, FSIS requests that the CCA provide a report on the verification of the adequacy of implementation of the corrective actions proffered to address the above reported findings.

In conclusion, the Costa Rican MIS has the legal authority to impose upon certified establishments, requirements for the development, implementation and maintenance of HACCP plans in a manner that is equivalent to the HACCP regulatory requirements of the meat inspection system organized and maintained by the U.S. However, the CCA was unable to demonstrate that the review process of the written HACCP programs prepared by the establishments was adequate. Although, the identified deficiencies did not have an eminent impact on the safety of the meat products, the CCA must ensure that HACCP plans are developed in an adequate manner. Furthermore, the CCA must ensure that the AU and DIPOA officials that review the written HACCP programs for approval possess the knowledge, skills and abilities required to adequately perform their duties. Additionally, FSIS requests a report of the corrective actions implemented by the CCA to address the reported findings related to this component.

The comments to this report that FSIS received from the CCA, contain assurances of its commitment to implement all corrective actions and to train inspection personnel periodically to ensure continuity of their proficiency. Furthermore, the CCA has delisted the RTE processing establishment due to its inability to meet the requirements of the Costa Rican MIS.

9. CHEMICAL RESIDUES CONTROL PROGRAMS

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residues Control Programs. This component pertains to regulatory requirements for the inspection system to have a chemical residue control program that is organized and administered by the national government. The program must include random sampling of tissues collected from organs and carcasses to be analyzed for the presence of chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential food contaminants. The program must also include regulatory measures to deter recurrence of violations to the presence of chemical residues in meat products.

FSIS assessed the Costa Rican residue control program by analyzing information provided by the CCA, prior to and during the audit of its central offices, the official chemical residue laboratory and two certified slaughter establishments. Documents submitted by the CCA included Law 8495, GLNSAH; MAG 29588, VISPPMR; and Costa Rica's Annual Residue Control Plan (2011 and 2012). The contents of these documents indicate that the MIS of Costa Rica has legal authority to regulate, plan and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of cattle slaughtered for processing of meat for human consumption. This regulatory task is accomplished with the participation of the residue laboratory of LANASEVE, and technical teams from the SENASA Directorates for Veterinary Pharmaceuticals, National Operations, Quarantine and DIPOA that work under the coordination of the Residues Program Manager (RPM), who reports directly to SENASA's Executive Office.

FSIS verified that SENASA, as the CCA has the authority and resources to remove violative product from the human food chain and to take regulatory action against individuals who introduce violative meat products in to the human food chain. The residues control program derives its legal authority from the GLNSAH that contains provisions that define the authority of SENASA to regulate the use of veterinary drugs and verify that they are used in accordance with their prescribed indications. SENASA has an administrative process in place for individuals that supply, process or distribute products of animal origin that are found to contain violative levels of chemical residues.

The RPM coordinates the review of test results, the elaboration of the annual residues plan, the design of control and monitoring activities implemented, the collection and analysis of data derived from analyses of samples, and the dissemination of compilations of gathered results among national and international bodies.

DIPOA prepares the annual sampling schedules and distributes instructions to the MVI for random sampling of tissues. Sampling, handling and transporting of samples is done in accordance with standard instructions contained in government issuance DIPOA-PG-015 provided to IIOs in the field.

FSIS verified during the onsite audit of the Costa Rican MIS the adequacy of the implementation of the residue control program. Observations and review of documents conducted at establishments and the LANASEVE laboratory demonstrated that the CCA provides regulatory guidance to IIOs, plant personnel and the official laboratory, to ensure effective monitoring of chemical residues at slaughter establishments certified to produce meat products for export to the U.S.

FSIS observed that IIOs appropriately verify traceability of all slaughtered animals and adequate identification of violators. During the evaluation of ante-mortem inspection, the FSIS auditor observed that government inspectors verify that all lots of cattle are accompanied by documentation that disclose their origin, describes their registered

branding, and includes a signed affidavit that attest that cattle owners have adhered to veterinary pharmaceuticals withdrawal periods. Once within the slaughter facilities, IIOs collect tissues of randomly selected slaughtered animals in accordance with the prescribed methodology provided by the RPM. In-plant officials collect samples of the required matrices for detection of specific analytes, while adhering to the prescribed sample collection schedules.

The sampling protocol in the residue control program followed includes provisions for test and hold practices test and hold practices for all instances in which samples for residue analysis is conducted to ensure that only products that have tested negative for the analytes of interest are released for export to the U.S. The procedure followed by SENASA officials when a positive result is identified, includes notification by the laboratory to the MVI via telephone. The laboratory also sends a memorandum to the DIPOA-Area Coordinator, who in turn officially notifies the MVI of the results to initiate follow-up activities to trace back and target the supplier for increased surveillance. IIOs formally notify the establishment of the results and request corrective actions that are to include an investigation of the reasons causing the presence of residues in the animals received.

The documents reviewed by FSIS show that LANASEVE serves as the official residue laboratory that conducts analyses of samples for the presence of nine groups of compounds. The Central Accrediting Entity (ECA), which is the agency of the Costa Rican government in charge of enforcement of Law No. 8279, National System of Quality, has audited this laboratory for accreditation and determined that it, meets the requirements of ISO 17025:2005. The chemical residues laboratory uses methods of analysis that include FSIS methods and validated methods that conform to international standards.

At the official laboratory, the FSIS auditor also reviewed training records and certifications associated with the qualifications of the analysts. The documents reviewed made evident that analysts had successfully participated in intra and inter laboratory evaluations administered by the laboratory manager and accrediting bodies. Furthermore, records and past laboratory audit reports demonstrate that laboratory managers readily respond to correct non-conformities identified during internal and external audits. Documentation on file at the laboratory also demonstrates that the analysts possess the academic qualifications, technical credentials and accreditations required to conduct analysis within their accreditation scope.

FSIS reviewed Costa Rica's residue monitoring plans results for years 2010 and 2011. The results indicate that the presence of veterinary drugs and environmental contaminants in beef products is being monitored. As it pertains to macrocyclic lactones (ivermectin, doramectin, moxidectin and abamectin) in slaughtered cattle, the results of sampling provided to FSIS, show that in 2010, there were seven out of 279 samples analyzed that tested above tolerance for ivermectin, but below maximum limits. The CCA in response instituted regulatory measures and subjected identified suppliers to increased surveillance of their herds. Additional measures included increasing the number of samples that were

to be collected in 2011 and conducting educational outreach on the importance of adherence of ranchers to withdrawal periods for veterinary drugs. The CCA also initiated modifications to Costa Rica's statutes to incorporate legal mechanisms to control the distribution of macrocyclic lactones (ML).

In 2011, a reduction of positive results for ML was observed. There were two positives out of 191 samples for ivermectin reported, both samples being below violative levels. Furthermore, in that same year, the CCA promulgated Executive Decree No. DG-D003-2011 that mandates that ML used as parasiticides, be only dispensed under the prescription of a veterinarian.

In conclusion, the MIS of Costa Rica has regulatory requirements for a chemical residue control program that is organized and administered by the national government. The program includes random sampling of internal organs and fat of carcasses for chemical residues and the program is adjusted on a yearly basis to address emerging concerns. The program also contains provisions that in accordance with Costa Rican law impose penalties on those that supply cattle with violative residue levels to establishments. Therefore, this component of Costa Rica's MIS meets ongoing equivalence requirements.

10. MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to microbiological analysis programs that the Costa Rican MIS administers to verify that products for export to the U.S. are safe and wholesome.

During this audit, FSIS evaluated the microbiological raw beef products sampling and testing programs for generic *E. coli*, *Salmonella*, *E. coli O157:H7* and *Listeria monocytogenes*. The assessment included analysis of information provided by the CCA in its SRT (2009 Version) and several DIPOA issuances that provide standardized instructions to field personnel on sampling, handling and shipping of samples and official control actions to be taken when positive results are received from the laboratory. In addition, FSIS conducted observations and review of records at government offices, the official microbiological laboratory and at three certified establishments.

The FSIS auditor verified that IIOs perform verification activities related to establishments' sampling program of raw products for generic *E. coli* and require corrective sanitary measures when sampling results exceed established tolerance levels. IIOs verify that establishments have samples analyzed at LANASEVE approved laboratories that use acceptable analytical methods. IIOs also collect weekly random samples to verify that the establishments' programs meet the regulatory requirements of the MIS of Costa Rica.

In reference to the *E. coli O157* testing program, documents reviewed by the FSIS auditor including government issuance DIPOA-PG-005, *E. coli O157:H7*, Sampling Instructions;

in-plant inspection records; and microbiology laboratory sample receiving logs, indicate that DIPOA officials collect samples of beef destined to the U.S.

The frequency of official sampling of raw beef products to verify the effectiveness of the establishments' interventions to control *E. coli* O157:H7 is, either weekly at establishments with their own verification sampling program, or daily, at establishments that elect to use official sampling to that effect. In all instances, collection of samples is done according to N-60 methodology, notifying the establishments of the importance to withhold the sampled products. The Costa Rican MIS has regulatory procedures in place that are to be implemented when products test positive for the presence of *E. coli* O157:H7. Those measures are consistent with current U.S. practices that include in-plant corrective actions and product recall if necessary. The FSIS auditor conducted an analysis of the records maintained by the establishments and DIPOA officials and verified that beef products from both establishment audited have not had a confirmed positive result for the presence of *E. coli* O157. Beef products from Costa Rican certified establishments have not tested positive for the presence of *E. coli* O157 at U.S. POE in the last three years.

During the audit, FSIS also verified that DIPOA samples and tests beef carcasses for the presence of *Salmonella* at certified slaughter establishments. Random samples are collected every 300 carcasses following standardized sampling methodology. The samples are then analyzed at the official microbiological laboratory using a validated and acceptable method to detect and quantify *Salmonella* in raw meat products. Corrective actions that are implemented when carcasses test positive include disposing of the affected product by a method acceptable to the MVI, intensifying sampling frequency and re-evaluating the dressing and sanitation procedures. Management officials at the microbiology laboratory indicated that the *Salmonella* sampling program has recently introduced an initiative by which all positive samples are further serotyped to characterize their prevalence and public health significance.

The *Lm* prevention and control program for U.S. certified establishments that SENASA administers requires that establishments producing RTE products consider *Listeria monocytogenes* (*Lm*) as a biological hazard reasonably likely to occur in the post lethality environment. Consequently, establishments must control *Lm* through their HACCP plans or prevent it from occurring in products and the post lethality environment with sanitation programs or other pre-requisite programs. SENASA officials indicated that establishments exporting RTE products to the U.S. have chosen Alternative 3 to prevent and control *Lm* in the post-lethality environment and in RTE products. Furthermore, the establishments have developed and included in their sanitation programs, procedures for testing of product contact surfaces in the post-lethality environment to ensure that the surfaces are sanitary and free of *Lm* or an indicator organism. IIOs in turn verify the adequacy of implementation of control and prevention measures by conducting verification sampling and regular sanitation monitoring records reviews.

Official microbiological sampling conducted at RTE establishments by DIPOA inspectors program includes sampling of products, food contact surfaces and non-food

contact surfaces. Sampling frequency is determined by the risk that type of product and the control and prevention alternative chosen by the establishment. The CCA, following FSIS *Lm* control guidelines, assigns to establishments that operate under Alternative 3, a high risk level and consequently, subjects them to more frequent sampling.

FSIS verified that DIPOA personnel stationed at establishments that produce RTE products have received training on verification activities for the control of *Lm* and follow instructions provided by government issuance DIPOA-PG-007, Sample Collection and Official Frequencies for RTE Establishments. The instructions contained in that document prescribe sampling protocols, sampling frequencies, as well as sample handling procedures. The FSIS auditor reviewed records maintained DIPOA officials at the establishment and at the microbiological laboratory that document that IIOs stationed at RTE producing establishments sample product, direct product-contact surfaces and non product-contact surfaces on a monthly basis. Product samples are sent to the LANASEVE microbiological laboratory to be analyzed for both *Lm* and *Salmonella*.

The FSIS auditor also verified that the audited RTE producing establishment conducted a hazard analysis that recognizes *Lm* and *Salmonella* as biological hazards reasonably likely to occur in the post-lethality environment. Therefore, the establishment decided to use its sanitation program to control and prevent those hazards. Consistently with DIPOA's regulatory requirements, the establishment verifies the adequacy of *Lm* and *Salmonella* control and prevention activities. The establishment's program contains provisions to be implemented when product contact surfaces test positive for the presence of *Lm* or an indicator organism. The protocol to be followed is consistent with the regulatory requirements contained in 9 CFR 430, which DIPOA has adopted as its regulatory requirement. The FSIS auditor review documents that included the sampling program and records of sampling collection, daily production and laboratory results. This review made evident that the establishment operates one production line and has identified all product contact surfaces, sites for sampling, sampling frequency, and actions to be taken when either the government or the establishment find a positive sample. Additionally, the records showed that the establishment followed its sampling protocol; technicians swabbed product contact surfaces prior and during production. Products are not released to the market until the results of the analyses are received and found negative for the presence of *Lm* and *Salmonella*. Product destined for the U.S. market is routinely tested and held. All establishment collected samples are analyzed by a private laboratory that uses a method of analysis approved by SENASA and the results of the sampling are shared with IIOs. Results of product and environmental surfaces sampling conducted by DIPOA and the establishment indicated that no positive results for the presence of *Lm* have occurred from the time the facility first initiated RTE production.

Additional documents reviewed by FSIS show that the microbiological laboratory of LANASEVE conducts analyses of official samples for the presence of microbial pathogens in Costa Rican meat products for export to the U.S. The Central Accrediting Entity (ECA), which is the agency of the Costa Rican government in charge of enforcement of Law No. 8279, National System of Quality, has audited the microbiology

laboratory for accreditation and determined that it, meets the requirements of ISO 17025:2005. The laboratory uses methods of analysis that include FSIS methods and validated methods that conform to international standards. The FSIS auditor also reviewed training records and certifications associated with the qualifications of the analysts. The documents reviewed made evident that analysts had successfully participated in intra and inter laboratory evaluations administered by the laboratory managers and accrediting bodies.

Furthermore, records and past ECA laboratory audit reports identified non-conformities related to standardization of recordkeeping practices, control of reagents and safety of personnel. Reported non-conformities related to control of forms, inadequate recordkeeping practices, harmonization of codification of records kept electronically and in hard copy documents and inconsistent documentation of analytical processes. As in the case of third party audits, QA auditors notify managers of the identified non-conformances, managers implement corrective actions and QA conducts follow-up audits.

Laboratory managers corrected non-conformities and ECA conducted a follow-up verification audit to close the non-conformities. FSIS also reviewed reports of monthly internal audits conducted by the LANASEVE Quality Assurance team. Non-conformities reported by QA were communicated to laboratory managers and corrective actions were being implemented as short term and long term depending on the nature of the non-conformities. Documentation on file at the laboratory also demonstrates that the analysts possess the academic qualifications, technical credentials and accreditations required to conduct analysis within their accreditation scope.

All analytical work performed by the sectors of the CCA that are involved in the administration of the microbiological testing programs is fully reimbursable by establishment operators who pay for services rendered to the treasury of the MAG.

In conclusion, the MIS of Costa Rica administers microbiological analysis programs to verify that products for export to the U.S. are safe and wholesome. Therefore, this component of the system meets equivalence requirements.

11. EXIT MEETING

An exit meeting was held on April 3rd, 2012 in Barreal, Heredia with the participation of representatives from the CCA, DIPOA and LANASEVE. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

The CCA understood the findings and indicated that upon receipt of the draft final report they would provide further information that documents implementation of corrective actions to the findings of this audit.

12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The audit outcome made evident that the current level of government oversight provided by the CCA requires improvement to ensure that ongoing equivalence of the Costa Rican MIS is maintained. The representatives of DIPOA address the findings that FSIS identified within the several components by implementing immediate and adequate corrective actions and proposed long term corrective measures to further address the findings of this audit, which are summarized below:

- Government Oversight Component
 - FSIS observed that at two of the three establishments audited, government oversight was not adequately implemented. Inspection officials were not ensuring full compliance of establishments with the regulations of the system for construction, design and maintenance of facilities, design of HACCP programs and post mortem inspection. This finding requires that the CCA improve the manner in which it oversees the performance of officials stationed at certified establishments to ensure adequate enforcement of the regulations of the system. Accordingly, the CCA must establish pertinent corrective actions to ensure that full regulatory compliance is consistently attained at certified establishments

- Statutory Authority and Food Safety Regulations
 - FSIS observed that the regulatory requirements of the Costa Rican meat inspection system, related to post mortem inspection, sanitation and HACCP components, were not being fully enforced. In addition, it is necessary for the CCA to assess the knowledge and/or the execution of duties performed by supervisory personnel to ensure that during periodic reviews, opportunities for improvement of regulatory services are appropriately recognized, acted upon and resolved

- Sanitation Component
 - The CCA must develop strategies to ensure that in plant officials effectively evaluate compliance of establishments with regulations pertaining to sanitary requirements at certified establishments. Accordingly, the CCA must ensure that in-plant officials improve their ability to consistently and adequately evaluate the sanitation programs implemented by slaughter and RTE processing establishments to ensure that they remain in compliance with the regulations of the system

- HACCP Component
 - The CCA was unable to demonstrate that the review process of the written HACCP programs prepared by the establishments was adequately conducted. Accordingly, the CCA must ensure that HACCP plans are developed in accordance with prescribed specifications and must also ensure that the DIPOA officials tasked with the responsibility to review

written HACCP programs for approval possess the knowledge, skills and abilities required to adequately perform their duties

DIPOA officials promptly addressed the findings summarized above by implementing immediate corrective actions. However, the need for the CCA to provide verifiable information concerning implementation of long term corrective measures still remains. Therefore, the CCA must provide to the FSIS, additional documentation pertaining to the effective implementation of the long term corrective actions that were proposed by Costa Rica to address the findings presented in this report. Specifically, FSIS requests a report that describes the actions taken by the CCA to:

- Verify that IIOs possess and utilize the KSAs to ensure full regulatory compliance of certified establishments with the regulations of the system
- Verify and document the adequacy of implementation of the long term corrective measures proposed by the establishments to address structural non-compliances
- Assess the knowledge and/or the execution of duties performed by supervisory personnel to ensure that during periodic reviews, opportunities for improvement of regulatory services are appropriately recognized, acted upon and resolved.
- Coordinate with plant management the permanent location and design of the IIO's carcass inspection stations
- Ensure that in-plant officials improve their ability to consistently and adequately evaluate the sanitation programs implemented by the establishments to ensure that they remain in compliance with the regulations of the system
- Ensure that the AU and DIPOA officials that review written HACCP programs for approval, possess the knowledge, skills and abilities required to adequately perform their duties

The CCA's comments to this report contain assurances of its commitment to implement all corrective actions and to train inspection personnel periodically to ensure continuity of their proficiency and to maintain equivalence with FSIS. Furthermore, the CCA has delisted the RTE processing establishment due to its inability to meet the requirements of the Costa Rican MIS.

Francisco Gonzalez, DVM
Senior Program Auditor



13. ATTACHMENTS TO THE AUDIT REPORT

Foreign Country Response to Draft Final Audit Report (when it becomes available)
Establishments Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|--|--------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Ganaderos Industriales de Costa Rica San Antonio del Tejar, Alajuela Costa Rica | 2. AUDIT DATE 3/27/2012 | 3. ESTABLISHMENT NO. Est. 9 | 4. NAME OF COUNTRY Costa Rica |
| | 5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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 | X |
| 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 | X |
| 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

Slaughter Establishment 9

39/51 Government Oversight/Sanitation

Local inspection officials regularly bring to the attention of plant management the need for correction of problems related to the maintenance of the facilities, but had not conducted a thorough assessment of the conditions of several areas of the establishment. The FSIS auditor observed many areas of the establishment that had become difficult to clean and sanitize. Rough welding in several overhead structures located throughout the establishment, caulking material unevenly applied to areas of the ceiling of the boning room, and corroded sections of overhead structures in the carcass holding coolers, require attention of the establishment and in-plant inspection officials. Supervisory inspection officials indicated that the establishment had obtained approval to remodel the production and storage areas in the near future, but would be required to maintain the facilities already in place. Supervisors added that the company has scheduled suspension of operations to remodel the facilities.

55. The carcass inspector could not inspect all areas of the carcasses presented. The design of the inspection station provided to the inspector did not allow for inspection of the hind portion of the carcass. The regulations of the system indicate that the inspector will inspect all areas of the carcass, and if necessary, lymph nodes located in the posterior limbs will be palpated. Under the current arrangement, the government inspector is unable to meet the Costa Rican regulatory requirement. The head veterinarian at the establishment and the supervisory official had not detected this deficiency. An evaluation of the competency of the inspectors at the carcass inspection station had not been conducted in the last twelve months. However, the wholesomeness of the carcasses is being achieved by compensatory measures that are part of the established dressing procedures. Several establishment employees are positioned on an elevated platform located after official carcass inspection to inspect and trim defects of the posterior portion of carcasses and quality control technicians verify the adequacy of the trimmers' work at the next station where additional inspection and trimming is conducted. Inspection officials initiated corrective actions to provide an adequate inspection station to the carcass inspector. As immediate corrective action the line speed was reduced and the inspector was provided with a stand that must climb to inspect the upper part of the carcasses followed by an evaluation of the performance of the inspector. In addition, long term corrective modifications will be made to the carcass inspection station.

61. NAME OF AUDITOR
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

 9/25/13

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|--|---------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION El Arreo S.A. La Ribera de Belen, Heredia Costa Rica | 2. AUDIT DATE 3/30/2012 | 3. ESTABLISHMENT NO. Est. 12 | 4. NAME OF COUNTRY Costa Rica |
| | 5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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 | X |
| 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. 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

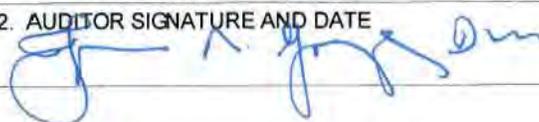
Slaughter Establishment 12

39. Several locations of the ceiling in the deboning room had unevenly applied caulking material that created surfaces that were difficult to clean and sanitize.

15. The hazard analysis recognized microbial contamination rather than microbial growth as the biological hazard to be controlled by the chilling process.

61. NAME OF AUDITOR
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

 9/25/19

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|--|--|---|
| 1. ESTABLISHMENT NAME AND LOCATION Ganaderos Industriales de Costa Rica S.A. San Antonio del Tejar, Alajuela Costa Rica | 2. AUDIT DATE 3/27/2012 | 3. ESTABLISHMENT NO. Est. 9J Processing | 4. NAME OF COUNTRY Costa Rica |
| | 5. NAME OF AUDITOR(S) Francisco Gonzalez, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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 | X |
| 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. 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

Processing Establishment 9J

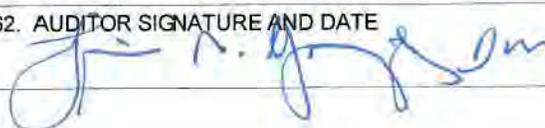
Verification of sanitary conditions in the post lethality environment conducted by plant personnel and official inspectors had not detected areas that could become potential sources of contamination. Pieces of equipment that have direct product contact surfaces and indirect contact surfaces were not designed in a manner that can allow easy cleaning and sanitizing. Caulking flakes on conduit joints, rough welding on indirect product contact surfaces, pieces of equipment such as scales, rollers and conveyor belts with sections that have been modified and are as a result difficult to clean and accumulated organic residue on the surfaces of long electric cords bundled in a manner that prevented their adequate cleaning.

Inspection personnel notified the establishment of the sanitary deficiencies and requested corrective measures. However, the need for the CCA to communicate to inspection personnel the manner in which inspection should be performed in the post lethality environment needs to be addressed too.

15. Reviews previously conducted by supervisory officials and in-plant officials had detected flaws in the design of the HACCP program and the identified deficiencies were adequately corrected. However, during the review of the hazard analysis, the FSIS auditor identified additional instances in which deficiencies existed. The stabilization step recognized the presence of pathogens, which had been eliminated during the lethality step rather than spore forming organisms as the biological hazard of concern. Corrective measures included in the HACCP plan state the water activity parameter to be less than .85 but did not provide a time-frame for the product to reach that limit.

61. NAME OF AUDITOR
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

 9/25/13



SERVICIO NACIONAL DE SALUD ANIMAL (SENASA)



Heredia, 19 de Setiembre de 2013
SENASA-DG-1047-2013

Dr. Shaukat H. Syed
DVM, Director
International Audit Staff
Office of Investigation, Enforcement and Audit
FSIS-USDA
United States Of America

Dear Dr. Syed:

In SENASA all efforts are directed in search of continuous improvement and successfully meet all nonconformities identified the audit conducted by FSIS in March 2012, and the findings detected, SENASA has developed an action plan:

- **Government Oversight Component**

With the purpose to ensuring with regulation the entire establishment approved to export to United States Of America, are conducted remodeling of their physical facilities according with regulation of Costa Rica and FSIS, the no complain about construction, design and maintenance of facilities, design of HACCP programs and Post mortem inspection will be corrected permanently.

Additionally SENASA, is planning for the next October re training in the regulation of slaughterhouses N° 29588 MAG-S, the trainings are subject to evaluation to determine technical competence official group.

In the 2014, SENASA starts with a new training process with emphasis on the issues identified in the audit of the FSIS to ensure and to emphasize the performance of official staff in the detection of non-compliance and the implementation of the regulation. For oversight activities SENASA be conducted performance evaluations for chief audit once a year, the area coordinator twice a year and the official veterinarian twice a year



SERVICIO NACIONAL DE SALUD ANIMAL (SENASA)



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- **Statutory Authority and Food Safety Regulations**

SENASA understood that in some aspects such as knowledge, is the ability to evaluate health programs and need strategies more effective education and training.

SENASA has the regulations and the means to enforce the law in establishments not comply and will be taken to SENASA court and apply the corresponding sanctions such as fines economic or closure of the establishment.

- **Sanitation Component**

SENASA proceed to remove from the list of exporters to the U.S. those establishments that do not comply with the requirements of sanitizing all the detail information will be sent to FSIS.

- **HACCP Component**

SENASA conducted a review of all the HACCP plans of the establishments in order to assess which are in conformity with the law.

The HACCP plan review will be modified so that assessment is conducted together with the official staff in the establishment and the Area Coordinator.

Additionally SENASA increases frequency the verification items of associated with HACCP.

If you need more information please contact me.

Sincerely

Dr. German Rojas Hidalgo
General Director

