USDA

United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW.
Washington, D.C. 20250

MAY 20 2015

Dr. Bernardo Jaén Hernández
Director General, Servicio Nacional de Salud Animal (SENASA)
Ministerio de Agricultura y Ganaderia (MAG)
Heredia, Costa Rica

Dear Dr. Hernández,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Costa Rica's meat inspection system from December 2 through December 11, 2014. 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.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-8609, by facsimile at (202) 720-0676, 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

DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN

COSTA RICA

DECEMBER 2 -11, 2014

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

May 20, 2015

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 December 2 -11, 2014, to determine whether Costa Rica's food safety system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Costa Rica currently exports raw intact beef to the United States, some of which is intended for grinding.

The audit focused on six system equivalence components: Government Oversight (Organization & Administration), Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), Sanitation, Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residue Control Programs, and Government Microbiological Testing Programs. In addition, the auditor verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the March-April 2012 audit findings had been fully implemented.

The audit results indicate that Costa Rica's food safety inspection system is performing at an "adequate" level in meeting the core criteria for all six equivalence components, for which the principal audit findings can be summarized as follows:

- FSIS identified a lack of enforcement on the part of the CCA concerning requirements related to retained water in beef carcasses.
- The audit identified a need for the CCA to improve the manner in which periodic supervisory reviews are conducted in order to better assess the knowledge and the execution of the duties performed by local personnel over time.
- FSIS identified a need for the CCA to better assess the corrective actions proposed by establishments certified for export to the United States in response to sanitation non-compliances.
- FSIS identified deficiencies within the government laboratory quality management system that might compromise the integrity of analyses.

An analysis of these findings did not identify any systemic deficiencies that represent an immediate threat to public health. However, as the ability of the inspection system to ensure export of product that is safe, unadulterated, and properly labeled can be compromised if left unchecked, FSIS requests that CCA provide a detailed response for each of the identified findings within 60 calendar days of receipt of this report.

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

TABLE OF CONTENTS

I. INTRODUCTION 1

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY 1

III. BACKGROUND 2

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION & ADMINISTRATION) 3

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS) 4

VI. COMPONENT THREE: SANITATION 7

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM 8

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE CONTROL PROGRAMS 9

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS 11

X. CONCLUSIONS AND NEXT STEPS 13

XI. ATTACHMENTS TO THE AUDIT REPORT 14

Attachment A: Individual Foreign Establishment Audit Checklist 14

Attachment B: Foreign Country Response to Draft Final Audit Report (when available) 14

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Costa Rica's food safety system from December 2 to December 11, 2014. The audit began with an entrance meeting held on December 2, in Heredia, with the participation of representatives from the Central Competent Authority (CCA) – the *Servicio Nacional de Salud Animal* (SENASA) and an auditor from the FSIS International Audit Staff (IAS).

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 meat products maintains equivalence to that of the United States, with the ability to export products which are safe, wholesome, unadulterated, and correctly labeled and packaged.

During the audit, areas of special emphasis included:

- Corrective actions proffered and implemented by SENASA in response to the previous FSIS audit in 2012.
- Implementation of a recently-developed government verification testing program, determined to be equivalent by FSIS, for non-O157 Shiga toxin-producing *E. coli* (STEC). This program was instituted by SENASA in order to address changes in FSIS domestic policy which occurred in May of 2012, as outlined in the *Federal Register*, Vol. 77, No. 105.

In pursuit of this objective, FSIS applied a risk-based procedure, which included an analysis of the country's performance within six equivalence components, product types and volumes, the frequency of prior audit-related site visits, port-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of the data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA, through a self-reporting process.

The FSIS auditor was accompanied throughout the entire audit by SENASA representatives from headquarters and local inspection offices. Determinations concerning program effectiveness focused on the CCA's performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards) , (3) Sanitation, (4) HACCP, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs.

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

At the time the FSIS audit plan was originally developed, six certified establishments were eligible to export to the United States. On October 16, 2014, FSIS received communication from the CCA reducing the number of certified establishments to three. Consequently, all three beef slaughter and processing establishments certified for export to the United States were audited. During the establishment visits, particular attention was paid to the extent to which industry and the 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.

The *Laboratorio Nacional De Servicios Veterinarios* (LANSEVE), a government laboratory conducting microbiological and chemical analyses related to U.S. exports, was audited in order to verify its ability to provide adequate technical support to the inspection system.

A summary of specific audit locations is provided in the following table:

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Heredia
	Local	3	• Heredia (2) • Alajuela (1)
Laboratories		1 (2 Divisions)	• LANSEVE (Heredia) 1. Microbiological Division 2. Chemical Residue Division
Establishments: Beef Slaughter and Processing		3	• Heredia (2) • Alajuela (1)

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 Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Costa Rica's inspection system for meat products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Sanitary/Phytosanitary Agreement.

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

- National microbiological testing program for STEC, and
- National control program for ready-to-eat (RTE) products.

III. BACKGROUND

Costa Rica is eligible to export beef products to the United States. From October 2012 to July 2014, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 30,558,869 pounds of beef products imported from Costa Rica. FSIS also performed re-inspection on 5,141,073 pounds at point-of entry (POE) for additional types of inspection (TOI).

Of these additional TOIs, a total of 13,938 lbs. (.05 %) was rejected for food safety reasons (contamination with ingesta). Costa Rica currently exports only raw intact beef to the United States, some of which is intended for further grinding. Since the latter part of 2012, Costa Rica has not certified any establishments producing RTE product for export to the United States. Consequently, no establishments producing RTE product were visited during the current audit.

FSIS last audited Costa Rica in 2012 and reported findings that pertained to post-mortem inspection, enforcement of sanitary performance standards, and HACCP recordkeeping. During the current audit, the FSIS auditor verified that these findings had been adequately addressed. The FSIS final audit reports for Costa Rica's food safety system 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

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION & ADMINISTRATION)

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

In accordance with Costa Rican 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 (VISPR)*, SENASA is the agency that serves as the CCA to administer the Costa Rican meat inspection system. The OSNAHS also designates the Directorate for National Veterinary Service Laboratories (LANSEVE) as the section of the CCA that oversees the functions of the chemical residue and microbiological laboratories that provide technical support.

SENASA oversees the functions of the Directorate for Food Safety in Products of Animal Origin (DIPOA), its subordinate agency in charge of regulating the meat industry and certifying establishments to export meat products to the United States. DIPOA-certified establishments undergo initial and continued eligibility evaluations to determine their ability to meet equivalent United States requirements related to the safe production of beef products.

The FSIS auditor verified elements of DIPOA-PG-006, *Procedure to Obtain Initial and Annual Certification to Export Meat Products* and noted that DIPOA officials require that establishments present, along with their applications for certification, a current SENASA license to operate, written Sanitation Standard Operating Procedures (SSOPs), a HACCP Program, and SENASA's Certification of Supplier of Raw Materials of Animal Origin. The auditor observed that inspection officials had reviewed the documents submitted by the establishments, audited the

facilities, and evaluated their ability to meet regulatory requirements prior to granting renewal of certification to export meat to the United States.

The central office of the DIPOA provides inspection officials with written operational procedures, directives, and notifications to ensure the uniform delivery of regulatory oversight at certified establishments.

FSIS verified that DIPOA is staffed with government-paid employees by reviewing form P-21-771-Rev (*Notification of Personnel Action*), which was available at local inspection offices. SENASA recruits veterinarians, who are graduates from government-approved universities and members of the National College of Veterinarians. Prior to assuming their official responsibilities, all official veterinarians receive on-the-job training on veterinary inspection at certified establishments to supplement their academic qualifications. Non-veterinary personnel are also provided with training when they first join DIPOA and receive additional training as needed to perform their assigned duties. The auditor noted that all members of the inspection staff were evaluated before being assigned to United States' export establishments, with outcomes of these evaluations documented on form DIPOA-PG-021-RE-005.

In response to the findings of the 2012 FSIS audit, SENASA has continued its efforts to maintain an adequately trained inspection force. The most recent example of training reviewed by the auditor included a three-day course that occurred in March of 2014. The training curriculum covered auditing of establishment HACCP systems, with specific emphasis on validation, verification, and recordkeeping. This course also included a pre-training evaluation and a final exam, so as to assess its effectiveness. The current audit's lack of identified findings within the HACCP component serves as additional testament regarding the effectiveness of this course.

In conclusion, the audit determined that the Costa Rican government organizes and administers the country's meat inspection system, and that CCA officials are assigned to enforce laws and regulations governing production and export of meat at certified establishments.

The analysis and on-site verification activities indicate that the CCA maintains equivalence and is operating at an "adequate" level for this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety 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.

FSIS verified that the MIS of Costa Rica continues to operate in accordance with Costa Rica's Law No. 8495, GLNSAH; MAG 3431 9, OSNAHS; MAG 29588, VISPR. These 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 statutes include equivalent provisions to address sanitary design, construction, and maintenance of facilities and equipment; production activities conducted in slaughter and processing rooms; and control of inedible and condemned materials. The system also provides requirements for full-time inspection presence whenever slaughter and processing operations are occurring, as well as official periodic supervisory reviews of certified establishments.

The FSIS auditor observed that during ante-mortem inspection, inspection personnel verify the identification and origin of arriving cattle and inspect all animals at rest and in motion and document the results on DIPOA-PG-002-RE-026, *Ante-mortem Disposition Sheet*, in accordance with procedure DIPOA-PG-018 [B], *Ante-mortem Inspection of Cattle*. The auditor also verified that only animals that pass ante-mortem inspection and have been properly documented on RE-DIPOA-002-PG-028, *Ante-mortem Pen Card*, continue on to slaughter. Inspection officials also verify that operators comply with humane handling requirements, and that the results are documented on DIPOA-PG-002-RE-020, *Verification Log for the Humane Handling of Livestock*. The disposition of suspects during ante-mortem and post-mortem inspection, and the verification of acceptability of the final product, is the responsibility of the official veterinarian, who prepares daily post-mortem disposition reports to document any official control actions. Official veterinarians have the legal authority to condemn carcasses and adjust production rates in accordance with the incidence of pathology and other observed characteristics of the livestock being inspected.

The FSIS auditor verified that inspection personnel follow the procedures outlined in DIPOA-PG-013, *Post-mortem Inspection of Bovines*, in order to conduct post-mortem inspection of heads, viscera, and carcasses. The auditor conducted a follow-up of the corrective actions taken at one establishment in association with the previous audit, during which it was observed that the carcass inspector stood in a fixed position at floor level and could not inspect the caudal surfaces of the posterior quarters. This finding was addressed by installing a mobile stand, which was confirmed as now permitting inspection of the entire carcass.

The auditor verified that the CCA effectively implements the requirements outlined in DIPOA-PG-013-IN-004, *Identification, Removal, Segregation, and Disposal of Specified Risk Materials (SRM)*, which also includes provisions preventing the slaughter of non-ambulatory disabled cattle. The results of daily inspection verification activities for SRM control are documented on form DIPOA-PG-002-RE-012. No concerns were identified during the onsite review of these documents.

Periodic supervisory reviews of certified establishments are conducted by the DIPOA Director, the Chief of the Auditing Department, and the Area Coordinator. During this audit, FSIS verified that supervisory personnel had documented outcomes of periodic reviews, which occur every three months in slaughter establishments.

FSIS' assessment of the documentation associated with supervisory reviews indicated that these reports: a) contained extensive documentation of facility non-compliances, but b) present only limited guidance to onsite inspection officials to correct the deficiencies and develop their

competence. Consequently, the extensive nature of non-compliances identified during supervisory reviews pose some concern about the daily verification performed by local inspection personnel between supervisory visits.

Discussions held with the individuals responsible for conducting periodic supervisory reviews indicated that they had already acknowledged this need for improvement, and that modifications within the system were planned for January 2015. Proposed modifications include an increase in the frequency of assigned inspection tasks, as well as mechanisms to provide a more critical analysis of employee performance during periodic supervisory reviews. In response to this audit report, FSIS requests that SENASA provide to FSIS documentation showing that these changes have been effectively implemented.

The auditor also noted that Costa Rica's meat inspection system did not have a verification methodology to ensure that: a) carcasses and parts are not permitted to retain water resulting from post-evisceration processing unless the establishment demonstrates that any retained water is an inevitable consequence of the process used to meet applicable food safety requirements, and b) establishments disclose, on the label of the meat products, the maximum percentage of retained water in the raw product.

At one visited establishment, the FSIS auditor observed that carcass sprays are regularly used in chillers on product exported to the United States, without an accompanying ability to demonstrate that no additional water was added during the process. FSIS requires that both domestic and foreign establishments operate water spray systems in a manner that does not result in an increase in the average weight of a group of livestock carcasses produced during a scheduled period of operations over the carcasses' pre-chilled weight. Under FSIS regulations, a product is adulterated if, among other circumstances, "any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is." Similarly, a product is misbranded if, among other circumstances in which it might be misbranded, "its labeling is false or misleading in any particular." An additional explanation of the requirements related to retained water can be found in *Federal Register*, Volume 66, Number 6; and 9 CFR 441.

This finding poses additional concerns in that FSIS' analysis of import data indicates that the establishment in question is responsible for approximately 50 percent of the product received from Costa Rica. However, on the day of the audit, establishment management and DIPOA immediately committed to working together to develop the necessary protocols to ensure that any added water (if present) would be fully disclosed on the product label.

In response to this audit report, FSIS requests that SENASA provide a detailed description of corrective actions taken by the exporting establishment to address this finding, as well as global changes instituted by the inspection system. These changes should be communicated within 60 days of receipt of the audit report. Furthermore, it is requested that no additional establishments implementing a similar chilling system be certified for export to the United States by the CCA until FSIS communicates its acceptance of the corrective actions submitted.

The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and the development and implementation of sanitation standard operating procedures (SSOP).

FSIS verified that SENASA 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* to verify that the establishments adequately implement pre-requisite programs such as SSOPs, good manufacturing practices, and sanitation performance standards.

The FSIS auditor observed in-plant inspection verification of operational sanitation procedures at all three establishments that were visited. Pre-operational verification activities were also reviewed at one of the three locations. Audit evidence was gathered through direct observation of establishment operations and a review of the establishments' associated records. The auditor noted that, for the most part, the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintain sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticate these records with initials or signatures and the date. No concerns arose as the result of these document reviews.

However, FSIS observed inadequate ventilation in a carcass chiller at one establishment. The body heat from recently slaughtered bovine carcasses produced excessive water vapor that was condensing on surrounding structures, thereby creating insanitary conditions that could result in the contamination of product (although no direct product contamination was observed). Discussions with inspection personnel indicated that the observed conditions were an ongoing occurrence, and the auditor verified that the establishment had drafted plans to construct a new chiller in order to address this issue. While this is acceptable in the long term, inspection personnel should have required the establishment to take immediate action to address this situation by increasing ventilation in this area. As part of a short-term solution to this finding, inspection personnel committed to working with the establishment to increase vigilance in this area (including wiping down structures as needed) and increasing airflow by installing additional fans.

In conclusion, the results of the assessment of the sanitation programs conducted by FSIS demonstrate that the inspection system provides requirements equivalent to those of the U.S. system for sanitation performance standards and the sanitary handling of products and for the development and implementation of SSOPs that prevent direct product contamination. However,

the CCA must ensure that in-plant officials improve their ability to evaluate the sanitation programs implemented by the establishments to ensure that they remain in compliance with applicable government regulations and policies. Furthermore, FSIS requests that the CCA verify and document the adequacy of implementing the corrective measures proposed by the slaughter establishment and provide FSIS with the results of the verification activities within its comments to this report.

The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component.

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

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

The verification of this component was based on information provided in the SRT, including Costa Rica's Law No. 8495, GLNSAH; MAG sections 34319, 29588, and 26559; and DIPOA-PG-002-I-01, *General Instructions for Auditing HACCP Systems*. These issuances require that establishments exporting to the United States develop, implement, and maintain HACCP programs that the CCA must approve. The auditing unit of DIPOA manages the HACCP program reviews and auditing activities. The design and implementation of all certified establishments' HACCP programs are reviewed yearly, prior to granting their export certification renewal.

The approval process includes a review of all aspects of the written HACCP programs, based on procedure DIPOA-PG-002-I-01. The auditing unit within DIPOA reviews HACCP program documentation to verify that the design of the program meets regulatory requirements and verifies 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.

In-plant personnel are responsible for performing daily verification activities, including a review of monitoring records and hands-on procedures to assess the adequacy of the implementation of the HACCP plans on the part of the establishments. Official veterinarians receive weekly assignments that direct them to conduct specific HACCP program verification tasks and prepare daily reports of findings and the actions taken. Monthly reports describing the results of verification activities are provided to DIPOA headquarters.

At the three audited slaughter establishments, the FSIS auditor conducted an onsite review of the zero tolerance (feces, ingesta, and milk) CCP records generated during the past year. In addition, the FSIS auditor reviewed the in-plant inspection records associated with zero tolerance

verification at these locations. All the establishments that were audited conduct 100 percent monitoring of carcasses for this CCP. The review of the establishments' corrective actions in response to the few observed deviations from the zero tolerance critical limit indicated that all four parts of the corrective actions were correctly addressed when they occurred. The physical CCP monitoring location for government verification was before the final wash in all establishments audited.

Each slaughter establishment had adequately reassessed their HACCP plans for the presence of STEC in raw beef. All establishments have validated interventions for these pathogens (peroxyacetic acid carcass sprays) and conduct final product testing for *E. coli* O157:H7. In addition, one establishment conducts additional VTEC (STX_1, STX_2) testing. No concerns arose from the auditor's review of these programs.

The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "average" level for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE CONTROL PROGRAMS

The fifth of six equivalence components that the FSIS auditor reviewed was Chemical Residues. The inspection system is to have a written chemical residue control program that is organized and administered by the national government and that includes random sampling of the internal organs, fat, and muscle of carcasses for chemical residues as identified by the exporting country's relevant authorities or by FSIS as potential contaminants.

FSIS based its verification of Costa Rica's residue control program on information contained in Law 8495, GLNSAH; MAG 29588; and Costa Rica's Annual Residue Control Plan (2014), in association with the previous year's (2013) testing results. These documents indicate that SENASA continues to maintain the 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 meat and meat products for human consumption. This regulatory task is accomplished with the participation of the residue laboratory of LANSEVE, 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.

DIPOA prepares the annual sampling schedules (DIPOA-PG-015-RE-001) and distributes instructions to the official veterinarians for the random sampling of tissues. Sampling, handling, and transporting of samples within the field are done in accordance with instructions contained in government issuance DIPOA-PG-015. While the routine monitoring program does not require that product be held until sample results are received, product is held and precluded from export during any subsequent follow-up sampling that occurs as part of an initial violative result. FSIS observed that inspection personnel appropriately verify the traceability of all slaughtered animals and adequately identify violators.

During the evaluation of ante-mortem inspection, the auditor observed that government inspectors verify that all lots of cattle are accompanied by documentation that discloses their origin, describes their registered branding, and includes a signed affidavit that attests that cattle owners have adhered to veterinary pharmaceuticals' withdrawal periods. Once within the slaughter facilities, inspection personnel collect tissues of randomly selected slaughtered animals in accordance with the prescribed methodology provided by the RPM. A review of the documentation at the three local inspection offices that were audited indicated that in-plant officials collect samples of the required matrices for detection of specific analytes and adhere to the prescribed sample collection schedule.

The procedure followed by SENASA officials when a positive result is identified includes an initial notification by the laboratory to the official veterinarian. The laboratory also sends a memorandum to the DIPOA Area Coordinator, who in turn officially notifies the official veterinarian of the results, which initiates follow-up activities to trace-back and target the supplier for increased surveillance. The follow-up includes testing of the next 15 shipments of animals from the farm of origin in question, during which product will be held until test results are received. The official veterinarian also formally notifies the establishment of the results and requests corrective actions, including an investigation into the possible cause of the violation. FSIS' review of the monitoring results for year 2013 indicated that the only group of compounds presenting violative samples was macrocyclic lactones. Within this group, three samples from a total of 277 tested positive for violative levels of ivermectin. The auditor's examination of documents related to these incidents indicated that the corrective actions taken by both government and industry were consistent with the above-outlined protocols. From the import perspective, FSIS has not identified any violations for chemical residues during the routine testing of product that occurs at POE.

The residue division of LANSEVE serves as the official laboratory conducting analyses of government samples for the presence of chemical residues in meat products. This laboratory has ISO 17025:2005 accreditation by 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*. This laboratory maintains a web-based system (SOLTIC) to ensure accurate tracking and reporting of all samples received, and it employs validated methods of analysis found to be equivalent by FSIS.

During the audit of LANSEVE, FSIS reviewed the 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 internal laboratory audit reports (PG-002-RE-006) demonstrate that laboratory managers readily respond to correct non-conformities identified during internal and external audits. The documentation on file also demonstrated that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analyses within their accreditation scope.

In conclusion, the meat inspection system of Costa Rica has the regulatory requirements that are necessary for a chemical residue control program that is organized and administered by the national government. The program includes random sampling of the internal organs, muscle,

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.

The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was government Microbiological Testing Programs. The system must be designed to implement certain sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome.

During this audit, FSIS verified that the CCA had implemented the raw beef products sampling and testing programs for generic *E. coli*, *Salmonella spp.*, and STEC (*E. coli* O157:H7, O26, O45, O103, O111, O121, and O145). This assessment was based on information provided by the CCA in its SRT, and several DIPOA issuances that provide standardized instructions to field personnel on the sampling, handling, and shipping of samples, as well as the official control actions to be taken when positive results are received. FSIS conducted observations and reviews of records at SENASA headquarters, the microbiological division of LANSEVE, and at three certified establishments.

The FSIS auditor verified that inspection officials perform verification activities related to establishments' programs for sampling raw beef carcasses for generic *E. coli* and include required corrective sanitary measures when sampling results exceed established performance standards. Inspection officials verify that establishments have samples analyzed at LANSEVE-approved laboratories, and that the laboratories use acceptable analytical methods. Inspection officials also collect weekly random samples to verify the results of establishment testing programs.

In reference to the STEC testing program, the FSIS auditor verified documents that evidenced that DIPOA officials conduct appropriate sampling and testing of beef destined for the United States. These documents included the government issuance for sample collection (DIPOA-PG-005); in-plant inspection records; and microbiology laboratory sample receiving logs,
The frequency of official STEC verification sampling of raw beef products is either weekly at establishments with their own verification sampling program (as was the case in all establishments audited), or daily, at establishments that do not conduct their own testing. In all instances, collection of samples is done according to N-60 methodology, with sampled lots held pending laboratory results.

The FSIS auditor's review of the records maintained by the establishments and DIPOA officials identified one STEC positive in association with government testing, for which the following key elements were verified:

- The government enforcement strategy ensured proper disposition of product (cooking, in this case).
- The government enforcement strategy reflected an intensified approach, which included the establishment's reassessment of its HACCP system and additional government product testing.
- No adulterated product was shipped to the United States.

The auditor also verified that DIPOA samples and tests beef carcasses for the presence of *Salmonella spp.* at certified slaughter establishments, for which SENASA has adopted the FSIS performance standards outlined in 9 CFR 310.25. These samples are analyzed at LANSEVE using a validated and acceptable method to detect *Salmonella spp.* in raw meat products. The corrective actions taken when performance standards are exceeded include re-evaluation of the dressing and sanitation procedures, and additional follow-up testing. All positive samples are further serotyped to characterize their prevalence and public health significance.

The microbiological division of LANSEVE serves as the official laboratory conducting analyses of government samples for the presence of microbial pathogens in meat products. This laboratory is ISO 17025:2005-accredited by 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*. This laboratory employs the validated methods of analysis FSIS found to be equivalent. All analytical work performed by LANSEVE is fully-reimbursable by establishment operators who pay for services rendered to the treasury of the MAG.

The FSIS auditor reviewed the training records and certifications associated with the qualifications of the analysts, which demonstrated that they possess the academic qualifications, technical credentials, and accreditations required to conduct the analyses within their accreditation scope. The documents reviewed also made evident that analysts had successfully participated in intra- and inter-laboratory evaluations administered by the laboratory managers and accrediting bodies.

The FSIS auditor reviewed reports of monthly internal audits conducted by the LANSEVE Quality Assurance (QA) team. Non-conformities reported by QA were communicated to laboratory managers, and corrective actions were implemented as short-term or long-term, depending on the nature of the non-conformities.

The auditor noted that some laboratory practices within its quality management system were not consistent with the policies established by the FSIS Office of Public Health Science (OPHS). These policies were developed with the intent of focusing on specific control points within the testing program that might compromise the integrity of analyses or the CCA's capacity to prevent the shipment of potentially adulterated product to the United States.

- LANSEVE does not utilize time/temperature parameters in conjunction with media preparation but instead relies on the use of bio-indicators and autoclave tape.
- LANSEVE does not conduct calibration of autoclaves.
- Water conductivity testing is only conducted monthly (FSIS policy requires weekly testing).

- Micropipettes are calibrated only yearly (FSIS policy calls for calibration every 6 months).

The auditor's off-site assessment of the non-conformities conducted in conjunction with OPHS reaffirmed that, while the deficiencies did not represent an immediate risk to public health, they could ultimately impact the accuracy of test results. The most significant of these pertain to the use of autoclaves and the potential over-processing or under-processing of culture media. Consequently, FSIS requests that the CCA communicate any changes made within the context of LANSEVE's quality management system to ensure the accuracy of future results within 60 days of receipt of the audit report.

The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on December 11, 2014, in Heredia with SENASA. At this meeting, the FSIS auditor presented his preliminary findings. The CCA understood and accepted the findings.

The audit results show that Costa Rica's food safety inspection system is performing at an "adequate" level in meeting the core criteria for all six equivalence components, for which the principal audit findings can be summarized as follows:

- FSIS identified a lack of enforcement on the part of the CCA concerning requirements related to retained water in beef carcasses.
- The audit also identified a need for the CCA to improve the manner in which periodic supervisory reviews are conducted in order to better assess the knowledge and the execution of the duties performed by local personnel over time.
- FSIS identified a need for the CCA to better assess the corrective actions proposed by establishments certified for export to the United States in response to sanitation non-compliances.
- FSIS identified deficiencies within the government laboratory quality management system that might compromise the integrity of analyses.

An analysis of these findings did not identify any systemic deficiencies that represent an immediate threat to public health. However, as the ability of the inspection system to ensure export of product that is safe, unadulterated, and properly labeled can be compromised if left unchecked, FSIS requests that CCA provide a detailed response for each of the identified findings within 60 calendar days of receipt of this report.

XI. ATTACHMENTS TO THE AUDIT REPORT

Attachment A: Individual Foreign Establishment Audit Checklist

Attachment B: Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Coopemontecillos R.L. Montecillos, Alajuela	12/3/2014	8	Costa Rica
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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	O
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

Est.#: 8
City and Country: Montecillos, Alajuela, Costa Rica
Date: 12/3/2014

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L. Lauro 12/3/2014

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	12/4/2014	9	Costa Rica
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
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	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Est.#: 9
City and Country: San Antonio del Tejar, Costa Rica
Date: 12/4/2014

41/51. Inadequate ventilation was identified in a carcass chiller. The body heat from recently slaughtered bovine carcasses produced excessive water vapor which was condensing on surrounding structures, thereby creating insanitary conditions which could result in the contamination of product (no direct product contamination observed). Discussions with inspection personnel indicated that the observed conditions were a regular occurrence, yet they had not been previously documented as part of daily verification activities. As part of a short-term solution the establishment had committed to increased vigilance in this area (including wiping down structures as needed) while it is being loaded and until carcass temperatures stabilize, and a long term solution includes construction of a new chiller [Regulatory reference: DIPOA-PG-002-IN-001].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L. Lauro 12/4/2014

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
CIISA – El Arreo La Ribera de Belén	12/5/2014	12	Costa Rica
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
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	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Est.#:12
City and Country: La Ribera de Belén, Costa Rica
Date: 12/5/2014

25/51. SENASA does not routinely verify that: a) carcasses and parts are not permitted to retain water resulting from post-evisceration processing unless the establishment demonstrates (via written protocol) that any retained water is an inevitable consequence of the process used to meet applicable food safety requirements; b) Establishments disclose on the labeling of the meat products the maximum percentage of retained water in the raw product [Regulatory references: *Federal Register*, Volume 66, Number 6; 9 CFR 441].

Within this establishment, the auditor observed that carcass sprays were regularly used in chillers on product exported to the U.S. in the absence of such written protocol or additional product labeling.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	12/5/2014

Heredia, 11 de mayo del 2015
SENASA-DG-628-2015

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

Dear Dr. Syed:

SENASA makes the best efforts in search of continuous improvement to be in compliance with laws, regulations and the findings written down in the audit carried out by FSIS in December 2014, that's why SENASA developed an action plan.

Statutory Authority and Food Safety

The audit also identified a need for the CCA to improve the manner in which periodic supervisory reviews are conducted in order to better assess the knowledge and the execution of the duties performed by local personnel over time.

DIPOA response:
Supervising activities are based in the performance evaluation of the Inspector in Charge (IIC). DIPOA addresses this issue with the DIPOA-PG-010-RE-002 V03 Auditoría Interna para la Supervisión del MVI (Annex 1) The objective is to evaluate the personnel knowledge and the skills to make changes in verification activities, to meet these requirements DIPOA has the following strategy: In the first semester the inspection team will go to the establishment and makes monthly meetings to train and discuss cases, non-compliances and a workshop with the aim to have a unique criteria and methodology (Annex 2). In the second semester DIPOA is going to start with

performance evaluation, it's expected to make an evaluation once a month. The internal audit objective is to identify specific training needs for the inspection team and to strength weak areas.

FSIS identified a lack of enforcement on the part of the CCA concerning requirements related to retained water in beef carcasses.

DIPOA Response:

DIPOA requires all of the establishments to make a scientific study. The establishment must show that the water spray objective is to reduce the carcass temperature (food safety intervention). If the study demonstrates that the water coming from sprays is included into the muscle and gaining weight, the establishment is required to take a decision.

The establishment has two ways:

-discontinuing the use of water spray or diminish the amount of water that is sprayed with a new study.

- If the establishment wants to export to the US, a procedure must be implemented to ensure that every single carcass/beef to export to US were not sprayed

-If the establishment wants to continue spraying the carcasses or beef intended to be exported to the US, the establishment must submit a new label to be approved by FSIS (Label Submission and Approval System (LSAS).

The verification activities included in the General Instructions for Auditing HACCP Systems, in the section D-3 says: Verification of the Amount, Type and Product Labeling in the specific items: Verify that the product type is described on the label and it has written terms of this section and no records. With this tool, DIPOA verifies compliance by the establishment; the verification is once a month.

Sanitation

FSIS identified a need for the CCA to better assess the corrective actions proposed by establishments certified for export to the United States in response to sanitation non compliances.

DIPOA Response

The Implementation of a new chiller will help the facility to improve carcasses cooling and condensation control, but to control condensation is necessary that the establishment makes a complete evaluation, for this reason the veterinarian makes an Official Communicate (Annex 3) the purpose is to bring establishment back in compliance with decree N°29588 Article 28 letter (d) conditions that control and prevent the condensation. The establishment implements corrective actions (Annex 4) to control the condensation.

The verification activities are included in the general instructive to audit the HACCP system in the section A-6 Inspection of the Ventilation (Checking the condensation, steam and, odors). The specific items Controlled and / or eliminate condensation efficiently in all areas of the plant; the ventilation system prevents the accumulation of steam, dust and odors; corrective actions for failure of the ventilation system detected in the pre-operational and operational inspection:

a) They have properly a- contaminated or adulterated products disposal of
b- Restores health conditions
c- Prevent recurrence risk (contamination or adulteration) Product
d- Are reevaluated or modified in the SSOP but are effective

With this tool, DIPOA verifies compliance by the establishment, the frequency of this verification is four times per month

Government Microbiological Testing Programs

With the purpose to comply the non compliances in the report: "Draft final report of an audit conducted in Costa Rica December 2 -11, 2014 evaluating the food safety system governing meat products exported to the United States of America. Component six: Government microbiological testing programs", the LANASEVE makes the cause analysis and the determination of the actions, for each one of the non-compliances, based on the LANASEVE's quality assurance system according with the general requisites of the standard "INTE-ISO/IEC 17025:2005 general requirements for the competence of testing and calibration laboratories.

"LANASEVE does not utilize time/temperature parameters in conjunction with media preparation but instead relies on the use of bio-indicators and autoclave tape" "LANASEVE does not conduct calibration of autoclaves" "The most significant of these pertains to the use of autoclaves and the potential over-processing or under-processing of culture media".

LANASEVE Response

LANASEVE makes a revision of the results of the quality control for the media prepared and used for the different analysis, these revisions demonstrate that the sterility, selectivity, and effectiveness of these media have not been affected. The evidence of this information is recorder in the document SEG-PE-005-RE-001"Control de esterilidad", SEG-PE-005-RE-002 "Control de selectividad de medios de cultivo" and SEG-PE-005-RE-003 "Control de efectividad en medios de cultivo". LANASEVE evaluates the results of the internal controls for each set of samples, this information is recorded in the following documents: IA-MBA-PE-012-RE-003 "Control Interno por set de muestras – Análisis Cualitativo" and IA-MBA-PE-012-RE-004 "Control Interno por set de muestras – Análisis cuantitativo".

The results of these analyzes have been satisfactory. For instance, colonies with the typical morphology, detection by PCR methods (BaX System™). This indicates that the detection limit is reached.

In addition, the unit in charge of the media preparation, corrected the methology used to record the time and temperature of the media sterilization process. In the coming weeks, a digital logger system will be implemented. . This information is recorded in the document SEG-PO-001-RE-002 "Control de uso de autoclave".

Also, the calibration of the thermometer and manometer for the two autoclaves in use (coded A-1 y A-2) , is performed. The company CAMERICA performed this calibration and issued the calibration certificate R01-CAM-PA-003, considered satisfactory.

Furthermore, LANASEVE requests a characterization of the autoclaves coded A-3,A-6,A-7 and A-8 to the company SCM Metrología before its use.. These autoclaves have a built-in digital recorder for time and temperature of the process.

Water conductivity testing is only conducted monthly (FSIS policy requires weekly testing).

LANASEVE issues a request to the Laboratorio Nacional de Aguas AyA (National Water Laboratory) to perform chemistry control for the distilled water. The samples are being sent weekly for conductivity tests.

Micropipettes are calibrated only yearly (FSIS policy calls for calibration every 6 months)

LANASEVE evaluates the calibration certificates of the micropipettes and concluded that the measurement error that these instruments have is 2% or less, indicate for the microbiologic methods.

There´s no observed tendency that indicates that the frequency of these calibrations should be changed.

What process did SENASA go through to approve third party labs (Geneseek, used for STEC confirmation)? Are there criteria established? Are audits conducted by SENASA?

Existing decree N° 34493-MAG"Reglamento para Laboratorios Oferentes de Referencia y con Ensayos Oficializados por SENASA" determines the criteria stablished for formalization of laboratories. In addition, the procedure SENASA-PE-003 "Oficialización de Personal Particular y Ensayos de Laboratorio" describes in detail the step by step process for the formalization of these laboratories.

In this case, LANASEVE asked Geneseek coporation Neogen (LINCOLN, NE 68504) to comply with the formalization process, this is currently underway. The formalization audit will be carried out in the second semester of 2015.

Sincerely

SERVICIO NACIONAL DE SALUD ANIMAL - COSTA RICA - DIRECCION GENERAL

Dr. Bernardo Jaén Hernández
General Director

Fecha:	Nº de Oficio: SENASA-DIPOA-A-_____-_____
Nombre de UP o establecimiento:	Nº Establecimiento:
Nombre y Firma del Auditado:	
Nombre y Firma del Auditor(es):	

Nota: La aplicación de este documento en las unidades periféricas de la DIPOA será tomado en cuenta como una auditoría interna, la cual debe ser analizada por el auditado, presentando en un plazo de ocho días hábiles, en el formato DIPOA-PG-010-RE-004, las acciones correctivas, y fechas de ejecución, con el fin de que la desviación no se vuelva a encontrar. Cuando la no conformidad corresponda a un fallo de oficinas centrales la misma será comunicada al Director DIPOA por parte del responsable de realizar la evaluación, para su análisis y corrección.

Se deben realizar al menos 2 auditorías internas al año.

Inspector Auxiliar (IA): Para efectos de este documento; se refiere al Inspector de Inocuidad según el Servicio Civil, y aplica para los Inspectores que no están bajo supervisión permanente por parte de MVI, y que son los responsables directos de los establecimientos donde están asignados.

NOMENCLATURA	
RESULTADO (R)	TIPO DE SUPERVISIÓN
A: Aceptable NC: No Conforme NA: No Aplica NFR: No Fue Revisado	AC: Acompañamiento In Situ RR: Revisión de Registros EN: Entrevista
PERSONAL SUPERVISADO	
MVI: Médico Veterinario Inspector	IA: Inspector Auxiliar

ELEMENTOS DE SUPERVISIÓN TÉCNICA	Tipo de Supervisión			R
1. CONDUCTA DEL PERSONAL	AC	RR	EN	
1.1. El MVI o IA cuando aplique; conoce el Código de Conducta: Orientaciones para el personal SENASA-MC-001-IN-001 y documenta el refrescamiento anual al personal a su cargo.				
1.2.El MVI o IA cuando aplique; se comporta acorde con lo estipulado en el Compromiso del personal SENASA-PG-005-RE-001, y en el Código de Conducta: Orientaciones para el personal SENASA-MC-001-IN-001.				
1.3. El MVI o IA cuando aplique; conoce el formato que debe usar en caso de presión comercial DIPOA-MC-001-RE-007, y su contenido.				
2. MANEJO DE PERSONAL A CARGO	AC	RR	EN	R
2.1. El MVI tiene evidencia escrita de capacitaciones impartidas y reuniones efectuadas con el personal de inspección a cargo durante el último semestre, estas se documentan en el formato; Registro de asistencia de capacitaciones SENASA-PG-005-RE-014 y MINUTA DE REUNIONES SENASA-PG-004-RE-001 según corresponda.				
2.2. El MVI realiza evaluaciones periódicas al personal de Inspección a su cargo y mantiene evidencia escrita de esta evaluación, en el formato de Auditoría Interna para la Supervisión del IA DIPOA-PG-010-RE-003; mínimo 2 evaluaciones al año.				
2.3. El MVI asigna y supervisa con regularidad in situ las labores de inspección, muestreo, entre otras, del personal a su cargo, y existe evidencia documental que lo respalde.				

© Documento Normativo Propiedad del SENASA, el documento vigente se encuentra en INTERNET cualquier versión impresa es una copia no controlada

3. ACTIVIDADES DE VERIFICACION ANUAL	AC	RR	EN	R
3.1. El MVI o IA cuando aplique; verifica que la información plasmada en el documento sobre Caracterización de Establecimientos autorizados para exportar y proveedores de materia prima DIPOA-PG-001-RE-001, es verídica y refleja las condiciones actuales del establecimiento. En caso de cambios en el establecimiento se asegura que sean retransmitidos a la DIPOA, al Departamento de Registro.				
3.2. El MVI o IA cuando aplique; verifica que el Registro anual del CVO y el Certificado de Exportación del establecimiento están vigentes.				
3.3. El MVI o IA cuando aplique; revisa al menos una vez al año de forma completa, la totalidad de los Manuales HACCP que el establecimiento tiene implementados y documenta dichas revisiones en el formato de Auditoria Documental del Plan HACCP para establecimiento exportadores DIPOA-PG-002-RE-002. (Para el caso de Procesados Cárnicos y Lácteos, el coordinador del área definirá el número de planes HACCP a revisar de cada establecimiento).				
3.4. El MVI o IA cuando aplique; se asegura que el Plan HACCP es reevaluado[1] por el establecimiento al menos una vez al año y refleja las condiciones actuales del proceso.				
3.5. El MVI o IA cuando aplique; revisa al menos una vez al año, de forma completa los Manuales de Pre-requisitos y SSOP del establecimiento y documenta dicha revisión en la documentación oficial correspondiente. (Resumen de Auditoría Externa del Sistema HACCP-DIPOA-PG-002-RE-001).				
4. ACTIVIDADES DE VERIFICACIÓN DIARIA/MENSUAL	**AC**	**RR**	**EN**	**R**
4.1. El MVI o IA cuando aplique; retransmite la información recibida de la DIPOA al establecimiento y a su personal a cargo cuando aplica y hace uso de recibido.				
4.2. El MVI o IA cuando aplique; cuenta con las regulaciones actualizadas que le aplican al área en que se desempeña, las mismas se mantienen impresas o en forma digital ordenadas en una carpeta exclusiva para legislación.				
4.3. El MVI o IA cuando aplique; cumple con el cronograma de actividades establecido por la DIPOA en la Plantilla de Verificación Semanal o Guía de Auditoria específica para cada área.				
4.4. El MVI o IA cuando aplique; documenta los ítems verificados (por cronograma o guía o ítems adicionales) en el formato Reporte de Verificación Semanal para la Auditoría Interna del Sistema HACCP DIPOA-PG-002-RE-004.				
4.5. El MVI o IA cuando aplique; utiliza el Instructivo General de Auditoria del Sistema HACCP DIPOA-PG-002-RE-001 o la Guía de Auditoría específica para cada área, para conducir las actividades de verificación.				
4.6. El MVI o IA cuando aplique; garantiza la verificación de todos los sub elementos contemplados en el Instructivo General de Auditoria del Sistema HACCP DIPOA-PG-002-RE-001 o la Guía de Auditoría específica para cada área, en el tiempo establecido por cada coordinador.				
4.7. El MVI o IA cuando aplique; documenta diariamente en el Reporte de Verificación Semanal para Auditoria Interna del Sistema HACCP DIPOA-PG-002-RE-004; las actividades de verificación mediante observación, medición física y revisión de registros, efectuadas en el establecimiento.				

[1] **Reevaluación del Plan HACCP:** Una Revisión del sistema HACCP del establecimiento para asegurarse de que las actualizaciones de rutina u otros cambios (por ejemplo, para cumplir con los requisitos reglamentarios, mejorar las operaciones o procesos, agregar nuevos productos, etc.) han sido plenamente analizado y se están aplicando de manera efectiva.

© Documento Normativo Propiedad del SENASA, el documento vigente se encuentra en INTERNET cualquier versión impresa es una copia no controlada

	AC	RR	EN	R
4.8. El MVI o IA cuando aplique; asegura que todas las no conformidades detectadas por el servicio de inspección se encuentran reportadas en el formato Reporte de No conformidades de Verificación Semanal para la Auditoría Interna del Sistema HACCP DIPOA-PG-002-RE-005. Estos registros se encuentran al día y están completos.				
4.9. Las No Conformidades reportadas están sustentadas legal y técnicamente, son claras, concisas, y contemplan los artículos e incisos reglamentarios que fueron incumplidos así como los requisitos de los manuales y procedimientos del sistema HACCP del establecimiento (Pre-requisitos y HACCP).				
4.10. Las No Conformidades reportadas por el MVI o IA cuando aplique; logran reflejar la realidad del establecimiento.				
4.11. El MVI o IA cuando aplique; le da seguimiento a los cronogramas de cumplimiento de la totalidad de las No Conformidades reportadas, independientemente del origen de las mismas.				
4.12. El MVI o IA cuando aplique; notifica a través de carta con oficio interno, al Coordinador del área las No Conformidades críticas así como aquellas que no se han logrado cerrar debido a incumplimiento o desacato, por parte del establecimiento y adjunta la evidencia.				
4.13. El MVI o IA cuando aplique; envía mensualmente al coordinador o al jefe del área respectiva la documentación solicitada (Informe de decomisos, Control de certificados, entre otros), en el tiempo establecido por la jefatura o el coordinador.				
4.14. Se utiliza la versión actualizada de los registros oficiales, los mismos se encuentran completos, sin tachones, sin corrector, firmados y sellados. En caso de errores en los registros se toman las medidas para realizar las correcciones.				
4.15. El MVI o IA cuando aplique; utiliza la Demanda de Acción Correctiva DIPOA-PG-002-RE-006 (DAC) para notificar al establecimiento de manera clara las No Conformidades mayores y las tendencias.				
4.16. El médico veterinario utiliza el Comunicado Oficial DIPOA-PG-002-RE-007 para notificar al establecimiento de manera clara las No Conformidades menores.				
4.17. El MVI o IA cuando aplique; verifica que el establecimiento responde de forma clara y oportuna las DAC y Comunicados. Las DAC y los Comunicados están completos, sin tachones, sin uso de corrector y debidamente firmados y sellados. En caso necesario, el servicio de inspección cuenta con la justificación respectiva del establecimiento, cuando una DAC o Comunicado Oficial no fueron cerrados en el tiempo propuesto.				
4.18. El MVI o IA cuando aplique; verifica y analiza que las respuestas emitidas por el establecimiento; sean concordantes con las No Conformidades planteadas y que las medidas y plazos propuestos sean satisfactorios para solventar las No Conformidades.				
4.19. El MVI o IA cuando aplique; da el seguimiento oportuno al cierre de las DAC y Comunicados, una vez que las fechas propuestas se hayan cumplido.				
4.20. En caso de que una DAC o Comunicado no hayan sido cerrados en la fecha propuesta, se cuenta con la solicitud de prórroga por escrito detallando las causas del por qué se incumplió la respuesta original, así como las nuevas medidas firmadas por el Gerente del establecimiento.				

© Documento Normativo Propiedad del SENASA, el documento vigente se encuentra en INTERNET cualquier versión impresa es una copia no controlada

5. ACTIVIDADES DE MUESTREO	AC	RR	EN	R
5.1. El MVI cumple con los Cronogramas de Muestreo Oficiales y envía el reporte mensual al coordinador del área, en caso de que este así lo solicite.				
5.2. El MVI o IA cuando aplique; toma las muestras de superficie, agua, hielo y producto de acuerdo con los procedimientos o instructivos oficiales, respectivos a cada área.				
5.3. El MVI realiza o solicita se realicen muestreos dirigidos para dar seguimiento a desviaciones ocurridas en el establecimiento.				
6. EVALUACIÓN IN SITU	AC	RR	EN	R
6.1. El MVI o IA cuando aplique; cuando realiza las labores de verificación in situ, demuestra seguridad, dominio, destreza, habilidad, conocimiento técnico y regulatorio.				
6.2. El MVI o IA cuando aplique; cuando realiza labores de verificación documental (registros, procedimientos, manuales entre otros), demuestra conocimiento técnico y regulatorio así como seguridad, dominio, destreza y habilidad para efectuar dicha labor.				
6.3. Ante una No Conformidad, el MVI o IA cuando aplique; demuestra habilidad en la forma de comunicarla, abordarla y darle seguimiento.				
6.4. El MVI o IA cuando aplique; toma las medidas necesarias para resguardar la inocuidad del producto ante No Conformidades críticas (retener, clausurar, decomisar, restringir u otros), cuenta con evidencia documental de las medidas tomadas (actas de decomiso y destrucción de producto).				
6.5. El MVI o IA cuando aplique; asegura la disposición adecuada de productos adulterados y/o mal etiquetados, existe evidencia documental que lo respalden.				
6.6. El MVI o IA cuando aplique; utiliza de forma correcta el equipo (termómetros, focos, cintas, reactivos, cuchillos, chairas, otros) durante las labores de inspección.				
7. CONTROL DE CERTIFICADOS, MARCHAMOS Y RESUMENES DE EMBARQUE				
7.1. El MVI o IA cuando aplique; lleva los siguientes documentos para el control de los certificados, marchamos y resúmenes de embarque de exportación, los mismos están al día y se encuentran completos:	AC	RR	EN	R
7.1.1. Solicitud de certificados oficiales y marchamos DIPO-PG-009-RE-002.				
7.1.2. Control de numeración de resúmenes de embarque en establecimiento con inspección oficial permanente DIPOA-PG-009-RE-001.				
7.1.3. Control de recibo y entrega de certificados de exportación en establecimientos con inspección oficial permanente DIPOA-PG-009-RE-003.				
7.1.4. Control de certificados de exportación DIPOA-PG-009-RE-004.				
7.1.5. Control de marchamos de exportación en establecimientos registrados en la DIPOA, DIPOA-PG-009-RE-005.				
7.1.6. Control de certificados de origen otorgados en establecimientos con inspección oficial permanente DIPOA-PG-009-RE-008 (cuando aplique).				
7.1.7. Control de certificados de libre venta otorgados en establecimientos con inspección oficial permanente DIPOA-PG-009-RE-009 (cuando aplique).				

© Documento Normativo Propiedad del SENASA, el documento vigente se encuentra en INTERNET cualquier versión impresa es una copia no controlada

8. EVALUACION IN SITU DE LAS EXPORTACIONES	AC	RR	EN	R
8.1. El MVI o IA cuando aplique; verifica que los productos que se van a exportar sean los aprobados por el país socio comercial y que se encuentren contemplados en los Manuales HACCP del establecimiento.				
8.2. En cada embarque de exportación, el MVI o IA cuando aplique; verifica que los productos que se van a exportar cuentan con la liberación del pre-embarque, y están consignados en el Resumen de Embarque y Certificado de Exportación, Certificado de libre venta, Certificado de Origen cuando aplique, y cualquier otro documento que solicite la autoridad competente del país socio comercial.				
8.3. El MVI o IA cuando aplique; realiza una verificación aleatoria de los productos previo a la carga de las exportaciones, tomando en cuenta los siguientes aspectos: temperatura, integridad del empaque y características sensoriales del producto y coteja la información de la etiqueta de los productos contra el resumen de embarque entregado por el establecimiento. Se cuenta con evidencia documental de esta verificación en el documento correspondiente.				
8.4. El MVI o IA cuando aplique; previo a la carga de las exportaciones, verifica las condiciones sanitarias (limpieza, desinfección e infraestructura) del medio de transporte a utilizar. Se cuenta con evidencia documental de esta verificación en el documento correspondiente.				
8.5. El MVI o IA cuando aplique; verifica que los productos a exportar cumplen con los requerimientos del país socio comercial.				
8.6. Previo a la liberación del contenedor, el MVI o IA cuando aplique; verifica in situ y documenta la temperatura del medio de transporte, en el documento correspondiente.				
8.7. El MVI o IA cuando aplique; notifica al establecimiento, las razones o causas que motivaron el rechazo de productos para la exportación, y se explica el por qué; a través de carta con oficio interno.				
9. INSPECCION ANTEMORTEM	**AC**	**RR**	**EN**	**R**
9.1. El MVI solicita al establecimiento las guías de movilización (cuando aplique) o historial ante-mortem (en el caso de aves); antes de iniciar la inspección.				
9.2. El MVI cuenta con áreas debidamente acondicionadas para llevar a cabo la inspección ante-mortem.				
9.3. El MVI efectúa o designa un inspector para realizar la inspección ante-mortem in situ tal como se establece en las guías, directrices, regulaciones o procedimientos internos.				
9.4. El MVI documentan los hallazgos en los registros de inspección ante-mortem establecidos por la DIPOA o por los programas nacionales respectivos.				
9.5. El MVI cuando aplique verifica el manejo y la disposición de los animales caídos no ambulatorios y los materiales específicos de riesgo de EEB con la frecuencia establecida. La extracción de cerebros de animales no ambulatorios se hacen de acuerdo al documento DIPOA-PG-013-IN-003 y se cumplen las disposiciones de identificación, segregación y eliminación de los MER, según el DIPOA-PG-013-IN-004.				
9.6. Conforme al artículo 95 de la ley 8495 (Ley SENASA), el MVI aplica y documenta las medidas sanitarias en caso de encontrar animales: recibidos sin guía de transporte, introducidos al proceso sin aprobación oficial, maltratados innecesariamente durante el manejo, con privación de agua o alimento, sin reposo o con abuso del mismo, hacinados por irrespeto a la capacidad instalada,				

© Documento Normativo Propiedad del SENASA, el documento vigente se encuentra en INTERNET cualquier versión impresa es una copia no controlada

caídos no ambulatorios, o con enfermedad infectocontagiosas, u otras.				
10. INSPECCION POST-MORTEM	AC	RR	EN	R
10.1. El MVI cuenta con áreas debidamente acondicionadas para llevar a cabo la inspección post-mortem.				
10.2. El MVI utiliza la información de las tarjetas o documentos de inspección ante-mortem para revisar cada lote de animales durante la inspección post-mortem.				
10.3. El MVI documenta el decomiso de canales y partes en los registros de inspección post-mortem establecidos por la DIPOA.				
10.4. Conforme al Art.95 de la Ley 8495, el MVI toma las medidas sanitarias necesarias *in situ* con las cabezas, vísceras y/o canales u otras partes de la misma, que son detectadas con defectos y/o patologías de acuerdo al procedimiento DIPOA-PG-013 y el artículo 141 del Reglamento N° 29588-MAG-S, para dar el dictamen final de las canales decomisadas.				
11. EVALUACIÓN	AC	RR	EN	R
11.1. Evaluación del conocimiento técnico de acuerdo con su área de atinencia, que puede ser escrita, oral u otra, según criterio del coordinador evaluador.				

Comentarios:

Se pueden agregar o eliminar las líneas que sean necesarias

© Documento Normativo Propiedad del SENASA, el documento vigente se encuentra en INTERNET cualquier versión impresa es una copia no controlada

ELEMENTOS DE SUPERVISIÓN DEL SISTEMA DE CALIDAD	Tipo de Supervisión			R
12. MANEJO DE DOCUMENTACION Y OTROS INSUMOS OFICIALES	AC	RR	EN	
12.1. El MVI o IA cuando aplique; mantiene la custodia adecuada de la documentación oficial, marchamos, sellos, tarjetas de decomiso, cintas, entre otros.				
12.2. El proceso de archivo de la documentación oficial generada se realiza a tiempo (máximo una semana posterior a que se genera). Se mantiene ordenada según lo establecido por cada coordinación (numeración e identificación de la información). Se sigue con los procedimientos establecidos para la eliminación de la documentación oficial.				
13. EXPEDIENTE DEL PERSONAL	AC	RR	EN	R
13.1. El MVI o IA cuando aplique; mantiene en su expediente los siguientes documentos:				
13.1.1. Curriculum vitae. Uso del formato SENASA-PG-005-RE-011 si aplica.				
13.1.2. Copia de la cédula de identidad.				
13.1.3. Registro de la Inducción del Personal SENASA-PG-005-RE-012 cuando aplica.				
13.1.4. Compromiso del Personal SENASA-PG-005-RE-001 actualizado, y el documento utilizado previamente con la misma finalidad.				
13.1.5. Competencias del personal SENASA-PG-005-RE-009.				
13.1.6. Supervisión del personal SENASA-PG-005-RE-015 completo y debidamente firmado por su superior inmediato.				
13.1.7. Registro del Personal sustituto SENASA-PG-005-RE-013.				
13.1.8. Copia de la publicación de la gaceta, o copia de la carta de nombramiento, y contrato de oficialización (según aplique donde se les acredita como oficial u oficializado). En caso de que el funcionario haya sido rotado a otra Unidad Periférica, cuenta con copia de la carta de notificación de dicho traslado.				
13.1.9. Para el caso de las capacitaciones que no son convocadas por las jefaturas inmediatas; cuenta con la evidencia de la comunicación y aprobación por parte del coordinador del área y del encargado de Gestión de la Calidad para asistir a las mismas.				
13.1.10. Copia de Certificados de capacitaciones, o registros de asistencia a capacitaciones en donde no se emite certificado.				
13.1.11. Copias de las auditorías internas que se le han aplicado –al menos la del último semestre- así como el Cronograma de Acciones Correctivas DIPOA-PG-010-RE-004 concerniente.				
13.1.12. Boletas de control de asistencia con su respectiva justificación (horas extras, asistencia a reuniones, permisos, entre otros), con el visto bueno del personal del establecimiento y para el caso de los oficiales, con el recibido por parte de SENASA.				
13.1.13. Evidencia que respalde que los horarios de inspección se ajustan a los horarios establecidos por el establecimiento (Caracterización de Establecimientos DIPOA-PG-001-RE-001).				
13.1.14. Evidencia de las boletas de incapacidades, vacaciones, permisos sin goce de salario, entre otros.				
13.1.15. Evidencia de las amonestaciones, o llamadas de atención en caso de que aplique.				

© Documento Normativo Propiedad del SENASA, el documento vigente se encuentra en INTERNET cualquier versión impresa es una copia no controlada

13.2. Evidencia de envío de la Competencia Técnica SENASA-PG-005-RE-006 actualizada, -al menos una vez al año-, al Área de Gestión de la Calidad para su publicación en la página web del SENASA.				
14. FACILIDADES PARA EL PERSONAL	AC	RR	EN	R
14.1. El MVI o IA cuando aplique; durante la jornada laboral, cuenta con carnet de identificación, y se encuentra actualizado.				
14.2. El MVI o IA cuando aplique; cuenta con una oficina exclusiva independiente de la planta, o en su defecto ha notificado por escrito al establecimiento y a las respectivas jefaturas. Se mantiene limpia y ordenada, y propicia un ambiente adecuado de trabajo.				
14.3. Se cuenta con acceso restringido a la oficina (bajo llave).				
14.4. El MVI o IA cuando aplique; cuenta con los equipos necesarios para desarrollar las tareas, tales como computadora con acceso a internet, teléfono, escáner e impresora, así como otros instrumentos para desarrollar las labores de inspección in situ (termómetros, reactivos químicos, cámaras fotográficas, cuchillos, chairas, entre otros); o en su defecto ha notificado por escrito al establecimiento y a las respectivas jefaturas.				
14.5. El MVI o IA cuando aplique; cuenta y utiliza indumentaria debidamente identificada como Inspección Oficial o en su defecto ha notificado por escrito al establecimiento y a las respectivas jefaturas.				

© Documento Normativo Propiedad del SENASA, el documento vigente se encuentra en INTERNET cualquier versión impresa es una copia no controlada

FECHA	31 / 12 / 2014 .	COMUNICADO Nº	06-2014

Nº DEL ESTABLECIMIENTO	9	NOMBRE	GANADEROS INDUSTRIALES DE C.R.

Estimado Señor (a):

Representante del Establecimiento: HELLEN CALVO, Gerente de Inocuidad.

Este día el establecimiento ha sido evaluado en diferentes programas del Sistema HACCP, las NO CONFORMIDADES encontradas han sido aclaradas y entendidas, y que de acuerdo al riesgo deberán ser atendidas lo antes posible de conformidad con la Ley (SENASA Nº 8495, Decreto Nº26559-MAG-S, Decreto Nº29588-MAG-S, Decreto Nº18696-MS-S, Ley de Bienestar Animal Nº7451), y presentadas mediante un cronograma de acciones correctivas y medidas al Médico Veterinario Inspector responsable en ocho días hábiles a partir del recibo de este documento y que se describen a continuación:

Durante la auditoria realizada por la autoridad oficial del FSIS el día 4/12/2014, se evidenció un aumento inadecuado del vapor en la cámara de canales #2, convirtiéndose en un factor de alta probabilidad de generar condensación en esta área. En ese momento, el establecimiento ejecutaba labores de secado de posible condensación en esta cámara.

El día de hoy, es manifiesto que el Establecimiento no ha establecido las condiciones idóneas para disminuir o prevenir el exceso de vapor en esta cámara.

Esta situación incumple lo establecido en el inciso d) del artículo 28 del Reglamento Nº 29588, el cual establece que "*Deberá proveerse una ventilación adecuada, si fuese del caso artificial, para permitir un ambiente fresco, evitar el calor excesivo y la condensación del vapor…*"; así mismo se incumple el artículo 111 del mismo reglamento "*Las cámaras y sus unidades de refrigeración deberán mantenerse en buen estado de conservación y operación, de tal forma que eviten la condensación*"

SERVICIO NACIONAL DE SALUD ANIMAL COSTA RICA DIPOA

DR. GUSTAVO ARAYA RODRÍGUEZ
Nombre y Firma
Médico Veterinario Inspector Responsable

Hellen Calvo
Nombre y Firma Representante Establecimiento
Fecha de Recibido: 5-01-2015

C: Director de la Dirección de Inocuidad de Productos de Origen Animal DIPOA.

New Chiller: Establishment 9, Ganaderos Industriales de Costa Rica S.A.