



United States Department of Agriculture

Food Safety and
Inspection Service

APR 13 2017

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Dear Dr. Fragoso Sanchez,

The Food Safety and Inspection Service (FSIS) onsite audit conducted from September 19 through October 11, 2016, supports that Mexico's inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Mexico are included as an attachment to the report.

If you have any questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
MEXICO

SEPTEMBER 19 TO OCTOBER 11, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
MEAT AND POULTRY PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

April 10, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 19 to October 11, 2016. The purpose of the audit was to determine whether Mexico's inspection for meat (slaughter and processing) and poultry (processing only), remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Mexico currently exports raw non-intact, raw intact, fully-cooked, and thermally processed/commercially sterile meat and poultry products.

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

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The Central Competent Authority (CCA) did not provide mechanisms to ensure that beef feet that derive from carcasses condemned at post-mortem inspection are precluded from human consumption. As this was a system-wide issue, the CCA elected to suspend the export of beef feet to the United States from all certified establishments until an appropriate identification system is developed at each location.
- FSIS identified variance in the manner in which the CCA is implementing its revised supervisory review program. In some cases, supervisory reports did not document the outcome of the assessment of the efficacy and technical competency of inspection personnel. In other cases, the documentation did not identify the competencies being assessed on a particular visit.
- The CCA has not kept up-to-date with recent FSIS labeling policy changes, e.g., labeling requirements for raw or partially cooked mechanically tenderized beef products as per 9 CFR 317.2(e) (3). During the exit meeting, Mexican officials committed to working with individual exporting establishments to ensure that the requirements outlined in 9 CFR 317.2(e) (3) are met.

Government Sanitation

Many of the isolated sanitation non-compliances identified during the audit should have been controlled through the establishments' sanitation programs. Consequently, FSIS believes it is important that the CCA provide additional verification to ensure that establishment operational sanitation monitoring is effective and properly documented, including control (prevention) of condensation.

Government HACCP System

FSIS identified systemic findings related to verification of HACCP plan development; recordkeeping requirements; and the zero tolerance standard for feces, ingesta, and milk.

Government Microbiological Testing Programs

- Government verification testing for *Salmonella* was not occurring in all ready-to-eat products. FSIS requests that the CCA update its requirements to ensure that government *Salmonella* verification testing occurs in all products exported to the United States, or provide additional rationale to support its testing approach.
- The CCA has not developed adequate verification procedures that will ensure production lots in commerce are microbiologically independent from other production lots of the same source beef which test positive for Shiga toxin-producing *E. coli*; and that establishments implement controls to assure the intact end use of beef primal and sub-primal cuts.

During the audit exit meeting, the CCA committed to begin to address the preliminary findings as presented.

TABLE OF CONTENTS

| | | |
|-------|--|----|
| I. | INTRODUCTION | 1 |
| II. | AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY | 1 |
| III. | BACKGROUND | 3 |
| IV. | COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION) | 4 |
| V. | COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING) | 5 |
| VI. | COMPONENT THREE: GOVERNMENT SANITATION | 7 |
| VII. | COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM | 9 |
| VIII. | COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS | 11 |
| IX. | COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS | 12 |
| X. | CONCLUSIONS AND NEXT STEPS | 15 |
| | APPENDICES | 17 |
| | Appendix A: Individual Foreign Establishment Audit Checklist | |
| | Appendix B: Foreign Country Response to Draft Final Audit Report | |

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Mexico's food safety system from September 19 to October 11, 2016. The audit began with an entrance meeting held on September 19, 2016, in Mexico City, Mexico with the participation of representatives from the Central Competent Authority (CCA) – the *Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* (SAGARPA) [Secretariat of Agriculture, Livestock, Rural Development, Fisheries, and Food] and two FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat (slaughter and processing) and poultry (processing only) maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Mexico is eligible to export slaughtered and processed meat (beef, pork, goat, and mutton) and processed poultry (not including ratites) to the United States. Raw pork from Mexico is permitted only from the States of Baja California, Baja California Sur, Campeche, Chihuahua, Nayarit, Quintana Roo, Sinaloa, Sonora, and Yucatán. Poultry products are only permitted if they are derived from raw poultry obtained from the United States or from other countries that FSIS has determined have a poultry slaughter inspection system equivalent to that of the United States.

In pursuit of this objective, FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, oversight activities of government offices, and the testing capabilities of the laboratories. The review process included an analysis of 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 auditors were accompanied throughout the entire audit by representatives from the CCA or representatives from the regional and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, four state inspection offices, and eight local inspection offices. The FSIS auditors evaluated the implementation of control systems in place, which ensure that the national system of inspection, verification, and enforcement is being implemented as intended. A sample of 8 establishments was selected from 66 establishments certified to export to the United States.

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 FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2 and §381.196, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat and poultry.

Additionally, one official laboratory was audited to verify its ability to provide adequate technical support to the inspection system.

| Competent Authority Visits | | # | Locations |
|--|----------|---|---|
| Competent Authority | Central | 1 | <ul style="list-style-type: none"> • CCA (SAGARPA) – Mexico City |
| | Regional | 4 | <ul style="list-style-type: none"> • Nuevo Leon Regional Office – Monterrey • Sonora Regional Office – Hermosillo • Jalisco Regional Office – Guadalajara • Queretaro Regional Office - Santiago de Querétaro |
| Laboratory | | 1 | <ul style="list-style-type: none"> • Centro Nacional de Servicios de Constatacion en Salud Animal (Microbiology and Residue) – Jiutepec |
| Beef slaughter and processing establishments | | 2 | <ul style="list-style-type: none"> • Escobedo and Ezequiel Montes |
| Pork slaughter and processing establishments | | 2 | <ul style="list-style-type: none"> • Hermosillo and Atotonilo el Alto |
| Goat slaughter/processing establishment | | 1 | <ul style="list-style-type: none"> • Cadereyta Jimenez |
| Meat and poultry processing establishment | | 1 | <ul style="list-style-type: none"> • Monterrey |
| Meat processing establishments | | 2 | <ul style="list-style-type: none"> • Guadalajara and Guadalupe |

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, et seq.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, et seq.);
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327);
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.); and
- The Food Safety and Inspection Service Regulations for Imported Poultry (9 CFR Part 381, Subpart T).

The audit standards applied during the review of Mexico’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.

Current equivalence determinations in place for Mexico include the use of private laboratories for analysis of samples for *Salmonella* and *Listeria monocytogenes* (*Lm*).

III. BACKGROUND

Mexico currently exports raw non-intact, raw intact, fully-cooked, and thermally processed/commercially sterile meat and poultry products to the United States. From January 1, 2013 to December 31, 2015, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 911,590,105 pounds of meat and poultry products exported by Mexico to the United States. Since the last FSIS audit in August 2014, the United States rejected a total of 40,871 pounds for the following food safety-related reasons. One lot of pork fat was contaminated with feces, one lot of fresh beef tested positive for Zilpaterol, one lot of boneless beef contained foreign materials, and transport-related spoilage was identified in two lots of product (beef feet and beef bones, respectively).

The audit included a visit to one of the establishments implicated in these POE violations, for which FSIS concluded that SAGARPA had satisfactorily worked with food business operators to identify the root cause of the problems and institute appropriate corrective actions.

The previous FSIS audit in 2014 identified the following findings:

- The CCA did not provide mechanisms to verify the accuracy of formulations or detect economic adulteration. This issue has since been resolved. However, the current audit (i.e., the 2016 audit associated with this report) noted that the CCA was not adequately staying abreast of FSIS labeling policy changes;
- Documentation of supervisory reviews was not being uniformly implemented throughout all regions of the system and presented only a limited evaluation of skills related to ante-mortem and post-mortem inspection. While the current audit noted that the CCA had made a significant effort to standardize its reporting processes that included a technical assessment of its inspection personnel, some variances were identified within the periodic supervisory review program; and
- At three of the four slaughter establishments that were audited, records for corrective actions did not correctly identify the root cause for zero tolerance contamination deviations, and the establishments continued to handle such deviations without successfully preventing their recurrence. The current audit identified similar concerns.

The current audit included visits to two beef establishments to assess controls for Shiga toxin-producing *E. coli* (STEC), including policies to identify common source materials that may be contaminated with STEC, and the CCA's adherence to updated FSIS labeling requirements in certain beef products. Findings related to these policies are discussed in subsequent sections of the report.

The FSIS final audit reports for Mexico's food safety system are available on the FSIS Web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>

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

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

The evaluation of this component included a review and analysis of the information provided by the CCA in the updated self-reporting tool (SRT) and observations during the onsite audit.

FSIS confirmed that the *Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* (SAGARPA) [Secretariat of Agriculture, Livestock, Rural Development, Fisheries, and Food] continues to serve as the CCA in charge of managing the overall regulatory oversight of animal health protection, slaughter of animals, and processing of foods of animal origin. In the same manner, the *Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria* (SENASICA) [National Service of Food and Agriculture Health, Safety, and Quality], continues to be the sub-agency of SAGARPA that administers inspection services to regulate the meat and poultry industry in Mexico.

Ultimate control of establishments certified to export to the United States is achieved through the remaining two intermediate levels. Within SENASICA, it is the *Dirección General de Inocuidad Agroalimentaria, Acuícola y Pesquera* (DGIAAP) [General Directorate of Food and Agriculture Safety, Aquaculture, and Fishing] and subordinate office, the *Dirección de Establecimientos Tipo Inspección Federal* (DETIF) [Directorate of Federal Inspection Type Facilities], which continues to provide direct oversight to the *Tipo Inspección Federal* (TIF) [Federal Inspection] establishments that produce meat and poultry products for domestic and international markets, including those certified for export to the United States.

SAGARPA has issued an updated process for the certification of establishments requesting approval for United States export in their *Manual De Procedimiento Para Autorización De Establecimientos Que Deseen Exportar (2016)* [Procedures for Establishments Requesting Export Eligibility]. Upon satisfactory outcome of the audit of the requesting establishment, final certification is granted by SAGARPA. While onsite, the FSIS auditors verified that the above-referenced approval process was implemented as intended.

As per Article 107 of Mexico's *Federal Law for Animal Health (2007)*, all individuals conducting in-plant inspection and verification at TIF establishments must possess a veterinary degree from a recognized university and obtain professional accreditation from the central government to work as veterinarians. The hiring process requires that a candidate for an in-plant inspector position successfully complete a CCA-administered examination to earn an authorized

veterinarian (AV) status. Upon becoming an AV, the candidate can then be hired by the *Organismo Internacional Regional de Sanidad Agropecuaria* (OIRSA) [International Regional Organization for Plant and Animal Health] as *Médico Veterinario Responsable Autorizado en Establecimientos TIF* [Supervisory Veterinary Medical Officer] or as *Medico Veterinario* [Veterinary Medical Officer]. Mexico's use of OIRSA inspectors has been determined acceptable by FSIS.

In-plant veterinary inspectors that join the inspection workforce receive induction training on the fundamentals of meat and poultry inspection and administrative responsibilities, which is further complemented with on-the-job training. While onsite, the FSIS auditors confirmed that AVs stationed at TIF establishments have completed academic work to earn a veterinary degree, received accreditation from the central government, passed the certification test administered by SAGARPA, and completed additional courses in HACCP and meat science.

The FSIS auditors also noted that SAGARPA provides continuous training opportunities to its inspection force, of which a portion of these activities were undertaken in response to the 2014 FSIS audit findings:

- *Training for International Auditors*: May 2015;
- *Healthy Foods International Forum*: September 2015;
- *Hazard Analysis and Critical Control Points (HACCP)*: October 2015;
- *FSIS Requirements for Egg Products*: November 2015;
- *TIF Supervisor Training*: August 2016; and
- *Hazard Analysis and Critical Control Points (HACCP) and Professional Competency certification*: September-October, 2016.

Technical laboratory support for microbiological and chemical residue testing within the CCA's meat inspection system is provided through the government's *Centro Nacional de Servicios de Constatacion en Salud Animal* (CENAPA) [National Service Center for Analysis and Animal Health]. CENAPA is the government laboratory that serves as the national reference laboratory under oversight of the CCA. The two analytical laboratories that comprise CENAPA analyze products and tissues for microbiological and chemical residues to verify that food safety controls are effective, and that meat and poultry products meet United States standards. Each laboratory within CENAPA is International Organization for Standardization (ISO) 17025 accredited through the *Entidad Mexicana de Acreditación* (EMA), Mexico's national accreditation body.

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

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over

establishment construction, facilities, and equipment; daily inspection; and periodic supervisory visits to official establishments.

The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT, and observations during the onsite audit.

The FSIS auditors verified that livestock brought to slaughter receive ante-mortem examination in accordance with the requirements in *Mexican Official Standard NOM-009-ZOO for Sanitary Meat Processing (1994)*. In-plant inspection personnel conduct ante-mortem inspection on the day of slaughter by observing all animals at rest and in motion prior to slaughter. As outlined in its *Manual for Identification, Separation and Removal of Specific Risk Materials for Bovine Spongiform Encephalopathy (2011)*, Mexico has adopted a zero tolerance policy against the slaughter of non-ambulatory disabled cattle. FSIS concluded that food business operators were effectively implementing their documented procedures to preclude non-ambulatory disabled cattle from entering the facility and being slaughtered for human consumption at the two bovine slaughter establishments visited.

FSIS assessed post-mortem inspection examinations through onsite record reviews, interviews, and observations of inspection activities in the five slaughter establishments. The FSIS auditors observed that, for the most part, proper presentation, inspection, and disposition of carcasses were being implemented. However, the following deficiencies were identified:

- While reviewing the slaughter process at one beef establishment, the FSIS auditors noted that the establishment did not implement a batching system or other tracking mechanism to ensure that beef feet that derive from carcasses condemned at post-mortem are precluded from human consumption. FSIS regulations require that that beef feet may pass for human consumption only when their identity is maintained with the carcass through the post-mortem carcass inspection process, and they are found to be not adulterated. Further discussions with inspection personnel indicated that this was a system-wide issue, for which SAGARPA elected to suspend the export of beef feet to the United States from all certified establishments until an appropriate identification system is developed at each location.
- At one of the swine slaughter facilities audited, it was noted that the head inspector was not adequately slicing and inspecting the mandibular lymph nodes, and the viscera inspector was not conducting a thorough visual inspection and palpation of mesenteric lymph nodes. While this deficiency by itself represents an isolated audit finding, it is important to consider its revelation within the context of SAGARPA's periodic supervisory review program that was recently revised to include additional focus on post-mortem inspection activities and failed to document these deficiencies.

The FSIS auditors verified implementation of corrective actions related to the previous FSIS audit (2014), during which it was noted that (1) the CCA did not provide mechanisms to verify the accuracy of formulations or to detect economic adulteration; and (2) the documentation of periodic supervisory reviews was not being uniformly implemented throughout all regions of the system and presented only a limited evaluation of skills related to ante-mortem and post-mortem inspection.

The FSIS auditors noted that SAGARPA is currently implementing a new procedure for labeling verification whereby a) TIF establishment industry personnel provide a completed version of form 7234.1 (*Application for Approval of Labels Marking or Device*) to the official veterinary staff; b) official veterinary staff takes annual samples, which are submitted to a reference laboratory for chemical analysis; and c) official veterinary staff perform additional label verification tasks (e.g., checking product formulation), for which the entire complex of verification activities are documented on form *FR-SM-EXP-ETQ-00/10*. This includes verification that source meat and poultry used in processing operations originates only from certified establishments in eligible countries.

- At one facility, the FSIS auditors noted that a label of a needle-tenderized beef product (“107 rib 2x2”) did not meet the requirements of 9 CFR 317.2. On May 18, 2015, FSIS published a final rule (80 *Federal Register* 28153: *Descriptive designation of needle- or blade-tenderized beef products*) to establish labeling requirements for raw or partially cooked mechanically tenderized beef products. The final rule amended the regulations by adding 9 CFR 317.2(e) (3), requiring that the product name for a mechanically tenderized beef must contain a descriptive designation, e.g., “Needle-tenderized.” The labels of raw or partially cooked needle- or blade-tenderized raw beef products destined for household consumers, hotels, restaurants, or similar institutions must bear validated cooking instructions. Onsite discussions with the CCA representatives indicated that they have not yet issued additional instructions to their inspection personnel to verify these requirements throughout the system. Consequently, while the changes undertaken within Mexico’s system in response to the previous FSIS audit represent a proactive approach to prevent economic adulteration of product, this finding represents an additional need for SAGARPA to keep up-to-date with FSIS labeling policy changes.

Regarding the second point (periodic supervisory reviews), the FSIS auditors noted that the CCA had begun implementing (since July 2016) a standardized program that incorporates elements of *FSIS Directive 4430.3, In-Plant Performance System (IPPS)* and includes individual performance evaluations for such elements as ante-mortem and post-mortem inspection techniques.

- The FSIS auditors noticed variance in the manner that the revised supervisory review program was being implemented. In some cases, supervisory reports did not document the outcome of the assessment of the efficacy and technical competency of inspection personnel. In other cases, the documentation did not identify the competencies being assessed on a particular visit.

The FSIS auditors’ assessment of Mexico’s inspection system revealed a need for the CCA to continue to improve both the manner in which supervisory reviews are conducted, and existing mechanisms to keep up-to-date with FSIS labeling policy changes.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to

develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions. The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT and observations during the onsite audit.

The FSIS auditors verified that SAGARPA 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 as per *Mexican Official Standard NOM-008-ZOO, Zoosanitary Specifications for Building and Equipping Establishments (1994)*. Furthermore, the FSIS auditors verified that inspection personnel exercise their official authority as prescribed by the regulations of the system and follow the requirements outlined in SAGARPA's *Supervision Manual for Official Verification and Inspection of Food Safety Systems in TIF Facilities Exporting to the United States (2010)* to verify that the establishments adequately implement prerequisite programs such as sanitation standard operating procedures, good manufacturing practices, and sanitation performance standards.

The FSIS auditors observed in-plant inspection verification of operational sanitation procedures at all establishments visited. Pre-operational verification activities were also reviewed at one location. Audit evidence was gathered through direct observation of establishment operations and a review of the establishments' associated records.

- While isolated findings are noted on the establishment checklists attached to this report (Appendix A), it is important to note that many of the sanitation non-compliances identified during the audit should have been controlled through the establishments' sanitation programs. Examples included the presence of condensation possibly affecting product, failure to properly sanitize product contact surfaces, the presence of flaking ice on boxes in the product freezer, and the presence of broken boxes with exposed product. However, a review of operational sanitation records indicated that the establishments failed to previously document these conditions, which were most likely present prior to the day of the audit. The FSIS auditors also noted that, in the majority of cases, establishment operational sanitation monitoring records focused on the cleanliness of product contact surfaces and equipment after mid-shift clean-ups, rather than when actual operations were occurring. Consequently, FSIS believes it is important that SAGARPA provide additional verification to ensure that establishment operational sanitation procedures are effective and properly documented.
- Non-compliances related to condensation were identified in three of the eight establishments audited. The FSIS auditors noted that a principal means to address condensation in many of the establishments visited was to conduct continuous monitoring and wiping of affected areas, rather than establish long-term measures to prevent its formation. However, it is important to note that FSIS requires that establishments exporting to the United States provide ventilation adequate to control condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions.

At the audit exit conference, the CCA provided the FSIS auditors with evidence that the facility sanitation non-compliances had been corrected. The FSIS auditors' assessment of Mexico's inspection system identified a need to improve sanitation verification and enforcement activities,

especially as they relate to operational sanitation monitoring and documentation, and measures to prevent the formation of condensation.

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

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

The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT and observations during the onsite audit. The *Manual for Official Verification and Inspection of Food Safety Systems in TIF Facilities Exporting to the United States (2010)* requires establishments exporting to the United States to develop and implement a HACCP program consistent with 9 CFR Part 417.

At the eight establishments audited, the FSIS auditors verified through record reviews and observations that the in-plant inspection personnel conducted daily verification of HACCP plans in accordance with the above-mentioned manual. The FSIS auditors reviewed zero tolerance (feces, ingesta, and milk) critical control point (CCP) records and verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities.

- The FSIS auditors identified findings in the following areas of SAGARPA's *Manual for Verification of Procedures to Control Feces, Ingesta, and Milk in Slaughter Operations (MO08.00)*:
 - *Government Carcass Selection*: Inspectors were not always conducting random selection of carcass groups for verification as required by *MO08.00*.
 - *Government Carcass Observation*: This activity is typically done by the on-line carcass inspector, rather than dedicated floor personnel. Concerning beef slaughter, it was noted that this individual is typically provided with sufficient time to perform the zero tolerance verification activity, as there is a sufficient pause between carcasses. However, during swine slaughter, it was noted that this individual is not always provided with sufficient time due to the uninterrupted stream of carcasses passing the verification point (e.g., 280 carcasses/hour). Consequently, it is important that inspection personnel be provided with sufficient time to conduct their zero tolerance verification activities (regardless of species slaughtered).
 - *Government Documentation of Identified Deviations*: Documentation did not always include the establishment's preventive measures.
- In addition, documentation of corrective actions taken in response to deviations from the zero tolerance CCP at two establishments was general in nature. Establishment personnel were using a series of codes such as "1. Retrained employee," rather than including specific details as to what was discussed or what other actions were taken for each particular event.

At the three establishments producing ready-to-eat (RTE) products, the FSIS auditors reviewed the HACCP programs for these processes with a special emphasis on lethality for *Salmonella* and other relevant pathogens. Establishments producing cooked pork products were adhering to the lethality and stabilization performance standards outlined in Appendices A and B of the *FSIS Compliance Guidelines for Cooking/Cooling Meat and Poultry Products*. One audited establishment included a validated CCP for post-lethality pasteurization in conjunction with the addition of potassium lactate and acetate, and was consequently operating under Alternative 1 guidelines for the control of *Lm* in the post-lethality environment.

- The FSIS auditor identified the following non-compliances related to HACCP plan development:
 - At one establishment, the hazard analysis for the production of RTE products did not address the addition of sodium nitrite during formulation. Although the establishment maintained a written program to demonstrate the control of nitrites and conducted product testing to show that the concentration of nitrite in final product was typically <10 parts per million (ppm), the failure to address all possible hazards within the establishment's written hazard analysis does not meet the export requirements outlined in section 3.2 of SAGARPA's *Manual for Official Verification and Inspection of Food Safety Systems in TIF Facilities Exporting to the United States (2010)*.
 - At two establishments, the hazard analysis addressing the production of RTE products did not accurately identify all the possible hazards associated with the cooling of product after cooking. Although products are subjected to a rapid cooling process (for which the guidelines in Appendix B were met), the failure to address all possible hazards within the establishment's hazard analysis does not meet the export requirements outlined in section 3.2 of SAGARPA's *Manual for Official Verification and Inspection of Food Safety Systems in TIF Facilities Exporting to the United States (2010)*.

The FSIS auditors verified that establishments approved for export to the United States have reviewed their specified risk material (SRM) control programs in accordance with SAGARPA's *Manual for Identification, Separation and Removal of Specific Risk Materials for Bovine Spongiform Encephalopathy (2011)*, to include: brain, skull, eyes, trigeminal ganglion, spinal cord, spinal ganglia roots, spinal column (excluding the caudal vertebrae, the transversal processes of the thoracic and lumbar vertebrae and sacral wings) of bovines 30 months of age and older, and the tonsils and the distal portion of the ileum for bovines of all ages.

During the exit meeting, SAGARPA presented evidence that it had taken immediate measures to resolve the non-compliances identified at the above-referenced locations, including issuance of non-compliance reports and verification that food business operators had modified their HACCP programs accordingly. FSIS requests that SAGARPA provide a description of long-term measures taken to improve the manner in which in-plant officials verify the implementation of establishment HACCP systems, particularly as it pertains to HACCP plan development, recordkeeping requirements, and the zero tolerance food safety standard for feces, ingesta, and milk.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed the *2016 Programa de Monitoreo y Control de Residuos Toxicos y Contaminantes en Alimentos de Origen Animal (PMCRT)* [Monitoring Program and Control of Toxic Residues and Contaminants in Food of Animal Origin], associated methods of analysis, and additional SRT responses outlining the structure of Mexico's chemical residue testing program.

The *PMCRT* covers animal species slaughtered for the production of meat and poultry products destined for domestic and international markets. The design of the sampling protocols has taken the following into consideration: the registered use of a chemical compound of interest; the likelihood of a residue occurring in animal tissues; the extent and pattern of use of the compound; incentives for misuse; known persistence of the compound in the environment; past monitoring results; and requirements of importing countries.

In February 2015, FSIS notified the CCA of a residue violation involving Zilpaterol in bovine muscle. This violation was discussed with the CCA at headquarters, and Mexican authorities provided documented evidence to demonstrate that appropriate trace-back procedures and related enforcement action had been undertaken. There have been no further chemical residue violations in meat and poultry products from certified Mexican establishments at POE since this time.

A review of the sampling records maintained at the four local inspection offices and related regional offices indicated that the 2016 sampling program was being adhered to as scheduled. During the evaluation of ante-mortem inspection at five slaughter establishments, the FSIS auditors observed that government inspectors verify that all lots of animals are accompanied by documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. Mexico has adopted a hold and test procedure within its *PMCRT*, for which the FSIS auditors were presented with sufficient audit evidence while onsite (e.g., review of inspection records, presence of "veterinary retained" cages) to demonstrate that this policy was being effectively implemented.

The FSIS auditors conducted an onsite audit of CENAPA, the principal laboratory providing technical support to Mexico's meat and poultry inspection system. The *Entidad Mexicana de Acreditacion (EMA)* has accredited the laboratory as meeting the criteria of ISO 17025 requirements. The FSIS auditors verified the review of the EMA Accreditation Certificate and Scope of Accreditation issued to CENAPA in the early part of 2016. The FSIS auditors' review of the internal standard operating procedures and onsite observations verified that sampling procedures, quality assurance procedures, calibration and temperature recording, and intra-

laboratory check samples for this laboratory are being properly implemented and recorded. Analytical procedures used by the laboratory were consistent with those reported in the *PMCRT*.

The result of the onsite audit activities indicate that Mexico 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 meat and poultry products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The evaluation of this component included an analysis of information provided by the CCA in the SRT and accompanying documents, and interviews and observations made during the onsite equivalence verification audit. There have not been any POE violations related to this component since the last FSIS audit.

The CCA has developed a *Salmonella* testing program for chilled livestock carcasses within its *Manual De Reducción De Patógenos Para La Detección De: Salmonella spp (2015)* that is equivalent with FSIS regulatory requirements outlined in 9 CFR Part 310.25(b). Generic *Escherichia coli (E. coli)* testing is carried out in accordance with section 9.1 of the *Manual for Official Verification and Inspection of Food Safety Systems in TIF Facilities Exporting to the United States (2010)*. All documents reviewed in relation to these microbiological testing programs led the FSIS auditors to conclude that adequate process control was being maintained in the five slaughter establishments visited.

The CCA considers *Lm* to be a hazard of concern in the production of RTE products that are post-lethality exposed to the environment. Specific requirements related to *Lm* control are contained in *Manual De Reducción De Patógenos Para La Detección DE: Listeria monocytogenes (2015)*, replicating the controls in 9 CFR 430.4 by providing the same three alternative controls to prevent post-lethality *Lm* adulteration in exposed RTE product. The onsite visit to three establishments processing RTE products indicated that inspection personnel were adhering to the sampling plans established by the CCA, and implemented test and hold protocols for each lot of product destined for export to the United States. The FSIS auditors noted that one establishment presented a single *Lm* positive in recent history (in response to government product testing), for which the FSIS auditors were provided with sufficient evidence to demonstrate:

- The CCA's notification of the positive result to the establishment (August 2015);
- Segregation of product, with a focus on microbiological independence of the lots in question, and immediate suspension of export of all similar products to the United States;
- Intensified cleaning of equipment and establishment sampling;

- Reassessment of the establishment's HACCP system and additional government testing (environmental, food-contact, product); and
- No adulterated product was shipped to the United States.

The FSIS auditors also noted that government verification testing for *Salmonella* was not occurring at one establishment producing RTE product (pork ribs) for the United States. Further investigation indicated that this was a result of the instructions outlined in *Section VI.I. of SAGARPA's Manual De Reducción De Patógenos Para La Detección DE: Listeria monocytogenes (2015)*, which calls for *Salmonella* testing only in RTE cured sausage, semi-cured sausage, dried sausage, and breaded pork or chicken products.

- In the absence of additional rationale to support why certain products would be excluded, it is FSIS' expectation that all RTE products be eligible for government verification testing for *Salmonella*. Since all audited establishments presented validated CCPs for cooking and were conducting independent *Salmonella* testing on each lot of exported product, FSIS considers these factors paired with the lack of positive findings at POE as sufficient evidence to support the safety of imported product at this time. However, it is important to note that the purpose of government testing is to provide an additional layer of control by verifying the effectiveness of an individual establishment's HACCP system.

Within its *Manual De Reducción De Patógenos Para La Detección DE: E. coli O157:H7, E Coli Productora De Toxina Shiga (2015)*, SAGARPA stipulates a zero tolerance policy for *E. coli* O157:H7, O26, O45, O103, O111, O121, and O145 in raw bovine products intended for grinding or other non-intact product exported to the United States. This document includes instructions for government sample collection (N-60) and submission procedures, interpretation of results, and outlines an enforcement strategy that includes immediate corrective actions, followed by HACCP reassessment and follow-up testing. The program specifically designates CENAPA as the only laboratory that performs screening and confirmation analyses of official samples. In addition, the number of verification samples collected is proportional to production volume, and the minimum frequency is one sample per month. The onsite visit to two beef establishments indicated that inspection personnel were adhering to the sampling plans established by the CCA, and implemented test and hold protocols for each lot of product destined for export to the United States. The laboratory reports for sampling conducted by both the establishment and government officials indicated that there had been no positive results for STEC in recent history.

- However, the FSIS auditors noted that SAGARPA has provided limited guidance to its inspection personnel with the purpose of verifying that production lots in commerce are microbiologically independent from another production lot of same source beef, which test positive for STEC. While one audited establishment provided a program to address High Event Periods (HEPs), local inspection personnel were not sufficiently familiar with its contents to verify its effective implementation in the face of positive STEC results. HEPs are those in which slaughter establishments experience a high rate of positive results for STEC (or virulence markers) in trim samples from production lots containing the same source materials. That is, the trim was produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift). A HEP may mean that a systemic breakdown of the slaughter dressing operation has occurred and

created an insanitary condition applicable to all parts of the beef carcass (e.g., primal cuts in addition to the beef manufacturing trimmings and other raw ground beef and patty components).

Verification of microbiological independence is important because, in the unlikely event that a STEC-positive sample is at POE, FSIS would expect the government of Mexico to immediately affirm that process controls were working as expected, and provide microbiological evidence demonstrating that no other shipments of raw beef are in transit to, or already in United States commerce. The results of this investigation should also inform FSIS about follow-up enforcement actions, including potential recall procedures.

Regarding recall procedures, FSIS' review of the CCA's *Procedimiento de Atención Rápida De Alertas (2014)* [Rapid Alert Procedure], indicated that it provides a comprehensive outline of the steps to be taken by both industry and inspection personnel with regard to positive laboratory results. This includes trace-back mechanisms to ensure that establishments maintain sufficient records so that investigations may identify the source of the contamination. However, as mentioned above, FSIS identified a need for the CCA to provide additional verification activities to ensure microbiological independence of lots as they relate to trace-forward procedures for those already in commerce.

- The FSIS auditors also noted that the CCA has provided limited instruction to its inspection personnel regarding verification of establishment controls to assure the intact end use of beef primal and sub-primal cuts. While onsite, the FSIS auditors observed that one establishment expressed that it had a verbal agreement with its client. Furthermore, it was noted that all beef establishments visited were conducting independent STEC testing (with aforementioned negative results) on all beef cuts exported to the United States, including primals and sub-primals. However, as the CCA has neither explicitly required establishment testing of primal and sub-primal cuts nor routinely includes these cuts in their government verification testing program, it is important for the CCA to develop verification procedures to assure their intact end use. Furthermore, while a verbal agreement demonstrates a positive intent, FSIS expects that food safety controls be documented within the context of the establishment's HACCP system and verified by inspection personnel on a regular basis.

During the visit to the CENAPA laboratory, the FSIS auditors noted that equivalent microbiological methods were used to analyze United States export samples. Verification of activities related to sample receiving and traceability was also performed. Laboratories maintain appropriate discard criteria to ensure the integrity of the sample and testing results.

FSIS concludes that the CCA continues to meet the core requirements for this component. However, it is important that SAGARPA address the systemic findings related to government verification testing in RTE products, measures to ensure that production lots in commerce are microbiologically independent from another production lot of the same source beef which test positive for STEC, and verification of establishment controls to assure the intact end use of beef primal and sub-primal cuts.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on October 11, 2016, in Mexico City, Mexico with SAGARPA. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

The current audit did not identify any concerns that represented an immediate threat to public health. During the audit exit meeting, the CCA committed to begin to address the preliminary systemic findings as presented and provided additional evidence that many of the isolated findings related to sanitation and HACCP described on the individual establishment checklists (Appendix A) had already been corrected.

The FSIS auditors identified the following systemic findings:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The SAGARPA did not provide mechanisms to ensure that beef feet that derive from carcasses condemned at post-mortem are precluded from human consumption. As this was a system-wide issue, SAGARPA elected to suspend the export of beef feet to the United States from all certified establishments until an appropriate identification system is developed at each location.
- FSIS identified variance in the manner in which the SAGARPA is implementing its revised supervisory review program. In some cases, supervisory reports did not document the outcome of the assessment of the efficacy and technical competency of inspection personnel. In other cases, the documentation did not identify the competencies being assessed on a particular visit.
- The SAGARPA has not kept up-to-date with recent FSIS labeling policy changes, e.g., labeling requirements for raw or partially cooked mechanically tenderized beef products as per 9 CFR 317.2(e) (3). During the exit meeting, Mexican officials committed to working with individual exporting establishments to ensure that the requirements outlined in 9 CFR 317.2(e) (3) are met.

Government Sanitation

Many of the isolated sanitation non-compliances identified during the audit should have been controlled through the establishments' sanitation programs. Consequently, FSIS believes it is important that SAGARPA provide additional verification to ensure that establishment operational sanitation monitoring is effective and properly documented, including control (prevention) of condensation.

Government HACCP System

FSIS identified systemic findings related to verification of HACCP plan development; recordkeeping requirements; and the zero tolerance standard for feces, ingesta, and milk.

Government Microbiological Testing Programs

- Government verification testing for *Salmonella* was not occurring in all RTE products. FSIS requests that the SAGARPA update its requirements to ensure that government *Salmonella*

verification testing occurs in all products exported to the United States, or provide additional rationale to support its testing approach.

- The SAGARPA has not developed adequate verification procedures that will ensure production lots in commerce are microbiologically independent from other production lots of the same source beef, which test positive for STEC; and that establishments implement controls to assure the intact end use of beef primal and sub-primal cuts.

During the audit exit meeting, the CCA committed to begin to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|--|--------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Frigorifico Agropecuaria Sonorense, S.A. de C.V. Calle De La Plata S/N, Casi Esquina Con Carretera A La Colorada Km. 4.5 Parque Industrial Hermosillo | 2. AUDIT DATE 09/29/2016 | 3. ESTABLISHMENT NO. TIF 66 | 4. NAME OF COUNTRY Mexico |
| | 5. AUDIT STAFF OIEA International Audit Staff (IAS) | | 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 SSOPs 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 | X |
| 14. Developed and implemented a written HACCP plan . | | 41. Ventilation | X |
| 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. | X | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | X | 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 | 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

The following non-compliances were not identified by Mexico's inspection officials during the establishment review:

26/51. Excessive hair was noticed on pig feet (final product). Establishment is currently exporting this product to the United States.

40/51. The lighting in a carcass cooler was approximately seven (7) foot-candles rather than the 30 foot-candles required by Mexican legislation.

41/51. Excessive condensation was observed in the carcass transit areas and carcass coolers. Although no direct product adulteration was observed at the time of the audit, inspection officials elected to take official control action by requiring the establishment to segregate and recondition carcasses which had transited these areas.

22/41 Documentation of corrective actions taken in response to deviations from CCP 1 (zero tolerance) was general in nature. This establishment was using a series of codes such as "1. Retrained employee," rather than including specific details as to what was discussed or what other actions were taken for each particular event.

In addition, the FSIS auditor noted the following findings related to implementation of Mexico's meat inspection system:

51. Inspectors were not always conducting *random* selection of carcass groups for zero tolerance verification as required by SENASICA's *Manual for Verification of Procedures to Control Feces, Ingesta and Milk in Slaughter Operations* (MO08.00). FSIS also noted that zero tolerance verification is typically done by the on-line carcass inspector, rather than dedicated floor personnel. However, it is unlikely that this individual is provided with sufficient time to conduct an adequate verification, due to the uninterrupted stream of carcasses passing the verification point (e.g., @ 280 carcasses/hour).

55. The post-mortem head inspector was not adequately slicing and inspecting the mandibular lymph nodes of swine.

55. The post-mortem viscera inspector was not conducting a thorough visual inspection and palpation of swine mesenteric lymph nodes.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|--|---------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Sigma Alimentos Noreste, S.A. de C.V. J. Cantu Leal No. 1320 Sur, Col. Buenos Aires Monterrey | 2. AUDIT DATE 09/27/2016 | 3. ESTABLISHMENT NO. TIF 100 | 4. NAME OF COUNTRY Mexico |
| | 5. AUDIT STAFF OIEA International Audit Staff (IAS) | | 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 SSOPs 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 | X |
| 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 | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | O |
| 25. General Labeling | | 53. Animal Identification | O |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | O |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | O |
| 27. Written Procedures | O | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | O | 56. European Community Directives | O |
| 29. Records | O | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | O | 59. | |
| 31. Reassessment | O | | |
| 32. Written Assurance | O | | |

60. Observation of the Establishment

The following non-compliances were not identified by Mexico's inspection officials during the establishment review:

45/51. Spray bottles used to sanitize product contact surfaces were being stored in condemned material containers in processing areas.

45/51. In the cooking area, manual hoist controls switches presented a build-up of grease and meat residue.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|--|---------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Meat, S.A. de C.V. Guadalajara | 2. AUDIT DATE 10/03/2016 | 3. ESTABLISHMENT NO. TIF 263 | 4. NAME OF COUNTRY Mexico |
| | 5. AUDIT STAFF OIEA International Audit Staff (IAS) | | 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 SSOPs have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | | 39. Establishment Construction/Maintenance | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan . | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | X | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | O |
| 25. General Labeling | | 53. Animal Identification | O |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | O |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | O |
| 27. Written Procedures | O | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | O | 56. European Community Directives | O |
| 29. Records | O | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. Microbiological Government Verification Testing | X |
| 30. Corrective Actions | O | 59. | |
| 31. Reassessment | O | | |
| 32. Written Assurance | O | | |

60. Observation of the Establishment

The following non-compliances were not identified by Mexico's inspection officials during the establishment review:

15/51. Establishment had not included direct observation of monitoring and records review as part of their verification procedures for the cooking CCP.

15/51. The hazard analysis addressing the production of RTE products did not accurately identify all the possible hazards associated with the cooling of product after cooking. This document did not address the possible germination and subsequent toxin production of spore forming organisms such as *Clostridium* during the cooling step. Although, products are subjected to a rapid freezing process, the failure to address all possible hazards within the establishment's hazard analysis does not meet the export requirements outlined in section 3.2 of SENASICA's *Supervision Manual For The Official Verification And Inspection Of The Food Safety Systems in TIF Facilities That Export to the USA*.

In addition, the FSIS auditor noted the following findings related to implementation of Mexico's meat inspection system:

58. The FSIS auditors noted that government verification testing for Salmonella is not occurring in RTE products exported to the United States from this establishment. This derives from section VI.I. of SENASICA's Pathogen Reduction Manual (MO.13.00), which requires *Salmonella* testing only in RTE cured sausage, semi-cured sausage, dried sausage, and empanadas. However, this does not meet the following FSIS equivalence criterion (all RTE product to be tested for Salmonella): 6.6.e. *The CCA and the establishments employ an analytical testing method for Lm, Salmonella, and Escherichia coli O157:H7 (in beef) for RTE products, and Lm on product contact surfaces, and environmental surfaces.*

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|--|---------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Consortio Internacional de Carnes, S.A. de C.V. Ignacio Zaragoza No. 525 Col. Centro, Guadalupe | 2. AUDIT DATE 09/26/2016 | 3. ESTABLISHMENT NO. TIF 300 | 4. NAME OF COUNTRY Mexico |
| | 5. AUDIT STAFF OIEA International Audit Staff (IAS) | | 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 | |
| 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 | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | O |
| 25. General Labeling | | 53. Animal Identification | O |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | O |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | O |
| 27. Written Procedures | O | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | O | 56. European Community Directives | O |
| 29. Records | O | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. SRM Program | X |
| 30. Corrective Actions | O | 59. | |
| 31. Reassessment | O | | |
| 32. Written Assurance | O | | |

60. Observation of the Establishment

The following non-compliances were not identified by Mexico's inspection officials during the establishment review:

15/51. Returned product was not included in the flow chart or considered in the hazard analysis.

58/51. The establishment was not maintaining records to document implementation of its written program for the removal of vertebral columns and dorsal root ganglia in carcasses 30 months of age or older received from another establishment. Discussions with inspection personnel and review of inspection records indicated that the establishment's written program was being implemented as intended and that the SRMs were routinely removed. However, this does not meet the requirements outlined section 18 of SAGARPA's *Manual for Identification, Separation and Removal of Specific Risk Materials for Bovine Spongiform Encephalopathy (2011)*, which calls for the "the maintenance of records that verify that the official establishment receiving carcasses or parts is effectively removing SRMs."

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

09/26/2016

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|--|---------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Distribuidora de Carne del Bajio, S.A. de C.V. Ezequiel Montes | 2. AUDIT DATE 10/06/2016 | 3. ESTABLISHMENT NO. TIF 338 | 4. NAME OF COUNTRY Mexico |
| | 5. AUDIT STAFF OIEA International Audit Staff (IAS) | | 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 | |
| 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

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|--|---------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Sonora Agropecuaria, S.A. de C.V. Km. 86.1 Carretera Federal 90Tramo Guadalajara-La Piedad Atotonilco, El Alto 47750 | 2. AUDIT DATE 10/04/2014 | 3. ESTABLISHMENT NO. TIF 467 | 4. NAME OF COUNTRY Mexico |
| | 5. AUDIT STAFF OIEA International Audit Staff (IAS) | | 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 SSOPs 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 | X |
| 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 | X |
| 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 | X |
| 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

Although the establishment slaughters hogs for the domestic market, this process is not approved by SENASICA for export to the US. Consequently, all source materials used in conjunction with product destined for US export derive from TIF 57.

The following non-compliances were not identified by Mexico's inspection officials during the establishment review:

15/51. The hazard analysis for the production of RTE products did not address the addition of sodium nitrite during formulation. Although the establishment maintained a written program to demonstrate the control of nitrites and conducted product testing to show that the concentration of nitrite in final product was typically <10 ppm, the failure to address all possible hazards within the establishment's written hazard analysis does not meet the export requirements outlined in section 3.2 of SENASICA's *Supervision Manual For The Official Verification And Inspection Of The Food Safety Systems in TIF Facilities That Export to the USA*.

15/51. The hazard analysis for the production of RTE products did not accurately identify all the possible hazards associated with the cooling of product after cooking. This document did not address the possible germination and subsequent toxin production of spore forming organisms such as *Clostridium* during the cooling step. Although, products are subjected to a rapid cooling process, the failure to address all possible hazards within the establishment's hazard analysis does not meet the export requirements outlined in section 3.2 of SENASICA's *Supervision Manual For The Official Verification And Inspection Of The Food Safety Systems in TIF Facilities That Export to the USA*.

39/51. Walls in some of the production areas presented numerous cracks and fissures which would render them difficult to clean.

39/51. A large gap was observed under the product warehouse entry door. Openings communicating with the outdoors must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice

41/51. Dripping condensation was observed in the RTE chicharrón (fully cooked deep fried pork in block form) packing room, which is considered an area of potential post-lethality exposure for *Listeria monocytogenes*. No product adulteration was observed at the time.

41/51. Beaded condensation was observed on overhead structures in a holding cooler. Furthermore, several cardboard boxes containing raw materials (pork) presented damp surfaces. Upon notification of this observation by FSIS, Mexican inspection officials took appropriate enforcement action to ensure that the safety of the product. This included official retention and subsequent repacking of the product by the establishment.

46/51. Excessive build-up of frost was found in the product freezer. Several boxes of product had frost on their surfaces which had flaked off from overhead structures.

46/51. Broken boxes presenting exposed raw meat (source materials for final product) were identified in various locations within the establishment. Upon notification of this observation by FSIS, Mexican inspection officials took appropriate enforcement action to ensure that the safety of the product. This included official retention and subsequent repacking by the establishment.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|--|--------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Ganaderia Integral S.K. S.A. de C.V. Libramiento Noreste Km. 25C, Carretera Laredo Saltillo Ciudad General Escobedo | 2. AUDIT DATE 09/22/2016 | 3. ESTABLISHMENT NO. TIF105 | 4. NAME OF COUNTRY Mexico |
| | 5. AUDIT STAFF OIEA International Audit Staff (IAS) | | 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. | X | 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 | X |
| 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 | X |
| 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 | 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

The following non-compliances were not identified by Mexico's inspection officials during the establishment review:

55/51. The establishment did not present a batching system or other tracking mechanism to ensure that beef feet which derive from carcasses condemned at post-mortem are precluded from human consumption. Mexican inspection officials elected to suspend the export of beef feet until an appropriate identification system is developed.

46/51. An employee was observed picking up trash from the floor with their hands in an active meat processing area (rather than using the metal dustpans which were assigned for this purpose).

10/51. The chute used to convey the viscera to the post-mortem inspection area was not sufficiently sanitized between carcasses. The spray nozzles of the chute's continuous washing system were blocked and the water temperature was 33° C, as opposed to the 82.5° C required by Mexican legislation. No offal is currently being exported to the United States from this establishment.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|--|--------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Sucabrito S.A., de C.V. Autopista Monterrey-Cadereyta Km 2.5 S/N Centro, Nuevo Leon, C.P. 67450 Cadereyta Jimenez, Nuevo Leon | 2. AUDIT DATE 09/23/2016 | 3. ESTABLISHMENT NO. TIF505 | 4. NAME OF COUNTRY Mexico |
| | 5. AUDIT STAFF OIEA International Audit Staff (IAS) | | 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. | X | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOPs 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. | X | 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 | X |
| 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 | X |
| 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 | X | 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

The following non-compliances were not identified by Mexico's inspection officials during the establishment review:

10/51. In the cooler, two goat carcasses were placed under a refrigeration unit which presented frozen condensation on its surface. No direct product adulteration was observed at this time. Upon notification of this observation by FSIS, Mexican inspection officials took appropriate enforcement action to ensure that the safety of the product. This included official retention and subsequent product reconditioning of the product by the establishment.

10/51. Hooks used to hang goat carcasses during the skinning process were not being routinely sanitized after each use.

16/51. Documentation of corrective actions taken in response to deviations from the "zero tolerance" CCP was general in nature. This establishment was using a series of codes such as "1. Retrained employee," rather than including specific details as to what was discussed or what other actions were taken for each particular event.

46/51. The establishment did not maintain the necessary documentation to demonstrate the safe and suitable use of the sanitizer (Citrosan®) used on goat carcasses (@ 720 ppm). This necessitated contacting the manufacturer (Diken) during the audit, which then supplied the necessary information to demonstrate both the safety of the product, and the fact that it met the Food and Drug Administration's (FDA) definition of a "processing aid," i.e., that it would not require inclusion of the compound on the final product label. However, it is FSIS' expectation that this type of information would have been available prior to the onsite audit, and that inspection officials routinely verify the safety and suitability of compounds used on products exported to the United States.

55/51. The lighting at the post-mortem inspection viscera table was insufficient. Lighting at this location was 38 foot-candles, rather than the 100 foot-candles required by Mexican legislation.

Appendix B: Foreign Country Response to Draft Final Audit Report



United States
Department of
Agriculture

Office of
Agricultural
Affairs

U.S. Embassy
Mexico City

Paseo de la
Reforma 305,
Colonia
Cuauhtémoc

06500 Ciudad
de México

April 7, 2017

Dr. Jane Doherty
International Coordinator Executive
USDA, FSIS, OIA, EID
1400 Independence Ave. SW
Room 2143 - South Building
Washington, D.C. 20250

Dear Dr. Doherty:

Attached is official communication #B00.04.01.0685/2017, dated March 28, 2017, and signed by TIF Director Francisco Jaime from the National Service of Health, Food Safety, and Food Quality (SENASICA). Through this letter, Dr. Jaime is submitting the comments regarding the requested information in the draft final audit report. We are providing a courtesy translation of the letter.

I take this opportunity to reiterate our willingness to continue to be an important partner in the working relationship between FSIS and SENASICA.

Sincerely,

A handwritten signature in blue ink, appearing to read "Mary Rose Parrish".

Mary Rose Parrish
Agricultural Attaché

Enclosures

cc. Shannon McMurtrey
Juan Rodriguez

COURTESY TRANSLATION

Memorandum B00.04.01.0685/2017

Mexico City, March 28, 2017

Ms. Jane H. Doherty
International Coordinator Executive
Food Safety and Inspection Service (FSIS)
United States Department of Agriculture

This is in regards of your official letter dated on January 10, 2017. Through this means, the corrective actions and the comments to the FSIS Draft Final Audit Report, done for Mexico's meat and poultry meat inspection system from September 19 to October 11, 2016, were requested. This is also in reference to your official letter dated on March 14, 2016, which granted an extension to submit the information.

To this respect, SENASICA would like to express the following comments:

- Within the draft audit report, section II "Objectives of the audit, scope and methodology", the visit to the Regional Office in the State of Queretaro, Ciudad el Marques de Queretaro has been omitted.
- In regards of the findings derived from the audit in each of the Federal Inspection Type establishments (TIF), the official personnel have performed punctual follow-ups for corrective and preventive actions, the same which have been verified with satisfactory results.
- In relation to the findings that could be considered "systemic", SENASICA has conducted the corrective actions as described in Annex 1, attached to this letter.

I would like to mention that all information that supports the investigations and corrective actions developed by the TIF establishments and this Directorate are filed in this office.

Without anything else in particular, I send you a kind regard,

Dr. Francisco Jaime Sandoval
Director

Draft of the Action Plan proposed by the CCA to the Food Safety and Inspection System (FSIS) about the draft of the audit report derived from the audit conducted in Mexico from September 19 to October 11, 2016. This is to evaluate the food security governmental system in the production of meat and poultry products intended to be exported to the United States of America, which was forwarded to this Directorate on January 1, 2017.

COMPONENT II STATUTORY AUTHORITY

OBSERVATION

1. SAGARPA did not provided mechanisms to ensure that beef feet that derive from carcasses condemned at post-mortem inspection are precluded from human consumption. As this was a system-wide issue, the CCA elected to suspend the export of beef to the United States from all certified establishments until an appropriate identification system is developed at each location.

PROPOSED ACTION BY CCA

SENASICA issued the instruction No. 18/2016 dated September 23, 2016, addressed to the legal representatives of TIF establishments eligible to export to the United States. This instruction requests that establishments implement procedures to ensure the identification and separation of bovine feet whose final destination is the United States; this is based on article 50 of the Federal Animal Health Law, in compliance with sections 310.3, 310.4 and 310.5 of Chapter 9 of the Federal Code of Regulations.

These procedures were prepared and presented as evidence of compliance at the exit meeting; additionally, the Circular No. 103/2016 dated September 30, 2016 was issued aimed to SENASICA's official staff posted at TIF establishments, instructing them to perform a surveillance procedure, both written and *in situ* through Form FR-SM -PST-DISPP-00 19.

OBSERVATION

2. FSIS identified variance in the manner on which the CCA us implementation its revised supervisory review program. In some cases, supervisory reports did not document the outcome of the assessment of the efficacy and technical competency of inspection personnel. In other cases, the documentation did not identify the competencies being assessed on a particular visit.

PROPOSED ACTION BY CCA

SENASICA, through the TIF Establishments Directorate, as per Circular 12/2016 (Annex), dated June 24, 2016, addressed to the Supervisors of TIF Establishments, indicates the enforcement of the new supervision methodology in establishments effective on July 1, 2016.

During the audit, the Information Supervision System had been in place for 3 months, so it was still at a development phase nationwide, both in forms and in the execution of the activities inherent to it. As a second step in the implementation of the Information Supervision System, three training courses were held for the veterinary personnel at TIF establishments, covering TIF establishments nationwide.

The instruction to give three teaching courses was given through memorandums 82/2016 (Annex), 92/2017 (Annex) and 106/2016 (Annex), respectively. They were about the Information Supervision System, addressing the correct implementation of the Supervision Manual. Thus reinforcing the homologation of criteria in, both, the daily inspection activities at establishments and in the supervision visits by official personnel, which although they presented variations during the audit, these were not significant differences. It is evident that a proper supervision of the activities of the TIF establishments is been carried out.

SENASICA developed the document "Evaluation to the performance of the Veterinary at TIF Establishments", being a section of the Information Supervision System, to objectively evaluate the technical competence of the official personnel.

For the second half of 2017, it is contemplated to begin with a pilot program that will allow the implementation of the aforementioned document, in compliance with FSIS In-Plant Performance System (IPPS) directive 4430.3.

At the end of the fiscal year, all official personnel are subject to a performance evaluation, being the method to measure the qualitative and quantitative aspects of the fulfillment of the functions and assigned goals, according to their abilities and capacities. This is based on the Article 54 of the Professional Career Service Act in the Federal Public Administration.

OBSERVATION

3. The SAGARPA has not kept up-to-date with recent FSIS labelling policy changes, e.g. labeling requirements for raw or partially cooked mechanically tenderized beef products as per 9 CFR 317.2 (e) (3). During the exit meeting, Mexican officials committed to working with individual exporting establishments to ensure that the requirements outlined in 9 CFR 317.2 (e)(3) are met.

PROPOSED ACTION BY CCA

In relation to the observation detected, it must be mentioned that the auditor refers to FSIS Notice 37-16 dated 6/6/16 that was not notified to this General Directorate by FSIS, and that at the time of the audit this notice was published only three months from that date.

The CCA issued two circulars, one addressed to the legal representatives, and the second one to the veterinary staff at authorized establishments to export to the US. This was done with the intention of making them aware of, while taking note, new labeling requirements for raw or partially cooked meat, mechanically softened with a needle or with a blade, as specified in 9 CFR 317.2 (e)(3). In the same context, the FR-SM-EXP-ETQ-00/10 form "Form for Verification of USAA Export Labeling of Establishments Producing Processed Products" was modified, which includes the verification in compliance with requirements established in 9 CFR 317.2 (e)(3).

COMPONENT THREE: GOVERNMENT SANITATION

OBSERVATION

1. Many of the isolated sanitation non-compliances identified during the audit should have been controlled through the establishments' sanitation programs. Consequently, FSIS believes it is important that the CCA provide additional verification to ensure that establishment operational sanitation monitoring is effective and properly documented, including control (prevention) of condensation.

PROPOSED ACTION BY CCA

A circular addressed to the supervisors will be issued, instructing them to confirm that the official veterinary staff posted at the establishments under their responsibility, are verifying the implementation of the maintenance of the operational records of the "Standard Sanitation Operating Procedures (SSOPs)".

With this, veterinarians must designate at least one day a week within their "Task Scheduling Schedule" (Form SIS 01) for the reviewing of records, based on the Sub-exit-codes D1 and D2 of the TIF System Supervision Manual, which describes:

D1)

- Request to the establishment the records and verify that they are signed by the staff that performs the activity and by the personnel who supervises the fulfillment of this activity; in addition, to check the date and time, to corroborate that the frequency complies with the standards.
- Verify that records are requested in real time.
- The staff of the establishment that verifies the SSOPs, shows in their records what type of verification was done. If it was documentary, observation of the process or verification of the activity; so that the actions of the personnel who performed the activity, as well as the personnel supervised, are evaluated, also, if they are properly documented.

D2)

- The pre-operational and operational registers consider the implementation, supervision and verification of the contact surfaces.
- The establishment shows by means of the records and in writing if the activity was efficient or deficient. This is registered.

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

OBSERVATION

1. FSIS identified systemic findings related to verification of HACCP plan development; recordkeeping requirements; and the zero tolerance standards for feces, ingesta, and milk.

PROPOSED ACTION BY CCA

The CCA will make a modification to the "Manual for the verification of procedures for the control of fecal matter, ingesta and milk in slaughter operations." In the same manner, it will instruct veterinary personnel at establishments authorized to export to the USA to observe the modifications. These amendments address the observations that the audit team issued during its visit, to comply with 9 CFR 307.2 (g) and (m), 310.3, 310.17 (a), 310.18 (a), 318.4 (b), 381.65 (e) and 381.76 (B) (3) (iv) and FSIS Directive 5000.1, Revision 1. The new material contains responsibilities of the inspector, with emphasis on the zero tolerance controls official verification of after the CCP established by the plant.

COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

OBSERVATION

1. Government verification testing for salmonella was not occurring in all ready-to-eat products. FSIS requests that the CCA update its requirements to ensure that government Salmonella verification testing occurs in all products exported to the United States, or provide additional rationale to support its testing approach.

PROPOSED ACTION BY CCA

Circular B00.04.01.03.002 / 2016 is issued and clarifies that all RTE products should be sampled for both *Listeria monocytogenes* and *Salmonella spp.*

Explanation to the new version PR-SM-TF-13 of the "Procedure for Verification of *Listeria monocytogenes* and *Salmonella spp* Control Activities in Ready to Eat Products", provided in March 2017.

OBSERVATION

2. SAGARPA has not developed adequate verification procedures that will ensure production lots in commerce are microbiologically independent from other production lots of the same source beef, which test positive for Shiga toxin-producing *E. coli*; and that establishments implement controls to assure the intact end use of beef primal and sub-primal cuts.

During the audit exit meeting, the CCA committed to begin addressing the preliminary findings presented. FSIS will assess the adequacy of corrective actions proposed by the CCA once received.

PROPOSED ACTION BY CCA

The adaptation of the PR-SM-TF-11 "Procedure for the verification of control activities of: *E. coli O157: H7*, *Echerichia coli* producing Shiga toxin (STEC's) and *Salmonella spp* in raw beef products", March 2017.

"FSIS Compliance Guidelines for establishments sampling beef cuts for the detection of *Escherichia coli* producing Shiga toxin (STEC) or virulence markers are published"

**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

*"2017, Año del Centenario de la Promulgación de la
Constitución Política de los Estados Unidos Mexicanos"*

Nº de Oficio B00.04.01.0685/2017

Ciudad de México a **28 MAR 2017**

MS. JANE H. DOHERTY
INTERNATIONAL COORDINATION EXECUTIVE
FOOD SAFETY AND INSPECTION SERVICE (FSIS)
UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

Estimada Jane:

Hago referencia a su oficio fechado del 10 de enero del 2017, por medio del cual se solicitan las acciones correctivas y comentarios del Reporte Preliminar de Auditoria del FSIS, al sistema de inspección de carnes y aves de México, llevada a cabo en el periodo del 19 de septiembre al 11 de octubre del 2016, así como a su oficio de fecha 14 de marzo, agradeciendo el otorgamiento de plazo adicional para el envío de la información.

Sobre el particular, este Servicio tiene los siguientes comentarios:

- En el reporte preliminar de auditoria, sección II "Objetivo de la auditoria, alcance y metodología", se ha omitido la visita a la Oficina Regional en el Estado de Querétaro, Ciudad el Marqués de Querétaro.
- En cuanto a los hallazgos derivados de la auditoria en cada uno de los establecimientos Tipo Inspección Federal (TIF), el personal oficial ha dado seguimiento puntual a las acciones correctivas y preventivas, mismas que han sido verificadas con resultados satisfactorios.
- En relación a los hallazgos que podrían considerarse "sistémicos", el SENASICA, ha llevado a cabo las acciones correctivas que se describen en el Anexo I, adjunto al presente oficio.

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**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

*"2017, Año del Centenario de la Promulgación de la
Constitución Política de los Estados Unidos Mexicanos"*

Nº de Oficio B00.04.01.0685/2017

-2-

No omito mencionar que toda la información que respalda las investigaciones y acciones correctivas desarrolladas por los establecimientos TIF, así como por esta Dirección se encuentran en expediente en esta oficina.

Sin más sobre el particular, reciba un cordial saludo.

**ATENTAMENTE
EL DIRECTOR**



MVZ FRANCISCO JAIME SANDOVAL



C.C.P. **MVZ HUGO FRAGOSO SÁNCHEZ**. DIRECTOR GENERAL DE INOCUIDAD AGROALIMENTARIA, ACUÍCOLA Y PESQUERA.- Para conocimiento.
MVZ MARIA CITLALI ORTIZ RICO GUEVARA. SUPERVISORA EN LÍNEA DE LA DIRECCIÓN DE ESTABLECIMIENTOS TIPO INSPECCIÓN FEDERAL.- Para conocimiento.

SICE 2017-00778, SICE 2017-2339

MCORG/jm


**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

*"2017, Año del Centenario de la Promulgación de la
Constitución Política de los Estados Unidos Mexicanos"*

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| Nº CONSECUTIVO | OBSERVACIÓN | ACCIÓN PROPUESTA POR ACC |
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| COMPONENTE II AUTORIDAD ESTATUTARIA | | |
| 1 | La SAGARPA no proporcionó mecanismos para asegurar que los pies de carne que se las canales condenadas a la autopsia quedan excluidas del consumo humano. Como se trataba de un problema sistemático, SAGARPA decidió suspender la exportación de los pies de carne a los Estados Unidos de todos los establecimientos certificados hasta que se desarrolle un sistema de identificación para cada ubicación. | El SENASICA expidió la instrucción con circular No. 18/2016 de fecha 23 de septiembre del 2016, dirigida a los representantes legales de establecimientos TIF elegibles para exportar a los Estados Unidos, dicha instrucción solicita que los establecimientos elaboren procedimientos que aseguren la identificación y separación de las patas de bovinos que tengan como destino final la exportación a los Estados Unidos, lo anterior para que en fundamento al artículo 50 de la Ley Federal de Sanidad Animal, de cumplimiento a los apartados 310.3, 310.4 y 310.5 del Capítulo 9 del Código Federal de Regulaciones. Dichos procedimientos fueron elaborados y se presentaron como evidencia de cumplimiento en la reunión de cierre de la auditoría; adicionalmente se expidió la circular No. 103/2016 con fecha 30 de septiembre de ese mismo año, dirigida a personal oficial del SENASICA adscritos a los establecimientos TIF, instruyéndoles a realizar vigilancia al procedimiento, tanto escrito como <i>in situ</i> mediante el Formato FR-SM-PST-DISPP-00 19. |

**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

*“2017, Año del Centenario de la Promulgación de la
Constitución Política de los Estados Unidos Mexicanos”*

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| <p>2</p> | <p>El FSIS identificó la variación en la manera en que la SAGARPA está implementando su supervisión. En algunos casos, los informes de supervisión no son resultado de la evaluación de la eficacia y competencia técnica del personal de inspección. En otros casos, la documentación no identificaba las competencias evaluadas en una visita particular.</p> | <p>El SENASICA a través de la Dirección de Establecimientos TIF, mediante la circular 12/2016 (Anexo), de fecha 24 de junio de 2016, dirigida a los Supervisores de Establecimientos TIF, instruye a comenzar con la nueva metodología de supervisión en los establecimientos a partir del 1 de julio de 2016.</p> <p>Durante la Auditoría, el Sistema Informático de Supervisión llevaba 3 meses de implementación, por lo que aún se encontraba en una etapa de desafío a nivel nacional, tanto en formatos como en la realización de las actividades inherentes al mismo. Como segunda etapa de la implementación del Sistema Informático de Supervisión se realizaron 3 cursos de capacitación para el personal veterinario de Establecimientos TIF, abarcando a todos los Establecimientos TIF del territorio nacional.</p> <p>La instrucción para realizar los 3 cursos se dieron mediante las circulares 82/2016 (Anexo), 92/2017 (Anexo) y 106/2016 (Anexo) respectivamente y fueron entorno al Sistema Informático de Supervisión, abordando la correcta implementación del Manual de Supervisión, reforzando con ello, la homologación de los criterios tanto en las actividades diarias de inspección en los establecimientos, como en las visitas de supervisión por parte de personal oficial, que si bien presentaron variaciones durante la auditoría, éstas no fueron diferencias significativas por lo cual queda de manifiesto que se lleva a cabo una correcta supervisión de las actividades de los Establecimientos TIF.</p> <p>SENASICA ha desarrollado el documento “Evaluación al desempeño del Médico Veterinario de Establecimientos TIF”, siendo un apartado del Sistema Informático de Supervisión, para evaluar de forma objetiva la competencia técnica del personal oficial.</p> <p>Para el segundo semestre del año 2017 se tiene contemplado comenzar con un programa piloto que permita la implementación del documento anteriormente mencionado, apegándose a lo descrito en la directiva 4430.3, In-Plant Performance System (IPPS) del FSIS.</p> <p>Al concluir el año fiscal todo el personal oficial está sujeto a una evaluación del desempeño, siendo el método para medir los aspectos cualitativos y cuantitativos del cumplimiento de las funciones y metas asignadas, en función de sus habilidades y</p> |
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**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

*"2017, Año del Centenario de la Promulgación de la
Constitución Política de los Estados Unidos Mexicanos"*

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| | | capacidades, lo anterior con fundamento en el Artículo 54 de la Ley del Servicio Profesional de Carrera en la Administración Pública Federal. |
| 3 | <p>• El SAGARPA no se ha mantenido al día con los recientes cambios en la política de etiquetado del FSIS, por ejemplo, Requisitos de etiquetado para los productos de carne de vacuno por 9 CFR 317.2 (e) (3). Durante la reunión de salida, los funcionarios mexicanos se comprometieron a trabajar con los establecimientos exportadores individuales para garantizar que los requisitos establecidos en 9 CFR 317.2 (e) (3) sean conocidos.</p> | <p>En relación a la observación detectada debe mencionarse que el auditor hace mención a la FSIS Notice 37-16 del fecha 6/6/16 y que la misma no fue notificada en ningún momento a esta Dirección General por el FSIS así como que al momento de la auditoría esta noticia contaba con tan solo tres meses de publicación.</p> <p>La ACC expidió dos circulares, una estará dirigida a los representantes legales y otra al personal veterinario en los establecimientos autorizados a exportar a EEUU con la intención de hacer de su conocimiento y tomar atención sobre los nuevos requisitos de etiquetado de la carne cruda o parcialmente cocida, ablandada mecánicamente con aguja o con cuchilla, tal y como se especifica en el 9 CFR 317.2 (e) (3). En el mismo contexto, se realizó la modificación del formato FR-SM-EXP-ETQ-00/10 "Formato para la Verificación del Etiquetado de Exportación a los EEUUAA de Establecimientos que Elaboran Productos Procesados", en el cual se incluye la verificación de acuerdo a los requisitos del 9 CFR 317.2 (e) (3).</p> |

**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

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Constitución Política de los Estados Unidos Mexicanos”*

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| COMPONENTE TRES: SANEAMIENTO GUBERNAMENTAL | | |
| 1 | <p>Muchos de los incumplimientos de saneamiento aislados identificados durante la auditoría deberían haber sido controlados a través de los programas de saneamiento de los establecimientos. En consecuencia, el FSIS cree que es importante que la SAGARPA realice una verificación adicional para garantizar que el monitoreo operacional de saneamiento es efectivo y debidamente documentado, incluyendo el control (Prevención) de la condensación.</p> | <p>Se realizará circular dirigida a los supervisores, instruyéndolos a constatar que el personal veterinario oficial adscritos a los establecimientos bajo su cargo, verifiquen la implementación del mantenimiento de los registros operacionales de los “Procedimientos Operativos de Sanitización (POES)”.</p> <p>Con ello, los médicos deben designar un día a la semana como mínimo dentro de su “Cronograma de Programación de tareas” (Forma SIS 01), para la revisión de registros, basándose en los Sub códigos de salida D1 y D2 del Manual de Supervisión del Sistema TIF, que describe:</p> <p>D1)</p> <ul style="list-style-type: none"> • Solicitar al Establecimiento los registros y verificar que estén firmados por el personal que realiza la actividad y por el personal que supervise el cumplimiento de esta actividad; además, revisar la fecha y hora, para corroborar el cumplimiento de la frecuencia. • Verificar que los registros se requisen en tiempo real. • El personal del establecimiento que verifica los POES, demuestra en sus registros que tipo de verificación realizó si fue documental, de observación del proceso o de constatación de la actividad; de tal forma que se evalué tanto las acciones del personal que realiza la actividad, como del personal que supervise, así mismo, si éstos son debidamente documentados. |

**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

*"2017, Año del Centenario de la Promulgación de la
Constitución Política de los Estados Unidos Mexicanos"*

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| | | <p>D2)</p> <ul style="list-style-type: none"> • Los registros pre operacionales y operacionales contemplan la implementación, supervision y verificación de las superficies de contacto. • El Establecimiento demuestra mediante registros y por escrito si la actividad fue eficiente o deficiente y ésta queda registrada. |
| <p>COMPONENTE CUATRO: SISTEMA DE ANÁLISIS DE PELIGROS Y PUNTOS CRITICOS DE CONTROL DEL GOBIERNO (HACCP).</p> | | |
| <p>1</p> | <p>El FSIS identificó hallazgos sistémicos relacionados con la verificación del desarrollo del plan HACCP; requisitos de mantenimiento de registros; Y el estándar de tolerancia cero en heces, ingesta y leche.</p> | <p>La ACC realizará modificación al "Manual para la verificación de los procedimientos de control de Material fecal, ingesta y leche en las operaciones de Sacrificio" de la misma manera girará instrucción al personal veterinario en los establecimientos autorizados a exportar a E.U.A. para la atención de las modificaciones. Dichas modificaciones atienden las observaciones que el equipo auditor emitió durante su visita, apegándose al 9 CFR 307.2 (g) y (m), 310.3, 310.17 (a), 310.18 (a), 318.4 (b), 381.65 (e) y 381.76 (b) (3) (iv) y a la Directiva FSIS 5000.1, Revisión 1. El nuevo material contiene responsabilidades del inspector, haciendo hincapié en la verificación oficial de los controles de cero tolerancia después del PCC establecido por la planta.</p> |
| <p>COMPONENTE SEIS: PROGRAMA DE PRUEBAS MICROBIOLÓGICAS DEL GOBIERNO</p> | | |

**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

“2017, Año del Centenario de la Promulgación de la
Constitución Política de los Estados Unidos Mexicanos”

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| 1 | <ul style="list-style-type: none"> No se han realizado pruebas de verificación gubernamental de <i>Salmonella</i> en todos los productos RTE. FSIS solicita que la SAGARPA actualice sus requisitos para asegurar que las pruebas de verificación de <i>Salmonella</i> del gobierno se realicen en todos los productos exportados a los Estados Unidos, o provea fundamentos adicionales para apoyar su enfoque de pruebas. | <p>Se emite la Circular B00.04.01.03.002/2016 mediante la cual se clarifica que todos los productos RTE deben ser muestreados tanto para <i>Listeria monocytogenes</i>, como para <i>Salmonella spp</i>.</p> <p>Se realiza la clarificación en la nueva versión PR-SM-TF-13 del “Procedimiento para la Verificación de actividades de control de <i>Listeria monocytogenes</i> y <i>Salmonella spp</i> en Productos Listos para Consumo” marzo 2017,</p> |
| 2 | <ul style="list-style-type: none"> La SAGARPA no ha desarrollado procedimientos de verificación adecuados que aseguren que los lotes de producción en el comercio son microbiológicamente independientes | <p>Se realiza la adecuación del PR-SM-TF-11 “Procedimiento para la Verificación de actividades de control de: <i>E. coli</i> O157:H7, <i>Echerichia coli</i> productora de toxina Shiga (STEC’s) y <i>Salmonella spp</i> en productos de carne de bovino cruda” marzo 2017.</p> |

**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**
Dirección de Establecimientos Tipo Inspección Federal

*"2017, Año del Centenario de la Promulgación de la
Constitución Política de los Estados Unidos Mexicanos"*

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| <p>de otros de la misma fuente de carne de vacuno, que arroje una prueba positiva para STEC; Y que los establecimientos implementan controles para asegurar el uso final intacto de los cortes primarios y secundarios.</p> <p>Durante la reunión de salida de la auditoría, la CCA se comprometió a comenzar a abordar los hallazgos preliminares presentados. El FISIS evaluará la adecuación de las acciones correctivas propuestas por la CCA una vez recibidas.</p> | <p>Se publican "Lineamientos de conformidad del FSIS para establecimientos que muestrean recortes de res para la detección de <i>Escherichia coli</i> productora de toxina Shiga (STEC) o de marcadores de virulencia"</p> |
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