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Dear Dr. Fragoso:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Mexico's Meat and Processed Poultry inspection system from August 28 through September 13, 2012. Enclosed is a copy of the final audit report.

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

Sincerely,

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

Enclosure

SEP 19 2013

FINAL REPORT OF AN AUDIT
AUGUST 28 THROUGH SEPTEMBER 13, 2012
THE UNITED STATES OF MEXICO

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
THE PRODUCTION OF MEAT AND PROCESSED POULTRY
PRODUCTS INTENDED FOR EXPORT TO
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a routine on-site verification audit conducted by the Food Safety and Inspection Service (FSIS) from August 28 through September 13, 2012, to determine if Mexico's food safety system governing the production of meat and processed poultry products continues to be equivalent to that of the United States, with the ability to produce products which are safe, unadulterated, and properly labeled.

The focus of the audit was on the ability of the Central Competent Authority (CCA), Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (SENASICA), to regulate meat and poultry products production. FSIS reviewed and verified the information provided by the CCA in the Self-Reporting Tool (SRT). The audit scope included one central, one state, and four local government offices; two beef slaughter and processing establishments; one Kosher beef processing establishment; one multi-species processing establishment producing ready-to-eat (RTE) product; and one government microbiological and chemical residue laboratory. Determinations concerning the effectiveness of Mexico's meat and processed poultry inspection system focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residues, and (6) CCA Microbiological Testing Programs.

The audit outcome showed that the CCA is able to meet the established criteria for four of the components, Statutory Authority and Food Safety Regulations, Sanitation, HACCP, and Chemical Residues. Government oversight must be improved based on the following findings:

- Government Oversight Component:
 - Supervisory reviews
 - Review of SSOP and HACCP programs
 - Documentation of non-compliances
 - Statutory Authority and Food Safety Regulations Component
 - Amending BSE/SRM regulations for SRM removal and recordkeeping
- Sanitation Component:
 - Pre-Operational sanitation implementation and monitoring
 - Operational sanitation implementation and monitoring
 - SSOPs content and records
 - Condensation
 - Direct product contamination
 - Non-compliance reports
- HACCP Component:
 - Corrective actions and preventive measures
 - Zero tolerance
 - HACCP plans
 - Non-compliance records
- CCA Microbiological Testing Programs Component:
 - Understanding, implementation, and verification of generic *Escherichia coli* programs within slaughter establishments

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority, [Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (SENASICA)]
CENAPA	National Center for Animal Health Diagnosis (Centro Nacional de Servicios de Constatación en Salud Animal)
CFR	United States Code of Federal Regulations
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
<i>Lm</i>	<i>Listeria monocytogenes</i>
MVRATIF	Certified Veterinarians-in-Charge at TIF Establishments
NOID	Notice of Intent to Delist
NOM	Norma Oficial Mexicana (Mexican Official Standard)
O.I.R.S.A.	International Regional Organization for Agricultural Health (Organismo Internacional Regional de Sanidad Agropecuaria)
PLE	Post-lethality exposure (of RTE products)
POE	Point-of-Entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
RTE	Ready-to-Eat
SAGARPA	Secretariat for Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentacion)
<i>Salmonella</i>	<i>Salmonella</i> species
SENASICA	National Service for Animal Health, Food Safety, and Agricultural and Food Quality Assurance (Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria)

SPS	Sanitation Performance Standards
SRM	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures
SRT	Self-Reporting Tool
STEC	<i>Shiga-toxin producing Escherichia coli</i>
TIF	Federal Inspection Type (Tipo Inspección Federal)

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Mexico's meat and processed poultry food safety inspection system from August 28 through September 13, 2012.

The audit began with an entrance meeting in Mexico City, Mexico on August 28, 2012, with representatives from the Central Competent Authority (CCA) Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (SENASICA) and the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS).

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure that Mexico's food safety system for meat and processed poultry continues to be equivalent to that of the United States, with the resultant capacity to produce products which are safe, unadulterated, and properly labeled.

The FSIS used a risk-based procedure to determine the audit scope which included an analysis of country performance within six equivalence components, production types and volumes, frequency of prior audit-related on-site visits, point-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included data collected by the FSIS over a three year timeframe in addition to information obtained directly from the CCA, through a self-reporting process, outlining the current structure of the country's inspection system and identifying any significant changes which have occurred since the last audit.

The FSIS auditor was accompanied throughout the audit by representatives from the CCA or from the state and local inspection offices. Program effectiveness determinations focused on performance within the following six equivalence components: (1) Government oversight, (2) Statutory authority and food safety regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems (HACCP), (5) Chemical residues, and (6) Microbiological testing programs.

Administrative functions were reviewed at the CCA headquarters, one state office, and four local inspection offices. The FSIS auditor evaluated the implementation of those management control systems in place which ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

A sample of four establishments was selected from a total of fifty-seven 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. Emphasis was placed on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2 / 381.96.

Additionally, one government central reference laboratory, supporting both microbiological and chemical residue functions, was audited to verify its ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	SENASICA Headquarters, Mexico City, District Federal
	State	1	Aguascalientes, Aguascalientes
Laboratories		1	Government central reference laboratory supporting both microbiological and chemical residue functions, Centro Nacional de Servicios de Constatación en Salud Animal (CENAPA), Jiutepec, Morelos
Establishments			
	• Beef Slaughter/Processing	2	TIF 101, Tierra Blanca, Veracruz TIF 301, Mexicali, Baja California Norte
	• Kosher Beef Processing	1	TIF 517, Zapotitlán, Hidalgo
	• Multi-species Processing (RTE)	1	TIF 158, Atitalaquia, Hidalgo

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
- The Poultry Products Inspection Regulations (9 CFR Part 381)

The audit standards applied during the review of Mexico's meat and processed poultry inspection system included: All legislation determined to be equivalent by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Mexico has equivalence determinations in place for the following:

- National Program for *Escherichia coli* (*E. coli*) O157:H7 (September 11, 2008)
- *Salmonella*:
 - Program for controlling the prevalence of *Salmonella* in raw products (June 25, 2009)
 - Private laboratories analyze samples for *Salmonella* (December 14, 1999)
- *Listeria monocytogenes* (*Lm*):
 - Control Program for Ready-to-Eat (RTE) (June 29, 2009)
 - Includes sampling for *Lm* and *Salmonella*
 - Use of private laboratories for analysis of *Lm* (June 29, 2009)
- Residue Program
 - The National Program for Residues (2011 for the 2009 Program)

4. BACKGROUND

Mexico is eligible to export raw and processed beef, veal, mutton, lamb, goat, and pork products to the U.S. as well as raw and processed poultry with place of origin restrictions. Between October 1, 2010 and September 30, 2011, Mexico exported 153,763,633 pounds of meat and processed poultry products to the U.S. including almost all processing categories. Of this export volume, 25,138,036 pounds were re-inspected at U.S. POE. A total of 56 pounds of 03H pork in one lot were refused entry and 96,049 pounds were rejected at POE, of which 27,960 pounds were rejected for positive pathogen sampling for *Escherichia coli* (*E. coli*) O157:H7, 3840 pounds were rejected for failure of species verification, and 11,212 pounds were rejected for zero tolerance failure. The remaining twelve findings from POE were for labeling verification (wrong shipping marks [off by one number, 5930 pounds]), wrong order of ingredients [onion vs. garlic, 174 pounds], an ingredient not listed [garlic, 174 pounds], ingredients listed as fine herbs rather than spices [696 pounds]), for a fly on the product (11,873 pounds), or for unlisted reasons (34,190 pounds). These rejections represent 03C, 03D, and 03G products and a total of seven establishments. There were six lots of labeling rejections from a single 03D establishment, but each rejection was only for 174 pounds and all six came on a single health certificate. There are no trends apparent.

The Animal and Plant Health Inspection Service (APHIS) has determined the disease status of Mexico as follows:

- Affected by Classical Swine Fever and Exotic Newcastle's Disease (in some states)
- Free of Classical Swine Fever and Exotic Newcastle's Disease (in some states) with Special Restrictions as listed in the APHIS regulations
- Free of African Swine Fever
- Free of Bovine Spongiform Encephalopathy
- Free of Foot and Mouth Disease
- Free of Swine Vesicular Disease

The Mexican food safety system was last audited in September/October of 2009 (FY 2009). The significant findings in the audit centered on the components of Government Oversight, Sanitation, and Hazard Analysis and Critical Control Points (HACCP) systems. Many of the findings pointed to either lack of or ineffective implementation of training. The FY 2009 audit had a finding in the area of conflict of interest since Mexico had a system in which veterinary inspectors were hired and paid by the establishments but allowed to perform regulatory duties on U.S.-destined product. Also of concern was the number of establishments in which the inspection personnel did not perform post-mortem procedures in accordance with Mexican and U.S. regulations. Of the 16 establishments audited in FY 2009, two establishments were given Notices of Intent to Delist (NOIDs). No establishments were delisted. Mexico submitted corrective actions for all establishments that had establishment non-compliances noted during the audit. Subsequently, Mexico also submitted corrective actions for all identified Government Oversight non-compliances including the issue of conflict of interest and the failure to perform post-mortem inspection following regulatory guidelines. One of the establishments that received an NOID in the previous audit was included in this audit. This audit confirmed that those corrective actions in the previously audited establishment were in place and effective except in the case of

the generic *Escherichia coli* program as noted in the Microbiological Testing Program component of this report.

The FSIS final audit reports for Mexico's Food Safety System are available on the FSIS's website at:

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

5. GOVERNMENT OVERSIGHT

The FSIS auditor reviewed Government Oversight as the first of the six equivalence components. The FSIS auditor verified that the inspection system was organized and administered by the national government of Mexico and provided standards equivalent to those of the Federal system of meat and poultry inspection in the United States (U.S.).

The National Service for Animal Health, Food Safety, and Agricultural and Food Quality Assurance (Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria) (SENASICA), a division/service of the Secretariat for Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), is granted the authority to enforce inspection laws and is responsible for regulating Mexico's meat and processed poultry inspection system and live-animal health requirements. This responsibility includes certifying and regulating Tipo Inspección Federal (TIF) establishments for the exportation of meat and processed poultry products to the United States.

The national meat and processed poultry products inspection service in the United States of Mexico (Mexico) is organized in the following manner:

- SAGARPA is the Secretariat of the Mexican government with control over livestock and animal health issues. The Federal Law of Animal Health establishes the Secretariat as the authority responsible for protecting animal health and well-being, and for good livestock practices in primary production and for TIF establishments devoted to the slaughter of animals and processing of goods of animal origin.
- SENASICA is the service/division of SAGARPA that is responsible for regulating Mexico's meat and processed poultry inspection system and live-animal health requirements. This responsibility includes certifying and regulating TIF establishments. These are the establishments that produce products for export.
- The General Directorate for Food Safety, Aquaculture, and Fisheries (Dirección General de Inocuidad Agroalimentaria, Acuicola y Pesquera [DGIAAP]) is a directorate in SENASICA. The Directorate overseeing the Federal TIF establishments (Dirección de Establecimientos Tipo Inspección Federal) falls directly under the General Directorate.
- The State Supervisors (Supervisores Estatales) answer directly to the Director of TIF establishments. The Veterinarians-in-Charge (VIC) within each TIF facility are supervised directly by a state supervisor and in turn supervise the other veterinarians

working in the establishment who are federal employees. Certified Veterinarians-in-Charge at TIF Establishments (MVRATIF) are veterinarians who are paid through a third-party system titled Organismo Internacional Regional de Sanidad Agropecuaria (O.I.R.S.A.) that is overseen by the federal government. These MVRATIF veterinarians are supervised by the VIC in each establishment.

The FSIS auditor reviewed current organization charts from the SRT and confirmed the above organizational structure was still in place. The supervisory chain in the establishments reviewed was verified and found to be in accordance with the above plan. The CCA does have direct authority, given by the Federal Law of Animal Health, over the personnel assigned by them to each TIF establishment. There is a new revision of the Federal Law of Animal Health (Law); the FSIS auditor was told that the new Law did not make changes in the organization of the food inspection system. This new revision was received by the FSIS auditor, but has not been evaluated because it has not been translated. Once translated and evaluated, FSIS will determine if follow up action is required

Certification within the TIF system is a procedure that guarantees meat (meat and processed poultry) products safety in slaughterhouses (and further processing establishments). The original Federal Law of Animal Health and the regulations written to implement the Law only dealt with slaughter and deboning processes and did not include further processing. Although these regulations and their subsequent guidelines and manuals were used to regulate further processing establishments, this was by extrapolation of the existing regulations for slaughter and deboning processes. The FSIS auditor was informed that this was one of the major reasons why the Federal Law of Animal Health was revised, so that all facets of the production of products of animal origin would be included.

SAGARPA/SENASICA maintains a single standard of laws and regulations applicable to all establishments certified for export to the United States. There are separate TIF lists for each country to which Mexico exports meat products. The TIF establishments conform to national and international health and hygiene requirements. Among the national standards to which these TIF establishments must adhere are Mexican Official Standard (NOM)-008-ZOO-1994 and NOM-009-ZOO-1994, which set standards for the construction and equipment requirements of facilities and for conducting meat processing operations. These NOMs demonstrate the single standard of laws and regulations.

In order to hold this TIF certification, the establishments must meet the requirements within their establishment. This work is dynamic and once certified, verification occurs from both central and state levels. The FSIS auditor received an outline during the audit with all applicable documents for the process of certification of a new establishment. These documents have not been evaluated as the translation from Spanish to English has just been received.

SENASICA employees must be trained in the special requirements of the countries for which the establishment in which they are employed is certified to export.

The CCA must certify, verify, and inspect compliance with the provisions of the Federal Law of Animal Health and of those deriving from it within the scope of its competence. The CCA must

regulate and certify the application of good livestock practices in primary production units and TIF establishments devoted to the slaughter and processing of goods of animal origin. The CCA must certify, verify, and inspect the application of good livestock practices in TIF establishments and animal-health activities directly or indirectly related to the production and processing of goods of animal origin; propose and evaluate operational animal-health and good livestock practice programs for the food of animal origin, in coordination with state governments and auxiliary animal-health bodies, and issue judgments on their execution and, if appropriate, recommend the proper measure; order the withholding, quarantine, disposal, or destruction of goods of animal origin which demonstrate or cause a suspicion of violations of the terms and assumptions indicated in this law, its regulations, the respective animal health directives; establish, promote, coordinate, and oversee the operation of the infrastructure in relation to the application of good livestock practices, good manufacturing practices, risk analysis, and control of critical points, sanitation standard operating procedures; foster and set up programs intended for the prevention and control of contamination through good livestock practice and good manufacturing practice arrangements in primary product units and TIF establishments devoted to the slaughter and processing of goods of animal origin.

Federal, state, and municipal officials and employees, in the sphere of their respective competencies, must assist the Secretariat in the performance of its functions when it so requests and they shall be obligated to report events of which they are aware on presumed violations of this Law or the provisions deriving from it.

The Veterinarians-in-Charge (VIC) in TIF establishments and their auxiliaries are responsible for reviewing documents to verify compliance with SSOP and HACCP regulations, and verifying compliance with established deadlines as well as corrective actions and preventive measures proffered as a result of noncompliance. The VIC documents the verification activities on a form titled "Checklist for Verification of Compliance."

SENASICA personnel maintain copies of the non-compliance reports (and letters to establishment management) only at the establishment level and the supervisors only see this documentation at the time of supervisory reviews or if they are requested to in response to a specific situation. The FSIS auditor reviewed monitoring and verification of corrective actions records. Records of corrective actions were sporadic. When forms were used, such as the non-compliance records (NCR), they were uniform; however, the NCR was almost never used. Letters to the company were the most common form of reporting non-compliances. Non-compliances detailed in the supervisory reviews did not generate NCRs written either by the supervisor or by the VIC. In some instances, there was a letter written to the establishment management; in other circumstances, the establishment management simply initialed the supervisory report.

Although SENASICA informed the FSIS auditor that there are plans for an internal audit procedure which would verify the compliance of inspection activities at certified establishments, this has not yet been implemented. No other program exists to assess performance of the inspection system.

The advertisement for veterinary personnel includes that the respondents must take an exam before they are considered as well as an evaluation of their experience and appraisal of merit including documentation furnished. This is followed by interviews. There is a requirement for a veterinary license or professional degree. There are on-line training programs through the intranet sites and also an ability to electronically track this training.

Twice a year a review is done of each of the SENASICA inspection personnel. In this review, the areas of consideration are individual components of a person's particular job, not just a cookie-cutter evaluation. An example is to "coordinate the issuance of expert advice to the certification process and TIF expansion according to the degree of compliance with applicable regulations." The Law on the Responsibilities of Public Servants details the actions that can be taken against public servants if they are demonstrating inferior performance.

The FSIS auditor reviewed documentation to ascertain that Veterinary Medical Doctors had the required veterinary degree as well as the required pre-employment training program and education. This documentation was reviewed for a sampling of veterinarians at the headquarters, state office, and in-plant levels. All training records reviewed showed that veterinary personnel had degrees in veterinary medicine and had certificates attesting to their required pre-employment training programs.

FSIS previously conducted training both in the U.S. and in Mexico to SENASICA state supervisors to facilitate SENASICA's development of a Food Safety Assessment (FSA) style review. This training was then given to responsible staff officers assigned to TIF establishments that produce RTE products for export to the U.S. by state supervisors and the state supervisor's coordinator during scheduled inspection visits. During the FY 2010, 16 FSAs were performed for routine reasons in the states of Nuevo Leon, Coahuila, Tamaulipas, Veracruz, San Luis Potosi, Queretaro, and Chihuahua. These reviews resulted in the suspension of the issuance of the Certificados Zoosanitarios de Exportacion (CZE) (export health certificates) at two locations until the required corrective actions were implemented.

There was a classroom style training program planned to begin in 2011, but it was budget dependent and much of the planned program was not delivered. Names of those personnel trained were not documented but records did give the area requesting the training, the name of the training class, the outcome (certification, induction to public service, development, strengthening, updating), objectives, total personnel estimated to be trained, and the month of the training. This program was to encompass training on new and existing FSIS inspection requirements. There is no requirement for a competency test before assignment to a U.S.-eligible TIF facility. One 2011 course, an online course, was "Basic Aspects of Agri-Food Safety," but the information received was just a schedule of classes and exams, not the content of the course.

The Training Program for 2012 was also provided to the FSIS auditor, but has not been translated. A verbal translation revealed that it included ten courses of which seven are totally online, two are both online and in classroom, and one is classroom only. Two of those courses are outlined below.

A two-day training session was given to all State Supervisors in February 2012. The presenters for that course were from the CCA headquarters and from the State Supervisors. The presentations covered the following food safety related topics:

- Revisions to FSIS Issuances – 9 CFR 416, 417, 310.22, 310.25 and Directives 5000.1, 6100.4, 8080.1, 10,010.1, 10,240.4, 10,240.5, and 10,300.1
- Specified Risk Materials
- Taking and submitting samples
- Inspection Manuals
- Pathogen Reduction Programs including *Salmonella* spp., *Listeria monocytogenes (Lm)*, generic *Escherichia coli (E. coli)*, and *E. coli* O157:H7
- Veterinary Inspection System
- Protocols for State Supervisors
- Veterinarians-in-Charge
- Clenbuterol
- MVRATIF Program
- *E. coli* Shiga Toxins
- Observations from the 2008 and 2009 FSIS Audits
- Observations from the Israel Audit
- Work Program for the Coordination of State Supervisors in TIF Establishments
- Inspection Manual for TIF Establishments for Exports
- Training Programs
- Work Programs
- Practical Exercise in Filling Out the SRT

Another training course that was given for one day in May 2012 covered the following food safety related topics:

- Procedures for the Authorization of TIF Establishments for Export
- Equivalence in the System of Veterinary Inspection
- Audit Protocols
- FSIS Issuances
- National Program of Pathogen Reduction
- Observations from the FSIS Audits of 2008 and 2009
- Expectations for Official Personnel during an Audit
- Manuals of Sanitary Inspection

Also, one member of the FSIS Office of International Affairs (OIA) Export Programs Staff and one member of the Office of Policy and Program Development, International Policy Division provided a SENASICA-requested class two weeks after the end of this audit covering subjects requested by SENASICA as well as some areas identified in this audit such as verification of written plans such as SSOPs, HACCP, and generic *Escherichia coli (E. coli)*. Other training topics included:

- FSIS and PHIS Directives 5000.1

- Meat Product Classification
- Pathogen Reduction
- Pathogen Sampling and its Relationship to Meat and Poultry Product Types
- Regulatory application for the STEC Shiga Toxins
- Food Defense
- Animal Welfare
- Establishment Inspection System
- Point of Entry Inspection for Meat
- New Regulation for Poultry Inspection

The Handbook for Inspections and Verification of Food Safety System for Veterinary Doctors at TIF Export Establishments Part 7.1.19 details the requirements for a Packaging and Labeling Program which has the following components:

- Review technical files and certification by competent authorities with regard to the use of containers, cans, wrappers, and labels
- Verify proper storage, sanitary preservation, and use
- Check that the storage site has conditions that prevent the presence of contaminants, vermin and humidity
- Check material and inventory entrance and exit registers
- Document deficiencies found on form INO-09

The FSIS auditor reviewed form INO-09 in the TIF establishments, but there were no deficiencies reported for labeling. A question has been asked of SENASICA about reporting on INO-09 as there is no reference there to labeling. The FSIS auditor was provided the NOM (NOM-051-SCFI-SSA1-2010, General specification of labeling from prepackaged food products and non-alcoholic beverages – Commercial and sanitary information) that specifies regulatory requirements for packaging and labeling. This document deals with:

- portions
- bulk product
- prepackaged product
- units of measure and symbols of unit of measure
- the principal display surface and other surfaces
- nutritional values
- allowable symbols and abbreviations

This document has not been analyzed to see how closely it agrees with FSIS standards as the translation from Spanish to English has just been received.

The inspection program is funded by the national government. The definition of an official veterinary doctor is a veterinary medical professional employed by the Secretariat. The Federal Law of Animal Health assures payment by the national government. The funds that they are paid from are appropriated funds. In the past, there was a practice of using “approved” veterinarians in the establishments; these veterinarians were hired by and paid by the establishment but

worked under the supervision of official veterinarians. There is now a system in place that renames these personnel as Certified Veterinarians-in-Charge at TIF Establishments (MVRATIFs), has them hired and evaluated by a third party, paid by the third party out of a general fund that is cost-recovered from the establishments, and working under the supervision of the official veterinarians. This was fully implemented in April 2011. This was in response to a finding of a potential conflict of interest from the FSIS audit of September/October 2009. The FSIS auditor reviewed the in-plant personnel files associated with the MVRATIFs. These files contained information about the employment history, payment, qualifications, veterinary requirements, and training of these personnel. There were no findings associated with the review of these files.

Official veterinarians are allowed to work outside of their assigned positions in TIF establishments. However, there are strict rules on conflict of interest as detailed in the Federal Law on Legal Obligations of Public Servants. Unlike in the FSIS, these personnel do not have to apply in writing for permission for outside employment.

The CCA through the State supervisors and the in-plant VIC assures that there is daily inspection coverage in establishments certified for export to the U.S. Federal Inspection Type (TIF) establishments must have a sufficient number of official veterinarians or MVRATIFs to conduct inspections or verifications to ensure their efficiency. Establishments that are authorized for exportation must have official veterinarians as determined by the Secretariat or required by the importing country. TIF animal slaughter and animal origin goods processing establishments will have at their disposal, during business hours, at least one authorized VIC for animal welfare management, epidemiological watches, and other animal health measures and good livestock practices.

The official staff is appointed from the central level according to the needs of the TIF establishments. A new organization chart of the state supervisors was provided to the FSIS auditor as a PowerPoint presentation. The documentation provided through the SRT and during the audit demonstrates that the TIF system and its employees are under the direct influence of the federal government (SAGARPA and SENASICA). About 90 veterinarians were moved to different locations in September of 2011, but there is no written procedure that was used to accomplish this or to plan for it for another time.

The Actualización del Manual de Inspección Sanitaria en Establecimientos de Sacrificio Tipo Inspección Federal (TIF) 2008, DGIAAP-MINP-08 (Updated Handbook for Sanitary Inspection at Federal Inspection Type (TIF) Slaughtering Establishments) contains very complete information about the slaughter procedures and post-mortem procedures for all the livestock species. However, this document does not address staffing. While there is no national regulation covering the assignment of relief inspection personnel to TIF establishments, adequate coverage is provided by the VIC or state supervisor. This is documented in the Handbook for Inspections and Verification of Food Safety System for Veterinary Doctors at TIF Export Establishments.

The FSIS auditor compared the documentation received prior to the audit on the MVRATIF program to what was in place in headquarters, the state office, and the audited establishments. In the establishment offices, the FSIS auditor requested any documentation they had on the hiring

and payment of wages to the MVRATIF personnel. This documentation reflected that payment came from O.I.R.S.A. and not the establishment. The FSIS auditor requested and was furnished specific documentation outlining the supervision of the MVRATIF and that they take direction from the VIC in each establishment. The state supervisor was asked what his relationship was to the MVRATIF and he stated that he observes their actions in the same manner as any of the other veterinarians in the establishment that are supervised by the VIC. In the checklist for reviews by the state supervisor, they review veterinary inspection personnel:

- performing ante-mortem procedures including activities concerning disabled and dead animals
- performing post-mortem procedures including disposition of carcasses and parts
- marking carcasses
- using seals
- assuring the correct destination of carcasses based on export determinations
- performing reinspection
- performing sampling activities of the Pathogen Reduction Program

The diagram of the approval process, titled *Licensing Procedures to Export Meat Products to the U.S. and Japan* goes as follows:

- A written request is submitted asking for the requirements.
- DGIAAP forwards the export requirements, including those specific for the U.S. and for Japan such as SSOP, HACCP, and SRMs.
- The interested parties forward their information for evaluation.
- DGIAAP reviews the information and issues an opinion – satisfactory or not satisfactory.
- If the opinion is not favorable, the interested party receives the observations to make corrections.
- If the opinion is favorable, there will be a visit scheduled to the facility by official personnel to verify compliance with the regulations and implementation of the other country requirements.
- If the establishment is found to be in compliance during the visit, the importing country is notified and the establishment is added to the list of establishments eligible to export.

The FSIS auditor was also furnished a document titled “*Authorization and certification of TIF establishments as eligible for the export of meat products to countries with which Mexico has equivalence between their systems of veterinary inspection*”.

The FSIS auditor reviewed documents from the certification process of the new establishments that were a part of this audit. State supervisors are not involved until after the establishments are certified from the central level. Checklists are not used in the certification process as it is initially just a TIF certification as an establishment eligible to export. The process consists of documentation review, a visit from headquarters CCA, and a letter of approval. Checklists are from the manual for supervisors used to certify for particular countries. Once the revised version of the Law of Animal Health is translated, the FSIS auditor will be able to evaluate whether there are changes to those Articles which may affect changes to this process.

The CCA (SENASICA) (Director General of Food Safety, Aquaculture and Fisheries) is not responsible for the direct oversight of government laboratories. This responsibility falls to the SENASICA, Directorate General of Animal Health. Dirección del Centro Nacional de Servicios de Constatación en Salud Animal (CENAPA) (National Center for Animal Health Diagnosis). CENAPA is responsible for the coordination and surveillance of private laboratories performing the analytical testing of product destined for the U.S. The verification checklist for the private laboratories that is used by CENAPA is based on the requirements of ISO 9001 and 17025. Private labs must submit their validation study to CENAPA for evaluation before they can conduct this method on official samples.

In the checklist that CENAPA uses for the review of private laboratories are questions about the processes for measurement, analysis, and improvement as well as determination of the processes used for certain clients and their requirements. There are additional questions about the methods themselves including validation, calibration, identification, and traceability.

The methods listed in the LAB-SRT for CENAPA for microbiological analyses are:

- generic *E. coli* - AOAC 998.08 with *E. coli* petrifilm
- species testing – NOM-ZOO-023, determination of animal species by immunodiffusion in gel
- *Listeria monocytogenes* – FSIS MLG 8.07
- *Salmonella* – MLG 4.04
- *E. coli* O157:H7 – MLG 5A.01 and MLG 5.04

In the arena of chemical residue testing, the methods used are not numbered but equipment specific such as GC-MS, HPLC, or ELISA.

CENAPA is divided into subdirectorates for the following areas:

- parasitology including ectoparasites and Diptera, hemoparasites and helminthes
- verification including toxic residues and contaminants, pharmaceutical and food chemicals, and executive coordination of animal origin (traceability)
- support of health and safety for aquaculture and fisheries including the departments of safety and of diagnostics
- the subdirectorate for the transfer of analytical technology which develops and validates analytical methods and tests as well as metrological verification

In the Residue Plan for Mexico for CY 2012, the functions of CENAPA are listed and include “assist in the accreditation and approval process of laboratories, as well as establish conditions for their approval and endorsement.” It also refers to CENAPA as the official “Laboratory of Reference.”

The FSIS auditor was provided the most recent copies of the third-party certifications of the CENAPA laboratory. Within the regulations, CENAPA is referred to as the official laboratory. There are definitions within the Federal Law of Animal Health that differentiate between

approved and authorized laboratories. Both types of laboratories are audited by CENAPA, the difference is in which types of samples are sent to a specified laboratory.

The requirements that are included in the checklist used by CENAPA all come directly from ISO 9001 and/or ISO 17025. A laboratory must have a satisfactory review to remain on the list of certified laboratories so therefore must be acceptable in terms of ISO 17025. Although CENAPA belongs to the Animal Health area of SENASICA, this would still be oversight by a government agency. Regular reviews are done by CENAPA with a total of 12 microbiology labs and 8 residue labs reviewed in the year preceding the submission of the CCA-SRT.

The FSIS auditor received copies of several CENAPA audits and follow-up audits for non-compliances observed from previous audits. These will be reviewed and evaluated once they are translated from Spanish to English. Further information on the laboratory reviews conducted in Mexico FY 2011 (mid-March 2011 to mid-March 2012) has been requested from SENASICA in mid-April 2013 but no answer has yet been received. The information requested is the number of microbiology and residue laboratory reviews conducted and the type of non-compliances found. The FSIS auditor was told that the approved laboratory methods are harmonized with United States and CENAPA methods. The laboratory reports reviewed within the establishments noted the correct methodology used for the analyses.

Proficiency testing is an integral part of the CENAPA laboratory system. Documentation was provided to the FSIS auditor detailing the interlaboratory and intralaboratory testing programs that are required and what has been completed. This has not been evaluated because it has not yet been translated from Spanish to English. Proficiency testing is evaluated in the official laboratory checklist which is used by CENAPA for all laboratory reviews. The FSIS auditor reviewed the laboratory personnel performance proficiency examination results. The review of results of proficiency testing showed that all analysts reviewed did well in these testing programs.

This checklist has a section on internal quality control procedures and a section on internal audits. The sections describe documentation and records control, and the person responsible for ensuring the controls have been implemented correctly. These internal quality control procedures include:

- corrective actions
- revisions
- preventive measure and continuous measurement of the efficacy of the control measures themselves
- the methods, the results, and the calibration of instrumentation

The FSIS auditor reviewed the Activities Section of the SRT, and determined inspection personnel routinely document inspection activities associated with the following components:

- SSOP Basic Requirements
- SSOP Ongoing Requirements
- HACCP Basic Requirements
- HACCP Ongoing Requirements

- Generic *E. coli* testing
- *Salmonella* Performance Standards
- Species Verification Testing
- Sanitation Performance Standards
- Other inspection Requirements
- Humane Slaughter and Handling of Livestock

SENASICA informed the FSIS auditor that Economic/ Wholesomeness requirements such as labeling, finished product standards, net weight, and economic sampling do exist contrary to what was stated in the SRT response. The references are NOM 009-ZOO-1994 and NOM 051-SCFI-1994. NOM 009-ZOO-1994 gives labeling standards. SENASICA has furnished further information on duties and responsibilities from the Federal Law of Animal Health, Section 214, section XI and NOM 009-ZOO-1995, point 16.

It was explained to the FSIS auditor by SENASICA that SENASICA does not verify Finished Product Standards, nor does SENASICA sample product to ensure compliance with labeling and formulation requirements. These activities are carried out by other parts of SAGARPA. The Handbook for Inspections and Verification of Food Safety System for Veterinary Doctors at TIF Export Establishments, in 7.1.19, Packaging and Labeling Program, instructs the VIC to review technical files and certification by competent authorities with regard to the use of containers, cans, wrappers, and labels and to verify use. The application of the mark of inspection on carcasses is verified by the VIC under this program.

SENASICA has several systems in place for the transference of FSIS inspection requirements to the state supervisors and their in-plant personnel. SENASICA sends hard copies of new FSIS documents to the state supervisors who then deliver them to in-plant personnel. Distribution of hard copies is being phased out and replaced with distribution through internet and intranet systems of SENASICA.

The FSIS auditor has visited the SENASICA internet site and this has sections in Spanish and also in English. The FSIS auditor observed access to the intranet site during the last and present FSIS audits. Circulars 3 and 24 were examples of information sent to the field – one was a change in required temperatures for processing and the other was to send the updated Pathogen Reduction Program. These were delivered by hard copy and only in Spanish. A number of new circulars have been provided, especially in response to requests for CA from the last audit although most of them did not occur until FSIS requested CA from the last audit – most were dated January 2012 while the audit concluded in October 2009 and the final report was delivered in July of 2011.

The FSIS auditor verified that the state office and the in-plant offices have up-to-date circulars and have access to translated documents providing instruction to state and in-plant inspection personnel.

Official verification and inspection activities are conducted in accordance with these programs, guidelines, and manuals that provide procedures for uniformly assessing food safety systems implemented by the establishments. The FSIS auditor performed on-site observations and

reviewed records maintained by inspection personnel at all levels, headquarters, state offices and in-plant SENASICA inspection offices. The findings are described in the appropriate equivalence component.

While officials use the authority conferred upon them by the laws of Mexico to enforce the rules of the meat and poultry inspection system, identify and document non-compliances, and verify the adequacy of corrective actions and preventive measures, the FSIS auditor determined that regulatory verification and inspection activities were not consistently implemented at all audited establishments.

The SRT had not been entirely completed by Mexico prior to the audit. In the Government Oversight component, there were several questions that were left to the FSIS auditor to collect the information during the 2012 audit. These questions were asked and responses given during the entrance meeting, in the progress of the audit and at the exit meeting by various SENASICA CCA individuals. Those questions and responses are as follows:

Question: Is there Mexican legislation or a guideline that explicitly states how many SENASICA in-plant veterinary personnel are required to staff a TIF establishment in relation to species slaughtered, line speed and/or style of slaughter?

Response: No, the establishments are staffed according to need including enough personnel to cover absences and vacations. Since the staffing is done by the state supervisor, that person is able to make adjustments within his area of responsibility to assure that all U.S.-eligible establishments have complete daily inspection coverage.

Question: Is there Mexican legislation or a guideline that instructs in-plant SENASICA inspection personnel to verify Mexico's rules and the FSIS import rules for other economic indicators such as product standards, net weight, etc?

Response: No, these responsibilities fall to another part of SAGARPA.

In conclusion, there were several system findings in Mexico's adherence to the criteria for organizational structure and staffing, ultimate control and supervision, the assignment of competent qualified inspectors, the authority and responsibility to enforce the laws and adequate administrative and technical support including laboratory oversight and the application of procedures and standards that are equivalent to the U.S. requirements. Government oversight must be improved in the areas of periodic supervisory reviews and how they are written including corrective actions and preventive measures, review of programs, and the documentation of non-compliances.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The FSIS auditor reviewed Statutory Authority and Food Safety Regulations (SAFSR) as the second of the six equivalence components. The FSIS auditor verified that the inspection system was organized and administered by the national government of Mexico. The FSIS auditor also verified that the system provided 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
- Periodic supervisory visits to official establishments

The Meat Sanitary Process Regulation states that no animal may be sacrificed without the prior authorization of the official or approved veterinarian and that this “pre-mortem” inspection must be made in the corrals of the establishment. There are very complete details about how to conduct the ante-mortem exam, decisions to be made, disposition following the decisions, and conditions that must be met. That same statement is made in the Regulation of Industrialization that within 24 hours of the anticipation of slaughter, a Medical Veterinarian must perform an exam or inspection of all of the animals the establishment is planning to use. The regulation goes on to list all conditions that might be encountered during ante-mortem and the appropriate dispositions. The list of assigned official SENASICA veterinarians showed personnel assigned to each TIF slaughter establishment.

The regulation on humane handling and slaughter details that any method of slaughter included in the Standard must be carried out by trained personnel and under the supervision of the establishment’s responsible veterinarian or by a veterinarian authorized by the person in charge of the establishment. It goes on to detail many different and the acceptable conditions of stunning. However, the primary emphasis of the document is on humane slaughter with only some mention of humane handling prior to slaughter.

There are additional Standards that deal with what must be present physically and furnished to the veterinarian to properly conduct ante-mortem inspection and disposition. Further direction is given for other ante-mortem activities. The Guide for Supervision of TIF Establishments Checklist has questions on the performance of ante-mortem.

Humane slaughter and the veterinary implementation of ante-mortem procedures has not been a problem in the past audits and the documentation provided seems to fulfill this criterion. The FSIS auditor observed conditions in the pens at the two slaughter establishments scheduled for this audit. The FSIS auditor observed ante-mortem inspection by SENASICA veterinarians and reviewed records for both establishment and SENASICA verification of humane slaughter and ante mortem inspection and decisions of suspect animals. No downer animals were present at the time of the audit. The FSIS auditor also looked for non-compliance records for humane handling and other problems that may be associated with ante-mortem. No records were found supporting problems with ante-mortem or humane handling. Humane handling was observed as cattle were moved in the pens to the knocking box and activities within the knocking box as well as subsequent hanging and bleeding.

The NOMs referenced below give both directions for the performance of post-mortem inspection and who should do it, but they still include the “approved” veterinarian as opposed to MVRATIF as a person who can perform this duty. The supervisors check list essentially covers establishment conditions but very little is included as far as the performance of the in-plant veterinarians. (At least in the post-mortem of cattle, the instructions to the person doing the post-

mortem inspection are the same as that for the U.S.) Directions for dispositions are very well detailed as well as the handling of condemned and inedible materials.

NOM-009-ZOO-1994 Section 7 describes what the establishment must do to prepare the carcass for post-mortem inspection. It also states that post-mortem inspection must be made by the official or approved veterinarian and/or by assistant staff. It deals with the identity of carcasses and parts for further exam. Part 8 goes on to generally define inspection technique, part 9 describes destination of inspected carcasses, and part 10 deals with labeling. However, nowhere in here does it say anything about supervisors observing the techniques of the personnel performing post-mortem inspection. In the inspection manual for TIF slaughter plants it says "The post-mortem inspection should be efficient and effective, which means that procedures must be adapted to actual circumstances. Conducting it properly requires an official risk analysis review." The Manual for Supervisory Inspection of TIF Establishments, in the responsibilities of the State Supervisors, says they must make a monthly review of the TIF establishments under their jurisdiction. In this review, they check that the in-plant supervisor has daily control of post-mortem. In another checklist, under post-mortem exam, the checklist asks the following questions under post mortem: 1.) Does the official veterinarian or the approved veterinarian successfully conduct post mortem inspection? 2.) Does the veterinarian correctly do the inspection techniques? 3.) Does the official or approved veterinarian make correct dispositions of the carcasses? 4.) Are the inspected carcasses correctly marked? However, this is the state supervisor's checklist, not the duties of the VIC.

In DGIAAP-TIF-001-M, under the duties of the VIC, it states that (he) is responsible for both ante mortem and post-mortem inspection. Also that (he) conducts and coordinates inspection activity among his auxiliaries.

From a regulatory standpoint, everything is in place and is equivalent. The problem is in implementation. The checklists for the supervisors look at the plant but not at the SENASICA personnel; therefore, it does not appear that supervisors are evaluating the performance of post-mortem procedures by their personnel either at the State Supervisor level or at the in-plant veterinarian-in-charge level. That may have lead to the previously observed problems in the correct implementation of post-mortem procedures.

During the last audit, there were three establishments where the post-mortem inspections were not being done correctly or at all in some cases in conjunction with either Mexican Standards or by FSIS regulations. Promises were made at the time of change of personnel and further training. Follow-up on this was conducted during this audit to determine implementation and effectiveness. The FSIS auditor did not note any failures in the implementation of post-mortem procedures in the two slaughter establishments audited.

NOM 008-ZOO-1994 is mandatory within the entire national territory and its purpose is to establish the characteristics that the establishments should comply with regarding location, construction, and equipment. This NOM is applicable to all establishments that are dedicated to animal slaughter, freezing, packing, and industrial plants of meat products and byproducts. The application of the provisions contained in this NOM should be upheld by the Directorate of Animal Health, the state and municipal governments and the Delegations of the Secretary of

Agriculture, Animal Husbandry and Rural Development, in the scope of their respective assignments and territorial constituencies without lessening the assignments of the Secretary of Health, in accordance with agreements of respective coordination.

This NOM goes into specific details of the facility and equipment requirements. The supervisor's checklist is also very complete in all areas of the facility and equipment. The handbook also goes into considerable detail about the facility including SSOPs and SPS. In their response to the Activities Section of the SRT, Mexico states that inspection personnel routinely document inspection activities associated with Sanitation Performance Standards which include these areas.

Inspection records were consistent from establishment to establishment. Also reviewed was whether what the inspection records stated and the condition of the establishment reflected the same state of affairs. In all establishments, the FSIS auditor reviewed non-compliance records (and letters to the establishment) and the associated corrective actions and preventive measures as well as the SENASICA verification of these. Comments on the results of that review are included in the Government Oversight portion of this report.

TIF establishments must have a sufficient number of official veterinarians or authorized individuals in charge of conducting inspections or verifications as to ensure their efficiency. Establishments that are authorized for exportation must have official veterinarians if determined by the Secretariat or required by the importing country. TIF animal slaughter and animal origin goods processing establishments will have at their disposal, during business hours, at least one authorized veterinarian in charge for animal welfare management, epidemiological watches, and other animal health measures and good livestock practices. Review of records within the establishments supported the daily presence of SENASICA inspection personnel.

Comparing the number of Point-of-Entry (POE) violations and the poundage of product that Mexico ships to the U.S., the proof seems to be that these programs are effective as FSIS has only one species violation, one *E. coli* O157:H7 violation, and one zero tolerance violation in the two-year period preceding this audit.

When carcasses, viscera or organs are found to have any type of injury, or condition which makes them ineligible for human consumption, the same will be labeled, sealed or marked with the legend "Inspected and Rejected, SARH, Mexico", proceeding immediately to the segregation or deposit in special recipients compartments or warehouses and conditioned for that purpose, remaining as from that moment under control of the official or approved personnel assigned to the plant.

Based on the injuries exhibited by the carcasses, viscera or organs, the official or approved veterinarian may carry out the follow procedures: a) isolation and retention until new inspection, in accordance with the disease or suffering; b) immediate destruction in the rendering plant or incinerating over; c) denaturalization with fennec (phenolic) acid or other substances authorized by the Department; d) total or partial exploitation in the production of non-edible products for industrial use.

The official staff assigned to the establishment shall see that all necessary sanitary measures are observed for the adequate cleaning and disinfection of machinery, equipment and personnel on

contact with carcasses, viscera and organs rejected during inspection. Rejected carcasses, viscera and organs will be stored separately from edible products. Approved carcasses, viscera and organs but contaminated due to contact with rejected products will be confiscated, unless the contaminated part is withdrawn. In-plant supervisors are instructed to assure compliance with special programs such as Specified Risk Materials (SRMs).

The Bovine Spongiform Encephalopathy (BSE)/SRM Manual has been provided and translated. It was quite detailed and seemed appropriate and fit for purpose. The only question came on the preparation of the formalin solution and that has been resolved with direction from SENASICA headquarters.

The direction provided in the Handbook for Sanitary Inspections at TIF Slaughtering Facilities states that the VIC must ensure that the procedures to prevent the risk posed by BSE are carried out at each and every facility and goes on to list the SRMs as well as reference to downed animals and non-ambulatory animals, the prohibition against air-injected stunning, the removal and disposition of SRMs, age determination, and to avoid mechanical separation of meat.

On page two when they list the SRMs, the list does not completely correspond with those in 9 CFR 310.22. The Mexican list is brain, spinal cord, eye, trigeminal ganglion, dorsal root ganglion, ileum and tonsils. The FSIS list is brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (with exceptions), and dorsal root ganglia from cattle over 30 months as well as distal ileum and tonsils from all cattle. So, the difference would be the skull and vertebral column from cattle over 30 months of age. In the Updated Handbook for Sanitary Inspection at Federal Inspection Type (TIF) Slaughtering Establishments, the list is divided into age groups as the FSIS list is, but the skull and vertebral column are not included. In addition they require in animals 30 months of age or older to also remove the spleen. Since these differ, the FSIS auditor questioned the VIC in each of the two beef slaughter establishments and they each understood the FSIS requirements and what would need to be done to satisfy those requirements as well as the requirements for other countries and for Mexico. Mexico needs to amend their instructions to inspection personnel for SRM removal so that these instructions (contained in the Updated Handbook) include the skull and vertebral column of animals 30 months of age or greater for animals eligible for export to the United States in order for this procedure to maintain equivalency with the U.S.

The BSE/SRM document gives a good history, symptomatic identification scheme, dental aging and removal of brain and brainstem techniques along with shipping and communication, but does not cover those parts in 9 CFR about “procedures for the removal, segregation and disposition of specified risk materials”, and “recordkeeping requirements.” The Updated Handbook states that the MVO must “ensure that risk material is removed. It must be separated and destroyed; under no circumstances may it be destined for human consumption nor for feeding ruminants.” Mexico must also amend their BSE/SRM document to include recordkeeping requirements.

A list is published of those establishments that are certified for export to the U.S., as well as lists which are published (all on the Web on the SENASICA site) for other specific export destinations such as Korea, Japan, and the EU. Establishments must go through a certain designated process (detailed previously in this report) to be allowed to be on the certified list. The list is updated whenever necessary with the published list changed and the importing country

notified (at least in the case of the U.S. and Japan). Those establishments that are certified to export carry a “TIF” designation and belong to an organization of TIF establishments. TIF establishments can also do product for domestic destinations, but non-TIF establishments cannot export products.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the on-site audit of the system. The following documents were reviewed:

- NOM 009-ZOO-1994
- Regulation of the Industrialization of the Meat Industry, Chapter 4, Article 28
- List of all veterinarians assigned to TIF establishments
- NOM 033-ZOO-1995, Humane Slaughter of Wild and Domestic Animals
- NOM 008-ZOO-1994, Animal Health Specifications for the construction and equipment of establishments for animal slaughter and those dedicated to the industrialization of meat products
- Laws and Regulations on Sanitary Processing of Meat - Federal Inspection
- Handbook for Inspections and Verification of Food Safety System for Veterinary Doctors at TIF Export Establishments
- NOM 024-ZOO-1995 – Zoosanitary specifications and characteristics for transportation of animals, their products and chemical, pharmaceutical, biological, and food byproducts for use on animals or to be consumed by them
- Guide to Supervision of TIF Establishments Checklist 4
- Federal Law of Animal Health, Articles 107 and 108
- BSE/SRM Manual
- Monthly Guide for the Supervision of TIF Establishments 8.1
- Checklist for Monthly Review and the Annex
- Manual of Sanitary Inspection in TIF Establishments
- Manual of Inspection for Supervisors in TIF Establishments
- Procedures for Supervisors in TIF Establishments dedicated to slaughter, cutting and deboning of Bovines
- List printed off of the Web detailing those establishments certified for export to the U.S.

FSIS equivalence criteria require that the CCA has the legal authority and associated responsibility to ensure that adulterated or misbranded product is not prepared for export to the U.S. The FSIS auditor reviewed the above documentation furnished in the Self-Reporting Tool (SRT), compared it to the equivalence criteria, and found that the CCA has not established net weight in-plant verification procedures. As previously stated, this is not a responsibility of SENASICA and is handled by another part of SAGARPA.

Periodic supervisory reviews were still completed based on a monthly schedule; however, with the implementation of the new regulations based on the revised Law of Animal Health, the required monthly supervisory review will be replaced by a risk-based schedule.

The following Statutory Authority and Food Safety Regulations findings were reported to SENASICA during the exit meeting:

- HQ SENASICA has given no guidance to establishments (TIF 101, TIF 301) for the development and implementation of generic *Escherichia coli* programs other than that they had to have them in order to export to the U.S. In addition, they also provided no guidance to SENASICA field personnel on how to review and verify these programs.
- SENASICA does not have a program to deal with the possibility of extended clean-up in processing operations (as is present in TIF 158) and how SENASICA personnel are to approve and verify the effectiveness of such programs.
- CCA HQ is in the process of a pilot program (at other establishments) for SENASICA in the area of humane handling (HH) and documentation of such. At this point in time there is no CCA requirement for documentation of HH verification audits.
- SENASICA residue programs do not require retaining carcasses that have been sampled for residue testing (TIF 101, TIF 301). Only positive results are relayed to the establishment; all results go to CCA HQ. The FSIS auditor was presented with a copy of a letter to all TIF slaughter establishments requiring inspection personnel to hold carcasses where samples had been taken for residue analysis. This does not include the special sampling program just beginning for Clenbuterol.

The SRT had not been entirely completed by Mexico prior to the audit. In the Statutory Authority and Food Safety Regulations component, there were several questions that were left to the FSIS auditor to collect the information during the 2012 audit. These questions were asked and responses given during the entrance meeting, in the progress of the audit and at the exit meeting by various SENASICA CCA individuals. Those questions and responses are as follows:

Question: In the BSE/SRM Program submitted in July, 2011, there is a footnote that explains the dilution of commercial formalin for the in-plant personnel. That dilution is incorrect and would not give the stated resultant solution of 10%. What has SENASICA done to remedy this formulation?

Response: This is not an action taken by in-plant SENASICA personnel. We have contacted the part of SAGARPA that does the BSE/SRM testing to make a correction to their manual and to inform their personnel to make the correct dilution.

Question: The list of SRMs differs (see page 24 of this report) between the submitted BSE/SRM Program, the Updated Handbook for Sanitary Inspection at TIF Slaughtering Establishments, and 9 CFR 310.22. The SENASICA CCA personnel accompanying the FSIS auditor were requested to provide documentation that demonstrated written instructions to in-plant personnel directing them to follow the U.S. SRM requirements for product exported to the U.S. from Mexico.

Response: The SENASICA responded that documented instructions do not exist but all supervisory personnel have been instructed to ensure that their personnel understand the FSIS SRM requirements.

The FSIS auditor asked each Veterinarian-in-Charge at two beef slaughter establishments to state the SRM requirements for export to the U.S. Each VIC was able to list the SRMs that must be removed for product destined for the U.S. The FSIS auditor requested information related to the documentation format and record keeping requirements associated with the disposition of SRM's for both the establishment and SENASICA personnel. Based on the information provided by SENASICA, the FSIS auditor determined that establishments are required to have their own programs with records. Much like FSIS, SENASICA does not require the establishments to have a common record format. The FSIS auditor reviewed establishment SRM disposal records which also had been signed by SENASICA personnel as being reviewed for accuracy and confirmed for disposal. There were not separate records maintained by SENASICA.

7. SANITATION

The FSIS auditor reviewed Sanitation as the third of the six equivalence components. The FSIS auditor verified that the inspection system provided requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. Verification of this component included a review and analysis of the information provided by the CCA in the SRT and observations during the on-site audit. The FSIS auditor reviewed legislation, regulations, official instructions and guidelines and verified that the CCA requires and verifies that the establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. Record review included monitoring and corrective action records of the establishments as well as verification, non-compliance, and supervisory review records of SENASICA.

FSIS determined the regulatory requirements of the sanitation component are equivalent. However two plants that had trends of insanitary conditions indicate that SENASICA should identify and implement a more stringent enforcement action to resolve the concerns.

The requirements for the sanitation component are contained in the following documents:

- Federal Law of Animal Health
- NOM 009-ZOO-1994, Sanitary Processing of Meat
- NOM 008-ZOO-1994, Animal Health Specifications for the construction and equipment of establishments for animal slaughter and those dedicated to the industrialization of meat products
- FSIS Directive 5000.1
- 9 CFR 416

The Federal Law of Animal Health states that the Secretariat, without detriment to the functions of other agencies of the Federal Public Administration, shall determine measures in the area of good livestock practices that must be applied in primary production and processing of goods of animal origin in TIF establishments, to reduce the contaminants or animal-health risks that may be present in them. Measures in the area of good livestock practices should be based in scientific principles or on international recommendations and, if appropriate, on risk analysis. The measures considered shall be determined in directives for contamination risk reduction which may include the requirements, specifications, criteria or procedures without detriment to other

legal provisions of other applicable legal provisions in the realm of public health. The Law goes on to cover the requirements of other countries and establishing SSOPs. There is a separate document, NOM 008-ZOO-1994 that deals with all the facility construction issues which correlates to our Sanitation Performance Standards (SPS) and covers all areas from stockyards through all stages of processing of products of animal origin.

Audit findings from the last several audits show that training in these areas may be incomplete, missing, not well understood, or not successfully implemented by some personnel. Previous non-compliances included inconsistent identification of contaminated product and product-contact surfaces, inconsistent documentation of non-compliances to reflect actual establishment conditions, inconsistent monitoring of establishment written procedures, and inconsistent establishment and SENASICA documentation of corrective actions and preventive measures. This is borne out in the sanitation findings listed below from this audit. In addition, the FSIS auditor observed pre-operational sanitation and operational sanitation and compared the conditions of the establishments to SENASICA documentation.

The following Sanitation findings were reported to SENASICA during the exit meeting:

- In two establishments, the associated SSOPs stated that operational sanitation would be monitored once per day. The SSOPs did not state when the monitoring would occur. However, there were frequencies greater than once per shift noted on the records themselves. The FSIS auditor observed that additional operational sanitation monitoring may be necessary as insanitary conditions such as excessive product on the floor, product contact belts that were fraying or missing links, and excessive product build-up at points in the process were found during operations. Neither plant management nor SENASICA identified the discrepancy between the written SSOP document and the implementation of operational sanitation monitoring procedures. However, as stated earlier, the sanitation was being monitored at least once per day.
- Establishment pre-operational sanitation implementation and monitoring for two establishments where the FSIS auditor observed SENASICA performing pre-operational sanitation verification had not been effective as evidenced by the findings of SENASICA during that day's pre-operational sanitation and on other days of pre-operational sanitation.

SENASICA performed pre-operational sanitation at both facilities after the establishments confirmed pre-operational sanitation had been completed successfully and the plant was ready for operation. In both establishments there was residue from prior day's operation to include, blood, fat, and other proteinacious residue on product contact surfaces. There were also facility maintenance non-compliances that included the erosion of the concrete undersurfaces of platform stands, residue from tape pieces and tape pieces on many product contact areas, poor maintenance of conveyor belts to include frayed edges and tears in fabric belts and broken and missing links in link-style belts, and broken edges of floor coving. Condensation was present in both plants above both product contact and non-product contact surfaces. There were flies in one plant.

- In the two slaughter establishments referenced in the previous paragraph, the SSOP records of the establishment did not include corrective actions (CAs) that accurately described the actions taken. Many of these were simply listed as “told supervisor” or “told maintenance” rather than any real actions. Recorded preventive measures (PMs) were non-existent. There was a trend of insanitary conditions that did not have long term corrective actions implemented. SENASICA retained control of the areas until all deficiencies had been corrected.
- In two establishments, the establishment SSOP records did not include adequate detail in the descriptions of findings or corrective actions to allow for adequate verification by SENASICA personnel. Neither SENASICA daily inspection tasks nor supervisory reviews had noted this non-compliance. The establishments agreed to include more detail.
- One establishment was slaughtering Zebu and Zebu cross cattle. The FSIS auditor observed that the animals are very long-legged and this caused some heads to contact the floor just before they were removed in the slaughter process. A new process will be developed so that the heads can be maintained at a higher level to prevent cross contamination from the floor. SENASICA will verify that this process is effective. The establishment spoke as though they had previously been aware of the problem, but had not developed any solutions. No past findings of this problem were found from SENASICA in-plant records or the supervisory reviews. In this same establishment product was also dragging the floor in the boning room. There was no evidence that the plant or SENASICA had identified this issue in the past. Immediate corrective actions for the insanitary conditions in the slaughter department and the boning department were taken by SENASICA while the FSIS auditor was in the plant.
- In one establishment SSOPs were unclear about the difference between daily pre-operational procedures and weekly “deep cleaning” procedures. One establishment had a type of extended clean-up, the plant works 24 hours a day but didn’t clearly define the difference between daily clean-up operations and those that are done as a “deep cleaning” once a week. SENASICA told the company personnel to clearly define which sanitation operations would occur on a daily basis and what the operations would be on the weekly “deep cleaning.” SENASICA in-plant personnel and the state supervisor will then decide if these procedures comply with Mexico’s sanitation requirements. The idea of extended clean-up does not appear in Mexican regulations. However, the FSIS auditor did not observe any insanitary conditions.
- SENASICA in-plant personnel only write non-compliance records (NCRs) for SSOP and HACCP non-compliances (all TIF establishments audited). All other non-compliances are handled by letters to the establishment. In this establishment, these letters do not require corrective actions (CAs) and preventive measures (PMs) and the establishment responses do not include specific CAs and PMs; also, the letters do not show any evidence of SENASICA verification as would be shown if the NCR form was used. The use of these letters is acceptable to the CCA. State supervisory reviews had not noted this lack of verification.

- In one establishment (TIF 101), in the deboning room, SENASICA identified that several of the operators were using their upper arms and shoulders in positioning the carcass for further shoulder removal and the contact was not a part of the uniform that was covered by a plastic sleeve or apron as is required by the establishment SSOPs. Uniforms are only changed at the discretion of an establishment supervisor in the area. The establishment agreed to reconfigure their uniforms for appropriate product protection.
- In one establishment (TIF 158), the SSOPs did not cover the handling of product in the peeling area for hot dogs. Product handling is considered to be covered by GMPs. As a rack of hot dogs was transferred from the cooking/cooling racks to the table to be fed into the peeler, a few end links swung under the table and contacted a non-product contact surface. When SENASICA pointed this out as possible contamination of the product, the operator grabbed the links hanging off the table and put them back onto the top of the rest of the links. SENASICA considered this as possible contamination of all products on that table. SENASICA then had all of the links on that table placed into a non-edible container and sanitize the table before any further peeling could occur at that location. All actions in this case were taken by SENASICA.
- In one establishment (TIF 158), the operator of the ham slicing machine removes the product film using a plastic tool that is required by the establishment to be kept in a sanitizer solution to prevent the possible spread of contamination from one roll of product to another as they are opened. During the tour of the establishment, there was no solution present and he was opening the film and feeding the product logs into the slicer. When the situation was detected by SENASICA, both the establishment and SENASICA took appropriate corrective actions (CAs) for the table and tool, sanitizing both and refilling the sanitizer. They retained the product present on the table, on the outside of the slicer, in the process of being packed and previously packaged back to the start time of that operator. However, they forgot to include the slicing machine itself. After cleaning up the area, they started opening logs and feeding them into the machine again without considering that if there was contamination or adulteration on the logs opened without sanitizer, that contamination might also still be on the inside of the machine, thereby contaminating all new product that passed through the machine even though it had been opened in the correct manner. The FSIS auditor pointed out this lack of consideration of the equipment and further product was retained and the inside contact surfaces of the machine were cleaned prior to continuing slicing. The SENASICA official personnel assigned to this TIF establishment issued a non-compliance report from which the establishment staff designed and executed an action plan which resulted in the retained product being tested for *Lm*, *Salmonella*, total coliforms, and aerobic mesophiles. All results were negative for the presence of any of these microorganisms. The product was then released.
- In one establishment the FSIS auditor identified black particles ranging from a fine dust (and possibly airborne) up to a few cms in size coming down from an overhead air flow unit and some had settled on the packaging equipment surfaces. The black particles did not directly contaminate the product since all products were packaged. Since it is

unknown how far the particles were traveling in the airflow and an area of post-lethality exposure of product was just a few feet away, the operation was shut down and product retained. This peeling and packaging line was shut down for the day pending analysis of the situation. Product from the day's production was retained for further analysis before disposition was determined. The SENASICA official personnel assigned to this TIF establishment issued a non-compliance report from which the establishment staff designed and executed an action plan which resulted in the retained product being tested for *Lm*, *Salmonella*, total coliforms, and aerobic mesophiles. All results were negative for the presence of any of these microorganisms. In addition, the retained product was examined by AQL methodology and none of the black material was found on or in the packages. The product was then released.

The SRT had not been entirely completed by Mexico prior to the audit. In the Sanitation component, there was one question that was left to the FSIS auditor to collect the information during the 2012 audit. This question was asked and the response was given during the entrance meeting. That question and response is as follows:

Question: Is there a document that instructs SENASICA personnel that they are to follow the provisions of the 9 CFR 416 regulations and FSIS Directive 5000.1?

Response: No, there is no document specifically instructing them to follow those provisions. Those requirements are included as references in the in-plant and supervisory guidelines, and we expect them to be followed. The FSIS auditor confirmed that the references are included in the in-plant and supervisory guidelines.

In conclusion, two of the establishments had documentation demonstrating trends of SSOP and SPS non-compliances over a 60-day period; and included both slaughter and processing departments. In two other plants, varying SSOP non-compliances occurred but were of the kinds that occur during normal operations. There were several non-compliances with regard to adequate descriptions within the SSOP document, but nothing that could be directly attributed to insanitary conditions, since the FSIS auditor didn't observe any insanitary conditions. FSIS equivalence criteria applicable to Sanitation Performance Standards and pre-operational sanitation were met. However, the findings indicate that SENASICA should implement enforcement activities that resolve trends of insanitary conditions in at least two plants. SENASICA should make a further assessment to determine if other plants warrant the same consideration. A similar recommendation was made during the fall 2009 and summer 2008 FSIS audits. These findings are similar to those from the previous audits.

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

The FSIS auditor reviewed HACCP as the third of the six equivalence components. The FSIS auditor verified that the inspection system required each official establishment to 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 SRT and observations during the on-site audit. The documents provided by the CCA in the SRT included:

- 9 CFR 417

- FSIS Directive 5000.1
- FSIS Directive 10,240.4 Rev 2
- Federal Law of Animal Health, Article 18
- NOM 009-ZOO-1994 Sanitary Processing of Meat
- Manual of Sanitary Inspection of TIF Establishments

The FSIS auditor verified that the certified establishments had developed, implemented, and maintained HACCP systems in accordance with the above Mexican laws and regulations. The FSIS auditor reviewed HACCP programs and monitoring, verification and corrective action records of the establishments as well as verification, non-compliance, and periodic supervisory review records of SENASICA.

The Federal Law of Animal Health states that the Secretariat, without detriment to the functions of other agencies of the Federal Public Administration, shall determine measures in the area of good livestock practices that must be applied in primary production and processing of goods of animal origin in TIF establishments, to reduce the contaminants or animal-health risks that may be present in them. Measures in the area of good livestock practices should be based in scientific principles or on international recommendations and, if appropriate, on risk analysis. The measures considered shall be determined in directives for contamination risk reduction which may include the requirements, specifications, criteria or procedures without detriment to other legal provisions of other applicable legal provisions in the realm of public health. The Law goes on to cover requirements of other countries and performing risk analyses, and establishing control of critical points.

Weekly schedules of verification tasks are produced by the respective state supervisors and distributed electronically or hand-carried to the SENASICA in-plant personnel in their areas of responsibility. However, when the FSIS auditor was reviewing the completion of these tasks within the establishments, it became clear that review and verification was only of the records of the critical control points, not of any other part of the HACCP system such as Hazard Analysis, supporting documentation, flow charts, etc. As the auditor read through the different parts of the HACCP system, both in-plant SENASICA personnel and supervisory SENASICA personnel were unable to answer questions and seemed unaware of the contents of any part of the system except the records. As SENASICA has not yet implemented an internal audit system, the auditor could not determine if anyone from SENASICA was reviewing the rest of the HACCP system.

The Mexican zero tolerance program is based on the requirements of FSIS Directives 6420.2 and 5000.1 as well as 9 CFR 307.2(g)(m), 310.3, 310.17(a), 310.18(a) and 318.4(b). The inspection officials must include zero tolerance verification in their daily activities. This activity is supervised by the veterinarian-in-charge in each establishment.

Activities of the daily verification of zero tolerance by SENASICA include random selection of carcasses, verification of the CCP prior to washing of the carcasses, conducting the verification in the same area that the establishment does their verification, internal and external visual inspection, verification of adequate light intensity, control for visible milk, ingesta and feces, recording of the results as well as review of the establishment's records, and verifying corrective actions. When zero tolerance violations are found for visible fecal material, ingesta, or milk, the

in-plant SENASICA personnel verify that the written corrective actions consider all points of 9 CFR 417.3 and that all measures are carried out prior to the carcass wash. In those establishments that do zero tolerance on every carcass, those actions would be for just that carcass. Although these findings do not cause the generation of a non-compliance document for each zero-tolerance failure by the establishment, the establishment does perform and record corrective actions for each failure. The SENASICA has the authority to retain all carcasses back to the previous acceptable SENASICA check for zero tolerance. The establishment must inspect every one of the retained carcasses and then the SENASICA will verify their inspection.

The FSIS auditor reviewed the implementation and documentation of establishment and SENASICA zero tolerance programs during the on-site audits of the two establishments conducting slaughter operations and found no non-compliances with the programs as written in each establishment. Records for the zero tolerance critical control point in each establishment did include written corrective actions for each failure. Records for SENASICA zero tolerance verification were also reviewed. Although non-compliances were observed and recorded by SENASICA, non-compliance records were not generated. The SENASICA findings were included in letters to the establishment management stating the findings. When the CCA officials accompanying the auditor were asked if the writing of letters rather than NCRs was acceptable in the SENASICA system, they indicated that this practice was acceptable.

The FSIS auditor assessed technical aspects of post-mortem inspection at two TIF beef slaughter establishments certified to export to the United States. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. In-plant veterinary inspectors were adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of the inspection personnel examining the beef heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes were made in accordance with SENASICA regulations which have been recognized as equivalent to FSIS requirements. They also met applicable portions of FSIS Directive 6100.2 "Post-Mortem Livestock Inspection". The design of the post-mortem inspection stations met Mexico's requirements. There were no findings from the observations of the SENASICA post-mortem inspection procedures.

The following HACCP findings were reported to SENASICA during the exit meeting:

- In two establishments, the HACCP records of the establishment did not include corrective actions (CAs) that accurately described the actions taken. The types of non-compliances observed were not what FSIS would associate with HACCP; the non-compliances did not involve CCPs, but rather equipment or parts of facilities in the processing areas located near the CCPs. The presence of condensation was noted in the remarks section of the HACCP records. In the slaughter area, there were CCPs for zero tolerance and for temperatures of offal products. Since the non-compliances noted did not usually involve the CCPs, there were no trends identified. The only non-compliances involving CCPs were for the zero tolerance CCP and that is discussed previously in this report. Many of these CA responses were simply listed as "told supervisor" or "told maintenance" rather than any real actions. Recorded preventive measures (PMs) were

non-existent. Neither SENASICA in-plant or supervisory records had identified these non-compliances. The establishments agreed to make these changes to their records.

- In one establishment, the establishment records showed very few failures for zero tolerance. SENASICA records show frequent failures for zero tolerance. SENASICA has written NCRs and letters to the establishment, but has either not received a response or the corrective actions taken have been ineffective. This was also noted by the CCA personnel accompanying the FSIS auditor. The in-plant SENASICA personnel are working with their state supervisor to solve this problem.
- In one establishment, the HACCP plan CCP verification lacked the observation of the monitor in the zero tolerance CCP and the calibration of process monitoring equipment in the deboning temperature CCP. The establishment agreed to add these to their plan. Neither the SENASICA records nor the supervisory reviews had identified this non-compliance.
- SENASICA in-plant personnel only write non-compliance records (NCRs) for SSOP and HACCP non-compliances (in all TIF establishments audited). All other non-compliances are handled by letters to the establishment. In this establishment, these letters do require CAs and PMs, but do not show any evidence of SENASICA verification as would be shown if the NCR form was used. The use of these letters is acceptable to the CCA. State supervisory reviews had not noted this lack of verification.

It is important to note that the two slaughter establishments that had trends for insanitary conditions also had all of the HACCP audit findings.

The SRT had not been entirely completed by Mexico prior to the audit. In the HACCP component, there were some questions that were left to the FSIS auditor to collect the information during the 2012 audit. These questions were asked and the responses were given by various CCA SENASICA personnel at various times during the entrance meeting, the in-plant audit, and the exit meeting. The questions and responses are as follows:

Question: Is there a document that instructs SENASICA personnel that they are to follow the provisions of the 9 CFR 417 regulations and FSIS Directive 5000.1?

Response: No, there is no document specifically instructing them to follow those provisions. Those requirements are included as references in the in-plant and supervisory guidelines, and we expect them to be followed. The FSIS auditor confirmed that the references are included in the in-plant and supervisory guidelines.

Question: The state supervisors produce the schedules of tasks (PBIS) for the SENASICA personnel in the establishments to perform. Is there a document telling them how to make these schedules, what to include, and the frequency for any particular task?

Response: No, there is not such a document. However, since the Federal Law of Animal Health and the Regulations supporting this law have just been updated this last summer, the NOMs will be going away and many of the Guidelines and Handbooks will be rewritten to reflect the changes. This type of information will then be included. The FSIS auditor has not

evaluated the revised law or regulations as they have not yet been translated from Spanish to English.

In conclusion, HACCP criteria were reviewed in all four establishments audited; however, these criteria were not met in two establishments. The CCA must address the non-compliances and the inadequate plant verification procedures and assure that SENASICA personnel have the knowledge, skills, and ability to assure compliance with the Mexican HACCP regulations.

9. CHEMICAL RESIDUES

The FSIS auditor reviewed Chemical Residues as the fifth of the six equivalence components. The FSIS criteria for chemical residues include a program managed by the CCA and established to carry out effective regulatory activities to prevent contamination of food products with chemical residues. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of the basis for its residue plan and the process used to design the plan. The plan must describe the actual operations of its residue plan. The CCA must provide a description of the actions taken to deal with unsafe residues as they occur. The CCA must have access to and supervision of analytical laboratories that have the capability to assure the validity and reliability of test data. The chemical residue component was found to be equivalent.

The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations during the on-site audit. The documents provided by the CCA during the audit and in the SRT included:

- Programa Nacional de Monitoreo y Control de Residuos Toxicos y Contaminantes en Alimentos de Origen Animal 2010 y Resultados del 2009
- Programa Nacional de Monitoreo y Control de Residuos Toxicos y Contaminantes en Alimentos de Origen Animal 2011 y Resultados del 2010
- Programa Nacional de Monitoreo y Control de Residuos Toxicos y Contaminantes en Alimentos de Origen Animal 2012 y Resultados del 2011
- DGIAAP-002-P Procedimiento de Supervisión de Establecimientos TIF dedicados al sacrificio, corte y deshuese de Porcinos
- DGIAAP-004-P Procedimiento de Supervisión de Establecimientos TIF dedicados al sacrificio, corte y deshuese de Bovinos
- NOM 004-ZOO-1994 Control de residuos tóxicos en carne, grasa, hígado y riñón de bovinos, equinos, porcinos y ovinos

The FSIS auditor verified that the inspection system has an organized governmental program established to carry out effective regulatory activities to prevent contamination of food products with chemical residues; that the SENASICA works with this program and provides some direction, coordination and oversight; that the various elements of the program are coordinated by the SENASICA in conjunction with the central reference laboratory of Direccion del Centro Nacional de Servicios de Constatacion en Salud Animal (CENAPA) (National Center for Animal Health Diagnosis) located in Jiutepec; and that the program has sufficient resources from Headquarters, the CENAPA laboratory, various private laboratories, and state and in-plant

personnel as well as funding to carry out the program. The FSIS auditor also verified the previously submitted laws, regulations and implementation documents defining the legal authority of the SENASICA to organize and implement a residue control program. This legal authority prescribes the conditions for the use of chemicals in the production of meat and poultry products, prohibits the use of compounds that may present unacceptable public health risks, provides the ability to control and monitor industrial and environmental chemicals that may lead to contamination and provides the ability to enforce these laws and regulations.

The internal SOPs for the laboratory were reviewed and the records provided as well as the on-site observations of the FSIS auditor showed that these SOPs were being properly implemented. The ISO 17025 certification report from an outside audit of the laboratory as well as the audits that the laboratory performs on private laboratories was reviewed. The FSIS auditor also reviewed the corrective action reports following these certification audits and the follow-up actions that were taken before certification was granted or extended.

The FSIS auditor verified that the design of the Mexico National Residue Program includes the required criteria including a description of the basis for the residue plan and the process used to design the residue plan. The residue plan also describes the various sampling schemes, lists the selected matrices for each compound, and includes a rationale and process for the choice of chemical compounds. Many of the choices of compounds and numbers for sampling are based on Council Directive 96/23/EC of 29 April 1996.

The FSIS auditor verified that the implementation of the plan at the headquarters, laboratory, state, and in-plant levels was proceeding in the manner outlined in the plan and that sampling was occurring on time and in the manner designated, analyses were completed in a timely manner, and results were distributed as directed. Additionally the FSIS auditor verified that the plan contained appropriate internal actions to be taken if a result was in question, what screening methods were involved, and what confirmation methods could be used.

Enforcement measures are delegated to another agency within SAGARPA, and all violative results are immediately reported to them and they act by retaining products, destroying products, conducting recalls, performing farm quarantines, and performing risk communication as appropriate to the violative substance. Investigation is done at the farm level to determine the probable cause of the residue's presence. The veterinarian doing the investigation focuses on the possession and use of veterinary drugs, the animal feed, and any environmental aspects. The veterinarian also emphasizes to the private companies the proper use of veterinary drugs as the label proscribes, respect for the proper withdrawal times, and the necessity of a veterinary prescription for the use of the drug.

In the case of a prohibited substance, an investigation related to the acquisition, distribution, and sale of the substance is initiated. Although Mexico does not publish a violators list as in the U.S., the establishment can be removed from the list of farms and feedlots eligible to take animals to SENASICA-certified TIF establishments. All of the farms and feedlots are aware of these potential actions following a violative result. Many of the meat industries in Mexico are vertically integrated which improves the ability for traceability.

The residue laboratory audit focused on the general capabilities of the central reference laboratory as well as what the capabilities are of the private laboratories certified within Mexico, and the laboratories used in other countries for confirmatory analyses of positive results found at the central reference laboratory. This included the ability to assure the validity and reliability of test data.

The central laboratory audit focused on the facility, equipment, personnel organization and qualifications. In addition, the FSIS auditor reviewed analytical methods, recordkeeping requirements, sample handling and traceability, corrective actions, inter-laboratory, intra-laboratory, and international proficiency testing programs and results, and accreditation. All above criteria for the operation of a residue laboratory were in place and operating effectively. All certifications, including ISO 17025, were current.

Most of the general information about the CENAPA laboratory is covered in the Government Oversight portion of this report.

The FSIS auditor reviewed the results of Mexico's current year's residue sampling program at the laboratory and in-plant levels. The program was operating as specified, results were delivered on time, and results were available at both levels. The 2012 Mexico National Residue Program has been submitted to the FSIS auditor, has been translated and is in the process of review by the FSIS auditor, the Office of Public Health Science (OPHS), and the Data Analysis and Integration Group (DAIG).

The National Program for the Monitoring and Control of Toxic and Contaminant Residues of Animal Origin 2012 references the performance of risk analysis studies performed by SAGARPA (the Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food), the SS (the Health Secretary) and SEMARNAT (the Environmental and Natural Resources Secretary), as well as a number of international studies, FSIS, and the scientific works of internationally and nationally recognized institutions, but there are no details. There is no reference to any risk analysis studies to be performed in the 2011 or 2012 plan. The document does discuss epidemiological studies, but the FSIS auditor was not able to determine if that was the same thing as a risk analysis baseline. Risk was also addressed as "the amount of samples required to be taken from different animal and food products is a reflection of the risk study of the use of agricultural drugs and chemical, retrospective of the results of the residues, production levels, the products' destination (export or local consumption) as well as the specification of the internationally accepted sampling statistics for the detection of chemical residues."

During the evaluation of the 2011 National Residue Control Program as well as the 2010 Residue Control Program Results, the FSIS auditor noted that there were no sections for either Ovine or Caprine slaughter. This omission was addressed to SENASICA in December of 2011. SENASICA had responded earlier (spring 2012) that an additional program would be set up to include these species for the remainder of 2012 and that they would be included in the program for 2013. SENASICA explained that the market in the United States for import of these species had only opened in the last few years and it was just an oversight that they were not included. Documentation of the 2012 additional program was provided to the FSIS auditor at the entrance meeting.

The FSIS auditor noted high positive results for beta-agonists in the 2009 and 2010 Residue Plan Results; these beta-agonists included Clenbuterol and Zilpaterol. There is a new drug in the beta-agonist class that has been coming up positive. This drug is called Zilpaterol and 2009 saw 23 violative results in bovines of 171 tested (13.5%), four in swine of 118 tested (3.4%), and six in equines of 172 tested (3.5%). The percentages of samples planned and samples tested are 91.0% for group A and 98.2% for group B for Bovines; 98.3% for group A and 90.5% for group B for swine; and 89.0% for group A and 85.0-100% for the different compounds in group B in poultry. Zilpaterol is only approved for use in cattle, also excluding veal calves and animals for breeding. Even with the increased positive results, there was no increase in sampling for those compounds. The response from SENASICA was two-fold. The answer received during the audit was that they did not change the sampling numbers, but they did change the distribution of where the sampling was to occur to the areas which seemed to have the most positive samples in the previous year. The numbers that Mexico uses to determine their residue sampling numbers is based on the CODEX number of samples required, adjusted to assure that they also conform to the European Union programs and then set for the total national production. The second part of the answer is the country-wide Clenbuterol study that was just about to begin during this audit and encompasses all stages of production. Zilpaterol action levels have been adjusted to meet those of the U.S. rather than the EU. Mexico, along with some other countries, is requesting from CODEX and other international bodies that an international action level for Zilpaterol be set. Further results for Zilpaterol in the following years are as follows:

- 2010 – 27 of the 179 bovine samples analyzed were positive
- 2010 – 0 of the 115 swine samples analyzed were positive
- 2011 – 3 of the 181 bovine samples analyzed were positive
- 2011 – 0 of the 179 swine samples analyzed were positive
- 2012 – 5 of the 169 bovine samples analyzed were positive
- 2012 - 1 of the 147 swine samples analyzed was positive

There is currently an evaluation of these numbers and the CCA response to the findings between the FSIS auditor, the FSIS OPHS, and the FSIS DAIG. Further information has been requested from the CCA to complete this evaluation.

Some of the sampling numbers were very small. These numbers were explained by the fact that they satisfy the requirements of the European Union (EU) residue requirements. Since FSIS accepts the EU residue program as equivalent, FSIS would also accept another country's program if it were accurately based on the requirements of the EU program.

Mexico has been granted equivalence for their Residue Control Program in the past. The last review was completed in 2011 on the 2009 National Residue Plan.

Prior to this audit, SENASICA residue programs did not require SENASICA personnel to retain carcasses that had been sampled for residue testing. A letter to SENASICA field personnel was shown to the FSIS auditor during the exit meeting instructing field personnel to hold carcasses used for residue testing. Carcasses will not be held for the mass screening for Clenbuterol mentioned above. Only positive results are relayed to the establishments; all results go to CCA Headquarters.

All of the established equivalence criteria for this residue component were met.

10. CCA MICROBIOLOGICAL TESTING PROGRAMS

The FSIS auditor reviewed the CCA Microbiological Testing Programs as the sixth of the six equivalence components. Mexico has microbiological testing programs included in the Pathogen Reduction Program for generic *Escherichia coli* (*E. coli*) in all slaughter species, *E. coli* O157:H7 in beef, *Salmonella* in raw and Ready-to-Eat (RTE) products, and *Listeria monocytogenes* (*Lm*) in RTE products. The FSIS auditor verified that the system has implemented certain sampling and testing programs to ensure that meat and processed poultry products produced for export to the United States are safe and wholesome and the equivalence criteria have been met.

In both of the establishments audited that were required to conduct generic *Escherichia coli* (*E. coli*) testing, there were deficiencies in the use of statistical process control charts to record results of the sampling. SENASICA personnel had not reviewed the generic *E. coli* programs of the establishments and had not reported the non-compliance.

The evaluation of this component included a review and analysis of the information provided by the CCA (SENASICA) in the SRT and observations during the on-site audit. The documents provided by the CCA in the SRT and during the audit included:

- Manual de inspección y verificación al sistema de seguridad alimentaria para Médicos Veterinarios de Establecimientos TIF de exportación (Handbook for Inspections and Verification of Food Safety System for Veterinary Doctors at TIF Export Establishments)
- Procedimiento de Supervisión de Establecimientos TIF dedicados al sacrificio, corte y deshuese de Porcinos
- Pathogen Reduction Program, Revision 2, January 1, 2010
- 9 CFR 310.25
- 9 CFR 417.2(b)
- Procedures for *Escherichia coli* (*E. coli*) O157:H7 and non O157-STECs
- FSIS Notice 61-04
- FSIS Directive 10,300.1 (2/3/09)
- FSIS Directive 10, 240.4 Rev 2 (2/3/09)
- FSIS Directive 10,240.5 Rev 2 (2/3/09)
- Summary of New RTE Product Verification Requirements for *Salmonella* and *Listeria monocytogenes*

For the generic *E. coli* programs, a letter was sent to the establishments on May 6, 1997 that states that plants interested in remaining on the list to export to the U.S. must implement generic *E. coli* sampling. In the Handbook for Inspections and Verification of Food Safety System for Veterinary Doctors at TIF Export Establishments, Part 7.1.4.1, the VIC is instructed to review the generic *E. coli* program to include the parameters that are stated in 9 CFR 310.25. This testing is conducted by the establishments.

In the *Escherichia coli* (*E. coli*) O157:H7 program of the Pathogen Reduction Program (Rev. 2, January 1, 2010), it is stated in the objective that the program is “to establish baselines to monitor and diagnose *E. coli* O157:H7 in meat products processed in TIF establishments authorized as eligible to export to the U.S. in accordance with the annual monitoring program. But, we do not know if a baseline has been established from the previous years of testing. In the *Listeria monocytogenes* (*Lm*) program, there is not an objective stated nor is there any reference to baseline studies. Baseline studies or documented analysis of anything beside the monitoring programs also is not mentioned in the Central Offices (DGIAAP) Responsibilities. In the *Salmonella* spp. program, a similar objective is stated in reference to establishing baselines for *Salmonella* in bovine and porcine carcasses as well as raw ground pork and beef for TIF establishments certified for export to the U.S.

SENASICA has an ongoing program for the detection of *Salmonella* spp. in raw product. This program is contained in the Pathogen Reduction Manual and titled “Permanent *Salmonella* spp. Detection Program in Establishments Authorized to Export Meat and Meat Products to the United States of America.” This program is detailed with all the specifics of the scope, objective, regulatory references, responsibility of official personnel, sampling program, sampling method, handling of results, materials necessary for sampling, collecting samples, detection methodology, collection procedures, shipment of samples and the laboratory testing method. Direction is given for both bovine and porcine carcasses and for ground beef or pork. These are all very detailed and bear a great resemblance to the FSIS guidelines for *Salmonella* spp. sampling in raw product. Pictures are also included to make the methodologies more clear. The designated laboratory method used to isolate and detect *Salmonella* spp. is USDAFSIS/MLG 4.04 Rev. 04 from 04/02/08. This analysis must be conducted at the CENAPA laboratory or another laboratory approved by SAGARPA. Government inspection personnel take the samples. There is a place on the “Annex” part of the monthly supervisory review to check on the individual establishment’s inspection personnel and their conducting of this *Salmonella* program. SENASICA personnel routinely verify this program and the results obtained from the analyses. There are specific steps outlined for actions to take in case of positive results. There are also directions for in-plant inspection personnel to verify establishment actions.

There are no establishment programs for *Salmonella*, only the government programs; however, the establishments do pay for the government testing programs.

Listeria monocytogenes and *Salmonella* in post-lethality exposed Ready-to-Eat (RTE) products are covered in the Pathogen Reduction Program. The title of the appropriate section is “*Listeria monocytogenes* – Official *Listeria monocytogenes* Verification Procedure for Ready-to-Eat (RTE) Meat and Poultry Products Prepared in TIF Establishments and Meant for Exportation to the U.S.” The sample size given in the submitted SRT is the size that the inspection personnel take to send to the lab, not the size used in analysis. It is listed as 500 grams for *Listeria monocytogenes* and 500 grams for *Salmonella*. The complete program is given in the Pathogen Reduction Program. The method given for *Salmonella* in RTE is FSIS Method MLG 4.04 and the method for *Lm* in RTE is FSIS method MLG 8.06 (02-19-08). When the methods used at the CENAPA laboratory were reviewed, the up-to-date FSIS MLG methods were in use. There is very complete detail within the Pathogen Reduction Program but when you get to the directions to the inspection personnel in the Handbook, it only deals with establishment programs. There

are requirements for establishment programs in these areas, but nothing about how they are to review the government programs for RTE.

The Pathogen Reduction Program (PRP) states that the Official Veterinary Doctor will establish the Establishment's specific sampling methodology for RTE based on risk factors such as the election of the alternative by the establishment, type of product, production volumes, schedules, and production shifts. The PRP does provide official verification programs. This program sets responsibilities for the establishments, for the VIC, for the CCA, and for the laboratory. Specific actions are designated to be taken in the case of positive results. There is also a plan included for intensified verification sampling sets for follow-up to positive results. The VIC sets up the specified program in each establishment for the choice of the appropriate product to be sampled.

The RTE testing for *Salmonella* and *Lm* is being conducted, but the consequent analysis only amounts to requiring the establishments to take corrective actions in the case of a positive result. Analysis of RTE results or trends performed at the CCA level was not documented in the SRT.

The FSIS auditor reviewed the Handbook for Inspections and Verification of Food Safety System for Veterinary Doctors at TIF Export Establishments, and determined that the forms they are using for daily verification are the FSIS forms for the initial set up of programs, i.e., SSOP, SPS, HACCP, and generic *E. coli*. These are the checklists that FSIS developed when HACCP first started and used for initial compliance of establishments and now for new establishments and the implementation of new processes. Therefore, the inspection tasks and records produced do not deal with ongoing compliance and verification; the inspection personnel are only looking for basic compliance.

In the training class in Guadalajara in February 2012, the subject of RTE sampling was covered. The FSIS auditor has requested more information on this training to see if it covered RTE sampling in a post-lethality environment. The FSIS auditor did find that the forms in the Manual are the ones being used in all of the establishments audited.

The *E. coli* O157:H7 program included in the pathogen Reduction Program was previously deemed equivalent by FSIS in order for Mexico to export raw beef products to the U.S. A complete monitoring plan is included in the program with the included establishments listed; however, a number of establishments have been listed by Mexico since then. All samples collected for *E. coli* O157:H7 must go to CENAPA for analysis; no other labs in Mexico are presently approved for this analysis. There is a requirement for the establishments to have their own programs and testing, and present the results to the SENSICA inspection personnel, but no labs are approved to do the testing and CENAPA does not have the capacity to do analyses other than the government testing samples. There is a SENASICA requirement that product found positive for *E. coli* O157:H7 and then cooked to destroy the pathogen, cannot be exported to the U.S., and the establishments are required to document this so it can be verified. FSIS MLG 5A.01 which is a screening method is used at this time. If a presumptive positive occurs, this is accepted as a positive and actions follow as though it is a confirmed positive. This was agreed to at a technical meeting between FSIS and SENASICA and consistent with the policy of FSIS.

Methods in use are AOAC and BX for screening and REVEAL for confirmation. The laboratory was to be reviewed for accreditation for these in methods in October 2012. At the time of the audit, the BAX could not yet be used for the STECs since only some of the reagents had been received. The receipt of these reagents was anticipated to be in the following few weeks.

Escherichia coli O157:H7 in semi-dry or fermented meat products containing bovine tissue testing is not currently being conducted as none of this product is being produced for export to the United States.

The new pathogen reduction annual plan for *E. coli* O157:H7 and non-O157 STECs had been implemented in 18 of the 20 TIFs certified to ship to the U.S. at the time of the FSIS audit. This plan has now been implemented in all TIFs certified to export to the U.S. All are scheduled to submit one sample per month. At least one of the two establishments listing ground beef is a grinding, not a slaughter establishment.

In the previous plan which FSIS had deemed equivalent at the time it was submitted (2008), there was no reference to boxed beef or sub-primal cuts designated for grinding. Nowhere in that program was the mention of boxed beef or subprimal cuts except if they were considering the raw beef components defined as esophagus, cow head meat, and cheek meat as being the components of boxed beef. The updated program for *Escherichia coli* O157:H7 and non-O157 STECs was provided to the FSIS auditor at the time of the review of the CENAPA laboratory. The FSIS auditor was told that raw beef manufacturing trim, boxed beef, and sub-primal cuts designated for grinding are all a part of the new Pathogen Reduction Program for *Escherichia coli* O157:H7 and non-O157 STECs.

The audit of the Central Reference Laboratory focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples and all parameters were met. Although private laboratories are used for many of the microbiological analyses set out in the National Pathogen Reduction Program, no private microbiological laboratories were reviewed during this audit due to time constraints of the audit.

There are 14 private laboratories overseen by CENAPA. A list of these private laboratories can be found at <http://www.senasica.gob.mx/?id=2563>.

Salmonella analyses done in the CENAPA laboratory are sorted to serotypes and a record of these results are maintained; however, serotypes are not reported to establishments. Further detail about the serotypes reported and possible trends has been requested from SENASICA.

Testing of non-O157 STECs is performed only at this laboratory and not at any of the other certified laboratories. This may change in the future. The first screening testing for non-O157 STECs began in the week prior to the FSIS audit, but the confirmation step is still missing some of the reagents; these were scheduled to arrive in the upcoming weeks. CENAPA is using test kits for which they have received a non-objection letter from FSIS-OPHS. The FSIS auditor did observe one test report in an establishment for non-STECS; the result was negative.

Baseline, prevalence, and pathogen reduction studies have not been conducted for any of the pathogens present in the Pathogen Reduction Program. A new software program is in the process of being distributed and tested in the approved laboratories which will give real-time databases for results. At this point they are still doing monthly reporting of results to Animal Health. They are now working with the Risk Analysis and Epidemiology section to accomplish this.

Reviews conducted in 2011 and 2012 of laboratories that CENAPA had certified were collected by the FSIS auditor. Additional documentation collected included:

- support of their various accreditations
- the appropriate NOMs and laws to support the authority and duties of CENAPA
- official Organigrams of CENAPA and their divisions
- the new *Escherichia coli* (*E. coli*) O157:H7 and non-O157 STECs program (dated August 2012)
- a blank checklist used for internal review and review of authorized laboratories (developed by CENAPA using ISO 9001 and ISO 17025 plus additional points)
- a CENAPA-organized training program
- a Circular detailing what labs must do to become and remain certified within the system

BSE testing is actually done by another Agency within the Department of Agriculture. The laboratory responsible for this analysis is a Biosafety Level 3 Laboratory belonging to the Comisión México-Estados Unidos para la Prevención de la Fiebre Aftosa y Otras Enfermedades Exóticas de los Animales (The Mexico-United States Commission for the Prevention of Foot and Mouth Disease and other Exotic Diseases) located in the District Federal. CENAPA only does testing for bovine tissue within feeds.

The SRT had not been entirely completed by Mexico prior to the audit. In the Microbial Testing Programs component, there were several questions that were left to the FSIS auditor to collect the information during the 2012 audit. These questions were asked and responses given during the entrance meeting, in the progress of the audit and at the exit meeting by various SENASICA CCA individuals. The questions and responses are as follows:

Question: Does the CCA perform documented analysis of the results of microbiological testing programs such as baseline, prevalence, or pathogen reduction studies?

Response: No, not really, we just have monthly results of on-going programs and are now developing and implementing real-time databases in order to more quickly respond to any situation or trend that may present itself.

Question: Was there an attachment to the letter of May 6, 1997, Oficio Circular No. BOO.02.03.02.020/97 that tells the establishments what they needed to do for the generic *Escherichia coli* (*E. coli*) sampling or just that they had to do it? Where does it reference that the establishments must do it by the direction of 9 CFR 310.25?

Response: That letter was all that was provided, just the direction from the CCA to do the sampling. We have been reminding the establishments and the in-plant SENASICA personnel as well as the supervisory SENASICA personnel to review their programs and have added generic *E. coli* to the checklist. FSIS auditor note: there was no documented proof of this except the FSIS

Basic Checklist used for generic *E. coli* when FSIS looks at a new establishment or a new program.

Question: Has the previously deemed equivalent program for *E. coli* O157:H7 been updated to reflect the additional products now being sampled, the change in the supporting documentation for the program, and the additional non-O157 STECS that are now a part of the program in the United States?

Response: Yes, an updated program has been developed and implemented including the additional products and the non-O157 STECs. This program was provided to the FSIS auditor but has not yet been evaluated because it has not been translated from Spanish to English. The FSIS Criteria for Assessing *Escherichia coli* (*E. coli*) O157:H7 Programs had previously been provided to the CCA. The FSIS auditor observed the kits in the laboratory but no testing was being done at the time of the CENAPA laboratory audit. The FSIS auditor also observed records of analyses in the laboratory including those for the non-STECS. All records reviewed had negative results.

The following Microbiological Testing Programs findings were reported to SENASICA during the exit meeting:

- The only item of concern actually is a SENASICA-CCA responsibility, not the laboratory. This is the question of in-plant and State Supervisor understanding of the generic *E. coli* programs. There really is no guidance except the 1997 letter that told TIF establishments that they must implement a generic *E. coli* program to be certified for the U.S. market. There is no written guidance for what SENASICA needs to do to evaluate and verify these programs and that has been evident for the last several audits. No real guidance has been provided to the establishments outside of referring to 9 CFR 310.25.
- In both slaughter establishments required to conduct generic *Escherichia coli* (*E. coli*) testing, the generic *E. coli* program records did not include statistical process control charts even though the establishments were using the sponging method of sample collection. There also was no moving window for 13 day analysis of results. Even though SENASICA had done a review of the program recently, SENASICA only used the FSIS Basic *E. coli* checklist and neither the in-plant personnel nor the supervisor had noted this non-compliance in either establishment. The establishments promised to correct these non-compliances. This demonstrates that SENASICA does not really understand how to review generic *E. coli* programs. There is no guidance from the CCA on how to accomplish these reviews. This is an on-going finding from past audits of TIF establishments and the lack of adequate supervisory oversight. For one establishment, this was the first audit as it was just recently certified by SENASICA. For the other establishment, this same finding was noted in 2009.

In conclusion, with the exception of the generic *Escherichia coli* programs, the National Pathogen Reduction Program for Mexico and the operation of the microbiological laboratories are in accordance with the established equivalence criteria. The CCA needs to improve the understanding, implementation, and verification of generic *Escherichia coli* programs within slaughter establishments.

11. EXIT MEETING

An exit meeting was held on September 13, 2012 in Mexico City with the SENASICA personnel. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

The CCA understood and accepted the findings.

12. CONCLUSIONS, PROFFERED CORRECTIVE ACTIONS, AND NEED FOR FURTHER ACTIONS

The audit outcome showed that Mexico's meat and poultry food safety inspection system maintains equivalence. However, as described in the corresponding sections of this report, there are concerns related to Government Oversight, Statutory Authority and Food Safety Regulations, Sanitation, the Hazard Analysis and Critical Control Point System, and the CCA Microbiological Testing Programs components of the system that require the attention of the CCA. Short term corrective actions were being implemented throughout the audit, but the effective implementation of long term corrective actions to address the findings summarized below remains pending.

- In the component of Government Oversight, the CCA must address supervisory reviews, the review of SSOP and HACCP programs, and documentation of non-compliances.
- In the Statutory Authority and Food Safety Regulations component, the CCA must amend their BSE/SRM programs and guidelines to include the skull and the vertebral column as SRMs that must be removed from cattle 30 months of age or older that are eligible for export to the U.S. This document must also be amended to include recordkeeping requirements.
- In the Sanitation component, the CCA must address pre-operational sanitation implementation and monitoring, operational sanitation implementation and monitoring, SSOP's content and records, condensation, direct product contamination, and non-compliance reports.
- In the Hazard Analysis and Critical Control Point System component, the CCA must address corrective actions and preventive measures, zero tolerance, HACCP plans, and non-compliance records.
- In the CCA Microbiological Testing Programs component, the CCA must address improving the understanding, implementation, and verification of generic *Escherichia coli* programs within slaughter establishments.

Two establishments provided corrective actions (CAs) to the FSIS auditor at the closing meeting.

However, these CAs did not reference all of the non-compliances at either of these establishments as noted within this report. CAs for the other two establishments have not been received.

Corrective actions for findings of government oversight within all components also have not been received.

Corrective action plans from all of the establishments should be followed up with a verification audit from the respective SENASICA state supervisors with a report of the implementation of the corrective actions and verification of their effectiveness. The CCA must also detail their CAs for government oversight to prevent these findings in the future. These reports and actions should then be transmitted to FSIS.

Rori K. Aaron, DVM
Senior Program Auditor

A handwritten signature in black ink, reading "Rori K. Aaron DVM", written over a horizontal line.

13. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Reports
Mexico (SENASICA) did not submit a response to the Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico de la Cuenca del Papaloapan S.A. de C.V. Km 25 + 100 Carr. La Tinaja – CD Aleman Tierra Blanca Veracruz, Mexico	2. AUDIT DATE 09/10/2012	3. ESTABLISHMENT NO. TIF 101	4. NAME OF COUNTRY MEXICO
5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	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	X
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	NA
29. Records	X	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Mexico TIF 101, 09/06/2012, beef slaughter and deboning

This establishment had received an NOID on the previous audit. All findings had been corrected except for the below-noted generic *E. coli*.

10 The establishment released the slaughter floor for SENASICA pre-operational sanitation verification in a state that demonstrated that implementation of sanitation procedures had not been conducted appropriately and that establishment verification of these procedures was also inadequate. The SENASICA inspector found numerous non-compliances including fat and product residue on product contact surfaces, poor maintenance on some conveyor belts, maintenance of some wall coving, and a number of areas of condensation. SENASICA retained control of the area until all deficiencies had been corrected. Both establishment and SENASICA records showed that this is a frequent occurrence. 9 CFR 416.13 This was handled entirely by SENASICA.

13/22/51 Both SSOP and HACCP records of the establishment did not include corrective actions (CAs) that accurately described the actions taken. Many of these were simply listed as "told supervisor" or "told maintenance" rather than any real actions. Recorded preventive measures (PMs) were non-existent. Neither SENASICA in-plant or supervisory records had identified these non-compliances. The establishment agreed to make these changes to their records. 9 CFR 416.16, 416.17, 417.3, 417.8

29/51 The generic *Escherichia coli* (*E. coli*) program records did not include statistical process control charts but the establishment was using the sponging method of sample collection. Even though SENASICA had done a review of the program in recent months, they only used the FSIS Basic *E. coli* checklist and neither the in-plant personnel nor the supervisor had noted this non-compliance. This was a finding from the previous audit and SENASICA had submitted a letter. The establishment promised to correct these non-compliances. This demonstrates that SENASICA does not really understand how to review generic *E. coli* programs. There is no guidance from the CCA on how to accomplish these reviews. This is an on-going finding from past audits of TIF establishments and lack of adequate supervisory oversight; this was the first audit of this establishment as it was just recently certified by SENASICA. 9 CFR 310.25(a)(3)(ii) The auditor noted this non-compliance.

41 Condensation was present in many area of the establishment. The establishment has no written program for condensation, but only wipes as they see it themselves or it is pointed out by SENASICA. SENASICA records show patterns and trends for this condensation. The establishment agreed to establish a written program for condensation. The establishment did have a sign up in the plant about condensation, but that was it. 9 CFR 416.4(d) This was handled entirely by SENASICA.

46/51 The establishment was slaughtering Zebu and Zebu cross cattle. These animals are very long-legged and this caused some heads to contact the floor just before they were removed in the slaughter process. All of the heads will be tested microbiologically for indicators of contamination. A new process will be developed so that the heads can be maintained at a higher level so that they do not touch the floor when these type of cattle are slaughtered. SENASICA will verify that this process is effective. The establishment spoke as though they had previously been aware of the problem, but had not developed any solutions. No past findings of this problem were found from SENASICA in-plant records or the supervisory reviews. 9 CFR 416.4(d) This was noted by the auditor.

46/51 In the deboning room, there was a muscle flap hanging off the neck that contacted the floor as the carcass neck and shoulder section was separated from the rest of the carcass. There was a metal stand under the area to prevent floor contact, but the muscle flap went off the end of the stand. The establishment put that flap in the inedible bin and will study the point to determine what corrective actions to put in place. At the time, they instructed the operators in the area to be aware of the potential for contamination. No records confirmed this as a previously noted problem. SENASICA will verify the implementation and effectiveness of corrective actions. 9 CFR 416.4(d) This was noted by the auditor.

47 In the deboning room, at the station next to the one mentioned above, SENASICA identified that several of the operators were using their upper arms and shoulders in positioning the carcass for further shoulder removal and the contact was not on a part of the uniform that was covered by a plastic sleeve or apron. The establishment agreed to reconfigure their uniforms for appropriate product protection. 9 CFR 416.5 This was handled entirely by SENASICA.

51 The reviews of the establishment over a week's time by the veterinarian in charge were then transferred to a letter to the establishment. Establishment responses were slow and incomplete. These were really long lists (several pages). No NCRs were written. After the letter was written, the notes were destroyed, only one recent set could be found. There was no recording of corrective actions, preventive measures or validation following the response. SENASICA sanitation records did not contain any preventive measures for product contact surfaces. The findings did not contain sufficient detail to determine what the non-compliance had been and many of the corrective actions recorded were "told supervisor" and "told maintenance." 9 CFR 416.17 This was noted by the auditor.

57 Supervisory reviews only state the non-compliances found, a determination of minor, major or critical and the date agreed upon for correction if corrective actions were not immediate. Then the supervisor initials when the task has been completed and records outstanding issues from previous audits. There is no request for or submission by the establishment for corrective actions or preventive measures nor is there any recording by the supervisor of what the establishment may have done for CAs in the immediately corrected items or may have orally suggested for PMs. Formal NCRs are not written following these reviews. 9 CFR 327.2(a)(2)(iii)(A) This was noted by the auditor.

NOTE: SENASICA residue programs do not require retaining carcasses that have been sampled for residue testing. Only positive results are relayed to the establishment; all results go to CCA HQ.

61. NAME OF AUDITOR

Rori K. Aaron. DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Aaron, DVM 9/10/2012

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sigma Alimentos Centro, S.A. de C.V. Planta Atitalaquia Carr. Atitalaquia-Refineria No. 27 Col. Llano de Iztzacuala, Cardonal Atitalaquia Hidalgo, Mexico	2. AUDIT DATE 09/04/2012	3. ESTABLISHMENT NO. TIF 158	4. NAME OF COUNTRY MEXICO
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	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.	X	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	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	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	NA
25. General Labeling		53. Animal Identification	NA
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	NA	54. Ante Mortem Inspection	NA
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	NA
27. Written Procedures	NA	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	NA	56. European Community Directives	NA
29. Records	NA	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	NA	59.	
31. Reassessment	NA		
32. Written Assurance	NA		

60. Observation of the Establishment

Mexico TIF 158, 09/04/2012, multi-species processing

TIF 158 produces three products eligible for export, hot dogs, ham, and pizza. At the present time, only hot dogs are being exported.

7/51 The establishment has a type of extended clean-up, the plant works 24 hours a day but doesn't clearly define the difference between daily clean-up operations and those that are done as a "deep cleaning" once a week. SENASICA told the company personnel to clearly define which sanitation operations would occur on a daily basis and what the operations would be on the weekly "deep cleaning." SENASICA in-plant personnel and the state supervisor will then decide if these procedures comply with Mexico's sanitation requirements. The idea of extended clean-up does not appear in Mexican regulations. 9 CFR 416.12 (a), (c), (d) This non-compliance was noted by the auditor.

12/51 The operator of the ham slicing machine removes the product film using a plastic tool that is required to be kept in a sanitizer solution. During the tour of the establishment, there was no solution present and he was opening the film and feeding the product logs into the slicer. When the situation was detected, both the establishment and SENASICA took appropriate corrective actions (CAs) for the table and tool, sanitizing both and refilling the sanitizer. They retained the product present on the table, on the outside of the slicer, in the process of being packed and previously packaged back to the start time of that operator. However, they forgot to include the slicing machine itself. After cleaning up the area, they started opening logs and feeding them into the machine again without considering that if there was contamination or adulteration on the logs opened without sanitizer, that contamination might also still be on the inside of the machine, thereby contaminating all new product that passed through the machine even though it had been opened in the correct manner. The auditor pointed out this lack and further product was retained and the inside contact surfaces of the machine were cleaned prior to continuing slicing. 9 CFR 416.15(a) This non-compliance was noted by the auditor.

12/51 The preventive measures (PMs) listed in the pre-operational SSOPs only dealt with chemical residues that might be left from the cleaning process, not with any of the real types of findings that were recorded on the monitoring records. The company did state that a non-compliance from chemical residues had never occurred but thought that since it might, they should address it. No other PMs were listed for any non-compliance for food contact surfaces. SENASICA instructed the company to come up with PMs that addressed the most commonly found non-compliances and to address PMs in their findings for monitoring of pre-operational sanitation. It is obvious from the content of the company SSOPs and the tasks completed by in-plant SENASICA personnel as well as the supervisory reviews, that a review of the establishment's actual SSOPs does not occur, only a review of records and neither SENASICA nor supervisory reviews noted the lack of PMs. PMs also were not included in any SENASICA records. 9 CFR 416.15(b), 416.17(a) This non-compliance was noted by the auditor.

41 Condensation was noted in several areas of the establishment, however, SENASICA personnel pointed out the areas and the company dried them. No product was at risk in the areas noted. The auditor did not note the specific areas as SENASICA appropriately handled the situation. 9 CFR 416.2(d) This non-compliance was completely handled by SENASICA.

46 SSOPs did not cover the handling of product in the peeling area for hot dogs. Product handling is considered to be covered by GMPs. As a rack of hot dogs were transferred from the cooking/cooling racks to the table to be fed into the peeler, a few end links swung under the table and contacted non-product contact surfaces. When SENASICA pointed this out, the operator grabbed the links hanging off the table and put them back onto the top of the rest of the links. SENASICA then had all of the links on that table placed into a non-edible container and sanitize the table before any further peeling could occur at that location. 9 CFR 416.4(d) This non-compliance was completely handled by SENASICA.

46/51 There were black particles ranging from a fine dust (and possibly airborne) up to a few cms in size coming down from an overhead air flow unit and some had settled on the packaging equipment surfaces. At the point of the unit, turkey dogs were fully packaged. The auditor was the person to note the presence of the black substance. Since it is unknown how far the particles were traveling in the airflow and PLE was just a few feet away, the operation was shut down and product retained. This peeling and packaging line was shut down for the day pending analysis of the situation. Product from the day's production was retained. 9 CFR 416.4(d) This non-compliance was noted by the auditor.

51 SENASICA in-plant personnel only write non-compliance records (NCRs for Mexico) for SSOP and HACCP non-compliances. All other non-compliances are handled by letters to the establishment. In this establishment, these letters do require CAs and PMs, but do not show any evidence of SENASICA verification as would be shown if the NCR form was used. The use of these letters is acceptable to the CCA. State supervisory reviews had not noted this lack of verification. 9 CFR 416.17, 417.8, 327.2(a)(2)(iii)(A)

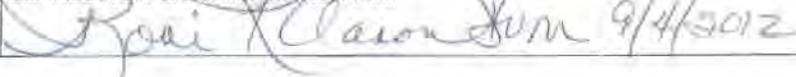
57 Supervisory reviews only state the non-compliances found, a determination of minor, major or critical and the date agreed upon for correction if corrective actions were not immediate. Then the supervisor initials when the task has been completed and records outstanding issues from previous audits. There is no request for or submission by the establishment for corrective actions or preventive measures nor is there any recording by the supervisor of what the establishment may have done for CAs in the immediately corrected items or may have orally suggested for PMs. Formal NCRs are not written following these reviews. The use of the Annex was sporadic, not present with every supervisory review as designated by HQ after the 2009 FSIS audit. 9 CFR 327.2(a)(2)(iii)(A) This was noted by the auditor.

NOTE: This establishment has an active food defense plan.

61. NAME OF AUDITOR

Rori K. Aaron, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Procesadora y Empacadora de Carnes del Norte S.A. de C.V. Km 13.5 Carr. San Felipe S/N Col. Cuatro Division 2 Cerro Prieto Mexicali, Baja California, Mexico	2. AUDIT DATE 09/06/2012	3. ESTABLISHMENT NO. TIF 301	4. NAME OF COUNTRY MEXICO
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	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.	X	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	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.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	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)		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	NA
29. Records	X	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Mexico TIF 301, 09/06/2012, beef slaughter and deboning

10 The establishment released the slaughter floor for SENASICA pre-operational sanitation verification in a state that demonstrated that implementation of sanitation procedures had not been conducted appropriately and that establishment verification of these procedures was also inadequate. The SENASICA inspector found numerous non-compliances including blood spots, fat, and product residue on product contact surfaces, eroding under-surfaces of platform stands, flies, edible and inedible product containers mixed together, the plastic covering of a not-in-use ice machine was dusty and covered with small debris, string from plumber's take and tape pieces and sticky residues on many surfaces and a number of areas of condensation. SENASICA retained control of the area until all deficiencies had been corrected. Production began 3.5 hours late. Both establishment and SENASICA records showed that this is a frequent occurrence with trends developing, especially in the area of condensation. 416.13 This was handled entirely by SENASICA.

10/51 Operational sanitation monitoring had been conducted appropriately in the past, but now was only done following the lunch-time clean-up before employees returned to the floor. This had not been noted by either SENASICA in-plant personnel or in the supervisory reviews. The establishment agreed to return to the past method of conducting operational sanitation monitoring while operations were in progress. 9 CFR 416.12 This non-conformance was noted by the auditor.

10/51 SSOP plan did not include a frequency for operational sanitation. There were frequencies noted on the records. Neither SENASICA daily inspection tasks nor supervisory reviews had noted this non-compliance. The establishment will correct their SSOP operational sanitation plans immediately. It is obvious from the content of the company SSOPs and the tasks completed by in-plant SENASICA personnel as well as the supervisory reviews, that a review of the establishment's actual SSOPs does not occur, only a review of records. 9 CFR 416.12(d), 416.17 This non-compliance was noted by the auditor.

12/51 Establishment SSOP records did not include adequate detail in the descriptions of findings, corrective actions or preventive measures to allow for adequate verification by SENASICA. Neither SENASICA daily inspection tasks nor supervisory reviews had noted this non-compliance. The establishment agreed to include more detail. 9 CFR 416.16(a) This non-compliance was noted by the auditor.

13/22/51 Both SSOP and HACCP records of the establishment did not include corrective actions (CAs) that accurately described the actions taken. Many of these were simply listed as "told supervisor" or "told maintenance" rather than any real actions. Recorded preventive measures (PMs) were non-existent. Neither SENASICA in-plant or supervisory records had identified these non-compliances. The establishment agreed to make these changes to their records. 9 CFR 416.16, 416.17, 417.3, 417.8

18 The establishment records show very few failures for zero tolerance. SENASICA records show frequent failures for zero tolerance. SENASICA has written NRs and letters to the establishment, but has either not received a response or the actions have been ineffective. This was also noted by the CCA personnel accompanying the auditor. The in-plant SENASICA personnel are working with their state supervisor to solve this problem. 9 CFR 417

19/51 The HACCP plan CCP verification lacked the observation of the monitor in the zero tolerance CCP and the calibration of process monitoring equipment in the deboning temperature CCP. The establishment agreed to add these to their plan. Neither the SENASICA records nor the supervisory reviews had identified this non-compliance. 9 CFR 417.4 (a)(2)(i),(ii), 417.8

29/51 The generic *Escherichia coli* (*E. coli*) program records did not include statistical process control charts but the establishment was using the sponging method of sample collection. There also was no moving window for 13 day analysis of results. Even though SENASICA had done a review of the program just last month, they only used the FSIS Basic *E. coli* checklist and neither the in-plant personnel nor the supervisor had noted this non-compliance. The establishment promised to correct these non-compliances. This demonstrates that SENASICA does not really understand how to review generic *E. coli* programs. There is no guidance from the CCA on how to accomplish these reviews. This is an on-going finding from past audits of TIF establishments and lack of adequate supervisory oversight; this was the first audit of this establishment as it was just recently certified by SENASICA. 9 CFR 310.25(a)(3)(ii) The auditor noted this non-compliance.

41 Condensation was present in many area of the establishment. The establishment has no written program for condensation, but only wipes as they see it themselves or it is pointed out by SENASICA. Records show patterns and trends for this condensation. Establishment states they have contacted a third party to evaluate their ventilation system and are addressing the problem. 9 CFR 416.4(d) This was handled entirely by SENASICA.

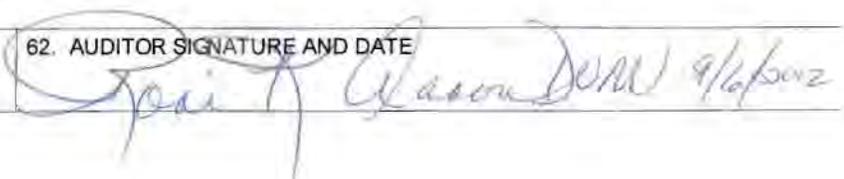
NOTE: SENASICA claims to be doing humane handling (HH) audits, but no documentation exists. CCA HQ is in the process of a pilot program (at other establishments) for SENASICA in the area of HH and documentation of such. At this point in time there is no CCA requirement for documentation of HH verification audits.

NOTE: Supervisory reviews are well done as the State Supervisor has developed her own follow-up form that does include the CAs and PMs and SENASICA verification. As the NOMs are going away, the whole supervisory review form will have to be re-written from HQs but some of the ideas of her form would be good for inclusion as that develops. The establishment is using NRs effectively and also writes letters but is getting good CAs and PMs in the response to those letters.

61. NAME OF AUDITOR

Rori K. Aaron. DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Kurson Kosher, S.A. de C.V. Eduardo Vera Gutierrez 555-A Colonia Pueblo Nuevo Zapotlan de Juarez 42190 Hidalgo, Mexico	2. AUDIT DATE 09/03/2012	3. ESTABLISHMENT NO. TIF 517	4. NAME OF COUNTRY MEXICO
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Mexico TIF 517, 09/03/2012, multi-species kosher processing

Although multi-species processing is occurring in the establishment, only beef is currently certified for export to the U.S.

10/51 SSOP plan did not include a frequency for operational sanitation. There were frequencies noted on the records. Neither SENASICA daily inspection tasks nor supervisory reviews had noted this non-compliance. The establishment will correct their SSOP operational sanitation plans immediately. It is obvious from the content of the company SSOPs and the tasks completed by in-plant SENASICA personnel as well as the supervisory reviews, that a review of the establishment's actual SSOPs does not occur, only a review of records. 9 CFR 416.12(d), 416.17 This non-compliance was noted by the auditor.

12/51 Establishment SSOP records did not include adequate detail in the descriptions of findings, corrective actions or preventive measures to allow for adequate verification by SENASICA. Neither SENASICA daily inspection tasks nor supervisory reviews had noted this non-compliance. The establishment agreed to include more detail. 9 CFR 416.16(a) This non-compliance was noted by the auditor.

51 SENASICA in-plant personnel only write non-compliance records (NCRs for Mexico) for SSOP and HACCP non-compliances. All other non-compliances are handled by letters to the establishment. In this establishment, these letters do not require corrective actions (CAs) and preventive measures (PMs) and the establishment responses do not include specific CAs and PMs; also the letters do not show any evidence of SENASICA verification as would be shown if the NCR form was used. The use of these letters is acceptable to the CCA. State supervisory reviews had not noted this lack of verification. 9 CFR 416.17, 417.8, 327.2(a)(2)(iii)(A) This non-compliance was noted by the auditor.

57 Supervisory reviews only state the non-compliances found, a determination of minor, major or critical and the date agreed upon for correction if corrective actions were not immediate. Then the supervisor initials when the task has been completed and records outstanding issues from previous audits. There is no request for or submission by the establishment for corrective actions or preventive measures nor is there any recording by the supervisor of what the establishment may have done for CAs in the immediately corrected items or may have orally suggested for PMs. Formal NCRs are not written following these reviews. The use of the Annex was sporadic, not present with every supervisory review as designated by HQ after the 2009 FSIS audit. 9 CFR 327.2(a)(2)(iii)(A) This was noted by the auditor.

61. NAME OF AUDITOR
Rori K. Aaron. DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Aaron DVM 9/3/2012