



United States Department of Agriculture

Food Safety and
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Dear Dr. Fragoso,

The USDA, Food Safety and Inspection Service (FSIS) conducted an on-site audit of Mexico's meat and poultry inspection system from July 15 through August 13, 2014. Enclosed is a copy of the final audit report. The comments received from the Government of Mexico are included as an attachment to the report.

If you have any questions, please feel free to contact me directly at jane.doherty@fsis.usda.gov.

Sincerely,

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
MEXICO

July 15 – August 13, 2014

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

April 26, 2016
Food Safety and Inspection Service
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Executive Summary

This report describes the outcome of an ongoing equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from July 15 – August 13, 2014, to determine whether Mexico's meat and poultry inspection system (MMPIS) continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled. Mexico exports beef, pork, and processed poultry products to the United States. Poultry products are only permitted if they are derived from raw poultry obtained from FSIS approved slaughter establishments or from other countries that FSIS has determined to have an equivalent poultry slaughter inspection system.

The audit was designed to verify equivalence of the six system components of MMPIS, i.e., Government Oversight (Organization & Administration), Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), Sanitation, Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residues Control Program, and Government Microbiological Testing Programs. Prior to the on-site audit, FSIS reviewed the self-reporting tool (SRT) provided by the Central Competent Authority (CCA) and reports of corrective actions that the CCA implemented to address findings in the FSIS 2012 audit and point-of-entry (POE) violations detected in 2013 and 2014.

The on-site audit reviewed management, supervision, and administrative functions at the CCA headquarters in Mexico City; at the official reference laboratories; at four regional offices; and at six local inspection offices (located at three cattle slaughter and processing operations, one swine slaughter operation, and two meat and poultry products processing establishments) to verify whether the national system of inspection, verification, and enforcement is being implemented as described by the CCA. Currently, Mexico has certified 56 establishments as eligible for export to the United States.

The 2014 audit results show that MMPIS is designed to meet FSIS equivalence requirements. FSIS auditors identified several concerns that the CCA has addressed by implementing immediate corrective actions and proffering long term measures that address the reported findings. FSIS will expect the CCA to submit evidence that demonstrate that the long term corrective actions were effectively implemented, and that they adequately address FSIS's concerns expressed in this report. FSIS will base future equivalence verification activities on the information provided.

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I. INTRODUCTION

FSIS conducted an ongoing equivalence verification of MMPIS that included an on-site audit of the performance of the system that took place from July 15 through August 13, 2014.

Mexico is eligible to export meat and poultry products to the United States. Poultry products are only permitted if they are derived from raw poultry obtained from FSIS approved slaughter establishments or from other countries that FSIS has determined to have an equivalent poultry slaughter inspection system. (Because Mexico is not equivalent for poultry slaughter, how the system addresses *Campylobacter* is not addressed in this report.) During fiscal year (FY) 2014, Mexico shipped 277,337,229 lbs. of meat and poultry products to the United States. From that amount, 150,499 lbs. were refused entry at FSIS' POE because of violations of food safety standards related to a zero tolerance for fecal, ingesta, and milk contamination (ZT) and the presence of chemical residues. In FY 2013, Mexico shipped 251,605,606 lbs. of the same products as above to the United States, and from that amount, FSIS refused entry to 172,961 lbs. due to POE violations related to ZT.

This audit was conducted pursuant to 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 Poultry Products Inspection Act (21 U.S.C 451 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906),
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction /Hazard Analysis and Critical Control Point (PR/HACCP) regulations, and
- The Poultry Products Inspection Regulations (9 CFR Part 381).

The audit standards applied to evaluate MMPIS included applicable legislation determined by FSIS to be equivalent as part of the initial equivalence process, as well as any subsequent equivalence determinations that have been made under provisions of the World Trade Organization's Sanitary/Phytosanitary Agreement.

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify whether Mexico's food safety system governing meat and poultry production continues to be equivalent to that of the United States, with the ability to produce and export products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six components of the program: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residues Control Program, and (6) Microbiological Testing Programs to determine if they are equivalent and can maintain the system's equivalence. FSIS also verified the

adequacy of the corrective actions implemented by the CCA of the MMPIS to address the reported findings of the FY 2012 FSIS audit and POE violations for FY 2013 and 2014.

III. AUDIT METHODOLOGY

For this equivalence verification audit, FSIS followed its established four-phase process: planning, execution (on-site), evaluation, and feedback, as described below.

The first phase involved an analysis, at FSIS headquarters, of the documents and data related to the pertinent corrective actions implemented by the CCA to address previous audit findings within the six equivalence components of the MMPIS. FSIS also reviewed data on product types and volumes imported from Mexico, as well as POE testing results and other data collected by FSIS since the last on-site audit. The auditors examined reports provided by the CCA on the verification of corrective actions implemented by sectors of the system, i.e., government offices, establishments, and laboratories, to address the POE violations reported by FSIS. Additional information reviewed by the FSIS auditors included the responses provided by the CCA via the SRT, outlining the current structure of the inspection system, and identifying significant changes that have occurred since the last FSIS audit in 2012.

The analysis of available information enabled the implementation of the second phase of the process in which FSIS performed on-site audits of the CCA headquarters office, four regional offices, six local inspection offices, six out of 56 establishments certified to export meat and poultry products to the United States, and two government laboratories. The six selected establishments included one swine and three bovine slaughter/fabrication facilities that export raw intact and non-intact beef and pork products, and two establishments that export processed products to the United States, one, fully cooked-not shelf stable beef, pork, and poultry products and the other marinated beef. The audit also included visits to the government laboratories that conduct microbiological and chemical analysis of product samples.

Audited Sites		#	Locations
Central Competent Authority	Headquarters	1	Mexico City
	Regional Offices	4	Yucatán, Veracruz, Nuevo León and Mexicali
	Local Offices	6	TIF 152, TIF 101, TIF 100, TIF 418, TIF 120, and TIF 301
Laboratories		2	<ul style="list-style-type: none"> • Official microbiology laboratory • Official residue laboratory
Establishments		6	<ul style="list-style-type: none"> • Three beef slaughter and processing establishments • One swine slaughter • Two meat and poultry products processing establishments

During the on-site verification, FSIS assessed the CCA’s ability to oversee the sectors of the system by conducting document reviews, interviews, and observations at the visited sites. The FSIS auditors reviewed management, supervision, and administrative functions of the CCA at headquarters and at the state and local inspection offices. FSIS verified that the national system of inspection, verification, and

enforcement was being implemented in accordance with Mexico's equivalent statutes and regulations applicable to food safety. The verification also assessed the adequacy of corrective measures implemented by the CCA to address the findings of the audit of the MMPIS conducted by FSIS in 2012 and the POE violations FSIS reported to the CCA in FY 2013 and 2014. In addition, FSIS assessed the adequacy of the CCA's oversight of its technical support by reviewing documentation related to the accreditation of the functions of the official laboratories to ensure that they continue to operate in accordance with internationally recognized technical and administrative standards.

FSIS paid particular attention to the extent to which the sectors of the MMPIS – government offices, establishments, and laboratories – interact at different levels to control hazards and prevent non-compliances that threaten food safety. The review placed particular emphasis on the CCA's ability to provide oversight through supervisory reviews, which ensure that the meat and poultry inspection system continues to operate in accordance with the regulations of the government of Mexico and fulfill the eligibility requirements specified in United States Code of Federal Regulations Title 9, Chapter III, Subchapter A, Part 327 and Part 381 Subpart T.

The evaluation phase of the equivalence verification audit takes place throughout the entire audit. The FSIS auditors evaluated information throughout audit verification process. The auditors, as well as FSIS management at FSIS headquarters, assessed the results of the evaluations to determine whether the CCA's performance is consistent with the information provided to FSIS, and whether the MMPIS remained equivalent to the United States' meat and poultry inspection system. The results of the evaluation are discussed in the corresponding sections of this report for each of the system's components.

The final phase of the audit process is feedback, which begins with FSIS providing a draft audit report to the CCA and giving them an opportunity to comment on the contents of the report. After reviewing the CCA comments and responses to all findings, FSIS finalizes the report. The CCA develops an action plan to address any issues raised by the audit, and FSIS monitors the resolution of all issues.

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

The first of the six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import eligibility requirements state that a foreign inspection system must be designed and administered by the national government of the foreign country, with standards equivalent to those of the United States system of meat and poultry inspection. Accordingly, FSIS evaluated this component, by first conducting a review and analysis of documentation submitted by the CCA, as support for the responses provided in the SRT. Subsequently, FSIS conducted on-site record reviews, interviews, and observations at targeted or randomly selected government offices, establishments, and laboratories of the system.

FSIS assessed the organization and administration of the MMPIS and confirmed that Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) - Secretariat of Agriculture, Livestock, Rural Development, Fisheries, and Food, in accordance with Mexican legislation, continues to serve as CCA in charge of managing the overall regulatory oversight of animal health protection, slaughter of animals, and processing of foods of animal origin. In the same manner, the Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) - National

Service of Food and Agriculture Health, Safety, and Quality, continues to be the sub-agency of SAGARPA that administers inspection services to regulate the meat and poultry industry in Mexico. Furthermore, within SENASICA, the Dirección General de Inocuidad Agroalimentaria, Acuícola y Pesquera (DGIAAP)- General Directorate of Food and Agriculture Safety, Aquaculture, and Fishing, has a subordinate office, the Dirección de Establecimientos Tipo Inspección Federal (DETIF)-Directorate of Federal Inspection Type Facilities, which continues to provide direct oversight to establishments Tipo Inspección Federal (TIF) that produce meat and poultry products for domestic and international markets, including those certified for export to the United States.

FSIS verified that MMPIS is organized and administered by the government of Mexico, and the CCA remains structured as reported during the 2012 FSIS audit. To improve the coordination and harmonization with United States requirements, the DETIF did create the position of United States Exports Coordinator, who serves as source of information on export requirements and maintains direct communication with SENASICA inspection officials and the TIF establishments involved in the production of meat and poultry products for export to the United States.

FSIS verified that Title 6, Chapter III, Article 218 of Mexico's regulatory requirements mandates that the CCA issue regulatory measures to ensure uniform and standardized processes, conditions, and requirements to which TIF establishments must adhere, and that officials must enforce. The CCA implements that mandate by developing and distributing technical manuals containing instructions and operational guidance to TIF establishments and inspection officials. Furthermore, the CCA exercises its legal authority to ensure that meat and poultry products eligible for export to the United States come from establishments that fulfill the regulatory requirements for certification.

Regional Supervisors (RS) assigned to field operations in the inspection service are also mandated to verify compliance of establishments with the regulatory requirements and to document deficiencies observed during periodic evaluations of construction and maintenance of their facilities and equipment, as well as sanitary processing operations. In turn, in-plant personnel verify on a daily basis that the establishments comply with the applicable regulations and the United States export requirements by assessing the adequacy of the food safety and sanitation programs and by collecting product samples for species identification and microbiological and chemical residue analyses. The vast majority of products exported to the United States by certified Mexican meat and poultry establishments consist of single ingredient products. Processed products are mostly raw-marinated cuts produced at establishments where inspection officials maintain direct control of the use of restricted ingredients and ensure that products are properly labeled.

In addition to the CCA, there are other regulatory agencies of the Mexican government enforcing compliance with the regulations regarding product weight and economic adulteration, which are the same as the relevant prohibitions in all foods offered for domestic commerce. Those agencies sporadically collect product samples to verify their compliance with national regulatory requirements. Re-inspection of products and sampling conducted by FSIS at POE in FY 2013 and FY 2014, have not detected any products that deviate from FSIS food chemistry standards. However, as the volume of processed meat and poultry products exported to the United States increases, the fact that the CCA does not verify that those products meet specific FSIS's requirements for food chemistry analysis related to the accuracy of formulations and economic adulteration could undermine the ability of the CCA to effectively ensure the compliance of certified establishments with FSIS standards.

During the audit conducted in 2012, the FSIS auditor assessed the adequacy of supervisory records and reported that the records did not document corrective actions and preventive measures. As a response, the CCA proposed introducing a form that would ensure that the RS adequately and uniformly recorded all portions of implemented corrective actions. However, during this audit, FSIS reviewed reports of supervisory evaluations of certified establishments and observed that inadequacies in documentation practices persist. The FSIS auditors observed that recordkeeping is not being uniformly implemented by the RS. Some RS record the results of establishment reviews on forms that have not been standardized and controlled by the CCA as official forms. In addition, one RS, rather than generating an official record of the results of the establishments' reviews, obtains a copy of the reported deficiencies recorded by the company's technicians/inspectors, along with a written commitment on the part of the company to implement corresponding corrective actions.

During the on-site audit, the FSIS auditors verified that the CCA maintains a regulatory presence at establishments that are certified to export meat and poultry products to the United States. A review of government and establishment records conducted by FSIS showed that in-plant government officials identify non-compliances, take official control actions, require corrective actions, and document all events. These officials also conduct daily evaluations of the facilities in accordance with a schedule of procedures that includes verification and inspection activities. Inspection personnel ensure that the food safety programs of the establishment are effective, and that livestock is adequately handled, slaughtered, and safely processed into food for human consumption.

In 2012, the FSIS auditor reported that the way in which deficiencies were communicated by inspection personnel to the regulated establishments was not being uniformly implemented. The CCA replied to that concern during the entrance meeting, stating that inspection personnel were allowed to communicate concerns to the establishments via meeting minutes, non-compliance records, or formal official letters. FSIS reviewed government records maintained at the establishments and observed that veterinarians-in-charge (VIC) were in fact using those options to present written requests for corrective actions to the establishments. Formal official letters to management and non-compliance records are both approaches that the CCA has approved for the VIC to communicate identified deficiencies that exclusively pertain to food safety. However, when formal letters are used, the documented regulatory process stops with the written proffered corrective actions provided by the establishments. In this manner, the records kept by some of the VIC's do not show that the VIC verified whether the corrective actions were in fact implemented, and that they adequately corrected the reported deficiency. The relevance of this deficiency is discussed further in the HACCP component portion of this report.

The CCA reports that to attain and maintain competent and qualified personnel in certified establishments, individuals who conduct in-plant inspection and verification must have completed academic work to obtain a veterinary degree from a recognized university and have obtained mandatory professional accreditation from the central government to work as veterinarians. The hiring process requires that a candidate for an in-plant inspector position successfully complete a CCA administered examination to earn an authorized-veterinarian (AV) status. Upon becoming AV, the candidate can then be hired by the *Organismo Internacional Regional de Sanidad Agropecuaria* (OIRSA)¹ as *Médico Veterinario Responsable Autorizado en Establecimientos TIF* (MVRATIF) or as *Medico Veterinario*

¹ OIRSA is the Spanish acronym for the International Regional Organization for Plant and Animal Health, an internationally recognized intergovernmental organization that provides technical assistance to the Ministries and Departments of Agriculture and Livestock of nine member states: Belize, the Dominican Republic, Guatemala, Honduras, Nicaragua, Panama, El Salvador, Mexico and Costa Rica

Official Responsable (MVOR) hired by the Mexican Federal Government to work as an inspector at TIF certified establishments.

The CCA informed FSIS that in-plant veterinary inspectors that join the inspection workforce receive induction training on the fundamentals of meat and poultry inspection and administrative responsibilities, which is complemented with on-the-job training to learn the methods and procedures needed to enforce the laws and requirements of the program at the inspected establishments. FSIS confirmed that, as reported in the CCA's SRT, both MVOR and MVRATIF stationed at certified slaughter/fabrication establishments have completed academic work to earn a veterinary degree, received accreditation from the central government, passed the certification test administered by SENASICA, and completed additional courses in HACCP and Meat Science. Additional documents reviewed by FSIS at the regional and local government offices make evident that the CCA provides opportunities for MVOR and MVRATIF to develop their technical competencies by enrolling in an online training program provided by the Universidad Autonoma de Mexico. That training program includes assignments that the officials must complete to earn a Food Safety Diploma. These courses are paid by OIRSA for the MVRATIF and the Federal government for the MVOR. CCA officials at headquarters monitor the performance of personnel engaged in the training program and ensure that the completion of assignments takes place within the allocated time frames.

A review of supervisory records and observations made by the FSIS auditors at the establishments indicate that the new veterinary inspectors are assigned to complete on-the-job training under the direct supervision of the VIC or another experienced veterinarian. The VIC or designated trainer veterinarian ensure that trainees master the required skills and abilities prior to permitting them to conduct their assigned duties independently. From that point on, the RS conducts periodic assessments of the proficiency of the veterinary inspectors, and the VIC regularly monitors their work for acceptability. However, supervisory documents maintained by RS and VIC fail to demonstrate the procedure and method they follow to objectively evaluate the skills and abilities of the veterinary inspectors.

The records presented by in-plant officials, and the information provided by the CCA, demonstrate that the MMPIS has a protocol in place to respond to FSIS reports of POE violations. The first step of the protocol is an immediate temporary suspension of certification of eligibility to export to the United States. That suspension is maintained until the establishment investigates the cause of the deviation and presents to the CCA a written plan of action to prevent recurrence. The plan of action is subsequently evaluated by the RS and VIC, and the suspension is lifted after the CCA concludes that the plan is effective.

FSIS verified that the CCA provides oversight to its technical support by auditing the performance of laboratories. In 2012, the FSIS auditor reported that the CCA did not provide oversight to the laboratories in the system. During the current audit, the CCA officials indicated that the reported statement was not correct and provided additional information that confirms that the central laboratories are part of the organizational scheme of the inspection system and receive oversight by the CCA. Officials stated that the Centro Nacional de Servicios de Constatacion en Salud Animal (CENAPA) is the national government laboratory that, under oversight by the CCA, serves as the national reference laboratory. The two analytical laboratories that comprise CENAPA analyze products and tissues for microbiological and chemical residues to verify that food safety controls are effective, and that meat and poultry products meet United States standards. CENAPA is a member of the Red Interamericana de Laboratorios de Analisis de Alimentos (RILAA), a network organization of laboratories in the Americas that conduct food analysis to which FSIS laboratories also belong.

Representatives of the CCA conduct regular evaluations, at each laboratory, of the technical and administrative aspects of CENAPA in accordance with the ISO/IEC Guide 17025. In order to maintain accreditation, the laboratory participates in inter-laboratory proficiency testing activities, by which analysts are periodically evaluated to establish their technical proficiency and expand their scope of analytical skills. This aspect of the system is further described in the Microbiological and Chemical Residue program components portions of this report.

The CCA is an agency of the national government of Mexico that provides oversight to the meat inspection system. The CCA organizes and administers standards equivalent to those of the Federal system of meat and poultry inspection in the United States. The ongoing analysis of available data and on-site audit verification activities indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. However, as discussed above, there are four matters related to government verification of certified establishments that require the attention of the CCA. Specifically: (1) The CCA does not conduct food chemistry analyses of processed meat and poultry products exported to the United States to verify the accuracy of formulations or to detect economic adulteration; (2) The RS recordkeeping practices are not being uniformly implemented throughout all regions of the system, and supervisors use forms that have not been standardized and designated by the CCA as official forms; (3) The records kept by VIC do not document in a consistent manner the corrective actions implemented to correct reported deficiencies; and (4) The procedure in use to assess the technical competence of in-plant inspection officials does not require the supervisor to conduct a periodic review to elaborate on how the regulatory knowledge and inspection skills (i.e., ante-mortem, post-mortem, and handling in connection with slaughtering) of individual in-plant personnel are assessed

FSIS assessed this component by conducting document reviews, site observations, and interviews of government officials, in combination with a review of the SRT and accompanying supporting documents. Based on the results of the audit, FSIS requests that the CCA implement effective corrective actions and submit documentation to FSIS showing that they have been effectively implemented to adequately address the findings presented in this report and, in that manner improve the performance of its inspection system to demonstrate its continued equivalence to FSIS.

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

The second of the six equivalence components that the FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. An equivalent inspection system operates an appropriate regulatory framework that demonstrates equivalence with FSIS requirements, including, but not limited to, HACCP, sanitation, chemical residue and microbiological sampling, humane handling, ante-mortem inspection (AMI), post-mortem inspection (PMI), establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to establishments eligible to export meat and poultry products to the United States. The evaluation of this component included an analysis of information provided by the CCA in the SRT and accompanying documents, as well as interviews and observations made during the on-site equivalence verification audit.

The FSIS review of government documents demonstrates that the CCA of the meat and poultry inspection system of Mexico has statutory authority to deliver inspection to all certified slaughter and processing establishments. Furthermore, the CCA has developed rules to require that official inspection

personnel, government laboratories, and certified establishments ensure that meat and poultry products meet equivalent United States requirements. In addition, the system has regulatory requirements for in-plant continuous presence on line inspection while slaughter activities take place and official inspection of products and premises, while processing activities are conducted, control of inedible and condemned materials, and periodic supervisory reviews of certified establishments.

The regulations enforced by the CCA state that government veterinarians must conduct AMI of all the animals the establishment is planning to slaughter on a particular day no more than 24 hours before slaughter is commenced. Instructions issued by the CCA to inspection personnel provide complete details on how to conduct AMI, including the decisions and dispositions that are to be made by the inspectors; i.e., whether the animals are to be passed, retained, and condemned. Additional regulatory requirements mandate that establishments provide facilities for the government veterinarian to properly conduct AMI and for further examination of segregated suspect-livestock. FSIS verified that MVOR and MVRATIF stationed at certified establishments adequately conduct AMI. The government veterinarians verify that livestock arrive accompanied by official documentation used to control their movement from region to region and to track animals and their products back to primary centers of production. In addition, inspection personnel verify the compliance of establishments with humane handling and humane slaughter regulations by conducting direct monitoring of livestock handling and stunning activities and by observing the establishment's implementation of its Humane Handling of Livestock program. Results of observations are documented and violations are brought to the attention of plant management to be resolved. FSIS verified that the CCA has assigned official veterinarians to conduct AMI at each TIF slaughter establishment and observed that AMI is adequately performed in accordance with equivalent CCA instructions.

The CCA reported in its SRT that veterinarians, who are government officials, conduct appropriate post-mortem inspection and verify further processing of products in official establishments. Official slaughter inspectors also verify the adequacy of dressing procedures, collect official verification samples of tissues that are to be analyzed by chemical and microbiological laboratories, and verify that establishments collect and analyze samples of their products to verify efficacy of sanitary controls. The FSIS auditors visited four certified slaughter establishments to assess PMI activities by reviewing government and establishment records and observing slaughter activities. FSIS confirmed that PMI is being conducted in accordance with the instructions and standards developed by the CCA, which are consistent with the United States' requirements for the examination of heads, viscera, and carcasses of slaughtered livestock.

The FSIS auditors observed at four slaughter establishments the post-mortem inspection procedures conducted by official veterinary inspectors and determined that inspection procedures for heads and viscera are consistently conducted following routines that include observations, lymph node incisions, and palpations to detect abnormalities. At these establishments, plant personnel along the slaughter line made a significant effort to ensure that dressing defects and contamination were adequately removed at a point before verification of zero tolerance by official inspection. However, at two of the four audited establishments, the FSIS auditors observed that the design of the carcass inspection stations made the performance of carcass inspection difficult. At one establishment, the inspector appeared to have difficulty inspecting the forequarters of carcasses because the platform where the inspector stood was in a fixed position, and the most anterior portion of the carcasses on the rail required the inspector to bend down to inspect that portion of the carcass. At another establishment, the inspector was not provided with a mechanism to stop the line to control the flow of carcasses. The FSIS auditors observed that the inadequate design of the carcass inspection stations has the potential to contribute to inadequate

detection of sanitary dressing defects that could weaken the ability of the system to meet this core requirement within this component.

The CCA requires that in-plant officials evaluate the conditions in the different areas of the establishments to ensure their compliance with the regulatory requirements that apply to the construction and maintenance of facilities and equipment. FSIS reviewed government and establishment documents and determined that government officials and establishments identify deficiencies related to the maintenance of the facilities and correct them to comply with the regulations of the program.

FSIS determined that, in accordance with the rules of the Mexican meat and poultry inspection system, the CCA ensures that daily inspection and verification is delivered to TIF establishments that export their products to the United States. Furthermore, as part of the oversight provided to the system, the RS conduct regular on-site reviews of the performance of the food safety systems of the TIF establishments certified to export to the United States. These periodic evaluations are designed to assess the level of regulatory compliance maintained by certified establishments, the performance of in-plant officials, and the action plans implemented by the establishments in response to FSIS's reports of POE violations. However, the FSIS auditors observed that supervisory records that document the results of past establishments review did not contain entries that could demonstrate that the RS had identified for correction the deficiencies described in this report.

The CCA, in accordance with its legal mandate, has developed rules that require that official inspection personnel, government laboratories, and certified establishments ensure that meat and poultry products meet equivalent United States requirements. The FSIS auditor verified that the CCA has adequately incorporated into its regulatory controls, recent regulatory changes pertaining to the sampling protocols for chemical residues and the additional Shiga toxin producing *Escherichia coli* recently adopted by FSIS. In addition, the system has regulatory requirements for in-plant continuous official inspection of slaughter and processing activities, control of inedible and condemned materials, and periodic supervisory reviews of certified establishments. The ongoing analysis of available data and on-site audit verification activities indicates that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. However, as discussed above, there are deficiencies in the manner in which the CCA uses its statutory authority that suggest that there is room for improvement. Specifically, the design of the carcass inspection stations is preventing inspectors from adequately completing their assigned tasks, and supervisory records do not demonstrate that the RS had identified, during supervisory reviews, the deficiencies described in the different portions of this report.

FSIS assessed this component by conducting document reviews, site observations, and interviews of government officials, in combination with a review of the SRT and accompanying supporting documents. Based on the results of the audit, FSIS requests that the CCA implement effective corrective actions and submit documentation to FSIS showing that they have been effectively implemented to adequately address the findings presented in this report and, in that manner improve the performance of its inspection system to demonstrate its continued equivalence to FSIS.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was Sanitation. An equivalent inspection system provides requirements for sanitation, sanitary handling of products, and

development and implementation of sanitation standard operating procedures to prevent direct product contamination.

The evaluation of this component included a review and analysis of the information provided by the CCA in the sanitation component portions of the SRT and observations gathered during the on-site verification audit of six certified establishments and their corresponding government offices. FSIS reviewed legislation, regulations, and official instructions to verify that the CCA exercises its legal authority to require establishments to develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

FSIS determined that the CCA requires that establishments develop and adhere to written programs that prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions. The CCA also requires that establishments monitor the adequacy of the construction of their facilities, and develop maintenance programs for equipment and structures. Government officials are to verify the compliance of certified establishments with sanitation requirements on a daily basis by reviewing establishment records and verifying the adequacy of the establishments' sanitation monitoring practices. Inspection personnel also review the written sanitation programs prepared by the establishments to verify that they describe the procedures they will follow to prevent direct product contamination by cleaning and sanitizing surfaces prior to the start of operations and monitoring production practices during operations.

FSIS verified the adequacy of the on-site functions of in-plant government officials by conducting observations of production activities, by reviewing monitoring records for pre-operational and operational sanitation that is maintained by the establishment and in-plant inspection personnel, and by observing inspection personnel as they evaluate the sanitary conditions of the plants. In addition, FSIS verified that the CCA had addressed the findings reported during the audit conducted by FSIS in 2012 and the corrective actions that the establishments and the CCA implemented at the in-plant level to address POE violations related to fecal matter and ingesta contamination on raw beef products that FSIS reported in FY 2013.

In 2012, the FSIS auditor reported that the monitoring frequency for operational sanitation did not detect or report inadequate flow of product that resulted in product falling on the floor, the inadequate maintenance of equipment and facilities, and an incomplete description of deficiencies entered in the sanitation records and insanitary dressing procedures. The CCA responded that during a national meeting of TIF establishments' supervisors, the negative sanitation findings were discussed, and instructions were issued for in-plant officials to require that establishments revise their procedures for monitoring operational sanitation, improve the description of deficiencies, and adequately maintain their facilities. The CCA also stated that establishments had been asked to adopt measures to respond to changes in conditions in the slaughter room by reducing the line speed when the type of cattle slaughtered could compromise sanitary dressing.

The CCA also reported to FSIS the results of the official verification of corrective actions implemented by the establishments to control and prevent POE violations related to fecal matter and ingesta contamination on raw beef products. As indicated in the CCA report, establishments had intensified their sampling of finished product and had improved the lighting at inspection sites. In the ante-mortem area, the holding pens were cleaned at a greater frequency, arriving livestock were thoroughly cleaned before slaughtering, and establishment personnel were re-trained on good manufacturing practices. In addition, the CCA proffered in the report that it would provide training to in-plant inspectors on

verification activities to monitor the adequate control of fecal material and ingesta, thereby providing a zero tolerance for such contamination during dressing procedures.

The FSIS auditors reviewed inspection records, observed the dressing procedures at the slaughter establishments, and verified that light intensity at carcass inspection stations is sufficient, and that establishment personnel are inspecting the surfaces of the carcasses and effectively trimming defects. However, during the review of establishments' sanitation monitoring records, the FSIS auditors observed that the records show that product contamination and insanitary handling of edible beef feet are repeatedly occurring. The establishment had not correctly determined the root cause of the contamination events, and the corrective actions implemented are not effectively preventing the reoccurrence of contamination of carcasses and parts. Furthermore, while assessing the implementation of sanitary dressing procedures, the FSIS auditors observed that management at the establishment is not effectively preventing the continued insanitary handling of edible beef feet.

From a review of establishment and official records, FSIS verified that in-plant inspection personnel use their authority to enforce sanitation regulations and follow instructions contained in their training manuals to accomplish their tasks. FSIS also observed government officials assess the adequacy of pre-operational and operational sanitation monitoring and verified that the establishments follow their sanitation program. However, at one certified processing establishment, the FSIS auditors observed that in the post-lethality areas, there were multiple structures with surfaces difficult to clean and sanitize that had potential to become sources of contamination if left unchanged. Furthermore, in the raw production areas of two of the six establishments audited, the overhead structures had accumulated residue that the cleaning crews had failed to remove.

These negative findings, although addressed by prompt corrective measures by the establishments, indicate that the instructions issued by the CCA in response to the findings of the 2012 audit are not being fully implemented. There is a persistent need for establishments to better monitor the sanitary conditions of their equipment and facilities, and the auditor observed that implementation of the operational sanitation program was inadequate to prevent the recurrence of contamination during the dressing of carcasses. In addition, in-plant officials need to assess in a more critical manner the implementation of sanitation programs to identify and require the correction of potential sources of product contamination.

Mexico's meat inspection system has legal authority and a well-documented regulatory framework to implement equivalent requirements for Sanitation programs. The sanitation concerns identified by FSIS during this audit were promptly addressed with short-term corrective actions. The results of FSIS's on-site audit call into question whether the CCA can continue to maintain the equivalence of the MMPIS for this component. As a result, FSIS requests that the CCA implement long term, effective corrective actions and submit documentation to FSIS showing that it has effectively implemented these actions, and that they adequately address the findings presented in this report. The CCA also needs to demonstrate that these actions will improve the performance of its inspection system to the extent that it will continue to be equivalent to the U.S. system.

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

The fourth of the six equivalence components that the FSIS auditors reviewed was HACCP. This component of the system calls for the CCA to use its legal authority to require that certified

establishments develop, implement, and maintain HACCP systems for the production of meat and poultry products for export to the United States. The evaluation of this component included a review and analysis of the responses provided by the CCA in the HACCP portion of the SRT and supplemental documents that included inspection manuals and samples of forms used by officials to document results of monitoring activities. Additionally, FSIS conducted on-site observations and conducted interviews of official personnel to assess the operations of the eligible establishments and government offices.

The auditors verified that the CCA has issued regulations that mandate that establishments develop, implement, and maintain HACCP systems. For that purpose, the CCA provides instructions to inspection personnel that are supplemented with training materials and regulatory guidelines. The regulations also mandate that in-plant officials verify the adequacy of the establishments' implementation of their HACCP plan every day, by reviewing records and performing measurements to monitor critical control points (CCP). The rules also delegate to the RS the responsibility to assess the design and implementation of the establishments' HACCP systems during periodic supervisory visits, to verify that they remain aligned with the seven principles of HACCP and in compliance with regulatory requirements of the MMPIS.

FSIS conducted observations, document reviews, interviews of personnel, and analyses of information to confirm that the MMPIS imposes regulatory requirements for the development, implementation, and maintenance of HACCP systems in establishments prior to their receiving authorization and certification to produce meat and poultry products for export to the United States. In addition, FSIS confirmed that slaughter establishments include in the slaughter HACCP plan a CCP for ZT contamination (i.e. fecal matter, ingesta, and milk contamination). Furthermore, FSIS verified that in-plant officials and the RS periodically assess the adequacy of establishments' HACCP systems. Records and documents, as well as on-site observations, indicate that CCA officials assess the design and execution of the HACCP programs, including the adequacy of the hazard analysis, monitoring of CCPs, corrective actions, recordkeeping, and verification activities. In addition, the records document that in-plant officials, verify daily, during each production shift, the adequacy of CCP monitoring procedures by reviewing the establishments' HACCP records and by conducting hands-on verification of adequacy of critical control points.

During this on-site audit, FSIS verified the adequacy of the corrective actions implemented by the CCA to address the findings of the audit conducted by FSIS in 2012, and the corrective actions implemented by slaughter establishments and government offices to respond to POE violations reported by FSIS in FY 2013 and 2014 related to deviations from the CCP for ZT.

In 2012, the FSIS auditor reported that CCP monitoring and calibration of measuring devices had been omitted from establishments' HACCP plans, government officials detected greater CCP for ZT deviations than the establishment, and the CCP for ZT deviations were not consistently documented as HACCP plan implementation deficiencies. The CCA indicated that those audit findings were discussed with all RS, and that instructions had been issued for in-plant personnel to verify that HACCP plans included monitoring and calibration activities. The establishments' sampling procedure was also revised to sample 100 percent of carcasses and officials have received instructions to verify that deviations were consistently documented as HACCP deficiencies. The CCA also reported that to address eight POE violations related to deviations from the CCP for ZT, the frequency of HACCP verification activities was increased to better monitor the implementation of the establishments' HACCP plans. Establishments reassessed their prerequisite program for sanitary dressing procedures, and better lighting was provided to the technicians and slaughter line workers to improve the examination of

carcasses and to prevent spillage of contaminants from the gastric system. CCA officials also reported that they had conducted reviews of the establishments' HACCP system and had concluded that they were working as intended. FSIS has not detected POE violations involving fecal matter, ingesta, or milk in raw beef products from Mexico since July 2014.

To verify the adequacy of the corrective actions and verification activities reported by the CCA, the FSIS auditors reviewed inspection and establishments' records and conducted in-plant observations during production hours. The verification activities demonstrated that, in accordance with regulatory requirements, establishments maintain HACCP documents that include flow of product charts, written hazard analyses, and HACCP plans and information that supports the results of the hazard analysis, the decisions made to establish CCPs, and critical limits. Additionally, as part of the verification activities, the FSIS auditors assessed the adequacy of HACCP recordkeeping by reviewing CCP monitoring and corrective actions records generated by the establishments, as well as records documenting monitoring of prerequisite programs. The verification activities demonstrated that design and implementation of the HACCP system at establishments was overall acceptable. However, the FSIS auditors observed the following deficiencies in the implementation of HACCP systems that require the attention of the CCA:

- At three of the four slaughter establishments that were audited, records for corrective actions did not correctly identify the root cause for ZT contamination deviations, and the establishments continued to handle such deviations without successfully preventing their recurrence. Furthermore, either the RS or in-plant officials had not detected this inadequacy in the implementation of the establishments' slaughter HACCP plan.
- Officials notify establishment of identified deviations from a CCP and take official control actions to ensure implementation of the HACCP plan, but they do not verify that establishments document the corrective actions implemented.

It is evident from the above listed findings that there is a need for the CCA to further evaluate the official HACCP verification procedures followed by in-plant inspectors stationed at certified establishments to ensure adequacy of dressing procedures and consequently prevent POE violations. CCA representatives accompanying the auditors indicated that the establishments would be required to implement immediate corrective actions to address the reported findings. FSIS requests that the CCA provide supporting documentation to FSIS on the measures implemented to address the findings presented in this report and, in that manner improve the performance of its inspection system.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUES CONTROL PROGRAM

The fifth of the six equivalence components that the FSIS auditors reviewed was Chemical Residues Control Programs. This component pertains to the regulatory requirement that the inspection system have a chemical residue control program that is organized and administered by the national government. The program must include random sampling of internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

FSIS conducted an assessment of this component of the MMPIS by reviewing the information provided by the CCA in the SRT, as well as the 2012 Programa de Monitoreo y Control de Residuos Toxicos y Contaminantes en Alimentos de Origen Animal (Monitoring Program and Control of Toxic Residues and Contaminants in Food of Animal Origin), (NRCP). The FSIS auditors also conducted interviews and document reviews at government offices and slaughter establishments. The FSIS auditors verified that the CCA coordinates the regulatory efforts of several agencies of the Mexican government that are

part of the NRCP. The NRCP, therefore, has statutory authority to ensure regulatory control and prohibition for the use of veterinary drugs and chemical compounds that could enter the food chain.

As described in the documents provided by the CCA, the NRCP covers animal species slaughtered for the productions of meat and poultry products destined for domestic and international markets. Additional information provided by the CCA to FSIS indicates that the NRCP maintains monitoring and surveillance activities by implementing sampling protocols for tissues and products at primary centers of production and at slaughter establishments. The designing of the sampling protocols has taken into consideration the registered use of a chemical compound of interest, likelihood of a residue occurring in animal tissues, extent, and pattern of use of the compound, incentives for misuse, known persistence of the compound in the environment, past monitoring results, and requirements of importing countries.

The CCA delegates to the official reference laboratory, CENAPA, the analysis of tissues and product samples. This laboratory plays a central role in the implementation of the program by defining official analytical protocols, serving as a center of technical assistance, and serving as a source of subject matter experts that assist the CCA in developing regulatory standards. The FSIS auditors interviewed laboratory personnel and reviewed documents to establish the mechanisms that are in place to ensure that CENAPA provides good quality technical support to the system. The documents reviewed demonstrate that the Entidad Mexicana de Acreditacion (EMA)-Mexican Entity for Accreditation, a private institution specializing in the evaluation of laboratories and verification agencies in accordance with internationally recognized standards, is the accrediting body that assesses the performance of CENAPA on behalf of the CCA. EMA audits all functions of CENAPA every four years using the ISO 17025 standard and lately adding ISO 17043, an additional set of requirements necessary for CENAPA to adequately fulfill its obligation to evaluate. It also assesses the ability of approved laboratories to meet the ISO 17025 standard. EMA conducted the last accreditation review in 2013, and the technical and administrative functions of the laboratory were found to conform to international standards.

FSIS observations and documents conducted at the establishment level demonstrated that government inspectors collect samples in accordance with uniform instructions issued by CENAPA and sample animal tissues and products to determine their acceptability as a source of human food.

Among the findings contained in the FSIS 2012 audit report, the auditor indicated that in-plant inspection officials collected muscle samples for residue analysis but did not retain the carcasses from which the samples had been collected. The CCA has addressed that finding by issuing instructions for field personnel to retain the carcasses that are sampled and to release the held carcasses after the negative results are obtained.

The results of the sample analyses are compiled and analyzed by the CCA which assembles and distributes the data in annual reports, which are distributed to stakeholders and trading partners.

The NRCP results reported for 2012 show that in the bovine muscle tissues that were sampled, 16 samples were positive for clenbuterol and five positive for zilpaterol out of 169 tested. In muscle swine tissues, one sample tested positive for clenbuterol and one tested positive for zilpaterol out of 147 samples tested. The report also shows that in bovine, six muscle samples out of 169, and in swine, seven samples out of 147, tested positive for nitrofurans. Results reported for 2013 show that four out of 193 bovine samples tested positive for clenbuterol, and three out of 193 tested positive for nitrofurans. In swine, one out of 150 tested positive for chloramphenicol and two positive for nitrofurans. The data shows that the sampling protocol was expanded to include a greater number of samples, and that the

occurrence of clenbuterol in beef muscle samples has decreased in bovine and swine. The results also show that violations related to zilpaterol in bovine and swine muscle were not found in 2013. In each instance in which violations were detected, the Mexican authorities conducted a trace-back investigation to determine the likely cause of the violations, issued warning letters to the producers, and provided advice on adequate recordkeeping to livestock owners.

In June 2014, FSIS notified the CCA of a residue violation involving zilpaterol in bovine muscle, and in July 2014 FSIS notified the CCA of an additional violation involving sulphamethazine in bovine muscle. These issues were discussed with the CCA at headquarters and at the national reference laboratory to obtain information concerning the actions taken by the authorities to prevent recurrence of these types of violations. The CCA officials indicated that in each of the instances, once the POE violation notification was received, the CCA issued a temporary suspension of eligibility to export products to the United States to the involved establishments. At the time of the audit, the CCA was conducting an evaluation of the action plan presented by the relevant establishments to prevent the recurrence of those types of violations. Laboratory managers indicated that the equipment currently in use for the detection of beta agonists such as clenbuterol and zilpaterol is of high sensitivity, and that the analytical methodology employed by the laboratory has been validated. Furthermore, CENAPA officials provided documents that demonstrate that analysts assigned to the detection of beta agonist residues have completed the qualification requirements, and that their competency has been assessed and found to be satisfactory. Subsequent to these actions, there have been no chemical residue violations in meat and poultry products from certified Mexican establishments at POE.

In conclusion, FSIS verified that the CCA has a chemical residue control program that is organized and administered by the national government in accordance with United States' requirements. The document analyses and on-site audit verification of the Government Chemical Residues Control Program component criteria indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditors reviewed was Microbiological Testing Programs. This component pertains to the microbiological analysis programs organized and administered by the CCA to verify that meat and poultry products destined for export to the United States are safe and wholesome.

To verify whether Mexico maintains equivalence of this component, FSIS reviewed the responses provided by the CCA in the Pathogen Reduction Standards section of its SRT that describe generic *E. coli* and *Salmonella* sampling, as well as Mexico's *E. coli* O157:H7 and non-O157 Shiga toxin producing *Escherichia coli* (STEC) control programs. In addition, FSIS assessed on-site the daily implementation of the microbiological sampling and testing of product conducted by establishments and the CCA.

The main document reviewed to assess this component of the MMPIS was the Manual para la Reduccion de Patogenos (MRP) - (Pathogen Reduction Manual) issued by the CCA for use by in-plant inspection officials, CENAPA, and the establishments. The MRP provides a description of responsibilities, legal authorities, and operational procedures that are in use by all sectors of the system to ensure compliance with the export requirements of the United States. Pathogens covered in the manual include STEC, *Listeria monocytogenes*, and *Salmonella spp.*

Additional documents reviewed during this ongoing equivalence audit demonstrate that the CCA administers a national regulatory microbiological monitoring program for establishments producing meat and poultry products for export to the United States. The program is designed to monitor sanitary dressing procedures and production practices and to verify the effectiveness of each certified establishments' food safety controls.

FSIS confirmed that the microbiology laboratory of CENAPA and the approved private laboratories are authorized by the CCA to sample and analyze meat and poultry products from certified establishments. Prior to initiation of product testing, private laboratories must successfully complete an evaluation of their performance, conducted by CENAPA, and be listed in the official roster of approved laboratories. The functions of approved private laboratories are limited to the analysis of samples for *Salmonella* and *Listeria monocytogenes* (*Lm*) under the oversight of CENAPA. The CCA has delegated to CENAPA the responsibility of assessing the adequacy of the performance of private laboratories. CENAPA auditors evaluate on a yearly basis the adequacy of the quality control and administration of each private laboratory, and the technical competence of analysts in accordance with standard ISO 17025.

FSIS audited the national microbiological laboratory during the on-site verification portion of this audit and reviewed official documents including the reports and records containing the results of evaluations, proficiency tests, and verification of corrective actions. The FSIS auditors verified that EMA had audited each laboratory facility, including the scope of accreditation, adequacy of the records that are generated, and the corrective actions that are taken to address the results of past audits in accordance with the guidance provided by ISO 17025. Reports of the audits are distributed to CCA officials who have the responsibility of ensuring the continuity of adequacy of the technical support for the system. FSIS established that the CCA maintains oversight of the national laboratory to ensure that it follows official protocols and performs its functions adequately. The CENAPA ensures that the approved laboratories that provide services to the certified establishments maintain a level of performance that is consistent with the international standards that analytical laboratories must meet.

Documents reviewed by FSIS and observations made at certified slaughter establishments demonstrate that the testing of raw products for generic *E. coli* and *Salmonella* is conducted at slaughter facilities. Collection and handling of samples is conducted by government inspectors in accordance with the instructions provided in the MRP, which is issued by the CCA. The samples are analyzed at CCA-approved, CENAPA-accredited laboratories that are required to use FSIS methods of analysis and to report the results of the analyses to CCA officials and establishments at the same time.

The findings contained in the FSIS 2012 audit report indicate that the CCA had not provided instructions to in-plant inspection officials on how to verify the adequacy of the establishments' generic *E. coli* sampling programs. The CCA indicated that work instructions have been provided to all in-plant veterinarians specifying the steps they must take to evaluate the adequacy of the establishments' sampling programs. FSIS conducted record reviews and interviews and conducted on-site observations at the slaughter establishments to confirm that the corrective actions had been adequately implemented to address the reported finding. In-plant officials demonstrated a good understanding of the official procedures to verify implementation of the establishments' generic *E. coli* sampling programs. Furthermore, a review of the sampling programs showed that their design is consistent with the instructions provided by the CCA, meets FSIS requirements, and includes actions that would be taken when the tolerances were exceeded.

The CCA also issued regulations that are imposed upon producers that require raw products that include carcasses and comminuted product to be sampled by inspection officials. The samples are analyzed at authorized, approved laboratories for the presence of *Salmonella*. In a manner similar to the FSIS methodology and using FSIS performance standards, Mexican authorities implement a sampling protocol and corresponding regulatory actions based on FSIS regulations. FSIS verified that the establishments visited during this audit had completed their sampling set for the year and had not exceeded the established limits.

CCA officials presented to FSIS a request for an equivalence determination of its STEC control program. The initial request was followed up by the submission of an updated version of the MRP that includes revisions that address testing protocols and actions to be taken during the implementation of the STEC control program that includes O157:H7 and the additional six strains recently introduced by FSIS and test and hold procedures. FSIS has concluded that the STEC control program presented by the CCA meets equivalence criteria. The program specifically designates CENAPA as the only laboratory that performs screening and confirmation analyses of official samples. In addition, the number of verification samples collected is proportional to production volume, and the minimum frequency is one sample per month.

CENAPA provided documents for review by FSIS that included the results of testing raw ground beef components for STEC. The documents demonstrate that analysts have developed an acceptable proficiency in conducting microbiological analysis using FSIS methodology. The STEC program has detected positive samples during screening and has confirmed the presence of strains such as O103, O157, and O111. In each instance, officials and establishments were notified, and actions were taken in accordance with the instructions provided in the MRP. In addition, on each occurrence, follow-up sampling, including 16 additional samples, was implemented, and no positive results were obtained.

As part of the introduction of the additional testing required for beef products, CENAPA managers have initiated development programs for analysts and actively participate in capacity building projects by which in-plant personnel are trained to learn sampling methods and the handling of samples for microbiological analysis. As reported for the chemical residues laboratory, the analysts at the microbiology laboratory are evaluated on a yearly basis, and training is provided to expand the scope of their competency.

The CCA reports in its SRT that it requires that establishments producing ready-to-eat products (RTE) recognize *Lm* and *Salmonella spp.* as biological hazards reasonably likely to occur in the post-lethality environment. Correspondingly, it requires that the establishments' food safety control systems include measures to address those biological hazards and requires the official sampling of products for *Lm* and *Salmonella* and of surfaces in the post-lethality environment for *Lm* to assess the efficacy of the prevention and control programs implemented by certified establishments. Observations conducted by the FSIS auditors at one establishment that processes RTE products for export to the United States demonstrated that in-plant officials collect product samples at a frequency established by the CCA, and that the establishments follow test and hold protocols for each lot of product destined for export to the United States. The laboratory reports for sampling conducted by both the establishment and government officials show that there have been no positive results for *Lm* and *Salmonella spp.* in RTE products. Sampling of RTE products conducted by FSIS at POE also have not shown any positive results for the presence of *Lm* and *Salmonella spp.*

The microbiological testing programs component of the MMPIS is organized and administered by the national government to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with the United States requirements. The document analyses and on-site audit verification of the Microbiological Testing Programs component indicate that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

The 2014 audit results show that MMPIS is designed to meet FSIS equivalence requirements. FSIS auditors identified several concerns that the CCA has addressed by implementing immediate corrective actions and proffering long term measures that address the reported findings. FSIS will expect the CCA to submit evidence that demonstrate that the long term corrective actions were effectively implemented, and that they adequately address FSIS's concerns expressed in this report. FSIS will base future equivalence verification activities on the information provided.

APPENDICES

APPENDIX A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sigma Alimentos Noreste, S.A. de C.V. Cantu Leal N 1320 Sur. Col. Buenos Aires C.P. 64580 Monterrey, Nuevo Leon, Mexico	2. AUDIT DATE July 30, 2014	3. ESTABLISHMENT NO. TIF 100	4. NAME OF COUNTRY Mexico
	5. NAME OF AUDITOR(S) Francisco Gonzalez and Juan Rodriguez		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	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Processing establishment

10. In the post-lethality area there were several areas of the walls that had crevices and rough surfaces difficult to clean and sanitize. There were also multiple pipes grouped in the overhead space creating a section difficult to clean and sanitize.

In the hotdog processing room, there were dark particles on the upper surfaces of the vacuum packer. There were also multiple areas in which the establishment had applied caulking material as sealant but the manner in which the caulking material had been applied created multiple areas difficult to clean that in instances had begun to form mold on its surfaces. The employee assigned to cleaning condensation from overhead structures, moved from the post-lethality area to the non-post-lethality area and back, using the same mop to clear condensation.

38. There was a fly resting on the electric cord supplying electricity to a lamp in the mixing room area adjacent to the raw product area.

39. Several overhead structures in the raw product area had become discolored by accumulated organic residue that remained on their surfaces. There was also a constant drop falling from a cooling unit on to the pathway where personnel and products moved through.

51. Recordkeeping is part of the regulatory monitoring of the production activities of the establishment. The use of formal letters to management is a current practice. The establishments acknowledges receipt of letter and responds in writing providing corrective actions that include preventive measures, however, there is not a follow up step that documents that the implemented measures were acceptable to the government or that the matter, if unresolved, would be escalated.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM and Juan Rodriguez, 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 Frigorífico de la Cuenca del Papaolapan, S.A de C.V Predio La Ceiba, Km. 25+100 Carretera Tinajas Ciudad Aleman CP 95100 Tierra Blanca, Veracruz, Mexico	2. AUDIT DATE July 25, 2014	3. ESTABLISHMENT NO. TIF 101	4. NAME OF COUNTRY Mexico
	5. NAME OF AUDITOR(S) Francisco Gonzalez and Juan Rodriguez		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.

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9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Bovine slaughter establishment

15. A review of HACCP monitoring records kept by the establishment shows that the establishment has inaccurately identified the root cause of contamination of carcasses with feces. Consequently, the preventive measure that the establishment presents inadequately addresses the deviation. Inspection personnel had brought to the attention of the company the need for an adequate corrective measure for the occurrence of fecal contamination, however, the verification of the corrective actions has failed to recognize the inadequate analysis of the root cause of the deviations. The hazard analysis prepared by the establishment has not considered the additional STECs as pathogens reasonably likely to occur in the slaughter of cattle. In addition, contamination of carcasses during skinning has occurred and documented, however, the establishment has not considered biological hazards at this point of the process.

38. FSIS auditors identified flying insects in the dry storage rooms which connects with the raw production areas via a chute used for transporting boxes.

55. The carcass inspection station was modified to provide to the inspector the ability to inspect the uppermost portions of the carcass hindquarters. FSIS auditors observed that the modification to the inspection station, while it solved the initial problem, created a condition which prevented the inspector from adequately inspecting all surfaces of the carcass forequarters being presented to the station.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM and Juan Rodriguez, 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 Grupo Porcicola Mexicano, S.A. de C.V. KEKEN Km. 3.5 Carretera Uman-Poxila CP 97390 Uman, Yucatan, Mexico	2. AUDIT DATE July 22, 2014	3. ESTABLISHMENT NO. TIF 152	4. NAME OF COUNTRY Mexico
	5. NAME OF AUDITOR(S) Francisco Gonzalez and Juan Rodriguez		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Swine Slaughter establishment

10. In-plant inspection personnel consistently identify issues related to the maintenance of the facilities and communicates sanitary concerns that require management's attention to the maintenance supervisor, who is not listed among the parties responsible for the implementation of SSOP. Furthermore, the SSOPs do not contain provisions by which the maintenance supervisor is granted authority and responsibility to respond to sanitary concerns expressed by the inspection service.

22. The establishment indicates in its hazard analysis that it uses carcass chilling as a prerequisite program to prevent growth of microorganisms on carcasses. However, the record of temperature measurements maintained as part of the program, does not show who actually verifies the temperature of the carcasses and makes the required entries in the record. Furthermore, the record does not contain any indications that, as indicated in the program, a supervisor has verified that monitoring of the temperatures is being done correctly by the responsible parties.

39. In the fabrication room, FSIS auditors observed indicators of inadequate programming for the cleaning of overhead structures. Pieces of equipment located above work areas had accumulated residue and appeared discolored as a result. There were also structures that once had been kept in place by electric tape that had become unglued and created surfaces difficult to clean. In another section of the room the auditors observed a section of the wall that had many small openings and gaps that could allow accumulation of contaminants and another section where a wall panel at the wall-floor junction that was torn and remained partially unattached creating additional areas difficult to clean and sanitize.

61. NAME OF AUDITOR

Francisco Gonzalez DVM and Juan Rodriguez, 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 Carretera San Felipe. Colonia 4, Division 2. Del. Cerro Prieto C.P. 21700. Mexicali, Baja California, Mexico	2. AUDIT DATE August 6, 2014	3. ESTABLISHMENT NO. TIF 301	4. NAME OF COUNTRY Mexico
	5. NAME OF AUDITOR(S) Francisco Gonzalez and Juan Rodriguez		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Beef Slaughter/Deboning establishment

11. A review of establishment’s SSOP monitoring records shows that the establishment does not identify the root cause of deficiencies accurately. Consequently, the preventive measures proffered do not target accurately the sanitary deficiency to be prevented.

51. The VIC communicates sanitary concerns and deficiencies in need of abatement to the establishment via formal letters and sometimes with non-compliance reports (INO Form 04). As observed and reported for other locations, the regulatory process of notifying the establishment orally or by means of formal letters, does not include documenting conclusions or escalation of issues. FSIS observed that deviations identified by government officials at the Critical Control Point (CCP) for Zero Tolerance (ZT) were documented by the officials in official forms not shared with the establishment and that the findings of ZT deviations were orally communicated to the establishment. This practice does not permit the VIC to evaluate the implemented corrective actions and planned preventive measures needed to prevent recurrence of deviations.

61. NAME OF AUDITOR

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION SuKarne Produccion, S.A. de C.V. Km. 13.5 Carretera Mexicali-Tijuana Poblado La Rosita C.P. 21610 Mexicali, Baja California, Mexico	2. AUDIT DATE August 5, 2014	3. ESTABLISHMENT NO. TIF 120	4. NAME OF COUNTRY Mexico
	5. NAME OF AUDITOR(S) Francisco Gonzalez and Juan Rodriguez		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	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	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Beef Slaughter establishment

18. The government officials have brought to the attention of management findings of deviations identified at the critical control point (CCP) for zero tolerance (ZT) for visible feces, ingesta and milk contamination by means of formal letters and non-compliance records. A lack of an adequate response has prompted the veterinarian in charge (VIC) to mandate that the establishment increase the monitoring frequency to a 100 percent examination of carcasses. However the establishment’s HACCP monitoring records for the CCP for ZT document that monitoring continues at the frequency stated in the HACCP plan, less than the monitoring frequency mandated by the VIC. In addition, the monitoring records document corrective actions that inaccurately identify the root cause of the repetitive deviations and provide inadequate preventive measures.

51. In-plant inspection personnel assess the ability of the establishment to prevent direct product contamination, as deficiencies in implementation of the good manufacturing practices (GMPs) program rather than to assess those events as deficiencies in the implementation of the SSOP program of the establishment. Records maintained by inspection personnel and the establishment show that insanitary practices recur without the officials taking additional regulatory action or the establishment instituting adequate preventive measures.

When identified, deficiencies are presented to management by means of letters, the establishment provides a written response, but inspection personnel do not maintain records indicating they have verified that the corrective actions and/or preventive measures proffered by the establishment were implemented as written by the establishment. Official record keeping includes the use of formal letters to communicate sanitary concerns to the establishment. However, as was observed at other local inspection offices, that documentation process does not include a step that reports that the government officials have verified the adequacy of the corrective actions implemented by the establishment and thus bring the case to closure.

55. During the tour of the establishment, FSIS auditors observed that the carcass inspector did not exert official authority in an acceptable manner and was not provided with a mechanism to stop the line to ensure that trimming of contamination was adequately accomplished or to conduct additional carcass examinations.

11. Inspection personnel had brought to the attention of plant management, both orally and in writing, the observed recurrence of cattle arriving with a full rumen that caused spillage of gastric contents during dressing. The establishment allegedly had implemented corrective actions and/or preventive measures. However, the FSIS auditors observed that spillage was occurring as cattle were shackled and raised after stunning, thus showing that the corrective actions and/or preventive measures were either not implemented or remained ineffective.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM and Juan Rodriguez, 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 Praitmit S.A de C.V. Articulo 123 No. 1208. Col. Talleres C.P. 64480 Monterrey, Nuevo Leon, Mexico	2. AUDIT DATE July 31, 2014	3. ESTABLISHMENT NO. TIF 418	4. NAME OF COUNTRY Mexico
	5. NAME OF AUDITOR(S) Francisco Gonzalez and Juan Rodriguez		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
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8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Processing establishment (beef products)

During the audit of this establishment FSIS did not identify any concerns.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM and Juan Rodriguez, DVM

62. AUDITOR SIGNATURE AND DATE

APPENDIX B: Mexico's Comments to Draft Final Audit Report

SAGARPA

Secretaría de Agricultura,
Ganadería, Desarrollo Rural,
Pesca y Alimentación
[Secretary of Agriculture,
Livestock, Rural
Development, Fisheries, and
Food]



SENASICA
SERVICIO NACIONAL DE INSPECCIÓN
DE CADERA Y CALIDAD
AGROALIMENTARIA

[National Health Service, Food
Safety, and Quality]

**GENERAL BUREAU OF FOOD SAFETY,
AQUACULTURE, AND FISHERIES**

Memo No. B00.04.01.01.-1333 /2016

Mexico City, MAR 31, 2016

MS. JANE HENRIQUES DOHERTY
INTERNATIONAL COORDINATION EXECUTIVE
FOOD SAFETY AND INSPECTION SERVICE (FSIS)
U.S. DEPARTMENT OF AGRICULTURE (USDA)

Reference is made to the draft report of the Food Safety and Inspection Service (known by the English acronym FSIS) following its audit visit to our country during the period July 15 to August 13, 2014, and referred to the Directorate General on July 2, 2015, to assess the Government's food safety system regarding the production of meat and poultry products intended for export to the United States.

On that subject, and in following up on the various email communications regarding the matter in question, attached hereto please find the explanatory comments and action plan developed by SENASICA in its preliminary response to the aforementioned draft report, with the expectation that the actions proposed by this National Service will be sufficient to afford consideration of the recommendations submitted by the FSIS auditors.

Lastly, I appreciate your kind support in completing the final report on the indicated audit.

There being nothing further, please accept our warmest regards.

**SINCERELY
THE DIRECTORATE GENERAL**

[Signature]

MVZ HUGO FRAGOSO SÁNCHEZ



[TN: General Bureau of Food Safety, Aquaculture, and Fisheries]

Ccs: **MVZ ENRIQUE SANCHEZ CRUZ**, CHIEF DIRECTOR OF SENASICA – For information
MVZ JOAQUIN BRAULIO DELGADILLO ALVAREZ, DIRECTOR GENERAL OF ANIMAL HEALTH – For information
Mr. DAVID WOLF, AGRICULTURAL AFFAIRS, U.S. EMBASSY – For information
Mr. JOSEPH LOPEZ, MANAGER OF AGRICULTURAL AFFAIRS, U.S. EMBASSY – For information
DR. ALICIA HERNANDEZ, AGRICULTURAL AGGREGATE AT THE U.S. EMBASSY IN MEXICO – For information

[Signature] FIS/MCORG

Boulevard Adolfo Ruiz Cortines No. 5010, Piso 7. Colonia Insurgentes Cuicuilco. Delegación Coyoacán. C.P. 04530.
Ciudad de México. Tel: (55) 5905-1300 Ext. 5105 and 51536 www.senasica.gob.mx



United States
Department of
Agriculture

Oficina para
Asuntos
Agropecuarios

Embajada de
los Estados
Unidos de
América

Paseo de la
Reforma 305,
Colonia
Cuauhtemoc

06500 Mexico,
D.F.

August 28th, 2015

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

Dear Dr. Doherty:

Attached is official communication #B00.04.01.4869/2015, dated August 25th, 2015, and signed by Dr. Hugo Fragoso Sánchez, General Director from the National Service of Health, Food Safety, and Food Quality (SENASICA). Through this letter, Dr. Fragoso is sending his comments in reference to the last meeting held in Washington on several issues of mutual interest.

We are providing a courtesy translation of the letter.

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

Sincerely,

Alicia Hernandez
Agricultural Attaché

Enclosures

COURTESY TRANSLATION

The National Service of Health, Food Safety, and Food Quality
Agro-Food, Aquaculture and Fishery Safety General Directorate

Memorandum B00.04.01.4869/2015

Mexico City, August 25th, 2015

DVM. JANE DOHERTY
International Coordinator Executive
USDA, FSIS, OIA, IID
Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 2143
Washington, D.C. 20250-3700

Dear Jane,

This is in reference to the Official Communication dated July 10, 2015 where you mention the details of our meeting held in Washington D.C. and enlist our mutual technical issues of interest on Food Safety. Below is my response to each point:

Final Project of the Audit made by FSIS to SENASICA

I confirm the reception of this report and also inform that once the analysis of the report finalized, we noticed that component 2 related to **the Legal Authority and Food Safety Regulation** (Inspection System Operation and Products Regulation) in the first paragraph asseverates that *-this component is designed to obtain the equivalence and is operating at an "appropriate" level-* later it points out *-"However, the results of this audit call into question if the ACC may keep the SIPCAM equivalence for this component"*.

On this respect, we consider that the last sentence contravenes the initial paragraph, besides there are not observations of such gravity that could reach this result conclusively. Based on this, we kindly request whether to rewrite the first comment, or the elimination of the second one from the report.

I also would like to express that we are currently working on the action plan in order to comply with the mentioned observations. This will be submitted on time, according to the stipulated dates.

Also, the draft of this report lacks the Annex A: Individual Audit Checklist. I kindly request your support to add the mentioned Annex to respond to the observations made to each one of the establishments.

Update of the Reference Terms FSIS-SENASICA

All the comments that SENASICA have made, have been attached electronically. We would like you to consider the opportunity that technicians from both agencies work together on terms and definitions for a better understanding on the document and particularly Annex 3.

Self-Reporting Tool and e-Authentication Register

Please find a CD attached with all the documents sent regarding the SRT for poultry when drawbacks aroused to access to the information.

In reference to the register process and Authentication Level 2, we have initiated this process and we have concluded 3 steps from 4. Up to date we have not received the confirmation e-mail.

Import Certificates- necessary changes to fulfill with FSIS import rules

It is very important that we could move forward on the e-certification for meat products. Therefore I kindly request a meeting in the following months between our correspondent electronic areas and technicians in charge of the zoo-sanitary requirements in order to speed up the mutual information exchange.

In reference to the Imports Inspection Format, we have translated it and our official personnel in charge have been instructed to fill it in, according to the HACCP criteria.

I kindly request your support for a new date to implement completely this measure on the products to be exported. We propose September 25, 2015. Likewise, we also request that in case of any mistake on filling in the format during its implementation, it does not represent a cause of rejection of the exported products.

Necessary Information for FSIS on POEVs

It is important to mention that all the supportive information of these investigations is filed by this office and they are focused on the requested points of interest made by your office.

The files of some of these POEVs were checked by the auditors who came in the last Audit on August 2014, and according to the Audit Report, Mexico has taken the necessary measures for the deviations, including suspension of establishments and requesting corrective actions that solve the deviations.

In reference to the report that you are requesting for each POV, I inform you that we are gathering the information and the correspondent summaries.

Likewise, I kindly request the necessary arrangements to receive information as detailed as demanded from your side, for each of the rejected imported products to Mexico by critical defects. This, because we have not received response to our notifying communications of identified rejections at the Ag Safety Inspection Offices at the border.

Violations for critical defects have been sent to the U.S. Embassy of Mexico individually and recently through Official Communications B00.04.01.1824/2015 and B00.04.01.03.4424/2015. They are being attached for your reference.

Receive my kind regards,

DVM Hugo Fragoso Sánchez
Director

Nº de Oficio B00.04.01.-4369/2015

México, D.F. a 25 AGO 2015

Ms. JANE HENRIQUES DOHERTY
EJECUTIVA DE COORDINACION INTERNACIONAL
UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)
PRESENTE

~~Estimada Jane~~ *Jane*

Hago referencia al comunicado de fecha 10 de julio del presente año, a través del cual comenta los pormenores y temas tratados durante nuestra pasada reunión en Washington, D.C. y asimismo enlista las cuestiones técnicas de interés mutuo para la seguridad alimentaria, a los cuales a continuación enlisto y doy respuesta:

Proyecto final de la auditoria que realizó el FSIS al SENASICA

Sobre el particular, confirmo la recepción del informe y le comento que una vez realizado el análisis de la información contenida, observamos en el componente 2 relativo a **la Autoridad Legal y Reglamento de Seguridad Alimentaria (Funcionamiento del Sistema de Inspección y Normatividad de los Productos)** que en una primera redacción se asevera que *-este componente está diseñado para mantener la equivalencia y que se encuentra operando a un nivel "adecuado"*, por otro lado más adelante señala *"Sin embargo, los resultados de esta auditoria ponen en tela de juicio si la ACC puede seguir manteniendo la equivalencia del SIPCAM para este componente"*.

Al respecto, le comparto que consideramos que este comentario contraviene lo señalado en el párrafo inicial y adicionalmente no hay observaciones de tal gravedad que hagan llegar a ese resultado de manera contundente. Derivado de lo anterior, se solicita amablemente que el mismo sea replanteado o en su caso se elimine el segundo comentario del informe.

2...



Nº de Oficio B00.04.01.4869 /2015

(2)

De la misma manera me gustaría poner de manifiesto que nos encontramos trabajando en el plan de acción correspondiente a fin de atender las observaciones señaladas, mismo que será remitido de acuerdo a los tiempos estipulados.

Asimismo el borrador del reporte carece del anexo A: Checklists de auditoría individual, por lo que solicito su valioso apoyo para que el mismo pueda ser integrado con la intención de atender las observaciones en cada uno de los establecimientos.

Actualización de los Términos de Referencia FSIS-SENASICA

Sobre el particular adjunto de manera electrónica el referido documento, que contiene los comentarios que el SENASICA ha realizado. Poniendo a su consideración la oportunidad de que técnicos de ambas agencias trabajen de manera conjunta en un apartado de términos y definiciones que apoyen al entendimiento del documento y en particular del anexo 3.

Self Reporting Tool y registro de e-autenticación

En relación al SRT de aves y sobre los inconvenientes que han tenido para tener acceso a la información, sirva encontrar adjunto al presente un CD que contiene todos los documentos que fueron remitidos en su momento.

En lo referente al registro y autenticación de nivel 2 le comento que ya hemos iniciado con ese proceso de registro y a la fecha hemos concluido el paso 3 de 4 por lo que estamos en espera del correo electrónico de confirmación que no ha sido recibido.

3..



Nº de Oficio B00.04.01.- 4869/2015

(3)

Certificados de Importación – cambios necesarios para cumplir con las reglas de importación del FSIS

En este tema, es muy importante que podamos avanzar en la certificación electrónica de los productos cárnicos, motivo por el cual agradeceré que en los próximos meses tengamos una reunión entre nuestras áreas informáticas y técnicos encargados de los

requisitos zoonosológicos, para establecer un plan de transición a medios electrónicos que nos permita agilizar nuestro intercambio de información.

En lo referente a la implementación del Formato de Inspección de Importación. Para que sea llenado conforme a los criterios de categorización de HACCP. Le comunico que hemos traducido el mismo y estamos dando instrucción a nuestro personal oficial, para el llenado.

Solicito su valioso apoyo, para que se nos conceda un plazo, no mayor al 25 de septiembre del año en curso para que la medida sea completamente implementada en los productos a exportar. Solicitando de igual manera que los errores de llenado en los que se pueda incurrir durante su implementación no causen el rechazo a la exportación de estos productos.

Información necesaria para el FSIS de las violaciones en punto de entrada (POEVs)

Es importante comentar que la información que respalda las investigaciones se encuentra en un expediente en esta oficina y en términos generales se atienden los puntos por ustedes indicados

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**DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA,
ACUÍCOLA Y PESQUERA**

"2015, Año del Generalísimo José María Morelos y Pavón"

Nº de Oficio B00.04.01.4869 /2015

(4)

El expediente de algunos de estos POEV fue revisado por los auditores en la pasada visita de agosto de 2014, y como se puede ver en el reporte de la auditoría, México toma las medidas ante las desviaciones incluso con la suspensión del establecimiento y la solicitud de las acciones correctivas que resuelvan la desviación.

En relación al informe que requiere sea proporcionado para cada uno de los POEV, le comento que estamos preparando la información y los resúmenes correspondientes.

En este mismo orden de ideas, aprovecho la oportunidad para solicitar sus valiosas gestiones para que se nos proporcione la información, con el mismo grado de detalle, para cada uno de los rechazos de producto por defectos críticos que se han tenido en los productos que se importan a México. Toda vez que no hemos recibido respuesta a nuestras comunicaciones en las que se notifican los rechazos identificados en las Oficinas de Inspección de Sanidad Agropecuaria (OISA 's) ubicadas en la frontera

Las violaciones por defectos críticos se han hecho llegar a la Embajada de los E.U.A en México individualmente y recientemente mediante los oficios B00.04.01.1824/2015 y B00.04.01.03.-4424/2015 se han hecho llegar en un resumen de las 13 desviaciones, mismo que adjunto para mayor referencia.

Sin más por el momento, reciba un cordial saludo.

**ATENTAMENTE
EL DIRECTOR GENERAL**

MVZ HUGO FRAGOSO SÁNCHEZ



C.c.p. **MVZ ENRIQUE SÁNCHEZ CRUZ**, DIRECTOR EN JEFE DEL SENASICA, Para conocimiento
MVZ JOAQUÍN BRAULIO DELGADILLO ÁLVAREZ, DIRECTOR GENERAL DE SALUD ANIMAL, Para conocimiento

V. del DGIAAP
FJS/MCORG

Draft Action Plan proposed by the ACC on the draft audit report created by FISIS (Food Inspection and Safety Service) resulting from the audit visit carried out in Mexico during the period of July 15 to August 13, 2014 for the evaluation of the government food safety program for the production of meat and poultry products intended to be exported to the United States of America, which was sent to this Agency on July 2, 2015.

CONSECUTIVE NO.	NOTE	ACTION PROPOSED BY ACC	Support documentation
1	The ACC does not perform chemical analysis of processed meats and poultry products that are exported to the United States to verify the accuracy of the formulations or to detect any type of adulterations (commercial adulteration).	<p>Currently, the National Service for Agricultural Health and Food Safety [Servicio Nacional de Sanidad Agropecuaria e Inocuidad Alimentaria - SENASICA] is developing and implementing a procedure for verification of labeling at exportation companies, by means of which once the label for the product to be exported to the US is validated by the USDA, the Federal Inspection Type [Tipo Inspección Federal - TIF] company authorized to export to the US will provide the FORM 7234.1 (Application for Approval of Labels Marking or Device) to the official veterinary staff for their file and verification program.</p> <p>Moreover, the official veterinary staff will take annual samples using a random process of an export product at each plant authorized for this purpose; the sample will be sent to a reference laboratory so that its labeling can be analyzed according to NOM-051-SCFI-SSA; the criteria for making a decision regarding the product to be sampled will be as follows:</p> <ul style="list-style-type: none"> - If the company processes more than one product, the MVO will take a sample of the product with the highest production volume in the company and/or - The product that contains the most food allergens. 	

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		The operational procedure will be reflected in the SRT and the approved version will be submitted to the headquarters of FSIS at the end of April 2016.	
2	The manner in which the Regional Supervisors report the practices and deficiencies found in the companies is not uniformly implemented across all regions in the system, and their records are often unofficial and are not designated by the ACC.	<p>The report on deficiencies is one of the routine activities that is carried out by the official veterinary staff responsible for regional oversight; it should be noted that the indicated observation mentions a difference in a single TIF Company regarding how the Monitoring form is presented; however, filling out these documents ensures that their content and their purpose are fulfilled without presenting significant differences, from which it is apparent that proper monitoring of the activities of the TIF company is carried out.</p> <p>Regarding what was observed on the official status of the records for SENASICA, any document issued by the official veterinary staff of the company, whether in the form of a report, note, or guide, and whether electronic or printed, acquires an official status. Notwithstanding the foregoing, SENASICA has prepared the following documents as part of a continuous improvement process that ensures uniformity in the Monitoring activities:</p> <ol style="list-style-type: none"> 1. Instructions for filling out the TIF Companies Monitoring Guide 2. Updating the Monitoring Guide 3. Implementation of instruction codes 1 to 6 for the evaluation of the Company. 4. Verification procedures for the 6 codes. 5. Procedure for Notification of Deviation and form for Notification of Deviation, 	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Establishments.</p> <p>Appendix 2 Manual for supervisors</p>

Draft Action Plan proposed by the ACC on the draft audit report created by FISIS (Food Inspection and Safety Service) resulting from the audit visit carried out in Mexico during the period of July 15 to August 13, 2014 for the evaluation of the government food safety program for the production of meat and poultry products intended to be exported to the United States of America, which was sent to this Agency on July 2, 2015.

		<p>These documents are currently in a period of trial and implementation and they will be officially communicated on May 30, 2016 by the Directorate of TIF Companies to official staff and they will be placed in the system's internal network.</p>	
<p>3</p>	<p>The records created by Western Veterinary Medicine [Medicina Veterinaria Occidental - MVO] do not consistently document that the corrective actions implemented to correct the deficiencies reported are adequate and are carried out by the company.</p>	<p>During the implementation of the audit, it became apparent to the auditors that the daily inspection that the official veterinary staff performs in the TIF company authorized to export is performed during all work hours, based on Article 107 of the LFSA, which enables identification and immediate tracking of deviations detected by the official veterinary staff so that it can visually see that the deviations have been corrected, which allows the company to continue operating routinely, since if a situation that compromises safety in product development should persist, the official veterinary staff has the legal authority to stop the company's operation, and retain the goods being produced and all finished products, as long as the processes are not compliant with the regulations of the destination country on the basis of Article 50 of the LFSA.</p> <p>However, and in order to provide more evidence of the activity that the official veterinary staff performs daily, the following document has been prepared:</p> <ol style="list-style-type: none"> 1. Instructions for the Notification of Deviations and the form for Notification of Deviations, whose main function will be to strengthen the recording and tracking of notifications of reported deviations done by the official veterinary staff of the company; it should be noted that these documents are currently in a period of trial and implementation and will enter into force on May 30, 2016. 	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p>

Draft Action Plan proposed by the ACC on the draft audit report created by FISIS (Food Inspection and Safety Service) resulting from the audit visit carried out in Mexico during the period of July 15 to August 13, 2014 for the evaluation of the government food safety program for the production of meat and poultry products intended to be exported to the United States of America, which was sent to this Agency on July 2, 2015.

<p>4</p>	<p>The procedure used to evaluate the efficacy and technical competence of the MVOs dedicated to inspection at the company does not require the supervisor to conduct a periodic review to evaluate in more detail the regulatory operation and inspection skills (e.g. ante mortem, post mortem inspections, and handling during slaughter) of the staff working at the company.</p>	<p>SENASICA considers it relevant to note that in the academic training profile for hiring Inspectors, it is an enforceable requirement that they have an academic degree or the equivalent to an undergraduate degree in Veterinary Medicine, which is why their technical capabilities from their training and entry are implicit from the moment they are hired, while they must also undergo a series of psychometric, knowledge, and reliability tests, and a final candidate interview, all based on the Federal Law on Professional Career Service.</p> <p>Also, the school curriculum in Mexico is five years and includes subjects such as inspection of meat products (e.g. ante mortem, post mortem inspection, handling during slaughter, sanitary inspection of animal products), which ensures the capability and technical competence of our inspectors.</p> <p>Added to the above, once the official veterinary staff is assigned to this National Service, as public servants, they are subject to an annual evaluation in which their hierarchical supervisor provides a rating based on the assessment of their individual discharge of the functions and goals that are consistent with their job description, which indicate the following:</p> <ol style="list-style-type: none"> 1. Ensure that products of animal origin produced in the federal inspection type (TIF) companies are safe, by checking and inspecting the Facilities and procedures, and monitoring compliance with the applicable regulations in this sector, in order to ensure the quality and safety of the country's meat industry. 2. Inspect the processes carried out in the TIF companies, in compliance with 	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p> <p>Appendix 3 Evaluation procedure for the performance of the MVOs</p>
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		<p>the applicable national and international regulations in the sector, with the purpose of ensuring compliance with the health and safety standards which are determined by the national and international markets.</p> <ol style="list-style-type: none"> 3. Inspect and monitor the meat products and sub-products for import, which are destined to go to a federal inspection type company, in accordance with national regulations to ensure their safety. 4. Monitor the implementation of good manufacturing practices (GMP) of the operators working in the TIF companies by verification of compliance with the established regulations and procedures, with the purpose of strengthening actions to ensure the safety and quality of products of animal origin for end consumers. 5. Monitor the quality of the water used in the processes of obtaining products of animal origin that are carried out in the TIF companies, ensuring that they comply with the regulations established for their use with the purpose of preventing their contamination. 6. Monitor the implementation of pest control programs in the TIF companies through physical inspection to monitor proper implementation, with the purpose of avoiding sources of contamination and to ensure the safety of the products of animal origin. 	
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		<ol style="list-style-type: none"> 7. <u>Inspect the health status of the animals to be used in the processes to obtain products of animal origin, in accordance with national and international regulations to ensure safety for the benefit of the end consumers.</u> 8. <u>Carry out ante mortem and post mortem inspection through the review of compliance with established procedures, with the purpose of preventing contamination of products of animal origin and ensuring their safety.</u> 9. Retain products of animal origin that are suspicious and perform sampling according to the techniques and procedures related to safety, with the purpose of sending them to the official laboratory for testing to determine the safety of these products. 10. Apply corrective security measures or destroy contaminated meat products and sub-products based on the diagnosis and results issued by the authorized official laboratory and in coordination with the supervisor of TIF companies in the region, with the purpose of preventing distribution and consumption of contaminated products. 11. Implement the monitoring program for residual toxins and contaminants through sampling of products of animal origin, with the purpose of following up on the results for consistent application of security and safety measures. 	
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		<p>12. Review the samples from products of animal origin obtained from TIF companies based on the applicable verification and inspection procedures, with the purpose of sending them to the official laboratory for analysis and diagnosis which will enable determinations to be made in regard to security and safety.</p> <p>13. Immediately report any disease that is required to be reported based on the required instrumentation to inform the department of epidemiological surveillance, with the purpose of ensuring animal health in the national territory.</p> <p>14. Review and monitor internal, national, and international audits, as well as monitoring visits through the established procedures and processes, with the purpose of evaluating the internal organization and generating actions to ensure the safety of products of animal origin in the country.</p> <p>As can be seen in paragraphs 7 and 8, they allude to inspection skills (e.g. ante mortem, post mortem inspection, and handling during slaughter) of the staff working at the company, among many others that have been considered.</p> <p>In this same sense, public servants are also evaluated in regard to their management skills, associated performance levels, and teamwork, as well as results orientation.</p>	
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		<p>Along the same line of ideas, Article 52 of the LAW ON PROFESSIONAL CAREER SERVICE IN FEDERAL PUBLIC ADMINISTRATION mandates the following: "Professional career servants must undergo evaluation to certify their professional skills under the terms determined by the Ministry at least every five years. The evaluations must certify that the public servant has developed and maintains the required profile and skills up to date for the performance of his or her duties."</p> <p><u>"This certification shall be a mandatory requirement for a Career Public Servant to remain employed in the system and in his or her area of responsibility."</u></p> <p>Notwithstanding the abovementioned information, a procedure has been developed that incorporates elements of Directive 4430.3 on plant system performance, which shall be aligned with the requirements for performance evaluations at the national level, as mentioned above. Providing by means of this the sufficient regulatory framework to apply the provisions of the Law mentioned above.</p> <p>It should be noted that these documents are currently in a period of trial and implementation and will enter into force on May 30, 2016.</p>	
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<p>5</p>	<p>Legal Authority The design of the carcass inspection stations prevent physicians who conduct the inspections from properly completing their assigned tasks, and the monitoring records do not show that the Supervisor has identified the deficiencies described in the various sections of this report during the monitoring visits.</p>	<p>SENASICA would like to state that it is working on updating the current official regulations in which one of the most important items will be the facilities and veterinary inspection, so that this document includes the consideration that the veterinary inspection areas must be suitable for the type of activity taking place. Particularly in the area of carcass inspection, it has been stipulated that the stations must have mobile platforms that allow adequate inspection, covering the distance between the caudal and cranial ends of the carcasses inspected, thus facilitating the work of the official veterinary staff.</p> <p>As an immediate corrective action, the TIF companies that were audited were requested to ensure that their facilities be adapted so that inspection activities could be done more efficiently. As a result of this request, the two TIF companies referred to in the report carried out the corrective actions requested; and SENASICA would like to mention that in one of the two TIF companies, a mechanism was required to prevent the carcasses from being removed without prior authorization from the official veterinary staff, demonstrating the authority that SENASICA has for correction of details that could take place in a greater situation. In the second TIF company, a more aggressive modification was designed in the implementation of an extension of the entire slaughter room (the immediate corrective action plans applied to the companies are attached).</p>	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p>
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		<p>The audit supervisor has received training in which the need to implement even stronger actions to minimize the risks of unsanitary conditions has been shown. It should be mentioned that although this Inspection service is concerned with the ergonomics of its staff, as is the case with providing industrial safety equipment, no situations have been shown in which this has prevented inspections by the official veterinary staff.</p> <p>However, and in order to provide more evidence of the activity that the official veterinary staff performs during inspections, the following documents have been prepared:</p> <ol style="list-style-type: none">1. Instructions for filling out the TIF Companies Monitoring Guide2. Updating the Monitoring Guide3. Implementation of instruction codes 1 to 6 for the evaluation of the Company.4. Verification procedures for the 6 codes.5. Procedure for Notification of Deviations and form for Notification of Deviations. It should be noted that these documents are currently in a period of trial and implementation and will enter into force on May 30, 2016.	
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<p>6</p>	<p>SANITATION</p> <p>During the review of the sanitation monitoring records of the companies, the FSIS auditors noted that the records show that product contamination and unsafe handling of edible parts (feet) are occurring repeatedly. The company did not correctly determine the cause of the contamination incidents, and the corrective actions implemented do not effectively prevent the re-occurrence of contamination of the carcasses and parts. Moreover, while they were evaluating the sanitary treatment procedures, the auditors observed that the management of the company is not effectively preventing the</p>	<p>In this sense, SENASICA would like to emphasize that this situation was only observed in a TIF company, and that carcasses are processed under monitored sanitary conditions in accordance with the HACCP plan at the point of zero tolerance of the company, and that the official staff carries out the routine veterinary inspection aligned with Directive 6420.2 so that the findings should focus only on the area and the TIF company where this situation has been determined, referring only to the handling of products that do not enter the slaughtering line and thus do not go through a visual inspection of zero tolerance. In this sense and based on the Framework of the Operational Relationship of the National Health, Food Safety, and Quality Service of Mexico and the Food Safety and Inspection Service of the United States with respect to the Trade in Meat, Poultry, and Egg Products between the United Mexican States and the United States of America, that was agreed on February 19, 2016 – and in particular Appendix 3, which refers to the guidelines for the monitoring of corrective actions – once this type of deviation is detected, information is provided that is sufficiently detailed, as well as support documentation, such that the importing country clearly understands what the investigation by the exporting country identified as the primary cause of the problem and avoids its recurrence, as well as the verification that the corrective actions implemented are sufficient and applied in their entirety.</p> <p>The guidelines on the additional information that the exporting country must provide to the CCA of the importing country includes, but is not limited to, the following:</p> <ul style="list-style-type: none"> • A summary of the investigation carried out and the results of the investigation of the problem identified in the repeat inspection upon return of the 	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p>
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	<p>inadequate and unsanitary handling of the edible parts (feet).</p>	<p>merchandise, as well as those identified during the audit or the deficiencies identified by alternate methods;</p> <ul style="list-style-type: none"> • The primary cause(s) and violation(s); • A description of the corrective actions and the preventive measures specified by each of the identified primary causes; • Support documentation that shows that the corrective actions and preventive measures are adequate and implemented; • A description of every change in the policies or other actions that have been carried out by the national inspection system derived from the result of the investigation carried out by the CCA of the exporting country, including the criteria for the decision and the rationale used to determine whether the changes to the inspection system were made or not. • The findings and results obtained by the CCA of the exporting country on the routine verifications that are made of the food safety system (HACCP and SSOP) in the certified companies questioned and any other corrective action associated with the violation; • Findings of non-compliance or concerns related to food safety derived from the results of the routine verification activities carried out by the CCA of the exporting country at a certified company, including the prior period during which a violation at the entry point has been detected; • Results of any applicable surveillance, administrative verification, or monitoring activity that has been carried out by the CCA of the exporting country that is relevant to a particular case; 	
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		<ul style="list-style-type: none"> • Verification activities by the CCA of the exporting country or any change in the program that is pending during the preparation of the response, as well as the tentative date of conclusion; and • Any other findings that the CCA of the exporting country determines to be significant. <p>Therefore, SENASICA has prepared the following documents as a continuous improvement process that ensures sufficient uniformity in the Monitoring activities:</p> <ol style="list-style-type: none"> 1. Instructions for filling out the TIF Companies Monitoring Guide 2. Updating the Monitoring Guide 3. Implementation of instruction codes 1 to 6 for the evaluation of the Company. 4. Verification procedures for the 6 codes. 5. Procedure for Notification of Deviation and form for Notification of Deviation <p>These documents are currently in a period of trial and implementation and will enter into force on May 30, 2016.</p>	
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7	<p>In one of the certified process companies, the FSIS auditors observed that in the post-lethal area, there were multiple structures with surfaces that were difficult to clean and disinfect, which had the potential to become sources of contamination if they were left unattended. Moreover, in the area of production of raw products, two of the six companies had accumulated residues in the elevated structures, which the cleaning team could not remove.</p>	<p>SENASICA considers it extremely important to note that the situation observed is aimed at prophylaxis, since no presence of the products involved was able to be observed in the packing area. However, SENASICA agrees that corrective actions should be implemented for these non-contact surfaces that could, at any given time, be the cause of unsanitary conditions. Therefore, as an immediate corrective action, the TIF companies were requested to establish corrective actions aimed at an immediate solution and prevention of the problem, so that in the first instance, the TIF company carried out a thorough cleaning of the area involved and, as a preventive action, it increased the cleaning frequency, with this being done on a weekly basis in addition to being verified by the official veterinary staff.</p> <p>Moreover, in relation to the accumulation of residues on elevated structures that are considered to be non-contact surfaces, the TIF companies involved implemented immediate corrective and preventive actions that consisted of increasing the cleaning frequency.</p>	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p>
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		<p>The verification of the cleaning and sanitary programs is carried out by official veterinary staff assigned to the company as part of their routine activities, with a reminder that the role of the MVO is one of verification and not of being the monitor of the company.</p> <p>However, this activity will be strengthened through the implementation of the new version of Scheduling of activities, and by the fact that the official veterinary staff will continue monitoring based on the 6 assessment codes and their verification procedures that apply to TIF Companies. In case deviations are detected, activities will be carried out that are focused on compliance with official regulations, authorizing the official veterinary staff to implement regulatory actions if necessary.</p> <p>These documents are currently in a period of trial and implementation and will enter into force on May 30, 2016.</p>	
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Draft Action Plan proposed by the ACC on the draft audit report created by FISIS (Food Inspection and Safety Service) resulting from the audit visit carried out in Mexico during the period of July 15 to August 13, 2014 for the evaluation of the government food safety program for the production of meat and poultry products intended to be exported to the United States of America, which was sent to this Agency on July 2, 2015.

<p>8</p>	<p>There is a continuing need on the part of the companies to monitor the sanitary conditions of their equipment and facilities. The auditor observed that the application of the sanitation program that was being used was insufficient to prevent the recurrence of contamination during the preparation of the carcasses. In addition, the doctors assigned to the plants must assess the implementation of the sanitation programs more critically to identify and demand correction of possible sources of contamination of the product.</p>	<p>SENASICA considers it extremely important to note that the situation observed is aimed at prophylaxis, since no presence of the products involved was able to be observed in the packing area. However, SENASICA agrees that corrective actions should be implemented for these non-contact surfaces that could, at any given time, be the cause of unsanitary conditions. Therefore, as an immediate corrective action, the TIF companies were requested to establish corrective actions aimed at an immediate solution and prevention of the problem, so that in the first instance, the TIF company carried out a thorough cleaning of the area involved and, as a preventive action, it increased the cleaning frequency, with this being done on a weekly basis in addition to being verified by the official veterinary staff.</p> <p>Moreover, in relation to the accumulation of residues on elevated structures that are considered to be non-contact surfaces, the TIF companies involved implemented immediate corrective and preventive actions that consisted of increasing the cleaning frequency.</p> <p>The verification of the cleaning and sanitary programs is carried out by official veterinary staff assigned to the company as part of their routine activities, with a reminder that the role of the MVO is one of verification and not of being the monitor of the company.</p> <p>However, this activity will be strengthened by the implementation of the new version of scheduling activities and the fact that the official veterinary staff will continue monitoring based on the 6 evaluation codes and their procedures for</p>	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p>
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Draft Action Plan proposed by the ACC on the draft audit report created by FISIS (Food Inspection and Safety Service) resulting from the audit visit carried out in Mexico during the period of July 15 to August 13, 2014 for the evaluation of the government food safety program for the production of meat and poultry products intended to be exported to the United States of America, which was sent to this Agency on July 2, 2015.

		<p>verification that apply to the TIF Companies; if any deviations are detected, activities will be carried out that are focused on compliance with official regulations, authorizing the official veterinary staff to apply regulatory actions if necessary.</p> <p>These documents are currently in a period of trial and implementation and will enter into force on May 30, 2016.</p>	
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Draft Action Plan proposed by the ACC on the draft audit report created by FISIS (Food Inspection and Safety Service) resulting from the audit visit carried out in Mexico during the period of July 15 to August 13, 2014 for the evaluation of the government food safety program for the production of meat and poultry products intended to be exported to the United States of America, which was sent to this Agency on July 2, 2015.

<p>9</p>	<p>HACCP In three of the four slaughtering companies in which the records on corrective actions were audited, it was found that the cause of the contamination deviations was not correctly identified by CT, so the companies did not take preventive measures and these deviations continued to occur, so that the recurrence of the problem continued. Moreover, both the SR and the officials at the plant did not detect this deficiency in the implementation of the HACCP plan in the companies.</p>	<p>Updating the forms has been considered, in order to strengthen the documentation of the activities that the official veterinary staff carries out on a daily basis, to include the following:</p> <ol style="list-style-type: none"> 1. A schedule of activities 2. Instructions for Notification of Deviation and form for Notification of Deviations. 	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p>
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<p>10</p>	<p>The officials notified the company about the deviations identified in a PCC and took official control actions to ensure the application of the HACCP plan, but they did not verify that the companies documented the corrective actions implemented.</p>	<p>Updating the forms has been considered, in order to strengthen the documentation of the activities that the official veterinary staff carries out on a daily basis, to include the following:</p> <ol style="list-style-type: none"> 1. A schedule of activities 2. Instructions for Notification of Deviation and form for Notification of Deviations. 	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p>
<p>11</p>	<p>There is a need for the ACC to perform a more detailed check on the official verification procedures of the HACCP that are carried out by the inspectors in the plant that are designated for the certified companies to ensure compliance with the procedures and, therefore, prevent violations in the PEs.</p>	<p>Updating the forms has been considered, in order to strengthen the documentation of the activities that the official veterinary staff carries out on a daily basis, to include the following:</p> <ol style="list-style-type: none"> 3. A schedule of activities 4. Instructions for Notification of Deviation and form for Notification of Deviations. 	<p>Appendix 1 Manual for Verification of the Monitoring System in Federal Inspection Type Companies.</p> <p>Appendix 2 Manual for supervisors</p>