USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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FEB 1 1 2019

Q.F.B. Amada Velez Méndez
Director General
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Servicio Nacional de Sanidad, Inocuidad y
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Col. Insurgentes Cuicuilco, C.P. 04350
Alcaldia de Coyoacán, Ciudad de México

Dear Q.F.B. Velez,

The United States Food Safety and Inspection Service's (FSIS') onsite audit of Mexico's food safety inspection system was conducted from August 6 through August 22, 2018. FSIS provided Mexico with a draft audit report, and Mexico provided responses to that draft report. FSIS is evaluating your response, including Mexico's preliminary corrective actions, and will be evaluating those actions to determine whether Mexico is maintaining a meat and poultry inspection system equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Mexico are included as an attachment to the report.

Mexico's actions in response to the FSIS audit findings will guide the scope and frequency of future equivalence verification activities, including the frequency at which FSIS reinspects products from Mexico at the United States point-of-entry. For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at InternationalCoordination@fsis.usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

MEXICO

AUGUST 6 TO AUGUST 22, 2018

EVALUATING THE FOOD SAFETY INSPECTION SYSTEMS GOVERNING

MEAT AND POULTRY PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 7, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from August 6-22, 2018. The purpose of the audit was to determine whether Mexico's food safety inspection system governing raw meat (beef, pork, lamb, and goat), processed meat (beef, pork, lamb, and goat), and processed poultry (chicken and turkey) remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

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

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. However, the following findings were identified:

Government Oversight (e.g., Organization and Administration)

The Central Competent Authority (CCA) has not provided sufficient instructions to its inspection personnel to ensure proper implementation of thermally processed commercially sterile (TPCS) regulatory requirements in certified establishments eligible to export to the United States, specifically:

- The inspection personnel did not verify that the TPCS products establishments have process schedules or supporting documents from the processing authority specific to each product; and
- The inspection personnel did not verify that the TPCS products establishments have process indicators and retort traffic controls in place (e.g., heat sensitive indicators in each retort load) to prevent unprocessed product from bypassing the thermal processing operation.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Mexico's food safety inspection system from August 6-22, 2018. The audit began with an entrance meeting held on August 6, 2018, in Mexico City, Mexico, during which the FSIS auditors discussed the audit objective, scope, and methodology with the representatives from the Central Competent Authority (CCA) – the *Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria* (SENASICA) [National Service of Food and Agriculture Health, Safety, and Quality].

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety inspection system governing raw meat (beef, pork, lamb, and goat), processed meat (beef, pork, lamb, and goat), and processed poultry (chicken and turkey) remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Mexico currently exports raw non-intact, raw intact, heat treated–shelf stable, heat treated but not fully cooked–not shelf stable, fully-cooked–not shelf stable, and thermally processed, commercially sterile (TPCS) meat products and raw-intact, heat treated but not fully cooked–not shelf stable, fully cooked–not shelf stable, and TPCS poultry products to the United States.

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

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at the CCA headquarters and four regional offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended. During this evaluation, the FSIS auditors were able to verify the proper implementation of the CCA's proposed corrective actions in response to the previous FSIS audit conducted in September and October 2016.

The FSIS auditors visited a sample of 11 establishments from 70 establishments certified as eligible to export meat and poultry products to the United States. These included three beef

slaughter, one pork slaughter, one lamb/goat slaughter, five meat processing, and one poultry processing establishments. During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety. The FSIS auditors examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) § 327.2 and § 381.196.

Additionally, FSIS audited one government laboratory and one private laboratory to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• CCA (SENASICA) – Mexico City
	Regional	4	• Durango Regional Office, Durango • Nuevo Leon Regional Office, Monterrey • Veracruz Regional Office, Xalapa • Yucatan Regional Office, Merida
Laboratories		2	• Centro Nacional de Servicios de Constatación en Salud Animal (CENAPA), Chemical Residue and Microbiology, Jiutepec • Central Microbiology Laboratory (Private Microbiology Lab), Merida
Beef slaughter establishments		3	• Establishment #101, Frigorífico de la Cuenca del Papaloapan, S.A. de C.V., Tierra Blanca • Establishment #105, Ganadería Integral SK, S.A. de C.V., Escobedo • Establishment #645, Ganadería y Rastro de la Laguna, S.A. de C.V., Tlahualilo
Pork slaughter establishment		1	• Establishment #152, Grupo Porciola Mexicano, S.A. de C.V., Uman
Lamb slaughter establishment		1	• Establishment #422, International Amma Foods, S.A. de C.V., Teoloyucan
Meat processing establishments		5	• Establishment #209, Sigma Alimentos Congelados, S.A. de C.V., Linares • Establishment #241, Productora de Bocados Cárnicos, S.A. de C.V., Apodaca • Establishment #451, Comercializadora Mache, S.A. de C.V., Monterrey • Establishment #517, Kosher Mexico International, S.A. de C.V., Zapotlan De Juarez • Establishment #681, Empacadora Frape, S.A. de C.V., Torreon
Poultry processing establishment		1	• Establishment #158, Sigma Alimentos Centro, S.A. de C.V., Atilalaquia

FSIS performed the audit to verify that Mexico's food safety inspection system met requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, *et seq*.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq*.);
- The Meat Inspection Regulations (9 CFR § 301 to the end);
- The Poultry Products Inspection Act (21 U.S.C. 451 *et seq*.); and
- The Poultry Products Inspection Regulations (9 CFR § 381).

The audit standards applied during the review of Mexico's food safety inspection system included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*. Current equivalence determinations in place for Mexico include the use of private laboratories for screening of samples for *Salmonella* and *Listeria monocytogenes* (*Lm*).

III. BACKGROUND

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Mexico as "negligible risk" for Bovine Spongiform Encephalopathy, free from Foot-and-Mouth Disease, free from African Swine Fever, and free from Classical Swine Fever with special restrictions. APHIS has temporary restrictions in place for Highly Pathogenic Avian Influenza and considers the states of Campeche, Quintana Ro, and Yucatan free from Newcastle Disease in poultry. Therefore, poultry products are only permitted entry into the United States if they are derived from raw poultry obtained from the United States or from other countries that FSIS has determined to have a poultry slaughter inspection system equivalent to that of the United States. During the on-site audit, the FSIS auditors verified through interviews and records review that SENASICA ensures its meat and poultry exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website.

From April 1, 2015 to March 31, 2018, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,268,471,743 pounds of meat and 38,562,805 pounds of poultry from Mexico. This included 895,687 pounds of TPCS beef; 452,546 pounds of ready-to-eat (RTE) fully-cooked beef; 968,545,061 pounds of raw intact beef; 189,431,991 pounds of raw non-intact beef; 9,358,013 pounds of not ready-to-eat (NRTE) otherwise processed beef; 507,852 pounds of raw intact goat; 37,224 pounds of raw intact lamb; 3,241,712 pounds of TPCS sterile pork; 245,167 pounds of RTE pork fully-cooked without subsequent exposure to the environment; 6,491,449 pounds of RTE fully-cooked pork; 75,493,285 pounds of raw intact pork; 2,344,129 pounds of raw non-intact pork; 11,350,650 pounds of NRTE otherwise processed pork; 66,625 pounds of raw intact veal; 7,922 pounds of raw non-intact veal; 2,430 pounds of NRTE otherwise processed veal; 495,997 pounds of TPCS chicken; 178,949 pounds of RTE chicken fully-cooked without subsequent exposure to the environment; 8,946,973 pounds of RTE fully-cooked chicken; 80,362 pounds of raw intact chicken; 21,520,754 pounds of NRTE otherwise processed chicken; 63 pounds of NRTE otherwise

processed chicken; 152,557 pounds of TPCS turkey; 823,378 pounds of RTE turkey fully-cooked without subsequent exposure to the environment; and 6,363,772 pounds of RTE fully-cooked turkey exported by Mexico to the United States.

Of these amounts, additional types of inspection were performed on 59,662,733 pounds of meat and 5,643,214 pounds of poultry, including testing for chemical residues and microbiological pathogens (Shiga toxin-producing *Escherichia coli* [STEC] O157:H7, O26, O45, O103, O111, O121, and O145 in beef; and *Lm* and *Salmonella* in RTE products). As a result of these additional inspection activities, FSIS rejected 546,512 pounds of meat products and 6,242 pounds of poultry products for issues related to public health, including identification of *E. coli* O157:H7 (42,000 pounds), *Lm* (32,116 pounds), and fecal/ingesta contamination (42,541 pounds) in reinspected products. The remaining POE rejections were due to product exam failures (i.e., hair or extraneous material), container and vacuum sealing issues, and product ineligibility.

The FSIS final audit reports for Mexico's food safety inspection system are available on the FSIS website at: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

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

The FSIS auditors noted that there have not been any major changes in the CCA's organizational structure since the last FSIS audit conducted in 2016. Mexico's administration of its meat and poultry inspection system is vertically organized into central, regional, and establishment levels. At the central level, SENASICA, a sub-agency of the Ministry of Agriculture, Livestock, Rural Development, Fisheries, and Food [*Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* (SAGARPA)] serves as the CCA to regulate inspection activities related to the export of meat and poultry products to the United States. SENASICA's Directorate of Federal Inspection Type Facilities [*Dirección de Establecimientos Tipo Inspección Federal* (DETIF)] is responsible for providing direct oversight to the Federal Inspection Type [*Tipo Inspeccion Federal* (TIF)] establishments that produce meat and poultry products for domestic and international markets, including those certified as eligible to export to the United States.

At the regional level, the State Supervisors provide direct supervisory authority over the certified establishments in accordance with national legislation and FSIS' import requirements. The State

Supervisors are also responsible for conducting periodic supervisory reviews at the certified establishments. At the establishment level, the inspection personnel consist of a Veterinary Medical Official [*Médico Veterinario Official* (MVO)] and a number of veterinary inspectors who perform official controls and inspection activities continuously during slaughter operations and at least daily, once per shift, during processing operations under the direct supervision of the head MVO.

The FSIS auditors reviewed documentation that the inspection personnel located at the SENASICA headquarters and regional levels are full-time employees of the national government. At the establishment level, the in-plant inspection personnel consist of MVOs and contract employees known as Authorized Veterinary Medical Officials [*Médico Veterinario Responsable Autorizado en el Área de Establecimientos Tipo Inspección Federal* (MVRATIF)]. The FSIS auditors verified through review of the MVOs' payroll records that they are full-time government employees paid directly by the national government. The MVRATIFs are employed and paid by a third-party organization known as the International Regional Organization for Plant and Animal Health [*Organismo Internacional Regional de Sanidad Agropecuaria* (OIRSA)].

The FSIS auditors verified that the head MVO is on premises while contract employees are performing inspection duties for product intended for export to the United States. The head MVO assigns the contract employees their daily inspection tasks, mainly post-mortem inspection examination, and has direct supervision over their inspection activity and performance. Mexico's use of contract employees under direct supervision from an on-site MVO has been determined equivalent by FSIS. The contract employees' inspection activities did not include the closure of the noncompliance reports or issuance of export health certificates at the audited TIF establishments.

The FSIS auditors verified that MVOs were responsible for ensuring that the third-country export requirements were met in accordance with SENASICA's requirements prior to issuing an export health certificate. This included securing government seals, maintaining required documentation, and signing the export health certificate by an MVO. The MVO export verification activities included examination of product condition (type, volume, and source), review of associated documents including labeling and pre-shipment review records, and review of applicable laboratory testing results. The FSIS auditors did not identify any concerns.

The FSIS auditors verified that the in-plant veterinary inspectors possessed the appropriate educational credentials, training and experience to carry out their inspection tasks. Since the last FSIS audit in 2016, SENASICA has organized ongoing training programs for inspection personnel assigned in the certified establishments. Training courses have covered such subjects as pathogen reduction/HACCP, sanitation, sampling methodology, and specific export requirements concerning United States equivalence requirements. The FSIS auditors interviewed a number of the inspection personnel to assess their knowledge, skills, and abilities and reviewed their training records from 2017 to 2018. The FSIS auditors confirmed that inspection personnel assigned to TIF establishments certified as eligible to export to the United States have attended the ongoing trainings.

The FSIS auditors verified that SENASICA has maintained its legal authority and responsibility to certify or to suspend and withdraw export certification of establishments certified as eligible to export to the United States. The FSIS auditors reviewed the SENASICA approval process for certified establishments that apply to be designated as establishments that are certified to export to the United States. These establishments must operate under a HACCP system in accordance with SENASICA's requirements. Following the submission of an establishment's application, the inspection personnel review and conduct an on-site inspection. SENASICA has the authority to approve the application considering the results of the document review, on-site audits, and implementation of any applicable corrective actions.

Mexico's Regulation of the Federal Law on Animal Sanitation [*Reglamento de la Ley Federal de Sanidad Animal* (RLFSA)] mandates the issuance of a single standard of laws and regulations to ensure uniform and standardized implementation of inspection requirements at TIF establishments. SENASICA implements these requirements by developing and disseminating technical manuals containing instructions and operational guidance to the TIF establishment's operators and inspection officials. The information is disseminated through an intranet application known as SDG or "*Sistema de Seguimiento de Direcciones Generales*."

Prior to the current audit on July 23, 2018, SENASICA informed FSIS that certified establishments eligible to export TPCS products to the United States are required to operate under a HACCP plan to control hazards associated with their process. Furthermore, SENASICA informed FSIS those TPCS products establishments that certified as eligible to export to the United States would adhere to FSIS' TPCS regulations.

SENASICA has not provided sufficient instructions to its inspection personnel to ensure proper implementation or verification of FSIS' TPCS requirements in certified establishments eligible to export to the United States. The FSIS auditors noted that the in-plant inspection personnel have not fully enforced all TPCS regulatory requirements, specifically:

- The inspection personnel did not verify that the TPCS products establishments have process schedules or supporting documents from the processing authority specific to each product; and
- The inspection personnel did not verify that the TPCS products establishments have process indicators and retort traffic controls in place (e.g., heat sensitive indicators in each retort load) to prevent unprocessed product from bypassing the thermal processing operation.

Mexico's Federal Law of Animal Health provides SENASICA the legal authority to take enforcement measures as appropriate. These enforcement measures may include taking regulatory control action, withholding actions, or suspension. The FSIS auditors reviewed the *Notificaciones de Desviación* (NDs) that were generated by the in-plant inspection personnel. The FSIS auditors noted that the inspection personnel had identified and documented deficiencies in the NDs using a similar format as FSIS' noncompliance reports. The inspection personnel closed the NDs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The FSIS auditors reviewed a sample of all open and closed NDs and determined that the inspection personnel have adequately described noncompliances and verified the effectiveness of the establishment's corrective actions. The

FSIS auditors also noted that no elevated enforcement actions had been taken at any of the audited TIF establishments.

Mexico's Federal Law of Animal Health provides the legal authority and responsibility to SENASICA to activate, coordinate, and operate the National Animal Health Emergency Operative Mechanism whenever there is sufficient evidence that food of animal origin exceeds maximum limits of residues, contain microbiological pathogens, or has prohibited contaminants that may have an adverse effect on public health. SENASICA has developed recall procedures that are described in its Rapid Alert Procedure. The procedure provides a comprehensive outline of the steps to be taken by both industry and inspection personnel regarding positive laboratory results. In addition, it includes trace-back mechanisms to ensure that establishments maintain sufficient records so that investigations may identify the source of the contamination. The FSIS auditors noted that audited TIF establishments maintained a recall procedure, as well as records sufficient to conduct trace back activities if adulterated product were exported to the United States. No product recalls of products being exported to the United States have occurred since the 2016 audit.

Mexican Official Standard [*Norma Oficial Mexicana* (NOM)] NOM-051-SCFI/SSA1-2010 describes the general labeling requirements for products. The FSIS auditors verified the labels of products destined for export to the United States, for which no concerns were identified. The FSIS auditors also noted that in-plant inspection personnel verify that raw meat and poultry products originate only from establishments certified as eligible to export to the United States. The FSIS auditors verified the source of raw products by cross-referencing the export health certificates with the bills of lading and additional certifications (e.g., health certificates, transfer certificates, pre-shipment records) that accompany each shipment of raw source materials.

The FSIS auditors noted that a network of government and private laboratories conducts analyses of meat and poultry products intended for export from Mexico to the United States. All of these laboratories are accredited by the Mexican Accreditation Entity [*Entidad Mexicana de Acreditación* (EMA)] in accordance with the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025. EMA grants accreditation every four years for all methods under the laboratory scope; each year within the four-year period, EMA conducts a review of a different subset of methods. The government reference laboratory, National Service Center for Analysis and Animal Health [*Centro Nacional de Servicios de Constatacion en Salud Animal* (CENAPA)], conducts analyses of both microbiological pathogens and chemical residues.

A group of private laboratories is approved by SENASICA to conduct screening tests for certain microbiological pathogens and chemical residues. If a private laboratory discovers a screen-positive, the sample is transferred to CENAPA for further confirmation and/or quantitation of the result. The FSIS auditors reviewed the results of the accreditation audits for both government and private laboratories conducting testing of product destined for export to the United States. The FSIS auditors reviewed laboratory records and interviewed the laboratory analysts to assess their technical competency, training, and knowledge of the analytical methods. These reviews by the FSIS auditors did not identify any concerns.

Mexico's government organizes and administers the country's meat and poultry inspection systems, and SENASICA officials enforce most laws and regulations governing production and export of meat and poultry at TIF establishments certified to export to the United States. However, FSIS identified that SENASICA has not fully enforced all TPCS regulatory requirements.

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

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; inspection on the line during all slaughter operations; controls over condemned materials; controls over establishment construction, facilities, and equipment; inspection at least once per shift during processing and on-line inspection during slaughter operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified that in-plant inspection personnel are required to conduct ante-mortem inspection in accordance with SENASICA's requirements. The MVO conducts ante-mortem inspection on the day of slaughter by observing all animals at rest and in motion from both sides in designated holding pens. Inspection personnel document the results of ante-mortem inspection daily. The FSIS auditors noted that each audited slaughter establishment provides a holding pen designated for observation and further examination of suspect animals. The FSIS auditors observed and verified that all animals have access to water in all holding pens (including the pens used for suspect animals), and that if animals are held overnight, feed is provided. The FSIS auditors also noted that MVOs conduct humane handling and slaughter (animal welfare) verification activities including evaluation of the stunning and sticking procedures on a daily basis. The State Supervisor(s) also verifies and documents the proper implementation of this requirement during his/her monthly supervisory reviews.

The FSIS auditors reviewed the implementation of post-mortem inspection examinations through review of inspection records, interviews, and observations of post-mortem inspection activities in the five slaughter establishments. The FSIS auditors observed and verified that proper presentation, identification, examination, and disposition of each carcass and accompanying viscera are being implemented. The in-plant inspection personnel are adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditors observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes are made in accordance with SENASICA's requirements.

The FSIS auditors visited five slaughter and six processing establishments. SENASICA's staffing requirements require at least three on-line veterinary inspectors (head, viscera, and carcass inspection stations) and one off-line inspector in each slaughter establishment and at least one veterinarian in each processing establishment.

During the on-site audit of each slaughter establishment, the FSIS auditors interviewed MVOs and reviewed daily inspection records to verify that SENASICA has provided a sufficient number of inspection personnel to conduct daily inspection activities including ante-mortem and on the line and post-mortem inspection of each livestock carcass and parts for all operating shifts. The FSIS auditors also noted that SENASICA requires the daily presence of inspection personnel at processing establishments. The inspection documented verification procedures included direct observation and review of establishment records of establishment activities, including HACCP, sanitation standard operating procedures (sanitation SOPs), sanitation performance standards (SPS), and residue and microbiological sampling programs. However, SENASICA did not have a written staffing standard based on species slaughter and line speeds to ensure sufficient staffing in the event that there is an increase in production volume in the establishments certified as eligible to export to the United States.

The control of condemned materials is accomplished through the application of Mexican Official Standard NOM-008-ZOO-1994. The FSIS auditors verified that the relevant portions of this document were applied, including: (1) appropriate identification of inedible or condemned materials; (2) segregation in specially marked or otherwise secure containers; and (3) final documented disposal of these materials at rendering facilities.

The FSIS auditors accompanied and observed the function of State Supervisors responsible for conducting the periodic supervisory reviews with a minimum frequency of monthly (slaughter establishments), bi-monthly (processing establishments), and quarterly (cold storage facilities). During these reviews, the State Supervisors verified the requirements for ante-mortem inspection; humane handling and slaughter requirements; post-mortem inspection; *Salmonella*, generic *Escherichia coli (E. coli), E. coli* O157:H7, and non-O157 STEC sample collection; economic/wholesomeness/labeling; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities, including the zero tolerance critical control point (CCP) verification in the slaughter establishment. These reviews were recorded on a standard form that includes a follow-up section regarding the previous supervisory review findings. The FSIS auditors concluded that the State Supervisors conducted these reviews at the intended frequencies.

The FSIS auditors conclude that Mexico's food safety inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

The FSIS auditors reviewed the *Manual for Official Verification and Inspection of Food Safety Systems in TIF Facilities Exporting to the United States (2014)* that requires establishments exporting to the United States to develop and implement sanitation SOPs consistent with 9 CFR

§ 416. The FSIS auditors verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or adulteration. Each establishment's program included maintenance and improvement of sanitary conditions through routine assessment of the establishment's hygienic practices. The FSIS auditors confirmed that the in-plant inspection personnel conduct daily verification procedures of the implementation of each establishment's sanitation program. Inspection verification activities consist in a combination of document reviews, observations, and hands-on inspections.

The FSIS auditors assessed the adequacy of the pre-operational inspection verification by shadowing and observing the in-plant inspection personnel conducting pre-operational sanitation verification inspection in two of the audited establishments. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification inspection. The in-plant inspection personnel conduct pre-operational sanitation verification on a daily basis in accordance with SENASICA's established procedures.

The FSIS auditors also observed the in-plant inspection personnel perform actual operational sanitation verification in all of the audited establishments. The FSIS auditors noted that the inspection verification activities included direct observation of the actual operations and review of the establishments associated records. The FSIS auditors compared their overall observation of the sanitary conditions of the establishments with the in-plant inspection verification records. The FSIS auditors' record review included both the establishment's sanitation monitoring and corrective action records and the inspection records documenting inspection verification results, noncompliances, and supervisory reviews of establishments. The FSIS auditors' review of records generated by inspection personnel (including noncompliance and verification records) showed that the inspection personnel have identified and documented sanitation findings in their daily verification or periodic supervisory review records. The FSIS auditors observed that the inspection and establishment records mirrored the actual sanitary conditions of the establishments.

The FSIS auditors noted that SENASICA requires sanitary dressing of livestock at slaughter establishments. As a result, each audited slaughter establishment has implemented sanitary procedures to prevent potential carcass contamination throughout the process. These included sanitary procedures to prevent carcass contamination during hide removal; prevent direct contact between carcasses during dressing procedures; and prevent carcass contamination with gastrointestinal contents during evisceration including tying the bung and weasand. All five audited establishments utilized sanitary dressing procedures for each step in the process and monitored the implementation daily.

The FSIS auditors noted during the document review, that establishments maintained sanitation records sufficient to document the implementation and monitoring of sanitation procedures and any corrective actions taken. The inspection personnel provided additional verification records addressing the establishment's proposed maintenance schedule and any applicable enforcement actions taken by the inspection personnel. The establishment employees responsible for the implementation and monitoring of the sanitation procedures

correctly authenticated these records with initials or signatures and the date. The FSIS auditors identified isolated findings related to the inspection verification of SPS. The FSIS auditors did not observe any direct product contamination; however, these SPS findings may create an insanitary condition and the potential for direct product contamination. The inspection personnel took regulatory enforcement action by tagging the area or equipment. The SPS findings are noted in the individual establishment checklist provided in Appendix A of this report.

The FSIS analysis and on-site verification activities indicate that SENASICA requires operators of official establishments to develop, implement, and maintain sanitation programs. FSIS concludes that SENASICA continues to meet the core requirements for this component.

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

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

The FSIS auditors noted that the *Manual for Official Verification and Inspection of Food Safety Systems in TIF Facilities Exporting to the United States (2014)* requires establishments exporting to the United States to develop and implement a HACCP program consistent with 9 CFR § 417.

The in-plant inspection daily verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The official daily HACCP verification activities also include direct observation or record review of CCPs for all production shifts, with results of verification being entered in the associated inspection records.

The FSIS auditors conducted an on-site observation and document review of CCPs in all the audited establishments including the zero tolerance (for feces, ingesta, and milk contamination) CCP control records generated in the five audited slaughter establishments. At each slaughter establishment, the FSIS auditors together with the in-plant inspection personnel observed the establishment's employees conducting hands-on HACCP monitoring and verification activities for the zero tolerance CCP. The FSIS auditors also reviewed the establishment and the in-plant inspections' zero tolerance records. Both establishment (monitoring, verification, and corrective action) and the in-plant inspection (verification) records documented a few deviations from the zero tolerance critical limits. The FSIS auditors reviewed records and verified that the establishment took appropriate corrective actions. Furthermore, the FSIS auditors confirmed that the physical location of the zero tolerance CCP verification for both the establishment's employees and in-plant inspection personnel is before the final carcass wash in all audited slaughter establishments.

The FSIS auditors noted that beef slaughter establishments certified to export to the United States had addressed contamination of carcasses with STEC as a hazard reasonably likely to

occur within the context of their HACCP system. This included the use of a validated intervention organic acid spray and a zero tolerance CCP for the presence of fecal matter, ingesta, and milk. In addition, establishments have implemented a non-O157 STEC/*E. coli* O157:H7 sampling and testing program for products intended for further processing into non-intact products.

At the six establishments producing RTE products, the FSIS auditors reviewed the HACCP programs for these processes with a special emphasis on lethality for *Salmonella* and other relevant pathogens. The FSIS auditors noted that RTE producing establishments are following "FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products", "FSIS *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A", and "FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B". Consistent with FSIS policy, an RTE product is considered to be adulterated when either the product comes in direct contact with equipment or food-contact surfaces (FCS) contaminated with *Lm.* The FSIS auditors' review of the establishments' and government's verification testing programs and results for *Salmonella* in finished products and *Lm* in products, on FCS, and on environmental surfaces did not raise any concerns.

SENASICA defines specified risk materials (SRMs) as the brain, skull, eyes, trigeminal ganglion, spinal cord, spinal ganglia roots, spinal column (excluding the caudal vertebrae, the transversal processes of the thoracic and lumbar vertebrae, and sacral wings) of bovines 30 months of age and older, and the tonsils and the distal portion of the ileum for bovines of all ages. The FSIS auditors noted that all three audited beef establishments have procedures in place for identification, removal, segregation, and disposal of SRMs. The FSIS auditors reviewed the establishments' monitoring and inspection verification records concerning control and disposal of SRMs. In addition, the FSIS auditors observed the implementation of these requirements during the slaughter operation including the use of the dedicated equipment and safeguarding the disposed materials. The FSIS auditors concluded that the program is being implemented properly in all audited establishments.

The FSIS auditors identified isolated findings related to the inspection verification of HACCP record keeping requirements. These findings are noted in the individual establishment checklist provided in Appendix A of this report. The FSIS analysis and on-site verification activities indicate that SENASICA requires operators of official establishments to develop, implement, and maintain a HACCP system for each processing category. FSIS concludes that SENASICA continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue control program, organized and administered by the national government, which includes

random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS' residue experts reviewed Mexico's Monitoring Program and Control of Toxic Residues and Contaminants in Food of Animal Origin (PMCRT), previous years' (2016-2017) testing results, associated methods of analysis, and additional SRT responses outlining the structure of Mexico's chemical residue testing program. The PMCRT covers animal species slaughtered for the production of meat and poultry products destined for domestic and international markets. The sampling plan organizes residues into Group A and Group B compounds, similar to that of the European Union (EU), where Group A represents banned compounds and Group B represents compounds that have allowable residue levels, which are based either on the maximum residue limits (MRLs) adopted by Codex Alimentarius or the United States tolerances set in the CFR. Group B compounds also include organochlorine and organophosphorus pesticides and heavy metals.

The FSIS auditors noted that the in-plant inspection personnel who collect the residue samples receive periodic training that includes such subjects as sampling methodology, identification of animals, traceability, and sample security. The FSIS auditors verified that the inspection personnel are following SENASICA's PMCRT sampling protocol. This protocol includes sampling location, sample size, sampling frequency, and secure delivery of residue samples to designated laboratories. A review of the sampling records maintained at five audited slaughter establishments indicated that the 2017-2018 sampling program was being implemented as scheduled. In addition, the FSIS auditors verified the proper implementation of a "hold and test" program for chemical residues, in which sampled carcasses are held until the result is obtained.

The FSIS auditors visited CENAPA, the government reference laboratory accredited to ISO/IEC 17025 standards. CENAPA is the only laboratory testing governmental samples for chemical residues in meat and poultry. All methods that CENAPA uses for testing of chemical residues in meat and poultry have been reviewed by EMA and included in the laboratory's scope of accreditation. The FSIS audit of CENAPA's residue laboratory focused on sample handling, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and data collection, detection levels, percent recoveries, intra-laboratory check samples, and quality-assurance programs, including standards books and corrective actions. These reviews identified no concerns. The FSIS auditors noted that CENAPA earned ISO 17043 accreditation from EMA as a proficiency test provider; therefore, CENAPA is also responsible for providing external proficiency test samples to the network of private laboratories.

The FSIS analysis and on-site verification activities indicate that SENASICA continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in meat and poultry products destined for human consumption. FSIS concludes that SENASICA continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat and poultry products prepared for export to the United States are safe and wholesome.

SENASICA has developed a *Salmonella* official sampling and testing program for chilled livestock carcasses within its *Procedimiento para la Verificación Oficial del Estándar de Desempeño para Salmonella spp como Indicador de Proceso en Canales de Bovino, Porcino y Productos Crudos No Intactos* (2017) that is consistent with the FSIS performance standards. The FSIS auditors accompanied and observed the inspection personnel sample collection methodology for *Salmonella* in two audited slaughter establishments. The demonstrated methodology met SENASICA's requirements. The FSIS auditors' interviews and document reviews of the *Salmonella* microbiological testing programs did not identify any issues.

SENASICA has identified *E. coli* O157:H7 and six additional non-O157 STECs in beef manufacturing trimmings as adulterants and has established a zero tolerance policy. SENASICA requires in-plant inspection personnel to review and verify establishment's documents including sampling methodology and testing results. Establishments certified to export to the United States are required to conduct routine sampling of beef manufacturing trimmings in accordance with N60 methodology. In-plant inspection personnel also conduct independent N60 official verification sampling. SENASICA has provided instructions to its inspection personnel for N60 sample collection methodology and submission procedures, interpretation of results, and any potential enforcement strategies that includes immediate corrective actions, followed by HACCP reassessment and follow-up testing.

The FSIS auditors noted that the number of government verification samples collected is proportional to the establishments' production volume with a minimum frequency of three samples per month. During the onsite audit of one of the beef slaughter and processing establishments, the FSIS auditors observed and verified the proper N60 official sample collection methodology by in-plant inspection personnel in accordance with SENASICA's requirements. In addition, the FSIS auditors verified the implementation of "test and hold" protocols for each lot of product destined for export to the United States. CENAPA as the government reference laboratory is responsible for screening and confirmation analyses of official samples. CENAPA uses the FSIS methods for official analysis of *E. coli* O157:H7 [Microbiology Laboratory Guidebook (MLG) 5A.04] and non-O157 STECs (MLG 5B.05) in raw beef. If the product tests positive for either *E. coli* O157:H7 or non-O157 STECs, it is not eligible for export to the United States. The FSIS auditors' interviews and document reviews in relation to *E. coli* O157:H7 and non-O157 STECs microbiological testing programs did not identify any issues.

SENASICA requires RTE processing establishments that produce post-lethality exposed product to control *Lm* by adopting one of the three alternatives in a manner consistent with 9 CFR § 430.4. Specific requirements related to *Lm* control are contained in *Procedimiento para la Verificacion Oficial de Actividades de Control para: Listeria monocytogenes* y *Salmonella spp.*

En Productos Listos para Consumo (2017). SENASICA considers an RTE product adulterated when the product comes in direct contact with an FCS contaminated with *Lm*. The FSIS auditors verified, through interviews and records review, that SENASICA has implemented official ongoing verification sampling to test product, FCS, and environmental surfaces.

The in-plant inspection personnel collect samples, and the designated microbiology laboratory conducts analysis using the FSIS MLG methods for *Lm* (MLG 8.10) and *Salmonella* (MLG 4.09). The FSIS auditors verified the implementation of "test and hold" protocols for each lot of product destined for export to the United States. If the RTE product tests positive for either *Lm* or *Salmonella,* it is not eligible for export to the United States. The FSIS auditors' interviews and document reviews in relation to *Lm* and *Salmonella* microbiological testing programs for RTE products did not identify any issues.

The FSIS auditors visited the Central Microbiology Laboratory, a private microbiology laboratory approved by SENASICA and accredited by EMA to ISO/IEC 17025 standards. SENASICA and CENAPA conduct an annual technical review of this laboratory in support of the approval process. EMA grants accreditation every four years with annual verification reviews. Mexico is allowed to use private laboratories for analysis of official samples for *Salmonella* and *Lm*. This laboratory, as part of Mexico's private laboratories network, screens samples for *Salmonella* following the FSIS MLG method. Any screen-positive samples would be shipped to CENAPA for confirmatory testing by MLG methods. The Central Microbiological Laboratory also receives proficiency test samples from CENAPA for *Salmonella.* During the laboratory visit, the FSIS auditors reviewed documents pertaining to the sample receipt, timely analysis, analytical methodologies, analytical controls, and reporting of results. In addition, the FSIS auditors reviewed training records and the results of proficiency testing and did not identify any deficiencies.

During the visit to the CENAPA Microbiology Laboratory, the FSIS auditors noted that CENAPA performs analytical testing on meat and poultry products for *Salmonella, Lm*, and *E. coli* O157:H7 to include non-STECs using corresponding FSIS MLG methodology. CENAPA is also in the process of validating a method for *Campylobacter* for raw poultry products. The FSIS auditors reviewed records of analyst training, equipment calibration, media preparation and storage, method validation, sample handling and data entry procedures. The FSIS auditors did not identify any deficiencies during the review of documents.

The FSIS analysis and onsite verification activities indicate that SENASICA continues to maintain the legal authority to implement its microbiological sampling and testing programs to ensure that meat and poultry products are safe and wholesome. FSIS concludes that SENASICA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on August 22, 2018, in Mexico City, Mexico with SENASICA. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following systemic finding:

Government Oversight (e.g., Organization and Administration)

The Central Competent Authority (CCA) has not provided sufficient instructions to its inspection personnel to ensure proper implementation of thermally processed commercially sterile (TPCS) regulatory requirements in certified establishments eligible to export to the United States, specifically:

- The inspection personnel did not verify that the TPCS products establishments have process schedules or supporting documents from the processing authority specific to each product; and
- The inspection personnel did not verify that the TPCS products establishments have process indicators and retort traffic controls in place (e.g., heat sensitive indicators in each retort load) to prevent unprocessed product from bypassing the thermal processing operation.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorífico de la Cuenca del Papaloapan, S.A. de C.V. Tierra Blanca, Veracruz	08/15/2018	TIF 101	Mexico
	5. AUDIT STAFF: OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT: [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

22/51: The establishment's verification records did not include time or result of the verification activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	08/15/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Ganadería Integral SK, S.A. de C.V. Autopista de Cuota Periférico-Monterrey No. 5501 General Escobedo, Nuevo León C.P. 66050.	08/15/2018	TIF 105	Mexico
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

39/51: The hot water pipeline in processing room is covered with plastic and duct tape as a temporary fix to prevent leakage, creating insanitary condition- no direct product contamination observed.
39/51: The overhead structure above cryovac packaging machine in processing room is rusty and has spots of peeling caulking paste. The ceiling of injector and tumbler room has rusty spots.
41/51: The ceiling of boxing and labeling room has wide area of beading condensation, no direct product contamination observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/15/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Grupo Porciola Mexicano, S.A. de C.V. Uman, Yucatan	08/10/2018	TIF 152	Mexico
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

39/51: Loose silicon and rusted areas on the ceiling over exposed production in the production areas
41/51: Beaded condensate on the overhead structures in the swine carcass coolers.
The FSIS auditor did not observe any direct product contamination of products.

55: Swine kidneys were not popped out of their capsules; therefore, the viscera veterinary inspector was not able to perform a proper post-mortem examination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	08/10/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sigma Alimentos Centro, S.A. de C.V. Estado de Municipio de Atitalaquia, Hidalgo	08/16/2018	TIF 158	Mexico
	5. AUDIT STAFF: OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT: [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

22/51: The establishment’s verification records did not include time of the verification activities.

22/51: The establishment’s HACCP plan did not address its return product procedures in its hazard analysis or flow chart.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	08/16/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sigma Alimentos Congelados, S.A. de C.V. Industria Alimenticia 760, Cd Industrial, 67701, Cd Industrial, 67701 Linares, N.L.	08/14/2018	TIF 209	Mexico
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

41/51: The walls of the packaging room where bagged products are boxed are damp with cracked and chipping paint; inadequate ventilation.
41/51: The frame above a freezer door had beading condensation that is mixed with grease creating insanitary condition.
38/51: In the hallway leading to and from processing areas, the junction between a rolling door (red door) has large gap/ open crevice between the brick structure and door, creating a harbor for dirt or pest.
39/51: The overhead structure of raw product-mixing room has loose frame and open gap between ceiling tiles, creating insanitary condition.
46/51: The receiving room of raw products is not climate-controlled exposing incoming raw meat and poultry products to excess heat especially in warm days and whereas SENASICA inspection personnel evaluate product condition and source in that room.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/14/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Productora de Bocados Cárnicos, S.A. de C.V. Kilómetro 3, Carretera a Santa Rosa, Apodaca Centro, 66600 Cd Apodaca, Nuevo León.	08/13/2018	TIF 241	Mexico
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	X
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

39/51: Pipes of cooling units in processing rooms 1, 2, 3, and 4 are wrapped with aluminum foil as means of insulation or to prevent dripping. That wrapping is getting loose in some spots creating insanitary condition for stored products. There were no direct product contamination observed.
41/51: The products receiving room has moldy spots and dirt on the ceiling and walls. The cooling unit of receiving room has frozen condensate with several electric wires are exposed out of the cooling unit creating insanitary condition. In that room, the space between stored product pallets and the wall is inadequate. In some areas, the boxed products are almost touching the wall.
40/51: The light panel above cutting table in processing room (P2) has dirt on the external surface creating insanitary condition.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/13/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
International Amma Foods, S.A. de C.V Teoloyucan,Teoloyucan Estado de México	08/17/2018	TIF 422	Mexico
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

22/51: The establishment's verification records did not include time or result of the verification activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	08/17/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Comercializadora Mache, S.A. de C.V. Av Rodrigo Gómez 5703, Cnop, 64245 Monterrey, N.L.	08/13/2018	TIF 451	Mexico
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

39/51:Pipes of cooling unit in the receiving cooler is wrapped with duct tape as a temporary fix of leakage is getting loose in some spots, creating insanitary condition.

40/51: The lighting in processing rooms is inadequate, which may interfere with product processing and proper operational sanitation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/13/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Kosher Mexico International, S.A. De C.V. Zapotlan De Juarez, Hidalgo	08/20/2018	TIF 517	Mexico
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

22/51: The establishment's verification records did not include time of the verification activities.

22/51: The establishment's HACCP plan did not address its return product procedures in its hazard analysis or flow chart.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	08/20/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Ganadería y Rastro de la Laguna, S.A. de C.V. Carretera Gómez Palacio-Tlahualilo, Km 46, Lucero, 35265 Tlahualilo, Dgo., México	08/09/2018	TIF 645	Mexico
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment

No findings identified during this audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/09/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
"Empacadora Frape, S.A. de C.V." Av. Industria de la transformación, S/N Parque Industrial Ferropuerto, Parque Pymes, Torreón, Coahuila, C.P. 27297.	08/10/2018	TIF 681	Mexico
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	X
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

36/ 51: The Central Competent Authority has not provided sufficient instructions to its inspection personnel to ensure proper implementation of thermally processed commercially sterile (TPCS) regulatory requirements in certified establishments eligible to export to the United States.

36/ 51: The inspection personnel did not verify that the TPCS products establishments have process schedules or supporting documents from the processing authority specific to each product.

36/ 51: The inspection personnel did not verify that the TPCS products establishments have process indicators and retort traffic controls in place (e.g., heat sensitive indicators in each retort load) to prevent unprocessed product from bypassing the thermal processing operation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/10/2018

Appendix B: Foreign Country Response to Draft Final Audit Report

SADER
SECRETARÍA DE AGRICULTURA Y DESARROLLO RURAL

SENASICA
SERVICIO NACIONAL DE SANIDAD, INOCUIDAD Y CALIDAD AGROALIMENTARIA

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

"2019, Año del Caudillo del Sur, Emiliano Zapata"

N° de Oficio B00.04.01.0111/2019

Ciudad de México a 24 ENE 2019

PhD. MICHELLE CATLIN
COORDINADORA EJECUTIVA
INTERNACIONAL DEL FSIS
PRESENTE

Hago referencia a su documento de fecha 27 de noviembre del presente, donde se adjunta la versión preliminar del reporte Final de Auditoria llevada a cabo en nuestro país, en fechas del 6 al 22 de agosto del 2018, a fin de emitir comentarios al mismo.

Sobre el particular, le comento que después de haber realizado el análisis del informe preliminar, esta oficina tiene a bien emitir los comentarios en lo que respecta al componente uno "Supervisión del Gobierno" y componente seis "Programa de Pruebas Microbiológicas del Gobierno", en los siguientes párrafos:

Component One: Government Oversight
Page 7
A group of private laboratories is approved by SENASICA to conduct screening tests for certain microbiological pathogens and chemical residues. If a private laboratory discovers a screen- positive, the sample is transferred to CENAPA for further confirmation and/or quantitation of the result. The FSIS auditors reviewed the results of the accreditation audits for both government and private laboratories conducting testing of product destined for export to the United States.

Component Six: Government Microbiological Testing Programs
Page 15
The FSIS auditors visited the Central Microbiology Laboratory, a private microbiology laboratory approved by SENASICA and accredited by EMA to ISO/IEC 17025 standards. SENASICA and CENAPA conduct an annual technical review of this laboratory in support of the approval process. EMA grants accreditation every four years with annual verification reviews. Mexico is allowed to use private laboratories for analysis of official samples for *Salmonella* and *Lm.* This laboratory, as part of Mexico's private laboratories network, screens samples for *Salmonella* following the FSIS MLG method. Any screen-positive samples would be shipped to CENAPA for confirmatory testing by MLG methods. The Central Microbiological Laboratory also receives proficiency test samples from CENAPA for *Salmonella.* During the laboratory visit, the FSIS auditors reviewed documents pertaining to

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the sample receipt, timely analysis, analytical methodologies, analytical controls, and reporting of results. In addition, the FSIS auditors reviewed training records and the results of proficiency testing and did not identify any deficiencies.

En ambos componentes se hace la aclaración que en caso de muestras para análisis microbiológicos que resultaron positivas, no procede que los laboratorios privados envíen a confirmar al CENAPA, ya que el tiempo transcurrido entre la toma de muestra y el resultado se prolonga más de lo adecuado para un análisis confiable.

En el caso de los residuos químicos, la responsabilidad del análisis de muestras del *Programa Nacional de Control y Monitoreo de Residuos Tóxicos en Bienes de Origen Animal*, recae en el Laboratorio Oficial de Referencia CENAPA, dependiente de la Dirección General de Salud Animal del SENASICA.

Respecto a los hallazgos preliminares detectados durante la auditoría, los establecimientos TIF han dado seguimiento puntual a las observaciones y se han establecido las acciones correctivas y preventivas, mismas que han sido verificadas por el personal oficial con resultados satisfactorios.

En cuanto a los hallazgos considerados como sistémicos, este Servicio Nacional, ha llevado a cabo las acciones correctivas que se describen en el anexo adjunto al presente oficio.

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

Sin más por el momento, le envío un cordial saludo.

ATENTAMENTE
EL DIRECTOR

SENASICA | CENAPA
DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA, ACUÍCOLA Y PESQUERA
24 ENE 2019
DESPACHADO
DIRECCIÓN DE ESTABLECIMIENTOS TIF FEDERAL

MVZ FRANCISCO JAIME SANDOVAL

Copias al reverso...

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

"2019, Año del Caudillo del Sur, Emiliano Zapata"

N° de Oficio B00.04.01.0111/2019

C.c.p. QFB AMADA VELEZ MÉNDEZ.-DIRECTORA GENERAL DE INOCUIDAD AGROALIMENTARIA, ACUÍCOLA Y PESQUERA.-Presente.
MVZ IGNACIO ISRAEL HERNÁNDEZ ROJAS.-SUPERVISOR EN LÍNEA DE LA DIRECCIÓN DE ESTABLECIMIENTOS TIPO INSPECCIÓN FEDERAL.-Presente.
MVZ LILIAN JAZMÍN SALGADO RAMÍREZ.-SUBDIRECTORA DE SUPERVISION NACIONAL DE ESTABLECIMIENTOS TIPO INSPECCION FEDERAL.-Presente
MVZ PAMELA JIMENEZ HERRERA.-SUBDIRECTORA DE MANTENIMIENTO DE LA CERTIFICACIÓN DE INSTALACIONES ANIMALES, PROCESOS Y PRODUCTOS DE ESTABLECIMIENTOS TIPO INSPECCIÓN FEDERAL.-Presente.

IIHR/jja

Plan de acción propuesto por la Autoridad Central Competente (ACC) sobre el informe de auditoría realizado por el FSIS-USDA, derivado de la visita de auditoria desarrollada en México en el periodo del 06 al 22 de agosto del 2018, para la evaluación del sistema de inspección de la inocuidad de alimentos que regulan productos cárnicos y avícolas exportados a los E.U.A.

Hallazgo	Acciones propuestas por la ACC
Componente 1 Supervisión Gubernamental FSIS identificó que SENASICA no ha hecho cumplir plenamente todos los requisitos normativos de productos con Proceso térmico- Comercialmente Estériles (PTCE) La Autoridad Central Competente (ACC) no ha dado suficientes instrucciones a su personal de inspección para garantizar la correcta aplicación de los requisitos reglamentarios de la Normativa sobre productos PTCE	La ACC genero el documento *Procedimiento de Inspección para productos cárnicos tratados térmicamente comercialmente estériles en establecimientos TIF.* El procedimiento fue enviado al FSIS mediante oficio B00.04.01.-2824/2018 con fecha 10 de octubre del 2018, con el objetivo de implementar un programa específico para este tipo de productos a fin de constatar el cumplimiento de la normatividad vigente, a través de la supervisión, inspección y verificación de los procesos de producción de cada establecimiento por parte del personal veterinario asignado en los establecimientos TIF, además se toman especificaciones armonizadas con el FSIS-USDA El procedimiento en mención se divide en tres partes: elementos introductorios, requisitos para los establecimientos y actividades de inspección en los establecimientos TIF. En esta última parte enfocada a las actividades de inspección, se hace mención a las actividades específicas para productos PTCE contempladas en el Sistema Informático de Supervisión (SIS) bajo el Código 03 sub código E, así como las tareas HACCP de acuerdo al Código 02. Cabe aclarar que esta oficina continua trabajando para implementar las actividades de inspección de productos PTCE en el SIS. La ACC Con fecha 15 de diciembre del 2018 genero la Circular No. 0069/2018 dirigida a los Supervisores y Médicos Veterinarios Oficiales, adscritos a Establecimientos TIF elegibles para la exportación de productos bajo la categoría de PTCE a los E.U.A., con la finalidad de dar cumplimiento a los requerimientos del FSIS-USDA y se giraron instrucciones para implementar el *Procedimiento de Inspección para productos cárnicos tratados térmicamente comercialmente estériles en establecimientos TIF.*

Hallazgo	Acciones propuestas por la ACC
	Con fecha 17 de diciembre a través de una reunión por teleconferencia con los supervisores estatales, se llevó a cabo la capacitación del *Procedimiento de Inspección para productos cárnicos tratados térmicamente comercialmente estériles en establecimientos TIF,* con la finalidad de trasmitir la información al personal oficial a su cargo y a los establecimientos TIF.
Componente 1 Supervisión Gubernamental El personal de inspección no verificó que los establecimientos de productos PTCE del sistema de control del proceso tengan programas de procesamiento o documentos de apoyo de la autoridad de procesamiento específicos para cada producto	. Con número de oficio B00.04.01.2362/2018 de fecha 21 de agosto del 2018 se envió una instrucción al personal oficial para la verificación de acciones correctivas llevadas a cabo por el establecimiento, derivado de los hallazgos durante la auditoria. El resultado de la verificación fue satisfactorio
El personal de inspección no verificó que los establecimientos de productos PTCE tengan indicadores de proceso y controles de tráfico de retorta (por ejemplo, indicadores sensibles al calor en cada carga de retorta) para evitar que los productos no procesados eludan la operación de procesamiento térmico	Con número de oficio B00.04.01.2362/2018 de fecha 21 de agosto del 2018 se envió una instrucción al personal oficial para la verificación de acciones correctivas llevadas a cabo por el establecimiento, derivado de los hallazgos durante la auditoria. El resultado de la verificación fue satisfactorio
Componente 2 Autoridad Estatutaria (establecida) del Gobierno y Seguridad alimentaria y Otras Regulaciones de Protección al Consumidor El SENASICA no cuenta con una norma escrita de dotación de personal basada en el sacrificio de especies y la velocidad de la línea para garantizar una dotación de personal suficiente en caso de que se produjera un aumento en el volumen de producción en los establecimientos certificados como aptos para exportar a los Estados Unidos.	El SENASICA, en base la Ley Federal de Sanidad Animal (LFSA) en el Título Sexto, Capítulo II, artículo 107 hace mención a lo siguiente*: Los establecimientos Tipo Inspección Federal deben contar con médicos veterinarios oficiales o responsables autorizados que realicen la inspección o verificación en tal número que garantice la eficiencia de la misma. Los establecimientos autorizados para exportar deberán contar con médicos veterinarios oficiales si la Secretaría lo determina o el país importador lo requiere.* Cabe aclarar que si bien la LFSA no es tan especifica en cuanto al número de personal de inspección requerido en los establecimientos de sacrificio, teniendo en cuenta la velocidad de la línea, esta oficina trabaja en la revisión de la capacidad de inspección oficial dentro de los establecimientos TIF que exportan a los E.U.A., tomando como referencia el Título 9 del CFR parte 310.1

Document no. 800.04.01.0111/2019

Mexico City, **JANUARY 2 2019**

PhD. MICHELLE CATLIN FSIS
INTERNATIONAL EXECUTIVE
COORDINATOR PRESENT

I refer to your document dated November 27 of this year, where the preliminary version of the Final Audit report carried out in our country is attached, from August 6 to 22, 2018, in order to issue comments about it.

On this subject, I would like to mention that after having analyzed the preliminary report, this office has the right to comment on the component "Supervision of the Government" and component six "Microbiological Tests Government's Program", in the following paragraphs:

Component One: Government Oversight
Page 7
A group of private laboratories is approved by SENASICA to conduct screening tests for certain microbiological pathogens and chemical residues. If a private laboratory discovers a screen- positive, the sample is transferred to CENAPA for further confirmation and/or quantitation of the result. The FSIS auditors reviewed the results of the accreditation audits for both government and private laboratories conducting testing of product destined for export to the United States.

Component Six: Government Microbiological Testing Programs
Page 15
The FSIS auditors visited the Central Microbiology Laboratory, a private microbiology laboratory approved by SENASICA and accredited by EMA to ISO/IEC 17025 standards. SENASICA and CE**NAPA** conduct an annual technical review of this laboratory in support of the approval process. EMA grants accreditation every four years with annual verification reviews. Mexico is allowed to use private laboratories for analysis of official samples for *Salmonella* and *Lm.* This laboratory, as part of Mexico's private laboratories network, screens samples for *Salmonella* following the FSIS MLG method. Any screen-positive samples would be shipped to CENAPA for confirmatory testing by MLG methods. The Central Microbiological Laboratory also receives proficiency test samples from CENAPA for *Salmonella.* During the laboratory visit, the FSIS auditors reviewed documents pertaining to

the sample receipt, timely analysis, analytical methodologies, analytical controls, and reporting of results. In addition, the FSIS auditors reviewed training records and the results of proficiency testing and did not identify any deficiencies.

In both components the clarification is made that in the case of samples for microbiological analyzes that were positive, it is not appropriate for private laboratories to confirm to CENAPA, since the time elapsed between the sampling and the result is longer than the adequate for a reliable analysis.

In the case of chemical residues, the responsibility for the analysis of samples of the National Program of Control and Monitoring of Toxic Waste in Goods of Animal Origin, rests with the Official Reference Laboratory CENAPA, under the General Directorate of Animal Health of SENASICA.

Regarding the preliminary findings detected during the audit, the TIF establishments have followed the observations in a timely manner and corrective and preventive actions have been established, which have been verified by the official staff with satisfactory results.

Regarding the findings considered as systemic, this National Service has carried out the corrective actions described in the appendix attached to the present document.

I do not omit to mention that all the information that supports the investigations and corrective actions developed by the TIF establishments, as well as by this Directorate are in this office's files.

Without any further ado, I send a warm regards.

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Plan of action proposed by the Competent Central Authority (ACC) on the audit report carried out by the FSIS-USDA, derived from the audit visit carried out in Mexico during the period from August 06 to August 22, 2018, for the evaluation of the system of Inspection of the safety of foods that regulate meat products and poultry exported to the USA.

Finding	Actions proposed by the ACC
Component 1 Government Supervision FSIS has identified that SENASICA has not fully enforced all the normative requirements of Thermally-Commercially Sterile Process (PTCE) products. The Competent Central Authority (ACC) has not given sufficient instructions to its inspection personnel to ensure the correct application of the regulatory requirements of the Regulations on CETP products.	The ACC generated the document Inspection procedure for thermally commercially sterilized carmcos products in TIF establishments. The procedure was sent to the FSIS through document B00.04.01.-2824/2018, dated October 10, 2018, with the objective of implementing a specific program for this type of product in order to verify compliance with current regulations, through the supervision, inspection and verification of the production processes of each establishment by the veterinary staff assigned in the TIF establishments, in addition harmonized specifications are taken with the FSIS-USDA The procedure in question is divided into three parts: introductory elements, requirements for establishments and inspection activities in TIF establishments. In this last part, focused on the inspection activities, there is mention of the specific activities for PTCE products contemplated in the Supervision System (SIS) under Code 03 sub code E, as well as the HACCP tasks according to Code 02. It should be noted that this office continues to work to implement the inspection activities of PTCE products in the SIS. The ACC On December 15, 2018, generated Memo No. 0069/2018 addressed to the Official Veterinary Supervisors and Physicians, assigned to eligible TIF Establishments for the export of products under the category of PTCE to the USA, with the purpose of complying with FSIS-USDA requirements and instructions to implement Inspection Procedure for commercially sterile thermally treated meat *meat products in TIF establishments.*

Finding	Actions proposed by the ACC
	On December 17 through a meeting by teleconference with the state supervisors, the Inspection Procedure training was carried out for commercially sterilized thermally treated products in TIF establishments, with the purpose of transmitting the information to the official staff in charge and the TIF establishments.
Component 1 Government Supervision Inspection personnel did not verify that the CETP product establishments of the process control system have a processing program or support documents of the specific processing authority for each product	With document number B00.04.01.2362 / 2018 dated August 21, 2018, an instruction was sent to the official personnel for the verification of corrective actions carried out by the establishment, derived from the findings during the audit. The result of the verification was satisfactory
The inspection staff did not verify that the establishments of CETP products have process indicators and retort traffic controls (e.g., heat sensitive indicators in each retort load) to prevent unprocessed products from escaping the thermal processing operation	With document number 800.04.01.2362/2018 dated August 21, 2018 an instruction was sent to the official personnel for the verification of corrective actions carried out by the establishment, derived from the findings during the audit. The result of the verification was satisfactory
Component 2 Government and Food Safety Statutory Authority (established) and Other Regulations of Consumer Protection SENASICA does not have a written norm for staffing, based on the slaughter of species and the speed of the line to guarantee sufficient staffing in case of an increase in the volume of production in establishments certified as eligible for export to the United States.	SENASICA, based on the Federal Animal Health Law (LFSA) in Title Six, Chapter II, Article 107, mentions the following: Federal Inspection Type establishments must have enough official veterinarians or authorized personnel responsible for the inspection or verification, to guarantee the efficiency of the verification. *Establishments authorized to export must have official veterinarians if the Secretariat determines it or the importing country requires it.* It should be noted that although the LFSA is not as specific as to the number of inspection personnel required in the slaughter establishments, taking into account the speed of the line, this office works on the revision of the official inspection capacity within the TIF establishments that export to the USA, taking as reference Title 9 of the CFR part 310.1