USDA

United States Department of Agriculture

Food Safety and
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NOV 1 0 2021

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Dear Q.F.B. ~~Vélez~~ Amada,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote verification audit of Mexico's meat inspection system from May 4 through June 17, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of the Mexico are included as an attachment to the report.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF

MEXICO

MAY 4–JUNE 17, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT AND POULTRY PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

November 8, 2021

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a routine equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) May 4–June 17, 2021. Due to the global COVID-19 pandemic, FSIS conducted the audit remotely using a combination of video conferences and records review. The purpose of the audit was to determine whether Mexico's food safety inspection system governing meat and poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Mexico currently exports meat and poultry products to the United States.

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 Point (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. The FSIS auditors identified the following finding:

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- Mexico's Procedure for the Collection and Shipping of Toxic Residue Samples in TIF Establishments in accordance with the administrative requirements described in the Federal Law of Administrative Procedure allows for a second chemical residue test on a companion sample when the initial test result is unacceptable. If the result from the second sample test is acceptable, then it negates the original unacceptable result. FSIS does not consider the practice of performing a second analysis to support or refute the original results to be equivalent.

During the audit exit meeting, the Central Competent Authority (CCA) committed to address the preliminary finding as presented. FSIS auditors were able to confirm through interviews and records review that testing of the second companion sample has never been requested by a TIF establishment for any products intended for export to the United States and that all positive or violative test results have been accepted as final. 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 a remote audit of Mexico's food safety inspection system from May 4–June 17, 2021. The audit began with an entrance meeting via videoconference on May 4, 2021, with representatives from the Central Competent Authority (CCA)- the National Service of Food and Agriculture Health, Safety, and Quality (SENASICA). Representatives from SENASICA participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that FSIS conducted remotely. The audit objective was to determine whether Mexico's food safety inspection system governing meat and poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Mexico is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Beef	Beef - All Products Eligible except Advanced Meat Recovery Product (AMR); Low Temperature Rendered Product (LTRP); Partially Defatted Beef Fatty Tissue (PDBFT); Partially Defatted Chopped Beef (PDCB); and Finely Textured Beef (FTB).
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Chicken	Chicken - All Products Eligible except Mechanically Separated
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise non-intact meat-other (Sheep, Goat)	Goat, Lamb, and Mutton - All Products Eligible except Mechanically Separated and AMR
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and AMR
Raw - Intact	Raw Intact Beef	Beef - All Products Eligible
Raw - Intact	Raw Intact Chicken	Chicken - All Products Eligible
Raw - Intact	Raw Intact Turkey	Turkey - All Products Eligible
Raw - Intact	Raw Intact Meat-Other (Sheep, Goat)	Goat, Lamb, and Mutton - All Products Eligible

[1] All source meat and poultry used to produce products must originate from eligible countries and establishments certified to export to the United States.

Process Category	Product Category	Eligible Products[1]
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Thermally Processed - Commercially Sterile	Thermally Processed, Commercially Sterile	Beef, Pork, Goat, Chicken, and Turkey - All Products Eligible
Heat Treated - Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Beef and Pork - All Products Eligible
Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Dried Meat	Beef and Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Beef and Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Beef, Pork, and Goat - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Poultry	Chicken and Turkey - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Beef, Pork, and Goat - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Poultry Fully-Cooked Without Subsequent Exposure to the Environment	Chicken and Turkey - All Products Eligible
Heat Treated but Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Beef, Pork, and Goat - All Products Eligible
Heat Treated but Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Poultry	Chicken and Turkey - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Mexico as "negligible risk" for Bovine Spongiform Encephalopathy (BSE), 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 throughout Mexico and considers the states of Campeche, Quintana Roo, and Yucatán free from Newcastle Disease in poultry. Poultry products from Mexico are permitted entry into the United States if they are produced using raw poultry obtained from the United States or from other countries that the FSIS has determined to have poultry slaughter inspection systems equivalent to the United States. Raw poultry products are only allowed to be exported from APHIS approved poultry processing establishments.

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed Mexico's Self Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether Mexico's food safety inspection system governing meat and poultry products is being implemented as documented in the country's SRT responses and supporting documentation.

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 SRT responses and supporting documentation.

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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed records related to administrative functions from the CCA headquarters and regional offices, as well as government verification records for the four local inspection offices. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to two meetings each week over a seven-week period. FSIS did not conduct virtual establishment visits as part of the remote audit. Through records review, the FSIS auditors evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of four establishments was selected from a total of 94 (as of May 4, 2021) establishments certified to export to the United States. This included three slaughter and processing establishments and one processing establishment. The products these establishments produce and export to the United States include raw lamb and goat; raw and processed meat (beef and pork); and processed poultry products.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include a review of establishments' conditions or records. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with the FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2 and 381.196.

The FSIS auditors also remotely audited the government microbiological and chemical residue-testing laboratories to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		**#**	**Locations**
Competent Authority	Central	1	• SENASICA, Mexico City
	State Offices	2	• Yucatán Regional office located in Mérida • Durango Regional office located in Ciudad Lerdo
Laboratories		2	• Laboratorios de Análisis de Productos Agropecuarios del Noreste, S.C. Focus on Drug Residues in Monterrey, Nuevo León

		• Laboratorio Central Regional del Norte, S.A. de C.V. Focus on Microbiology in Guadalupe, Nuevo León
Lamb and goat slaughter establishment	1	• Establishment No. 505, Sucabrito, S.A. de C.V., Cadereyta Jiménez, Estado de Nuevo León
Pork slaughter and processing establishment	1	• Establishment No. 57, Sonora Agropecuaria, S.A. de C.V., Municipio de Navojoa, Estado de Sonora
Beef slaughter and processing establishment	1	• Establishment No. 645, Ganadería y Rastro de la Laguna, S.A. de C.V., Tlahualilo, Durango
Beef, pork, and poultry processing establishment	1	• Establishment No. 681, Empacadora Frape, S.A. de C.V., Torreón, Coahuila

FSIS performed the remote audit to verify that the food safety inspection system meets 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.] Section 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Sections 1901-1906);
- The Meat Inspection Regulations (9 CFR Parts 301 to the end);
- The Poultry Products Inspection Act (21 U.S.C. Section 451 *et seq.*); and
- The Poultry Products Inspection Regulations (9 CFR Part 381).

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

III. BACKGROUND

From December 1, 2017 to November 30, 2020, the FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,708,515,006 pounds of meat and 35,234,992 pounds of poultry from Mexico. Of these amounts, additional types of inspection were performed on 70,215,067 pounds of meat and 3,865,660 pounds of poultry, including physical examination, condition of container examination for thermally processed/commercially sterile (TPCS) products, chemical residue analysis, and testing for microbiological pathogens (Shiga toxin-producing *Escherichia coli* (STEC)) O157:H7, O26, O45, O103, O111, O121, and O145 in beef or veal; and *Listeria monocytogenes (Lm)* and *Salmonella* in ready-to-eat (RTE) products. As a result of this additional testing, 63,434 pounds of meat products were rejected for issues related to public health: 59,572 pounds for chemical residues and 3,862 pounds for *Lm*.

The last FSIS audit in 2018 identified the following findings:

Summary of Findings from the 2018 FSIS Audit of Mexico
Component One: Government Oversight (e.g., Organization and Administration)
• The inspection personnel did not verify that the TPCS products in TIF 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 in TIF 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.

The FSIS auditors verified through records review that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

Recent FSIS final audit reports for Mexico's food safety inspection system is available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

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

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

The CCA of Mexico is SENASICA, a subagency of the Ministry of Agriculture and Rural Development (SADER). SENASICA has the overall responsibility to ensure meat and poultry products exported to the United States comply with FSIS import requirements and are certified for export prior to shipping. The Federal Law of Animal Health (FLAH) is obligatory throughout Mexico and gives SENASICA the legal authority and overall responsibility for policy, legislation, and implementation of official controls in relation to food safety and other requirements at establishments exporting products to the United States.

There are six general directorates within SENASICA, including the General Directorate of Agriculture Food Safety, Agriculture and Fisheries (DGIAAP) which is the administrative office responsible for overseeing the establishments certified to export meat and poultry products to the United States. Under DGIAAP is the Directorate of Federal Inspection Type Establishments (DETIF) which is directly responsible for providing oversight and supervision of Federal Inspection Type (TIF) establishments certified to export to the United States.

Within DETIF, the responsibility for providing oversight and supervision to the TIF establishments is divided among four subdirectorates. The Subdirectorate of Judgement and Certification is responsible for evaluating compliance of TIF establishments seeking to obtain certification and certified TIF establishments requesting to add additional processes. The Subdirectorate of Regulations, Inspection and Verification implements annual verification and

inspection programs to verify compliance with legal provisions regarding health and food safety in certified TIF establishments. Likewise, it oversees analyses and implementation of the regulations applicable to TIF establishments. The Subdirectorate of Harmonization and Equivalence is responsible for maintaining international regulation updates, attending international audits, negotiating protocols with other countries, and overseeing the requests of the TIF establishments by foreign countries. The Subdirectorate of National Supervision of Establishments and Operatives Programs, which is responsible for supervision and ensuring regulations are enforced at establishments. Additionally, this subdirectorate is responsible for ensuring that staffing is maintained at an adequate level at TIF establishments to meet any foreign countries' import requirements.

SENASICA employs state supervisors that oversee TIF establishments within their region to ensure staffing requirements are being met and daily government inspection activities are implemented. In TIF establishments, the Veterinary Medical Officials (MVO) supervise government inspection personnel and have the overall responsibility for ensuring that products exported to the United States meet FSIS import requirements by conducting daily, per shift government inspection activities. Additionally, SENASICA utilizes Authorized Responsible Veterinary Medical Officials (MVRATIF) in slaughter TIF establishments that primarily perform post-mortem inspection activities. The FSIS auditors verified through inspection records and supervisory reviews that SENASICA is ensuring TIF establishments certified to export to the United States have the required government inspection personnel and that government verification activities are conducted at appropriate frequencies.

SENASICA maintains the legal authority and responsibility to suspend and withdraw export certification of TIF establishments certified as eligible to export to the United States. The FLAH provides SENASICA the legal authority to take enforcement measures as appropriate. In accordance with Title 4 of the Federal Law of Administrative Procedure, violations of the law are addressed by imposing administrative measures that may result in temporary shutdown of production, definitive cessation of operations, suspension of authorization, certification, approval and permits, decertification, and fines.

The Supervisory Manual for the Federal Inspection Type System (MTF-SSN-SIS-02) describes the criteria to determine the risk category of the establishment's deviations or noncompliant findings. If government inspection personnel determine that the deviations (noncompliances) are critical and the establishment is not able to control them, or the deviations are part of a trend, then they are to refer to Chapter XIV of the aforementioned manual on how to document a deviation notification. SENASICA has not delisted or decertified any TIF establishments because of enforcement actions in the last two years. The FSIS auditors interviewed SENASICA inspection personnel about how they would decide to take an enforcement action and reviewed an enforcement action that suspended a process at a TIF establishment as an example. The FSIS auditors did not identify any findings during the audit associated with the SENASICA's ability to initiate and document enforcement actions as necessary.

If government inspection personnel identify noncompliance with regulatory requirements, they determine how it will be documented. Whenever it is determined to document a formal noncompliance, they refer to the MTF-SSN-SIS-02. This includes instructions on how to

complete and use the Form SIS-10 (Activities Report). Government inspection personnel verify that certified TIF establishments take appropriate corrective actions whenever a noncompliant report is issued according to the procedures outlined in the MTF-SSN-SIS-02. The FSIS auditors interviewed state supervisors and reviewed multiple noncompliance records during the audit and did not identify any issues with SENASICA's ability to document noncompliance or ensure corrective actions are acceptable.

The FLAH provides SENASICA with the authority to certify and decertify TIF establishments for export to the United States. During the audit, the FSIS auditors discussed the establishment certification process and reviewed a recent certification for a new establishment without identifying any findings. SENASICA uses an electronic export certification system to generate certificates of export for products destined for the United States. Prior to signing the export certificates, the MVOs are responsible for ensuring all requirements for export are met by reviewing documentation including veterinary health certificates, product labeling, HACCP pre-shipment review records, and microbiological and chemical test results to ensure product lots have been reported as satisfactory prior to shipping. The FSIS auditors reviewed export certification records during the audit and did not identify any findings.

The FLAH 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, contains pathogens, or has prohibited contaminants that may have an adverse effect on public health. SENASICA has developed the Rapid Alert Procedure, which outlines steps to be taken by both industry and government inspection personnel regarding product recalls. This procedure includes traceback mechanisms to ensure that TIF establishments maintain sufficient records so that investigations may identify the source of the contamination. SENASICA requires verification of the TIF establishments' recall and traceability procedures to be conducted at least once per year. No product destined for the United States had been recalled since the previous FSIS audit in August of 2018. Review of the government inspection recall and traceability verification activities did not identify any findings.

All raw meat and poultry source materials used in products being certified for export to the United States must originate from eligible TIF establishments, the United States, or from certified establishments in foreign countries determined to be equivalent for exporting raw meat and raw poultry to the United States. The FSIS auditors interviewed government inspection personnel and reviewed records documenting raw components from the United States being utilized for product being exported to the United States. The FSIS auditors did not identify any findings with SENASICA's ability to ensure only eligible raw meat and poultry materials are used in products intended for export to the United States.

SENASICA maintains a single standard of laws and regulations applicable to all TIF establishments certified for export to the United States. The Regulation of the Federal Law of Animal Health (RFLAH) requires that SENASICA issue regulatory measures to ensure uniform and standardized processes, conditions, and requirements to which the TIF establishments must adhere and that government inspection personnel must enforce. Information is disseminated through an intranet-based application known as the General Directorate Monitoring System.

During the audit, SENASICA demonstrated how recent materials were distributed to government inspection personnel at TIF establishments. Each state supervisor conducts establishment and employee audits that verify the standardization of the inspection system, as well as implementation of changes in the inspection system. The FSIS auditors reviewed and discussed the distribution of records and reviewed recent audit results from supervisors at TIF establishments without identifying any findings.

The FSIS auditors reviewed documentation confirming that inspection personnel located at SENASICA headquarters and regional levels are full-time employees of the national government. At the establishment level, the government inspection personnel consist of MVOs and MVRATIFs. 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.

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

The FLAH mandates that inspection activities be provided by a government agency and requires the assignment of MVOs to coordinate inspection at the TIF establishments in accordance with requirements of importing countries. The Animal Health Specifications for the Construction and Equipment of Establishments for the Animal Slaughter and those Dedicated to the Industrialization of Meat Products (NOM-008-ZOO-1994), defines the responsible official veterinarian as a professional paid and trained by SENASICA, who performs the sanitary inspection of animals and their products at the establishments. Additionally, the FLAH states that all individuals conducting inspection and verification activities at the TIF establishments must possess a veterinary degree from a recognized university and obtain professional accreditation from the central government to work as veterinarians. The FSIS auditors did not identify any findings regarding the funding, educational requirements, and training of veterinarians.

The National Service Center for Analysis and Animal Health (CENAPA) is the government laboratory that serves as the national reference laboratory under the oversight of SENASICA. CENAPA is comprised of nine microbiological and eight chemical residue laboratories that analyze products and tissues for microbiological and chemical residues to verify that food safety controls are effective, and that meat and poultry products meet United States import standards. In addition to the above-mentioned laboratories, CENAPA oversees and audits the performance of private (third-party) laboratories that are approved by SADER and accredited through Mexico's national accreditation body called the Mexican Accreditation Entity (EMA), which is

recognized internationally. CENAPA's quality assurance program complies with the Mexican Quality Norms, which are based on the International Organization for Standardization (ISO) Guides 17025 and 9001:2000 and on Eurachem Guidelines.

The FLAH states that SADER has the authority to approve laboratories pursuant to the provisions of this law and the Federal Law of Metrology and Standardization. The RFLAH mandates that SADER be the governmental agency that grants approval to laboratories that provide services to TIF establishments. The analytical performance of the laboratories is audited internally by qualified auditors and externally by EMA (every four years with surveillance verification audits once a year). The FSIS auditors reviewed EMA audit reports and interviewed government personnel without identifying any findings with the laboratory approval process, quality assurance, or auditing.

CENAPA has developed competency requirements for personnel conducting laboratory work. Additionally, CENAPA determines the required competence for personnel through the position profiles of each functional area, which describe the training, experience, and characteristics that personnel should have when carrying out the laboratory activities. These requirements are documented in position profiles for each functional area and describe the training, experience, and characteristics necessary for the work performed in that area. During review of CENAPA's requirements of laboratory personnel, the FSIS auditors did not identify any findings.

Mexico's government organizes and administers the country's meat and poultry inspection systems, and SENASICA officials implement and enforce laws and regulations governing production and export of meat and poultry products at TIF establishments certified to export to the United States. The FSIS auditors interviewed government inspection personnel, reviewed government inspection programs, and reviewed records without identifying any findings with the Mexican government's ability to provide oversight for the food safety inspection program.

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 equivalence component that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for good commercial practices in poultry; humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The Methods for the Humane Slaughter of Domestic and Wild Animals (NOM-033-SAG/ZOO-2014) has specific requirements pertaining to the humane handling and slaughter of livestock. That document also describes the general requirements for handling and moving livestock, stunning equipment, employee training, and proper slaughter methods including the stunning of animals. The Sanitary Inspection Manual in TIF Establishments (DGIAAP-MINP-08) requires TIF establishments to have a written manual describing the humane handling and slaughter

procedures that are to be implemented from the time the animals are received until the slaughter process. The MTF-SSN-SIS-02 outlines inspection procedures conducted by veterinarians at a frequency of three times per week and audited once annually by the state supervisor. The FSIS auditors did not identify any findings with SENASICA's requirements and implementation of humane handling procedures during interviews and the review of records.

All the livestock intended for slaughter at TIF establishments that export meat products to the United States receive ante-mortem inspection by an official veterinarian in accordance with the requirements described in the Sanitary Processing of the Meat (NOM-009-ZOO-1994). These requirements are implemented prior to animals entering the establishment by requiring authorization from an official veterinarian. They also include specific requirements applicable throughout the process such as entry into the facility, movement of animals, examinations, animal disposition, and other procedures ensuring the humane treatment of animals. The DGIAAP-MINP-08 describes the ante-mortem procedures conducted by the official veterinarians that are consistent with the requirements outlined in the NOM-009-ZOO-1994. Included in the procedures are proper handling and disposition of animals with certain conditions, such as bovine tuberculosis, bovine cysticercosis, BSE, and trichinosis in hogs. The FSIS auditors interviewed government inspection personnel and reviewed records during the audit and did not identify any findings with the implementation of ante-mortem inspection procedures.

Post-mortem inspection is conducted by an official veterinarian and in accordance with the requirements described in the NOM-009-ZOO-1994. These requirements include observation, palpation, and incision (where applicable and necessary) of each and every livestock foot, head, viscera, lymph node, and carcass for any abnormalities. The DGIAAP-MINP-08 provides instructions to government inspection personnel on how to conduct and document post-mortem inspection verification activities as well as the criteria used by the MVO for proper disposition of the livestock identified with diseases. The online official veterinarians perform these inspection activities to identify disease, lesions, nutritional status, and other abnormalities, and animals are retained when appropriate for disposition by a veterinarian. If the official veterinarian suspects disease and the diagnosis calls for laboratory tests, the carcass and its viscera are placed in a holding cage located in the cold-room until the test results are received and disposition is determined. During post-mortem inspection, any animals or parts determined unfit for human consumption are retained and condemned by SENASICA. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with post-mortem inspection procedures conducted by SENASICA.

The FLAH states that TIF establishments shall have enough official veterinarians or authorized individuals in charge to efficiently conduct inspections or verifications. This includes an adequate number of veterinarians based on the line speed at slaughter establishments. The line speed rate and the government staffing standards for on-line government inspection personnel at meat slaughter TIF establishments are consistent with the staffing standards described in 9 CFR 310.1. Daily records are generated to support the direct presence of government inspection personnel assigned by SENASICA to cover the TIF establishments. Each state supervisor manages the government inspection personnel in his/her jurisdiction to maintain the required presence and staffing levels. The FSIS auditors interviewed government inspection personnel

and reviewed records without identifying any findings with SENASICA's ability to meet staffing requirements.

The Performance Evaluation of the Veterinary Medical Official in TIF Establishments (DTIF-SSN-03) describes the procedure for the evaluation of the government inspection personnel. State supervisors visit the TIF establishments monthly, every other month, or every three months based on the size and HACCP categories. During these visits the supervisors evaluate both the government inspection personnel and TIF establishment. The evaluation of the TIF establishments is outlined in the Supervisory Activities at TIF Establishments (DTIF-SSN-02) and includes the entire process from the unloading of livestock to export certification.

The Supervision Information System (SIS) is used to manage the meat and poultry inspection activities of SENASICA field personnel and provides scheduling and recording of inspection procedures for verifying and enforcing regulatory requirements. The state supervisors, MVOs, and the MVRATIFs are the government inspection personnel responsible for implementing, monitoring, and maintaining this system. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with SENASICA's evaluation of government inspection personnel or TIF establishments.

The MTF-SSN-SIS-02 provides instructions for verifying complete separation of products certified for export to the United States from non-certified products. During the audit, SENASICA provided records demonstrating that products certified for export to the United States are separated during processing and storage at TIF establishments. Labeling requirements are verified on a monthly, bimonthly, or quarterly basis and during each occurrence of the export certification process. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with SENASICA's ability to maintain separation of certified products and verify the labeling requirements of products intended for export to the United States.

The General Directorate of Animal Health (DGSA) is the office in charge of maintaining the information related to the animal health status of regions and for communicating with the DGIAAP. In case of any new APHIS restrictions of products to be exported, the DGSA will notify the appropriate offices or personnel through official correspondence or via e-mail. The FSIS auditors did not identify any findings with the SENASICA communication and identification of APHIS requirements.

The Manual for Identification, Separation and Removal of Specific Risk Materials for Bovine Spongiform Encephalopathy Risk (M002.01) identifies the Specified Risk Materials (SRM) and procedures to follow for identification, separation, and removal of SRM in bovine animals. The MTF-SSN-SIS-02 provides instructions for the verification and documentation activities related to the verification of the SRM programs. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with SENASICA's SRM requirements and verification procedures.

TIF establishments are required to maintain receptacles that are specifically designated for inedible or condemned materials. Control and destruction of those materials take place under

inspection oversight. The MTF-SSN-SIS-02 outlines the government inspection verification activities related to the control of inedible and condemned materials. The proper control of inedible product is one of the criteria reviewed during the supervisory visits at the establishments. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with SENASICA's condemned material requirements and verification procedures.

The FSIS auditors concluded that SENASICA continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over meat and poultry establishments certified to export their products to the United States using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (sanitation SOP) to prevent direct product contamination or insanitary conditions, and to include requirements for sanitation performance standards (SPS) and sanitary dressing.

The Supervisory Manual for the Federal Inspection Type System (MTF-SSN-SIS-02) outlines the methodology for the government inspection personnel to follow in order to evaluate whether TIF establishments are in compliance with national and international requirements. The document states that TIF establishments must implement SPS and sanitation SOPs. Additionally, the document refers to the application of FSIS regulations consistent with 9 CFR Part 416-416.6 and 9 CFR Part 416.11-416.17 for SPS and sanitation SOPs, respectively, as well as the FSIS guidelines and directives in TIF establishments certified for export to the United States.

TIF establishments are required to develop, implement, monitor, document, and maintain procedures effective in ensuring slaughter, processing, handling, and storage of animal origin products occur in sanitary facilities and under conditions that control risks to the consumer of food products they produce. In addition to facility sanitation requirements and pre-operational and operational sanitation SOPs, TIF establishments are required to develop, implement, and maintain microbiological and toxicological control programs, traceability programs, follow-up programs of good practices on the farm (of animal suppliers for slaughter), labeling control programs, and employee training programs.

Official veterinarians verify compliance with sanitation requirements in accordance with the instructions in MTF-SSN-SIS-02. The FSIS auditors verified through document review and interviews that government inspection personnel conduct a daily pre-operational inspection after establishment personnel indicate the facility is ready for operations. An official veterinarian will randomly select equipment and areas of the establishment on Form SIS-11 (List of Areas and Equipment) to inspect and verify the adequacy of establishment cleaning and monitoring operations. The official veterinarian documents the results of the pre-operational inspection on Form SIS-16 (Sanitation SOP Veterinary Verification of Pre-operational), including any findings

of noncompliance. Official veterinarians reject equipment, if necessary, based on findings; observe establishment personnel correcting deficiencies; and re-inspect any areas prior to release for production. Official veterinarians also conduct daily procedures to verify operational sanitation with results of acceptable or noncompliant documented on Form SIS-01 (Activity Program). Additionally, depending on the noncompliance observed, the official veterinarian will complete Form SIS-10 (Activities Report) as well as Form SIS-02 (Notification of Deviation) to document critical findings or repetitive major findings.

The FSIS auditors verified through interview of SENASICA inspection personnel that TIF establishments are required to follow sanitary dressing procedures throughout slaughter operations. Daily, government inspection personnel ensure TIF establishments comply with requirements for sanitary carcass dressing in accordance with the SENASICA document DGIAAP-MINP-08. The inspection manual provides guidelines for verification of slaughter (sanitary) dressing procedures, thereby ensuring all activities are conducted in a manner to prevent cross-contamination and to maintain good hygienic practices throughout.

The Manual for the Verification of Procedures for the Control of Fecal Material, Ingesta and Milk at Slaughter Operations (MO08.00) provides government inspection personnel at TIF establishments with the methodology for enforcing the requirement that there be no visible fecal material, milk, or ingesta on livestock carcasses and on head meat, cheek meat, and weasand meat. The regulatory requirements used to develop the zero-tolerance manual were adopted from FSIS regulatory requirements found in 9 CFR Part 310.18. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with SENASICA's verification of zero tolerance requirements.

The FSIS auditors reviewed the corrective actions for two POE violations for contamination of raw product with foreign materials. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any issues with the corrective actions in response to the POE violations for product contamination.

The FSIS auditors determined that SENASICA requires TIF establishments to develop, implement, and maintain sanitation programs, and includes requirements for SPS and sanitary dressing. FSIS concludes that SENASICA continues to meet the core requirements for this component.

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

The fourth equivalence component that the FSIS auditors reviewed was Government Hazard Analysis and Critical Control Point (HACCP) System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

The Supervisory Manual for the Federal Inspection Type System (MTF-SSN-SIS-02) outlines the methodology for the government inspection personnel to follow in order to evaluate whether TIF establishments comply with national and international HACCP requirements. The document requires TIF establishments to adopt and implement a HACCP system. Additionally, the

document refers to the application of the FSIS regulatory requirements consistent with 9 CFR Part 417, as well as guidelines within the FSIS directives and the FSIS Microbiology Laboratory Guidebook, in TIF establishments certified as eligible to export to the United States.

On an annual basis, the official veterinarian performs a basic HACCP review using Form SIS-07 (HACCP Documentary Verification) whereby they document verification that each certified establishment's HACCP program includes product descriptions, written hazard analysis, flow charts, and HACCP plans to identify, evaluate, and prevent or control food safety hazards in the specific production processes. The HACCP plans must be validated, have monitoring and verification procedures, and have recordkeeping systems to include written corrective actions.

The official in-plant veterinarians schedule daily verification procedures on Form SIS-01 (Activity Program) for the upcoming month. On a daily basis the official veterinarians verify establishment controls, such as critical control points (CCP), through direct observation or record review for all production shifts, with results of verification being entered in the associated inspection records. Government verification activities include the evaluation of the establishment's written HACCP programs, records review, observation of establishment personnel performing monitoring and verification procedures, corrective actions when required, and documentation of results or recordkeeping activities.

The FSIS auditors reviewed documents confirming that SENASICA verifies CCPs in each certified establishment. Documents included in-plant inspection records of zero tolerance checks, daily CCP verification reviews, and documentation of findings when observed. Official veterinarians would document findings according to the MTF-SSN-SIS-02. When deviations from critical limits were observed, the government inspection personnel took action to identify and retain affected product, notify the certified establishment through documentation of the finding, and then review the establishment's corrective actions and responses to ensure all requirements were satisfactorily met. The FSIS auditors verified the official veterinarians used Form SIS-09 (Notification of Documentary Verification Result) to document any findings from the yearly verification review. Additionally, the FSIS auditors verified that either Form SIS-10 (Activities Report) or Form SIS-02 (Notification of Deviation) was completed by the official veterinarians and issued to the certified establishment requiring a response of corrective actions and preventative measures.

The FSIS auditors determined that SENASICA requires TIF establishments to develop, implement, and maintain a HACCP system for each processing category. FSIS concludes that the SENASICA continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing 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 products inspection authorities or by FSIS as potential contaminants.

The National Program on Toxic Residues (PNRT) 2020 outlines the chemical residue sampling plan for testing animal species slaughtered to produce meat products destined for domestic and international markets. The sampling protocols take the following into consideration: the registered use of a chemical compound of interest; the likelihood of a residue occurring in animal tissues; the extent and pattern of use of the compound; incentives for misuse; known persistence of the compound in the environment; past monitoring results; and requirements of importing countries. The chemical residue sampling plan also describes the applicable laws, laboratory criteria, corrective actions to be taken, various sampling schemes, selected matrices for each compound, and analytical methodology.

The PNRT for each year includes compounds that have been determined to represent a risk for the public health by SADER and the Secretary of Environmental and Natural Resources, by FSIS, or through the scientific works of internationally and nationally recognized institutions. The Inter-Secretarial Committee for the Evaluation and Follow-Up of the PNRT, coordinated by SENASICA, defines the priorities regarding the identification of toxic residues including antibiotics, sulfonamides, organochlorines, and organophosphate pesticides, antiparasitic products, growth boosters, and heavy metals. This committee also prioritizes analyses and assessment of the highest risk group for public and animal health. For meat products destined for export to the United States, SENASICA abides by tolerances set by FSIS and other United States governmental agencies.

SENASICA provides instructions to government inspection personnel to collect samples for residue testing as part of the PNRT. Inspectors collect meat, fat, liver, and kidney tissues from beef, lamb, sheep, swine, and goat species at slaughter facilities. The FSIS auditors verified through review of records and interviews that government inspection personnel collect the samples and that the program was implemented as designed. In addition, the FSIS auditors verified the proper implementation of a "hold and test" program for chemical residues, in which sampled carcasses are held at TIF establishments until the result is obtained. While verifying the implementation of the PRNT sampling procedures at TIF establishments, the FSIS auditors identified the following finding:

- Mexico's Procedure for the Collection and Shipping of Toxic Residue Samples in TIF Establishments in accordance with the administrative requirements described in the Federal Law of Administrative Procedure, which SENASICA is required to follow, allows the legal representatives of TIF establishments to appeal chemical residue samples with confirmed violative or unacceptable test results and to have an additional analysis conducted on the retention sample. A retention sample is a companion sample collected at the same time and collected from the same carcass and tissue as the primary sample. If the additional analysis result is negative, then the second result negates the original violative or unacceptable test result. This is not consistent with FSIS requirements for which the primary sample, analysis, and corresponding analytical result are expected to be representative of the sampled carcass. Therefore, FSIS does not consider the practice of performing a second analysis to support or refute the original results to be equivalent. Through interviews and records review, the FSIS

auditors were able to confirm that testing of the second companion sample has never been requested by a TIF establishment for any products intended for export to the United States and that all positive or violative test results have been accepted as final.

The PNRT describes how SENASICA notifies TIF establishments when the results of the official chemical residue tests exceed the established tolerance levels for the United States or contain unauthorized chemical compounds. Upon receiving the notification of nonconforming results, SENASICA issues an official letter to the state supervisor of the implicated TIF establishment, who in turn informs the establishment of the nonconforming results and requests the information regarding the traceability of the sample and the implementation of corrective actions. The state supervisor then verifies the corrective actions, which includes visits to the TIF establishment until case closure and providing SENASICA with a final report. The FSIS auditors verified how SENASICA responds to unacceptable chemical residue results by interviewing government inspection personnel and reviewing records.

Prior to the audit, the FSIS residue experts reviewed the PNRT 2020, associated methods of analysis, and additional SRT responses outlining the structure of Mexico's chemical residue testing program. There have been two POE violations related to this component since the 2018 FSIS audit. FSIS auditors verified the corrective actions for the two POE violations regarding violative residues since the 2018 audit.

The FSIS auditors verified that Mexico's meat inspection system continues to maintain a chemical residue testing program organized and administered by the national government. The SENASICA maintains 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 products destined for export to the United States. However, the FSIS auditors identified a systemic finding with SENASICA's residue sampling program, which allows by appeal for a second, companion sample to be tested when the first test is unacceptable. The second test result would either support or refute the first test result, and this type of repeat testing is not equivalent under FSIS requirements.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to verify that meat and poultry products prepared for export to the United States are safe and wholesome. This component also addresses requirements for TPCS meat products.

The Manual for the Verification of the Sampling Program of *Escherichia coli* Biotype I in Establishments Exporting Meat Products to the United States of America (MO07.00), outlines the SENASICA government inspection methodology for verifying requirements of TIF establishment sampling of livestock carcasses for generic *E. coli*. This manual includes instructions for inspection personnel to document noncompliance and assess corrective actions. The standards that SENASICA has set and that TIF establishments are required to follow are

consistent with FSIS requirements for U.S. establishments. The FSIS auditors confirmed through interviews and records review that the government inspection system verifies the requirements for generic *E. coli* sampling and testing at TIF establishments and did not identify any concerns.

SENASICA has an official sampling program for the detection of *Salmonella*. The Procedure for the Official Verification of the Performance Standard for *Salmonella* spp. as a Process Indicator in Cattle, Pork and Non-Intact Raw Products (PR-TF-SM-12), describes the *Salmonella* sampling requirements, including sampling method, detection methodology, and evaluation of results that government inspection personnel follow. This manual also outlines that government veterinarians take the samples and the requirements and the specific corrective actions to be taken by TIF establishments for unacceptable results. The FSIS auditors verified through interviews, test results, and records review that the government inspection system is meeting the sampling and testing requirements for *Salmonella* at TIF establishments without identifying any findings.

The Procedure for the Official Verification of Control Activities: E. coli O157:H7, Shiga Toxin-Producing Escherichia coli (STECs) and Salmonella spp., outlines the STEC government sampling and testing requirements for TIF establishments that export raw beef products as well as provides instructions to government inspection personnel for collecting and submitting samples of raw beef products for official verification testing. This procedure is applicable to all TIF establishments that process raw minced (ground) meat; hamburgers; raw ground beef components such as weasand meat, head meat, cheek meat, and heart meat; tongue; cuts of meat; marinated meats; and fermented bovine meat products. The seven serotypes of STEC (O157:H7, O26, O45, O103, O111, O121 and O145), are identified for testing to comply with the regulations applicable to TIF establishments certified as eligible to export raw beef products to the United States. SENASICA's inspection system requires establishments to implement appropriate corrective actions when testing identifies presence of STEC. The PR-TF-SM-11 addresses the procedures to be followed upon receiving presumptive and confirmed positive results for STEC as well as the traceability and recordkeeping mechanisms for the supplier(s) of adulterated product. The FSIS auditors verified through interviews, test results, and records review that the government inspection system meets the sampling requirements for STEC at TIF establishments without identifying any findings.

SENASICA requires TIF establishments that produce ready-to-eat (RTE) meat and poultry products for export to the United States to meet regulatory requirements consistent with 9 CFR Part 430. Additionally, SENASICA tests RTE products that have no post lethality exposure for *Lm.* The Procedure for the Official Verification of Control Activities for *Listeria monocytogenes* and *Salmonella* in Ready to Eat Products (PR-TF-SM-13), establishes a zero tolerance for both *Lm* and *Salmonella* in RTE meat and poultry products and identifies that RTE products are considered adulterated if products come into direct contact with a surface that tests positive for *Lm* or *Salmonella*. The PR-TF-SM-13 requires TIF establishments to maintain a microbiological sampling program independent from government sampling and testing, that meets requirements consistent with those in 9 CFR Part 430.

SENASICA conducts verification testing of RTE products routinely, on a random basis, and based on risk. For government sampling, the PR-TF-SM-13 outlines the sampling frequencies based on the alternative chosen by the establishment, type of product according to the risk, production volumes, and production schedules and shifts. All RTE samples are analyzed for *Lm* and *Salmonella*. If the products are cured, semi-dried, or dried beef or fully cooked beef patties, they will also be tested for *E. coli* O157:H7. Government inspection personnel are instructed via the MTF-SSN-SIS-02 to verify establishment sampling and testing results once per week and is included in the annual state supervisor audit.

Additionally, SENASICA performs a sample set to include food contact surfaces, non-food contact/environmental surfaces, and products for *Lm* and for *Salmonella* (if directed), at minimum once per year, as outlined in the PR-TF-SM-13. A pathogen positive result from official sampling will result in the official veterinarian suspending issuance of the export certification until the establishment's corrective actions have been implemented and verified, which includes completion of intensified verification testing.

The FSIS auditors reviewed the government's verification records of the establishment's sampling activities for *Lm* and *Salmonella* in RTE products. Additionally, the FSIS auditors confirmed SENASICA's verification sampling program for *Lm* and *Salmonella* in RTE products. These reviews included interviews of government inspection personnel, government test results, records review, and establishments corrective actions records. The FSIS auditors did not identify any findings with the government verification procedures for *Lm* and *Salmonella* control programs.

SENASICA requires all TIF establishments producing TPCS products to develop a HACCP program that addresses the food safety hazards associated with the production of TPCS meat and poultry products. The HACCP program is verified using the SIS manual, and the verification procedures are consistent with the FSIS verification instructions in FSIS Directive 5000.1 Verifying an Establishment's Food Safety System. Furthermore, SENASICA requires TIF establishments to follow the 2018 Inspection Procedures for Thermally Treated Commercially Sterile Meat Products in TIF Establishments, which provides detailed information on requirements and instructions to government inspection personnel on verifying compliance of the TPCS establishments. The requirements are consistent with those enumerated in 9 CFR Part 431. The FSIS auditors interviewed government inspection personnel and reviewed records without identifying any findings with SENASICA's verification of requirements at TPCS establishments.

During the remote audit, the FSIS auditors reviewed corrective actions from the 2018 FSIS audit finding regarding SENASICA's TPCS sterile requirements at TIF establishments and government inspection verification procedures. Additionally, the FSIS auditors reviewed corrective actions regarding the POE violations and government verification activities at the TPCS TIF establishment from which the FSIS inspectors identified swollen and leaking pouches of TPCS poultry products during FSIS POE reinspection. The FSIS auditors interviewed government inspection personnel and reviewed records and did not identify any issues with SENASICA's corrective actions for the findings from the previous the FSIS audit or POE violations.

The FSIS auditors determined that SENASICA maintains the legal authority to implement its microbiological sampling and testing programs to ensure that meat and poultry products destined for export to the United States are unadulterated, safe, and wholesome.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held remotely on June 17, 2021, 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 finding:

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- Mexico's Procedure for the Collection and Shipping of Toxic Residue Samples in TIF Establishments in accordance with the administrative requirements described in the Federal Law of Administrative Procedure allows for a second chemical residue test on a companion sample when the initial test result is unacceptable. If the result from the second sample test is acceptable, then it negates the original unacceptable result. FSIS does not consider the practice of performing a second analysis to support or refute the original results to be equivalent.

During the audit exit meeting, SENASICA committed to address the preliminary findings as presented. FSIS auditors were able to confirm through interviews and records review that testing of the second companion sample has never been requested by a TIF establishment for any products intended for export to the United States and that all positive or violative test results have been accepted as final. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

Appendix: Foreign Country Response to the Draft Final Audit Report

AGRICULTURA
SECRETARÍA DE AGRICULTURA Y DESARROLLO RURAL

SENASICA
SERVICIO NACIONAL DE SANIDAD, INOCUIDAD Y CALIDAD AGROALIMENTARIA

Dirección General de Inocuidad Agroalimentaria, Acuícola y Pesquera

N° de Oficio B00.04.01.4648 -2021

Ciudad de México a 26 OCT 2021

PhD. MICHELLE CATLIN
COORDINADORA EJECUTIVA
INTERNACIONAL DEL FSIS
PRESENTE

Me refiero a su oficio de fecha 01 de septiembre del presente año, mediante el cual envía a este Servicio Nacional una copia preliminar del informe final de la auditoría de verificación a distancia del sistema de inspección de carne, productos cárnicos y avícolas de nuestro país, llevada a cabo del 04 de mayo al 17 de junio del presente año.

Al respecto, esta Dirección General después de haber revisado el documento no tiene comentarios del informe de auditoría. En lo que respecta al hallazgo identificado en el componente 5 *"Pruebas Gubernamentales del Programa de Residuos Químicos"*, se anexa el plan de acción propuesto esperando sea aceptable para el FSIS-USDA.

Sin más por el momento, reciba un cordial saludo.

Atentamente
La Directora

SADER | SENASICA
DIRECCIÓN GENERAL DE INOCUIDAD AGROALIMENTARIA, ACUÍCOLA Y PESQUERA
26 OCT 2021
DESPACHADO

Q.F.B. Amada Vélez Méndez

C.c.p. DR. FRANCISCO JAVIER TRUJILLO ARRIAGA. - DIRECTOR EN JEFE DEL SENASICA. - Presente.
MVZ. JORGE PAREDES PÉREZ. - DIRECTOR DE ESTABLECIMIENTOS TIF. - Presente.

JPP/MIRM/jja

México 2021 Año de la Independencia

PLAN DE ACCION PROPUESTO POR LA AUTORIDAD CENTRAL COMPETENTE (ACC)

Informe final de una auditoria rutinaria de verificación de equivalencia, al sistema de inspección mexicano de carne, productos cárnicos y avícolas, realizada a distancia por el Servicio de Inspección y Seguridad Alimentaria (FSIS) del Departamento de Agricultura de los Estados Unidos (USDA) en el período del 04 de mayo al 17 de junio del 2021.

Hallazgo	Acción propuesta por la ACC
Componente 5 Pruebas Gubernamentales del Programa de Residuos Químicos El procedimiento de México para la recolección y envío de muestras de residuos tóxicos en establecimientos TIF, de acuerdo con los requisitos administrativos descritos en la Ley Federal de Procedimiento Administrativo, permite realizar una segunda prueba de residuos químicos en una muestra complementaria cuando el resultado de la prueba inicial es inaceptable. Si el resultado de la segunda prueba de la muestra es aceptable, entonces anula el resultado inaceptable original. El FSIS no considera la práctica de realizar un segundo análisis para apoyar o refutar los resultados originales. Los auditores del FSIS pudieron confirmar, mediante entrevistas y revisión de registros, que el análisis de la segunda muestra complementaria nunca ha sido solicitado por un establecimiento TIF para ningún producto destinado a la exportación a los Estados Unidos y que todos los resultados positivos o violatorios de las pruebas han sido aceptados como definitivos.	Se actualizó el "Procedimiento para la toma y envío de muestras en busca de residuos tóxicos en establecimientos TIF" (documento adjunto), en el cual, en la página 14 se coloca la siguiente leyenda: • *En los establecimientos autorizados para la exportación de productos y subproductos, y que soliciten procesar la muestra testigo para validar un resultado con presencia de residuos tóxicos, independientemente de que el resultado de la muestra testigo haya salido negativo, la canal, productos y subproductos únicamente podrán ser destinados para su comercialización nacional.* Con ello, si bien se mantiene el derecho que tienen las empresas para utilizar la muestra testigo, conforme a lo establecido en el artículo 144 de la Ley de infraestructura de la Calidad, también se busca dar certeza de que, para establecimientos TIF autorizados para la exportación que busquen utilizar la muestra testigo por tener un resultado fuera de límite, no podrán destinar ese producto para la exportación, esto con base en el artículo 50 de la Ley Federal de Sanidad Animal.

ACTION PLAN PROPOSED BY THE CENTRAL COMPETENT AUTHORITY (CCA)

Final report of a routine equivalency verification audit of the Mexican meat, meat products and poultry inspection system, conducted remotely by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) during the period May 4 to June 17, 2021.

Finding	Action proposed by CCA
Component Five: Government Chemical Residue Testing Programs Mexico's Procedure for the Collection and Shipping of Toxic Residue Samples in TIF Establishments in accordance with the administrative requirements described in the Federal Law of Administrative Procedure allows for a second chemical residue test on a companion sample when the initial test result is unacceptable. If the result from the second sample test is acceptable, then it negates the original unacceptable result. FSIS does not consider the practice of performing a second analysis to support or refute the original results to be equivalent. FSIS auditors were able to confirm through interviews and records review that testing of the second companion sample has never been requested by a TIF establishment for any products intended for export to the United States and that all positive or violative test results have been accepted as final.	The "Procedure for taking and sending samples in search of toxic residues in TIF establishments" (attached document) has been updated and the following legend has been added on page 14: • In establishments authorized for the export of products and by-products, and that request to process the control sample to validate a result with the presence of toxic residues, regardless of whether the result of the control sample was negative, the carcass, products and by-products may only be destined for domestic marketing. Thus, while maintaining the right of companies to use the control sample, as established in Article 144 of the Quality Infrastructure Law, it also seeks to provide certainty that establishments authorized for export that seek to use the control sample for having an out-of-limit result will not be able to use that product for export, based on Article 50 of the Federal Animal Health Law.

The National Service of Health, Food Safety, and Food Quality
Food Safety General Directorate

COURTESY TRANSLATION

B00.04.01.4648-2021

Mexico City, October 26, 2021.

PHD. MICHELLE CATLIN
INTERNATIONAL COORDINATION EXECUTIVE
FSIS
PRESENT

I refer to your letter dated September 1, 2021, addressed to this National Service which included a preliminary copy of the final report of the FSIS remote verification audit performed to Mexico's inspection system of meat and, meat and poultry products, carried out from May 4 to June 17, 2021.

In this regard, after reviewing the document, this Directorate General has no comments on the audit report. Regarding the finding identified in component 5 "Government Tests of the Chemical Residues Program", attached you will find the proposed action plan, hoping it will be acceptable for FSIS-USDA.

Receive kind regards,

Sincerely,

THE DIRECTOR

Q.F.B. Amada Velez Mendez