



United States Department of Agriculture

Food Safety and
Inspection Service

July 14, 2023

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Dear Ing. Aguilar,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Honduras' meat inspection system January 23–February 2, 2023. Enclosed is a copy of the final audit report. You are invited to provide comments regarding the information in the audit report. The comments received from the Government of Honduras are included as an attachment to the final report.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination at InternationalCoordination@usda.gov.

Sincerely,

**MICHELLE
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Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF
HONDURAS
JANUARY 23–FEBRUARY 2, 2023

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
RAW BEEF PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

July 13, 2023

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Honduras conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from January 23–February 2, 2023. The purpose of the audit was to determine whether Honduras' food safety inspection system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Honduras currently exports the following categories of beef products to the United States: raw-intact and raw-non intact.

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.

FSIS concluded that Honduras' raw beef products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The National Plant and Animal Health Service (SENASA), Honduras' Central Competent Authority, has required that the establishment certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, SENASA has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Honduras' food safety system from January 23–February 2, 2023. The audit began with an entrance meeting January 23, 2023, in Tegucigalpa, Honduras, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – National Plant and Animal Health Service (SENASA). Representatives from SENASA accompanied the FSIS auditor throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference on February 2, 2023.

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 beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Honduras 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); Beef Patty Product; Finely Textured Beef (FTB); Ground Beef; Hamburger; Partially Defatted Chopped Beef (PDCB); Partially Defatted Beef Fatty Tissue (PDBFT); and Low Temperature Rendered Product
Raw - Intact	Raw Intact Beef	Beef - All Products Eligible except Cheek Meat, Head Meat, Heart Meat, and Weasand Meat

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Honduras as free of foot-and-mouth disease, and as undetermined risk for bovine spongiform encephalopathy (BSE).

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Honduras' Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditor

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

conducted interviews, made direct observations, and reviewed records to determine whether Honduras' food safety inspection system governing raw beef 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 SENASA through the 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative functions at SENASA headquarters, and one local inspection office within the establishment. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

Honduras has one beef slaughter/processing establishment certified to export raw beef to the United States. The products this establishment produces for export to the United States include boneless manufacturing trimmings, edible offal, primals, and subprimals.

During the establishment visit, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor assessed SENASA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) Part 327.2.

The FSIS auditor also visited one laboratory to verify that this laboratory is capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• SENASA, Tegucigalpa
Laboratory		1	• LANAR, government laboratory, chemical residue and microbiological, Tegucigalpa
Beef slaughter and processing establishment		1	• Establishment No. 20M, Agroindustrias Del Corral, S. de R.L., Siguatepeque

FSIS performed the 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 Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR 301 to the end).

The audit standards applied during the review of Honduras' inspection system for raw beef 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 November 1, 2019, to October 31, 2022, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 4,756,648 pounds of raw beef from Honduras. Of these amounts, additional types of inspection were performed on 603,041 pounds of raw beef, including physical examination, chemical residue analysis, and testing for microbiological pathogens (*Salmonella* and Shiga toxin-producing *Escherichia coli* [STEC] O157, O26, O45, O103, O111, O121, and O145 in raw beef products). As a result of this additional testing, no raw beef products were rejected for issues related to public health. Sixty pounds of raw beef products were refused for other issues not related to public health including shipping damage, labeling, or other miscellaneous issues.

During the last audit in 2021, FSIS did not identify any findings. The most recent FSIS final audit reports for Honduras' food safety inspection system are 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 auditor reviewed was Government Oversight. FSIS 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.

In Honduras, the Phytosanitary Law Decree No. 157-94, and Decree No. 344-2005 state that, among its responsibilities, the Ministry of Agriculture and Livestock directs its efforts in strengthening food safety, the application of sanitation measures, approval of establishments and animal sanitation systems, and the accreditation of professionals and companies through SENASA, which is the CCA in Honduras. As Honduras' CCA, SENASA holds the overall responsibility for setting policy, implementing legislation, and managing official controls

regarding food safety in accordance with Decree No. 157-94 and Decree No. 344-2005. SENASA maintains the Official Inspector Guide for Meat Products (SGIA-GIPC-05), which provides procedures and guidelines for implementation of the inspection system based on Honduras' Regulation for the Inspection of Meat and Meat Products (Regulation No. 078-00). Decree No. 157-94 gives SENASA the authority to enforce the requirements. The FSIS auditor verified that SENASA continues to maintain the overall responsibility for policy, legislation, and implementation of official controls in relation to food safety in accordance with Decree Nos. 157-94 and 344-2005.

Within SENASA, the Technical Directorate of Food Safety (DIA) is responsible for the inspection of meat products intended for export to the United States. In 2021, SENASA revised its organizational structure and replaced the Sub-Directorate General for Agrifood Safety with DIA. The Technical Director of Food Safety carries out the general coordination tasks of DIA and conducts performance evaluations of the headquarters and National Supervisors. The Head of the Meat and Meat Products Department is responsible for annual audits of establishments, exports of meat products, and supervising the inspection and verification activities of personnel assigned to establishments in accordance with the provisions of Regulation No. 078-00. The Meat Products Supervisor is responsible for supervising government inspection personnel at establishments and performing routine audits of establishments throughout the year. Additionally, DIA is responsible for oversight, approval, and disapproval of laboratories conducting analyses for official government sampling programs.

The FSIS auditor verified SENASA maintains offices within each establishment that are responsible for conducting daily inspection verification procedures. SENASA's verification activities at the establishment certified for export to the United States are conducted by the Official Veterinarian Inspector (OVI), Official Auxiliary Inspector (OIA), and Official Veterinarian Supervisor (OVS). These procedures are designed to verify the establishments are meeting requirements set forth by SENASA, which includes any export requirements. OVIs and OIAs verify compliance with the HACCP system, sanitation, labeling and other requirements to including pre-requisite programs. The OIA reports directly to the OVI and performs any duties assigned and must report all findings to the OVI. The OVS performs verification audits of establishments and government inspection personnel and supervises the government inspection personnel during their verification tasks.

Only those establishments that are registered and under official inspection of SENASA may sell domestically or export raw beef products. SENASA is responsible for overseeing and managing the establishment authorization and certification process as well as making the final determination on whether to allow an establishment to export products. The procedure for the certification of establishments is described in SGIA-GIPC-05. After initial certification, establishments must apply for certification annually. Upon initial and annual certification SENASA follows the requirements outlined in Regulation No. 078-00. SENASA maintains the authority to suspend or delist establishments from export certification when requirements are not met. The FSIS auditor interviewed SENASA personnel and reviewed establishment certification records without identifying any findings.

Regulation No. 078-00 provides SENASA with the authority and responsibility to certify products for export. SENASA maintains procedures for certification of exported products. These procedures include verification that the export application is accurate and complete; the import requirements are met; the export certification checklist is complete; and the physical inspection of products to verify they are not adulterated or misbranded. Additionally, SENASA requires government inspection personnel to confirm any government and establishment sampling done on lots of product destined for the United States have acceptable test results prior to certification for export. SENASA has procedures for securing export certificates, stamps, seals, and certificate inventory records. The FSIS auditor interviewed SENASA personnel and reviewed examples of certification records without identifying any findings.

The FSIS auditor verified that if government inspection personnel determine that a noncompliance has occurred, they are to document the noncompliance finding using a Demand for Corrective Action (DAC) form. SENASA classifies the DAC as Minor (finding(s) does not constitute a direct impact on the safety of the product), Major (finding(s) could have a direct impact on the safety of the product), and Critical (finding(s) have a direct impact on the safety of the product). If the establishment does not address the required action within 5 days (for minor findings), 3 days (for major findings or two or more repeated minor findings), or 24 hours (for critical findings), the establishment could lose its certification for export.

The FSIS auditor verified SENASA has the authority to require corrective actions, take additional enforcement measures as appropriate, and verify the effectiveness of those actions. SENASA's SGIA-GIPC-05 outlines how and when government inspection personnel must pursue enforcement measures. Establishments that do not comply with SENASA's regulatory requirements receive a Notice of Intended Inspection Withdrawal, which means that government inspection personnel are to be removed from the establishment and SENASA will not approve the slaughter of any animals in the establishment. Establishments that do not comply with the regulatory requirements of an importing country receive a Notice of Intended Delistment and have 30 business days to provide a response to SENASA or they are removed from the certified establishment list.

The FSIS auditor verified SENASA requires establishments to develop a traceability and recall program and maintains inspection verification procedures for verification of these requirements. OVIs are required to verify establishments have designed and implemented product recall programs at least monthly. Verifications include product traceability and identification programs from farm to distribution. Establishments are required by SENASA to perform mock recall procedures that are verified by the OVI. The OVI must immediately inform the OVS upon receiving notification of adulterated or mislabeled product that has entered commerce for either the local or export market. In the event of a recall involving products exported to the United States, SENASA will immediately notify FSIS.

SENASA is notified via the FSIS automatic notification system of updates to FSIS import requirements. SENASA officials (1) review the FSIS notification document; (2) provide a summary of significant modifications; and (3) distribute electronically to field personnel. If needed, SENASA includes definitive and significant modifications in its next revision of the inspection guidelines or other programs established by SENASA for products intended for export

to the United States. FSIS interviewed government inspection personnel and verified that they were knowledgeable about work instructions, operational procedures, and regulatory guidance provided to them by SENASA to conduct inspection activities and verify that food safety controls at the establishment certified to export to the United States meet SENASA's requirements.

SENASA's inspection system is organized and staffed to ensure uniform enforcement of its laws and regulations governing meat inspection at the certified establishment. SENASA assigns official personnel for government inspection activities and has ultimate control and supervision over government inspection personnel. SENASA implements procedures to maintain adequate staffing at the establishment eligible to export to the United States to ensure inspection coverage throughout every slaughter period at least once during processing. SENASA requires continuous inspection during the slaughter of livestock in the certified slaughter establishment while slaughter activities are conducted. SENASA assigns OVIs, OIAs, and an OVS to inspect cattle and perform verification activities in all establishments that process animal products and by-products.

As part of the certification process, the establishment is required to have government inspection personnel assigned to the establishment the entire day of slaughter and processing. Regulation No. 078-00 describes that the OVIs and OIAs are to perform inspection duties according to the assigned schedule and that the OVI is responsible for inspection during the slaughter of all the animals or lot of animals that are destined for human consumption. Honduras does not source raw materials from other countries to manufacture FSIS regulated products for export to the United States. All product exported to the United States is certified directly from establishments that are eligible to export to the United States. The SGIA-GIPC-05 specifies that only establishments that are registered and under the inspection of SENASA may sell beef locally or for export. The FSIS auditor interviewed government inspection personnel and reviewed government verification records that demonstrated inspection coverage, including ante-mortem inspection and post-mortem inspection throughout slaughter, and at least once per shift during processing operations, was being provided.

SENASA is directly responsible for recruiting, hiring, and paying the wages of government inspection personnel from national budget appropriations and fees collected from the establishments. To avoid conflicts of interest and to ensure that government inspection personnel act in the public's interest, SENASA maintains requirements in Decree No. 36-2007 – Code of Ethical Conduct of the Public Servant. The FSIS auditor verified that government inspection personnel (OVIs, OIAs, and OVSs) assigned to the establishment certified to export raw beef products to the United States are SENASA employees paid directly by the Honduran government.

The FSIS auditor verified through document review that SENASA assigns competent, qualified inspectors to the certified establishment that exports products to the United States, and ensures that they have appropriate education credentials, training, and experience to perform their inspection tasks. All OVIs must have a Doctor of Veterinary Medicine or equivalent degree, and the OIAs must have specialized experience or education that enables them to perform their assigned duties. All new employees complete supplemental training on meat inspection

regulations, inspection and verification activities, and country-specific import requirements. Before any assignment to perform inspection and verification procedures, personnel are required to successfully complete training. Veterinary and non-veterinary personnel also receive on-the-job training when they are first assigned to the establishment certified to export to the United States.

SENASA requires periodic supervisory visits by the Head of the Department or the OVS to each certified establishment. The Head of the Department or the OVS must conduct monthly periodic supervisory reviews at each certified establishment and review documentation, records, and the establishment's written control programs to ensure compliance with SENASA's regulatory requirements. The Head of the Department or the OVS documents the results of the supervisory visit and conducts, at least once a year, an audit of the establishment's HACCP system and documents the results. Part of the supervisory reviews includes verification of the establishments' controls for pathogens. In addition, the National Laboratory for Residue Analysis (LANAR) provides SENASA with monthly reports on the establishments' compliance regarding performance standards for *Salmonella*, which are reviewed by the OVS.

SENASA utilizes LANAR for conducting analysis on samples taken from products intended to be exported to the United States. LANAR is required by SENASA to implement standards consistent with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards. Within LANAR are microbiology and chemical residue divisions that are required to use methods that are scientifically validated (e.g., ISO/IEC methods).

SENASA requirements include quality control procedures, training/educational requirements of personnel, maintenance of equipment/facilities, calibration of equipment, sample receipt/storage, reporting of results, traceability of samples, and proficiency testing. SENASA has the authority to approve and disapprove laboratories, and audits LANAR to ensure that ISO/IEC standards are maintained. SENASA conducts annual reviews of the laboratories to ensure that ISO/IEC 17025 standards are maintained. LANAR is also accredited by the Costa Rican Accreditation Entity (ECA). ECA is an agency within the government of Costa Rica that provides third party accreditation in accordance with ISO/IEC 17025 standards. ECA evaluations are conducted annually with a cycle of four years for review of the laboratory's scope of accreditation for microbiological and chemical residue methods. The FSIS auditor interviewed laboratory personnel and reviewed government records without identifying any findings regarding the laboratory conducting official analysis of samples collected from products intended for export to the United States.

The FSIS auditor verified that SENASA designated laboratories do not retest samples when results are found to be violative or unacceptable. The laboratories follow test methods required by SENASA for official samples of products intended for export to the United States. Test results are reported in a timely manner and products are held pending acceptable results prior to certification for export to the United States.

The FSIS auditor concluded that SENASA continues to organize, administer, and enforce its raw beef inspection system in a manner that meets the core requirements for this component.

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 the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and its 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.

Regulation No. 078-00 requires that all animals that are to be slaughtered undergo ante-mortem inspection by an inspector who will ensure humane handling and humane methods of slaughter. SENASA has humane handling and animal welfare requirements at the establishment certified for export to the United States that are verified daily by OVIs. SENASA's requirements include handling of animals from the time they are unloaded until the start of post-mortem inspection. This includes receiving, holding, access to water, feeding when required, movement, stunning, and bleeding of animals. SENASA provides verification procedures for OVIs regarding humane handling and animal welfare. The FSIS auditor verified OVIs conduct humane handling and animal welfare inspection verification procedures on all animals prior to slaughter.

Regulation No. 078-00 has requirements for ante-mortem areas, records, and the prevention of slaughter of animals with diseases or abnormalities that may make them unfit for human consumption. The FSIS auditor verified SENASA has ante-mortem inspection procedures that OVIs must perform, including ensuring that each animal receives inspection, at rest and in motion, prior to slaughter. Animals suspected of having a disease or abnormality are required to have a disposition performed by an OVI to ensure that animals not meeting SENASA's requirements will not be allowed to be slaughtered. Animals awaiting disposition are identified and segregated and not allowed to be slaughtered until OVIs have performed their disposition. If an animal is found unfit for slaughter, it must be identified as such and disposed of according to SENASA requirements.

Regulation No. 078-00 requires that cattle be subjected to a post-mortem inspection immediately after slaughter, and there be an examination of the head, organs, and tissues to ensure that there is no part affected with diseases or conditions that would make it unfit for human consumption. The FSIS auditor verified that SENASA requires every carcass and its parts to receive post-mortem inspection and maintains procedures that inspectors are required to follow while performing post-mortem inspection. SENASA maintains procedures to verify that carcasses are not contaminated with fecal material, ingesta, or milk. Additionally, the OIAs are to notify the OVI when they believe that the establishment's slaughter or dressing procedures are not under control leading to repeated issues with contamination of carcasses during processing. At the one establishment, the FSIS auditor verified SENASA maintains standards for post-mortem inspection that assign inspectors based on slaughter volume and are consistent with FSIS standards.

The FSIS auditor verified SENASA requires the OVS to make periodic (at least monthly) supervisory visits to the certified establishment for the purpose of evaluating the performance of the government inspection personnel (OVI and OIA). These reviews consist of on-site observations of the inspection personnel executing inspection and verification activities. The OVS assesses government inspection personnel assigned to perform official duties at the establishment in the following areas: ante-mortem inspection, humane treatment/welfare of animals, post-mortem inspection, sanitation, HACCP, labeling, export certification activities, sampling methodology and collection procedures for the microbiological and residue programs, and official control over condemned materials.

SENASA requires the establishment to maintain the identity of products and to control and segregate products eligible to be exported to the United States from products not eligible to be exported to the United States. The FSIS auditor verified that the certified establishment processed raw products only from livestock that were slaughtered on-premises and did not receive any raw materials from outside sources. Products intended for export are processed under the same conditions and standards as products for domestic consumption. Any additional requirements from importing countries are verified prior to the OVI signing the export certificate. SENASA requires complete separation of eligible packaged products intended for export to the United States from ineligible products by space or time in the coolers and freezers.

SENASA requires establishments to properly label products meeting the requirements of Regulation 078-00 and any additional requirements of importing countries. The FSIS auditor verified that government inspection personnel perform labeling verification procedures when assigned during daily inspection procedures. Additionally, prior to signing export certificates the OVI verifies that products being exported are labeled correctly meeting importing countries requirements.

The FSIS auditor verified SENASA ensures compliance with APHIS requirements. SENASA communicates with APHIS on animal disease requirements and monitors the APHIS website. SENASA has BSE requirements for bovine which are verified by the OVI and OVS during supervisory visits. Prior to signing export certificates, the OVI signing the certificate ensures APHIS requirements have been met. When changes occur, SENASA is notified through the APHIS regional office located in Guatemala and the USDA's Foreign Agricultural Service office in Tegucigalpa, Honduras. Pre-printed export certificates issued by SENASA for a given country are specific to species and commodity.

SENASA maintains a definition of specified risk materials (SRMs), which is consistent with FSIS requirements in 9 CFR 310.22. SENASA requires establishments to develop and implement segregation and control measures for SRMs, which include appropriate removal and disposal of all SRMs. SENASA's requirements are verified daily by the OVI and OVS during supervisory visits. Bovines that show signs of a central nervous disease or do not arrive in an ambulatory condition are condemned, and their carcasses and parts are considered inedible. The FSIS auditor verified the establishment addresses the control, removal, and disposal of SRMs in written programs and that government inspection personnel verify implementation of these procedures.

Regulation No.078-00 requires that carcasses, half carcasses, quarters, or parts that have been determined to be inedible are to be denatured with an odorless product approved by SENASA. The FSIS auditor verified that SENASA maintains inspection procedures for the control of inedible and condemned materials. These procedures require the identification of containers holding inedible materials, condemned materials, and SRMs. Government inspection personnel verify that these materials are destroyed at the establishment or denatured prior to leaving the establishment. The OVIs verify any of the materials leaving the establishment to be destroyed have records of destruction on file from the facility destroying them.

The FSIS auditor concluded that SENASA continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over raw beef 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 auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (SOP) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

Regulation No. 078-00 outlines the requirements for sanitation official establishments need to follow, and SENASA maintains inspection verification procedures based on this regulation. The regulation outlines requirements regarding the facility and equipment and is consistent with FSIS requirements found in 9 CFR 416.1–416.5. The establishment certified for export to the United States is required to develop and implement sanitation SOPs. SENASA’s requirements for sanitation SOPs are consistent with FSIS requirements found in 9 CFR 416.11–416.17.

SENASA has requirements for standards of construction, facilities, and equipment that include all areas of the establishment. SENASA also has inspection verification procedures for establishment construction, facilities, and equipment and holds the authority to take formal enforcement actions to direct an establishment to rectify both hygiene and structural deficiencies. The OVI performs verification activities each day to verify the establishment is meeting these sanitation standards. The OVS conducts verification procedures during supervisory reviews. The FSIS auditor did not identify any systemic findings during the audit with standards for construction, facilities, or equipment. However, observations regarding sanitary noncompliance were made at the audited establishment, as detailed on the establishment checklist provided in Appendix A. During the audit, SENASA provided corrective actions from the establishment in response to the observations identified.

The FSIS auditor verified the establishment certified for exporting products to the United States are required by SENASA to develop and implement sanitation SOPs to include pre-operational and operational procedures. The sanitation SOPs must include pre-operational and operational procedures designed to ensure meat is not adulterated during production and storage.

Preoperational procedures must outline the cleaning of food contact surfaces and equipment. Sanitation SOPs are required to be monitored by the establishment at least daily. The OVI performs verification activities each day to verify the establishment is meeting sanitation SOP requirements and that products are not being contaminated or adulterated. The OVS conducts verification procedures during supervisory reviews.

Regulation No. 078-00 sets the requirements for sanitary dressing of cattle throughout the slaughter operation. The FSIS auditor verified the certified establishment maintains sanitary dressing procedures designed to prevent carcass contamination during the process. SENASA requires verification procedures to be conducted daily by the OVI. The OVS conducts sanitary dressing verification procedures during supervisory reviews.

SENASA requires inspectors to perform inspection and verification procedures for the control of fecal material, ingesta, and milk. The FSIS auditor verified OIAs verify the establishment's controls for fecal material, ingesta, and milk during performance of post-mortem inspection at the last inspection point prior to any washing of the carcasses. For each occurrence, the OIA stops the line and requires the carcass to be reprocessed and reexamined. If the OIA identifies that the process is out of control by repeated observations of carcass contamination, the OVI is notified and a DAC is documented, requiring immediate corrective actions from the establishment. Verification is conducted daily by the OVI based on the number of animals slaughtered. The OVS conducts verification procedures during supervisory reviews.

The FSIS auditor determined that SENASA requires operators of the establishment certified to export to the United States to develop, implement, and maintain sanitation programs to prevent direct product contamination or insanitary conditions. FSIS concludes that SENASA's food safety inspection system 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 the FSIS auditor 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 auditor verified SENASA requires the establishment certified to export to the United States to meet requirements consistent with FSIS requirements found in 9 CFR 417 for the implementation of HACCP. SENASA, through Regulation No. 078-00, outlines regulatory requirements for the establishment exporting to the United States to develop, implement, and maintain a HACCP system that incorporates the seven principles of HACCP.

The FSIS auditor verified SENASA requires the establishment exporting products to the United States to maintain a flow diagram and conduct a hazard analysis for each process, such as slaughter and raw processing. The hazard analysis decisions must be supported, and a HACCP plan must be written for hazards identified as reasonably likely to occur. The HACCP plan must identify critical control points (CCP), critical limits (CL), monitoring of CLs at CCPs, verification activities, and corrective actions to be taken when a deviation of a CL occurs. A

record keeping system for the monitoring, verification, and corrective actions must meet the HACCP requirements SENASA has set for recordkeeping. Records must be maintained for a minimum of one year after they are created and be accessible to DIA personnel.

The FSIS auditor verified the establishment exporting products to the United States must conduct pre-shipment reviews ensuring that all critical limits, corrective actions, and other HACCP system requirements, such as prerequisite programs, are met for each lot of product prior to shipping. At least annually or whenever there is a change or modification that could affect the decisions made in the hazard analysis, establishments must conduct a reassessment on the HACCP system. HACCP plans must be signed and dated by a qualified establishment employee that has been trained on HACCP principles.

The OVI and OVS are required to verify the validity of an establishment's HACCP system by assessing whether the plan complies with SENASA's HACCP requirements. The verification includes review of documents that support the HACCP system. The FSIS auditor verified OVIs perform HACCP system verification procedures at least once per month. These verification procedures include direct observation and record reviews of the establishment's implementation of its HACCP system. OVSs verify SENASA's HACCP requirements monthly through supervisory visits at the certified establishment. These supervisory reviews include verifying the OVI's performance of HACCP verification procedures. At least once a year the OVS must conduct an audit of the establishment's HACCP system to verify its compliance and document the results.

The FSIS auditor determined that SENASA requires the establishment certified to export to the United States to develop, implement, and maintain HACCP programs. FSIS concludes that SENASA's food safety inspection system continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditor 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Prior to the audit, FSIS reviewed Honduras' 2022 National Residue Program (NRP) plan and 2021 results, including methods of analysis and additional SRT responses outlining the structure of Honduras' NRP. Methods of analysis are consistent with those outlined in the FSIS Chemistry Laboratory Guidebook or equivalent alternative.

Honduras' Phytosanitary Law states that SENASA must verify and enforce compliance of the maximum residue limits (MRL) for chemical compounds and food contaminants established in the NRP for food products intended for consumers. The NRP establishes MRLs for the compounds of interest according to Honduran regulations. For products exported to the United

States MRLs established by the United States Food and Drug Administration and the United States Environmental Protection Agency are followed.

SENASA requires NRP samples to be taken by OVIs or OIAs at the establishment. When taking samples, the OVI or OIA follows SENASA procedures for each sample, including for preparing, collecting, storing, signing, and sealing samples. The NRP states that sampled carcasses and parts are to be held until chemical residue results from LANAR are obtained. The NRP provides procedures for verification of analytical results and the action level for products being exported to the United States. The analysis report for samples from LANAR includes the sample result and the maximum residue limit or action level that has been determined in the NRP, which is harmonized with United States tolerances as described above. LANAR immediately notifies the OVI and OVS whenever a suspect or confirmatory violative result is detected. For each analysis the OVI verifies if the result complies with the established tolerance level for products exported to the United States. The establishment's chemical residue results from self-monitoring are also verified by the OVS every month during the supervisory reviews.

The NRP describes the follow-up procedures that SENASA takes for violative test results. The OVI issues a DAC and requests that the establishment investigate to identify the lot(s) involved and determine the disposition of the product. The establishment must identify the cause of the violative test result, reassess the HACCP plan, determine corrective actions, and develop preventive measures in response to the violation. SENASA will increase the number of government samples collected of products determined to have violative results and SENASA does not return to normal sampling frequencies until 16 consecutive non-violative chemical residue results are obtained from government sampling.

The FSIS auditor verified that government inspection personnel who collect the residue samples are following SENASA's sampling protocol. This protocol includes sampling methodology, identification of animals, sampling frequency, traceability, and sample security of residue samples. Beef carcasses and parts intended for export to the United States are not allowed to be processed and shipped until any chemical residue test result is reported as non-violative.

The FSIS auditor verified that Honduras' raw beef inspection system continues to maintain a chemical residue testing program organized and administered by the national government. SENASA maintains the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of chemical residues and contaminants in raw beef products destined for export to the United States. There have not been any POE violations related to this component since the previous FSIS audit in 2021.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that raw beef products prepared for export to the United States are safe and wholesome.

SENASA requires microbiological sampling programs be implemented by government inspection personnel and establishments for verification of the beef slaughter process at the establishment exporting products to the United States. These requirements include *Salmonella* and STEC sampling by OVIs and OIAs. The Establishment is required to implement a sampling program and test for generic *E. coli* as an indication of process control. Implementation of this program is verified by the OVI and OVS at the establishment.

The FSIS auditor verified SENASA requires the establishment to carry out the microbiological evaluation for generic *E. coli* in beef carcasses sampled to ensure that process control systems are effectively preventing fecal contamination. The OVI verifies the establishment's implementation of generic *E. coli* sampling and analysis by reviewing the results four times per month and verifying the sampling procedure once per month. The OVS verifies the implementation of the establishment's program quarterly. When violations occur, the establishment is required to identify the cause and control point that was ineffective and take corrective actions. Government inspection personnel must verify that these actions are working as intended and that the HACCP plan has been reevaluated. If noncompliance is observed with the establishment's generic *E. coli* sampling program, a DAC is issued, and the OVI verifies corrective actions once implemented.

The FSIS auditor verified SENASA requires government inspection personnel to sample beef carcasses for *Salmonella* at the establishment certified to export products to the United States. The FSIS auditor verified that SENASA's Program of Reduction of Pathogens (SGIA-PRPPC-05) outlines the procedures government inspection personnel are to follow when taking and analyzing samples and the performance standards by which the results are evaluated. SGIA-PRPPC-05 outlines random selection of carcasses, locations of sampling, sampling methodology, evaluation criteria, and frequency of sampling.

Regulation No. 078-00 and SGIA-PRPPC-05 describe the actions taken by SENASA when the establishment fails to meet the *Salmonella* performance standard criteria, which includes follow-up verification sampling (after the first and second failures) or suspension (after the third failure). The FSIS auditor verified that SENASA's *Salmonella* sampling and testing program for beef carcasses is being implemented as documented.

SENASA enforces a zero-tolerance policy and identifies STEC (including serogroups O157, O26, O45, O103, O111, O121, and O145) as adulterants in raw beef products intended for grinding or other non-intact product exported to the United States. The establishment is required to identify STEC as a hazard reasonably likely to occur in their hazard analysis, develop a HACCP plan with critical control points, and establish critical limits and procedures that are used to monitor these CCPs to prevent adulteration by STEC. These requirements are verified at least once per month by the OVI and OVS. Additionally, the OVS conducts an audit of the establishment's HACCP system at least once a year to verify its effectiveness.

The FSIS auditor verified that SENASA requires government sampling and testing for STEC by the OVI and OIA as described in the Program for the Control of STEC (DIA-PCEC-08). DIA-

PCEC-08 describes STEC verification sampling procedures including the N60 sampling methodology, sample weight, lot size definition, sample packing, and actions for positive results.

SENASA requires the establishment to design a written program for implementing verification testing for STEC. DIA-PCEC-08 requires inspectors to verify by direct observation how establishments sample and monitor results of their STEC testing program. The FSIS auditor verified OVIs conduct verification activities at least four times per month with OVSS conducting verification activities monthly during supervisory reviews. SENASA requires all product lots to be held pending negative test results from analysis for any raw beef products sampled for STEC by either SENASA or the establishment.

The FSIS auditor verified when an OVI finds any positive result for STEC in the establishment's testing records, regardless of any testing conducted by SENASA, they must verify that the establishment takes appropriate corrective actions according to their HACCP system. When noncompliance is observed, the OVI is to issue a DAC and require corrective actions. OVIs must take enforcement actions whenever the establishment fails to take corrective actions, or when corrective actions taken by the establishment are inadequate.

The FSIS auditor determined that SENASA maintains the legal authority to implement its microbiological sampling and testing programs to ensure that meat products destined for export to the United States are unadulterated, safe, and wholesome. There have not been any POE violations related to this component since the previous FSIS audit in 2021.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held remotely by video conference on February 2, 2023, with representatives from SENASA. FSIS concluded that Honduras' raw beef products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. SENASA requires that the establishment certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, SENASA has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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 Agroindustrias Del Corral, S. de R.L., Siguatepeque	2. AUDIT DATE 01/25-26/2023	3. ESTABLISHMENT NO. 20M	4. NAME OF COUNTRY Honduras
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	X
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. Periodic Supervisory Reviews	
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.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Raw intact beef

60. Observation of the Establishment

- 39- In the cut-up room, the overhead ceiling had loose caulking hanging in some areas and the surface was peeling in one section. No product contamination was observed.
- 42- In the cut-up room, a refrigeration unit on the ceiling was leaking from the joint where the drainage pipe connected, dops of water were observed dripping onto the floor. No product contamination was observed.

Appendix B: Foreign Country Response to the Draft Final Audit Report



Agricultura
y Ganadería

Gobierno de la República

Sanidad e Inocuidad
Agroalimentaria
SENASA



HONDURAS
GOBIERNO DE LA REPÚBLICA

Tegucigalpa, M.D.C.,
July 11, 2023

OFICIO.DGS.433.DIA.2023

DOCTOR

MICHELLE CATLIN

International Coordination Executive
Office of International Coordination
United States Food Safety and Inspection Service
Washington, D.C., USA

Dear Dr. Catlin:

I hope this letter finds you doing well. I would like to follow up on your letter from April 12, 2023, received by our Service on June 13, 2023, by which you submitted the draft final report of the FSIS onsite verification audit to Honduras' meat inspection system.

In this regard, I would like to confirm that we have no further comments on the report, and the corrective actions to the auditor's findings were presented during the onsite audit.

However, should you require further information you may contact us via email at: direccion.inocuidad@senasa.gob.hn; direccion.senasa@senasa.gob.hn; mbueno@senasa.gob.hn.

Sincerely,


ING. ANGEL EMILIO AGUILAR
General Director



cc: Dra. Mirian Bueno-Directora Técnica de Inocuidad Agroalimentaria
Sr. Juan Carlos Fiallos-US FAS Embajada Estados Unidos en Honduras
2023*

Elaborado por: MB/DIA



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