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Dear Dr. Velásquez,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote ongoing verification audit of Honduras’ meat and poultry inspection systems February 16 through April 9, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of Honduras are included as an attachment to the report.

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

Sincerely,

[Signature]

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure
FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF HONDURAS
FEBRUARY 16–APRIL 9, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING RAW BEEF AND RAW POULTRY PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

September 3, 2021
Food Safety and Inspection Service
United States Department of Agriculture
Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Honduras conducted by the United States Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) from February 16–April 9, 2021. Due to the global COVID-19 pandemic the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to determine whether Honduras’ food safety inspection system governing raw beef and raw 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. FSIS had determined that the Honduras inspection system for raw poultry is equivalent to that of the United States in a final rule issued on April 5, 2019. FSIS typically conducts an on-site audit within one year of the effective date (May 6, 2019) listed in the final rule of a final equivalence determination; this remote audit of the Honduras raw poultry inspection system is in lieu of that on-site audit.

Honduras currently exports the following raw-intact beef products to the United States: boneless manufacturing trimmings; edible offal; and primals and subprimals. Although FSIS determined Honduras to be equivalent for the export of raw poultry products on April 5, 2019, it has not exported any raw poultry products to the United States due to animal health restrictions. Currently, Honduras is unable to export raw poultry product to the United States because it is not recognized by APHIS as being free of Newcastle disease; therefore, no poultry establishments have been certified to export to the United States by Honduras.

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.

The FSIS auditors concluded that Honduras’ raw beef and raw poultry products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Central Competent Authority (CCA) has verified the implemented sanitation and HACCP system requirements to ensure controls of hazards in raw beef and raw poultry products. In addition, the CCA has implemented microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety system. An analysis of each component did not identify any findings that represented 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 a remote audit of Honduras’ food safety system from February 16–April 9, 2021. The audit began with an entrance meeting held via videoconference February 16, 2021, with the Central Competent Authority (CCA)—the National Plant and Animal Health Service (Servicio Nacional de Sanidad e Inocuidad Agroalimentaria [SENASA]) in Tegucigalpa, Honduras. During that virtual entrance meeting the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the CCA.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether the food safety inspection system governing raw beef and raw 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. Honduras is eligible to export the following categories of products to the United States:

<table>
<thead>
<tr>
<th>Process Category</th>
<th>Product Category</th>
<th>Eligible Products¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw – Non Intact</td>
<td>Raw ground, comminuted, or otherwise non-intact beef</td>
<td>Bench trim from non-intact; formed steaks; non-intact cuts; other non-intact; other non-intact products; sausages; and trimmings from non-intact.</td>
</tr>
<tr>
<td>Raw – Intact</td>
<td>Raw intact beef</td>
<td>Boneless manufacturing trimmings; edible offal; other intact; and primals and subprimals.</td>
</tr>
</tbody>
</table>

FSIS determined Honduras to be equivalent for the export of raw poultry products on April 5, 2019. FSIS typically conducts an on-site audit within one year the effective date (May 6, 2019) listed in the final rule of a final equivalence determination; this remote audit of the Honduras raw poultry inspection system is in lieu of that on-site audit.

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. APHIS restricts exports of raw poultry products to the United States because Honduras is not free of Newcastle disease. Additionally, APHIS restricts exports of raw pork to the United States because of classical swine fever (hog cholera).

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed Honduras’ self-reporting tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether Honduras’ food safety

¹ All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.
The inspection system governing raw beef and raw 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.

Determinations concerning program effectiveness during this remote audit 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 and oversight at the CCA headquarters, as well as government verification records from three local inspection offices. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to two meeting each week over an eight week period. FSIS did not conduct virtual establishment visits as part of these remote audits. 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.

Both meat establishments certified to export to the United States were selected for the remote audit. These are both bovine slaughter and processing establishments. However, only one of these establishments is actively exporting to the United States, and this establishment exports raw intact beef.

Additionally, this remote audit included one poultry slaughter and processing establishment to verify implementation of Honduras’ raw poultry products inspection system. Currently, Honduras is unable to export raw poultry product to the United States because it is not recognized by APHIS as being free of Newcastle disease; therefore, no poultry establishments have been certified to export to the United States by Honduras.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include review of establishments’ conditions or records. The FSIS auditors assessed the CCA’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) 327.2 and 381.196.

The FSIS auditors also remotely audited the government microbiological and chemical residue-testing divisions of Honduras’ National Laboratory (Laboratorio Nacional de Análisis de
Residuos [LANAR]) to verify that the laboratory is capable of providing adequate technical support to the food safety inspection system.

<table>
<thead>
<tr>
<th>Remote Audit Scope</th>
<th>#</th>
<th>Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent Authority</td>
<td>Central</td>
<td>• SENASA headquarters, Tegucigalpa</td>
</tr>
<tr>
<td>Laboratories</td>
<td>2</td>
<td>• LANAR (government laboratory) microbiological testing division, Tegucigalpa</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• LANAR (government laboratory), chemical residue testing division, Tegucigalpa</td>
</tr>
<tr>
<td>Cattle slaughter and processing establishments</td>
<td>2</td>
<td>• Establishment 4, Empresa Ganadera de Honduras, S.A. de C.V. (EMGAHSA), Catacamas</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Establishment 20M, Agroindustrias Del Corral, S. de R.L., Siguatepeque</td>
</tr>
<tr>
<td>Poultry slaughter and processing establishment</td>
<td>1</td>
<td>• Establishment CA-5, Avícola de Centroamérica, S.A. de C.V. (CADECA SOSOA) (NORAVES), Cortes</td>
</tr>
</tbody>
</table>

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 Humane Methods of Livestock Slaughter Act (7 U.S.C. Sections 1901-1906);
- The Meat Inspection Regulations (9 CFR 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 381).

The audit standards applied during the review of Honduras’ inspection system for raw beef 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 October 1, 2017 to September 30, 2020, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 10,665,548 pounds of raw intact beef exported by Honduras to the United States.

Of these amounts, additional types of inspection were performed on 2,308,824 pounds of raw intact beef products. These additional types of inspection included physical examination, chemical residue analysis, and testing for the following microbiological pathogens: Shiga toxin-producing *Escherichia coli* (*E. coli*) (STEC) O157:H7, O26, O45, O103, O111, O121, and O145 in beef products. During this time FSIS rejected one lot of raw beef product (42,000 pounds) for
the presence of fecal contamination. That rejection occurred prior to FSIS’ most recent on-site audit, which occurred in 2018 and concluded that SENASA had satisfactorily worked with the food business operator to identify the root causes of the problem and institute appropriate corrective actions.

The previous FSIS audit in 2018 identified the following findings:

<table>
<thead>
<tr>
<th>Summary of Findings from the 2018 FSIS Audit of Honduras</th>
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<tbody>
<tr>
<td><strong>Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)</strong></td>
</tr>
<tr>
<td>The FSIS auditor identified inconsistent official verification procedures related to the control of specified risk materials (SRMs) in cattle. At one of the two audited slaughter establishments, the official post-mortem head inspector performed removal of the lingual tonsils (rather than establishment personnel, as required by Honduras’ official written inspection procedures). In addition, the establishment was not maintaining records to demonstrate the removal of the brain, skull, eyes, trigeminal ganglia, tonsils, vertebral column, dorsal root ganglia, and distal ileum during implementation of its SRMs control program; only the removal of the spinal cord was recorded. This was a significant finding. However, this recently certified establishment had not yet exported to the United States.</td>
</tr>
</tbody>
</table>

| **Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System** |
| At one of the two audited slaughter establishments, the operating parameters associated with the application of an antimicrobial rinse were not consistent with the documentation maintained by the facility to support decisions within its HACCP system. The validation study maintained by the establishment referenced a lactic acid concentration of 2.5%, while the production records indicated that the acid concentration applied was typically below this value. |
| At one of the two audited slaughter establishments, the critical limit associated with the critical control point for carcass chilling addressed only internal temperature without a reference to time. A review of the establishment’s hazard analysis determined that this critical control point was established to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be applied when addressing the growth-curve of microorganisms. |

In this current audit, the FSIS auditors verified through records review that the corrective actions for the previously reported audit findings were implemented and effective in resolving the deficiencies.

The 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](http://www.fsis.usda.gov/foreign-audit-reports).
IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components the FSIS auditors 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.

The FSIS auditor verified that SENASA continues to maintain the overall responsibility for setting policy, implementing legislation, and managing of official controls in relation to food safety in accordance with Phytosanitary Law (Decree No.157-94) and Decree No. 344-2005. These laws establish SENASA as the CCA for Honduras. Chapter I, Article 2 of Decree No. 344-2005 states that, among its responsibilities, the Ministry of Agriculture and Livestock (Secretaría de Agricultura y Ganadería) 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. Specifically, the Sub-Directorate General for Agrifood Safety (SGIA) is the staff within SENASA that is responsible for the inspection of meat and poultry products that are intended to be exported to the United States. SGIA develops and standardizes enforcement of regulatory food safety controls and has the legal authority to provide verification and certification services at establishments certified to export raw beef and poultry products to the United States.

The FSIS auditors verified that SENASA has the authority and responsibility to ensure that adulterated product is not exported to the United States. SENASA provides a legal definition for adulterated product in Article 5, Numeral 6 of Regulation for the Inspection of Meat and Meat Products (No. 078-00) and Article 9, Numeral 6 of Regulations on Inspection, Slaughtering and Industrialization of Poultry and By-Products (No. 552-05). To ensure product is unadulterated and correctly labeled, the inspection personnel perform routine verification activities in all the establishments as scheduled in the Official Monthly Verification Plan (Cronograma Mensual de Actividades de Verificación Oficial (SGIA-CMAI-17)). If government inspection personnel identify adulterated or misbranded product, they are to document the noncompliance finding(s) using a Demand for Corrective Action (Demanda de Acción Correctiva - DAC) and if necessary, take enforcement measures as described in Section IV of the Guidelines for the Inspection of Meat Products (SGIA-GIPC-05) or Section IV of the Guidelines for the Inspection of Poultry Products (SGIA-GIIP-17).

Articles 126-129 of Regulation No. 078-00 provide SENASA with the authority and responsibility to certify products for export. The FSIS auditors confirmed export verification activities of SENASA through review of records outlined in Section X, Part 2 of SGIA-GIPC-05 that describe the procedures for certifying products for export. The export verification activities include: verification that the export application (Formulario de Solicitud de Exportación – FSE) is accurate and complete; verification that the import requirements are met and the checklist is complete; and inspection of the product to determine that the products are neither adulterated nor misbranded as established in Articles 124-129 and 345 of Regulation No. 078-00. SENASA
inspection personnel review and confirm acceptable laboratory results for official government and establishment testing for all the lots associated with the shipment and prior to approving the export certificate as described in Section X, Part 2 of SGIA-GIPC-05.

The Official Veterinary Inspector (OVI) also verifies that the products to be exported comply with the following labeling regulatory requirements: 9 CFR 317 and the Central American Technical Regulation (Reglamento Técnico Centroamericano - RTCA) 67.01.02.10 – General Requirements for Labeling of Pre-packaged Foods. Honduras does not source product from another country to export to the United States. All product exported to the United States is certified directly from slaughter processing establishments that are eligible to export to the United States. Issuance of an export certificate is accomplished through the use of an electronic system. The system includes validation checks, secure login, and generation of unique certificate numbers. The OVI uses a checklist to ensure thorough review prior to printing and signing the official certificate. The FSIS auditors confirmed that the government inspectors conduct verification activities to ensure adulterated and misbranded products are not prepared for export and that FSIS import requirements are met prior to certifying product for export to the United States.

Article 29 of Regulation No. 552-05 requires establishments to implement a traceability and recall program. SENASA provides direct government oversight of the recall systems and verifies that the systems have been effectively implemented. The official verification activities are described in Section IX of SGIA-GIPC-05 and Section XII of SGIA-GIIP-17. The FSIS auditors, through interviews and records review, confirmed that SENASA verifies that each audited establishment maintains comprehensive recall procedures and maintains records sufficient to conduct trace-back activities if adulterated products were exported to the United States. These verification activities are conducted by government inspection personnel monthly, as part of their routine verification activities as described in Section D, Numeral 4 of SGIA-CMAI-17. The FSIS auditors verified that SENASA ensures the establishments’ systems for traceability from the farm of origin through processing and distribution of products. The CCA has not recalled any product exported from Honduras in recent history.

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. Chapter V of Regulation No. 078-00 and Chapter VI of Regulation No. 552-05 set the requirements for the authorization of establishments that slaughter or process products derived from livestock and poultry, respectively. The procedures for the certification of establishments are described in Section X, Part 1 of SGIA-GIPC-05 and Section XIV, Part 1 of SGIA-GIIP-17. Personnel at SENASA HQ and the Supervisory Official Veterinarian (SOV) conduct annual audits to verify each establishment is complying with the appropriate national and FSIS regulatory requirements prior to determining annual establishment certification. The FSIS auditors conducted interviews and reviewed documents related to the authorization process of establishments certified by SENASA as eligible to export to the United States.

The FSIS auditors reviewed documents maintained by SENASA and verified that SENASA’s regulations and inspection guidelines are designed to enforce Honduras’ laws that apply to the
safe production of meat and poultry products for human consumption destined for export to the United States. SENASA is notified via the FSIS automatic notification system of updates to FSIS import requirements. A review of the FSIS notification document is conducted by SENASA officials and when relevant, a summary with the significant modifications is elaborated and translated, and administrative notifications are distributed electronically to government inspection personnel in the field. If needed, definitive and significant modifications are included in the next revision of the inspection guidelines or other programs established by SENASA. FSIS interviewed 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 establishments certified to export to the United States were adequate.

SENASA is directly responsible for recruiting, hiring, and paying the wages of the official inspection personnel from national budget appropriations and fees collected from the establishments. Chapter I, Article 8 of the Acuerdo Consejo Directivo (C.D.) SENASA-002-2018 states that the sanitary and phytosanitary certification of products for export are to be conducted directly by SENASA personnel, which is an exclusive and non-delegable competence of SENASA. To avoid conflicts of interest and to ensure that the 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 auditors verified through monthly payroll documents (SENASA Planilla Mensual de Salarios) and employment contracts (Contrato de Servicios Personales No.71/3) that government inspection personnel (OVIs and Official Auxiliary Inspectors (OAI)) assigned to establishments certified to export meat products to the United States are SENASA employees paid directly by the Honduran government.

SENASA’s inspection system is organized and staffed in a way that ensures uniform enforcement of the laws and regulations governing meat and poultry inspection in all certified establishments. SENASA assigns official personnel for inspection activities and has ultimate control and supervision over the inspection personnel. SENASA implements procedures to maintain adequate staffing at each establishment eligible to export to the United States to ensure official inspection coverage throughout every slaughter period and during every shift requiring inspection. Section III of SGIA-GIPC-05 and Section III of SGIA-GIIP-17 require that there be continuous inspection during the slaughter of livestock and birds in all certified slaughter establishments while slaughter activities are conducted. SENASA assigns OVIs, OAI, and an SOV to inspect cattle and chickens and perform verification activities in all the establishments that process animal products and by-products. The FSIS auditors reviewed government verification records that demonstrated inspection coverage, including ante-mortem inspection and, post-mortem inspection throughout slaughter, as well as at least once per shift during processing operations.

Regulation No. 078-00 and Regulation No. 552-05 require that the OVIs and OAI report to assigned establishments and perform inspection duties according to the assigned schedule. The same regulations state that the OVI is responsible for the verification that all the animals or lot of animals are slaughtered for human consumption. The FSIS auditors reviewed documented staffing records at the CCA headquarters for eligible meat establishments and the audited poultry establishment and confirmed that SENASA is ensuring sufficient staffing to perform inspection
and verification tasks at the establishments eligible to export to the United States during all operations requiring inspection.

SENASA assigns competent, qualified inspectors to certified establishments that export products to the United States, and ensures that they have appropriate educational credentials, training, and experience to perform their inspection tasks. The FSIS auditors verified through document review that inspection personnel possess the appropriate educational credentials, training, and experience to perform their inspection tasks. All OVIs must have a Doctor of Veterinary Medicine or equivalent degree, and the OAIIs must have specialized experience or education that allows them to perform their assigned duties. The FSIS auditors verified that inspectors had successfully completed the induction-training program outlined in Section II of SGIA-GIPC-05 and Section II of SGIA-GIPPC-17. All new employees complete supplemental training on meat inspection regulations, inspection and verification activities, and country-specific export requirements. Successful completion of training is the fundamental requirement for personnel to be assigned to perform inspection and verification procedures. Veterinary and non-veterinary personnel also receive on-the-job training when they are first assigned to establishments certified to export to the United States.

SENASA provides ongoing specialized training on FSIS requirements to inspectors at least once a year. The FSIS auditors reviewed attendance lists for training sessions conducted by SENASA in 2019 and 2020, including training on the applicable parts of 9 CFR, zero-tolerance verification, SENASA verification, humane handling and animal welfare, and ante-mortem and post-mortem inspection of livestock and poultry.

LANAR is the national government laboratory used for official government microbiological and residue sampling and testing programs for products that are exported to the United States. LANAR’s technical and administrative performance is verified with meetings by SGIA based on International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:2017 standards. SGIA is the staff within SENASA that has the authority to approve and disapprove laboratories and is part of the Technical Committee; therefore, SGIA staff members are representatives of the LANAR quality management system. The Technical Committee is comprised of LANAR management, technical chiefs, and SGIA, and meets multiple times each year to review and discuss technical issues related to the implementation of the official microbiology and residue sampling and testing programs. These meetings include the assessment of the quality requirements (i.e., non-compliant work, follow up on customer complaints, internal audits, revisions by direction, customer service, document control, corrective and preventive actions, purchases, contracts, storage of supplies, and confidentiality) and technical requirements (i.e., training, equipment, traceability, quality assurance, facilities, environmental conditions, analytical methods, validation, and sampling and handling of samples). In addition, Honduras has formed a Top Management team comprised of SGIA, a LANAR Quality Assurance manager, and a laboratory management representative that meets at least annually to evaluate compliance with all ISO/IEC standards. The FSIS auditors reviewed multiple Technical Committee and Top Management reports and verified implementation of the procedures as described.
The FSIS auditors verified that LANAR conducts analyses of raw beef products exported to the United States in compliance with ISO/IEC 17025 standards and prepared to conduct analyses of raw poultry products for export to the United States. Not all methods of analysis used by LANAR are ISO-accredited, but all of them are scientifically validated and are under the Quality Management System that is in place at the laboratory. SENASA’s Top Management team through SGIA conducts bi-annual reviews of the microbiological and residue sections of the laboratory to verify that they use scientifically validated and approved methods for the analysis of products destined for export to the United States. The Costa Rican Accreditation Entity (Ente Costarricense de Acreditación - ECA) also audits the LANAR laboratory annually. ECA is an organization in Costa Rica that provides third party accreditation in accordance with ISO/IEC 17025:2017 standards. The FSIS auditors reviewed the accreditation certificate, scope of accreditation, and accreditation audit reports and did not identify any concerns.

During the remote audit of LANAR, the FSIS auditors reviewed official reports of laboratory audits conducted by the ECA and records of evaluations of corrective actions taken in response to audit findings. Additionally, the FSIS auditors verified SENASA’s ability to coordinate evaluations of laboratory performance, including proficiency testing schemes for analysts, documentation of analysts’ proficiency evaluations, inter-laboratory proficiency testing results, and evaluations of the quality controls. The Quality Control Manager maintains a file of the authorization records, competence, academic and professional qualifications, training, skills, and experience of the technical and administrative personnel. FSIS also verified that laboratory managers possess relevant academic credentials and experience as analysts in their specialty areas. Laboratory technologists are subject to internal proficiency testing by LANAR. Annual training is provided for laboratory personnel to ensure that their qualifications and laboratory skills are maintained, and that equipment is properly maintained. LANAR participates in appropriate proficiency testing schemes for food analysis and maintains reporting and recordkeeping capabilities that can clearly track and link a test result to the correct establishment.

The FSIS auditors also verified that the laboratory maintained appropriate discard criteria to ensure the integrity of the sample and testing results. This included written standard operating procedures to ensure that samples arrive under government seal within specified timeframes and required temperatures, as well as outlining specific follow-up activities to be undertaken when these requirements are not met. Follow-up procedures are in place to notify the OVI and the SENASA headquarters. SENASA receives laboratory results directly from LANAR.

The documents reviewed remotely from the laboratory showed that the laboratory Quality Control Manager periodically evaluated the technical and organizational functions. Findings reported during the last ECA audit in 2020 were promptly addressed and corrective actions were documented. The FSIS auditors reviewed the accreditation audit documents and verified that LANAR was audited by ECA every 12 months.

The FSIS auditors concluded that SENASA continues to organize, administer, and enforce its meat and poultry 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 of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every 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.

Chapter IX of Regulation No. 078-00 requires that all animals that are to be slaughtered undergo ante-mortem inspection by a government inspector who will ensure humane handling and humane methods of slaughter. Through records review, the FSIS auditors confirmed that the OVIs at the beef slaughter certified establishments verify the humane handling and slaughter procedures at least once a month as per Section D, Number 5 of SGIA-CMAI-17. Furthermore, the OVI confirms humane slaughter by verifying that animals are rendered unconscious and immediately bled out after stunning. Ante-mortem inspection is conducted daily on all animals prior to slaughter in accordance with Regulation No. 078-00. Section I (3d-f) of SGIA-GIPC-05 requires the OVI to conduct ante-mortem inspection after reviewing required documentation accompanying the livestock, to ensure that all information (number of animals, origin of the lots, etc.) is accurately documented in ante-mortem records. Additionally, within Section VIII of SGIA-GIPC-05, SENASA has adopted a zero-tolerance policy against the slaughter of non-ambulatory disabled cattle.

Chapter IV, Article 111 of Regulation No. 552-05 requires that all birds intended for slaughter are to undergo ante-mortem inspection by a government inspector to ensure that any diseased birds do not undergo slaughter. Article 127 of Regulation No. 552-05 requires that all birds be handled and slaughtered using good commercial practices. Through records review, the FSIS auditors verified the OVIs at the poultry slaughter establishment verify the establishment’s handling and slaughter procedures daily as per Section VII of SGIA-GIIP-17. The OAI verifies and documents on a daily basis the slaughter practices such as correct stunning; adequate, and complete bleeding; that breathing has stopped before entering the scalding tank; and the establishment’s recordkeeping practices related to good commercial practices. Ante-mortem inspection verification activity is to be conducted by the OVI at the slaughter establishment and documented for every lot of birds to be slaughtered using the following form: Ante-Mortem Poultry Inspection Form – Code: DIA-FIAA-15. Section VII of SGIA-GIIP-17 requires the OVI to conduct ante-mortem inspection after the review of the sanitary documentation of the birds to ensure that all verifications are performed appropriately.

The results of verification activities are recorded on the government verification forms maintained in the government inspection offices at certified establishments. The FSIS auditors determined that the verification procedures employed by the OVIs related to humane handling
and slaughter of livestock and good commercial practices in poultry were in accordance with SENASAG’s requirements.

Articles 288 and 289 of Regulation No. 078-00 require that cattle be subjected to online post-mortem inspection of each and every carcass immediately after slaughter, and include 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 consumption. SENASA requires post-mortem inspection procedures to be performed by OVIs in accordance with Article 289 of Regulation No. 078-00 that describes the post-mortem inspection procedure and indicates that the inspection is to consist of visual palpation, cutting of organs and glands, viscera, and parietal muscles. Chapter IV, Article 112 of Regulation No. 552-05 describes that post-mortem inspection in poultry is to take place in all slaughter establishments according to their slaughter speed and requires all processing to be conducted under official veterinary inspection. Furthermore, it requires that carcasses and viscera be presented individually to the inspector to determine which carcasses will be passed as fit for consumption, sent for reprocessing, or be condemned. Through records review of livestock and poultry post-mortem records documenting disposition of carcasses and parts, the FSIS auditors verified that the OVIs are adequately trained in performing their online post-mortem inspection duties.

The FSIS auditors reviewed SENASA records that are maintained at headquarters and at each audited establishment. The FSIS auditors verified that SENASA provides appropriate oversight and direction to the OVIs for them to use their regulatory authority to enforce requirements for Honduras’ meat and poultry inspection systems. Procedures for the supervisory visits are described in Section V of SGIA-GIPC-05, and Section V of SGIA-GIIP-17, instructing the SOV to conduct reviews at a frequency of at least once per month (meat) and quarterly (poultry). The SOV assesses the implementation of the meat and poultry inspection systems at the establishments and the OVI’s inspection activities and the evaluation of the performance of government inspectors. The scope of these reviews includes ante-mortem and post-mortem inspection; official controls over good manufacturing practices (GMP) and sanitation; HACCP; control of export certificates; chemical and microbiological testing programs and results; and control over condemned materials. The results of periodic supervisory visits are documented on form FIMEC-01 (meat) and SI-PA-05 (poultry). The FSIS auditors reviewed the supervisory reports from 2020 and 2021 and verified that official SOVs conducted these reviews at the intended frequencies for each establishment remotely audited. The OVI documents DACs and verifies corrective actions in response to the findings and the SOV verifies the corrective actions during the next supervisory review. Through records review, the FSIS auditors confirmed that corrective actions were verified by the OVI and by the SOV.

SENASA ensures that the SOV makes periodic supervisory visits to each certified establishment for evaluating the performance of the inspection personnel (OVI and OAI), monthly for meat inspectors and quarterly for poultry inspectors, culminating in an annual review. These reviews consist of onsite observations of the inspection personnel executing inspection and verification activities. The SOV assesses the inspection personnel in the following areas: ante-mortem inspection, post-mortem inspection, GMPs and sanitation standard operating procedures (sanitation SOPs) verification, export certification activities, sampling methodology and
collection procedures for the microbiological and residue programs, and official control over condemned materials in Section V of *SGIA-GIPC-05*. The SOV documents the results of the supervisory visit using the following forms: *SGIA-EDIA-05* (for OAs) and *SGIA-EDIV-05* (for OVs). The SOV documents personnel deficiencies, if any, using the form *SGIA-ACSIO-12* to detail the corrective actions and follow up with a new evaluation in six months. The FSIS auditors reviewed performance appraisals for the OVs and OAs and had no concerns.

Requirements for complete separation of establishments certified for exporting product to the United States from other facilities or areas that are not certified are outlined in Article 156 of *Regulation No. 078-00*. SENASA requires establishments 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 auditors were informed that the audited establishments processed raw products only from livestock that were slaughtered on-premises and do not receive any raw materials from outside sources. Through records review and interviews, the FSIS auditors confirmed that SENASA verifies a complete separation of eligible products intended for export to the United States from ineligible products by space or time in the coolers and freezers. Products intended for export are processed under the same conditions and standards as products for national (domestic) consumption. The inspection personnel verification procedures are described in Section X of *SGIA-GIPC-05*. The OVs evaluate each request for export to ensure that the documentation supports eligibility, and official inspection personnel reinspect export lots at the time of loading.

The FSIS auditors confirmed that SENASA verified that the audited establishments have developed and implemented traceability and recall procedures in accordance with SENASA’s requirements. The establishments’ procedures are to provide written instructions that include traceability mechanisms to ensure source materials originate from establishments certified to export to the United States and recordkeeping requirements are met. The in-plant inspection personnel verify the efficacy of these procedures during their inspection verification activities. The FSIS auditors found that the in-plant inspection personnel have documented verification records and associated traceability records. The FSIS auditors found no concerns.

Article 7, Number 14, and Articles 124, 125, and 129 of *Regulation No. 078-00* establish labeling requirements to ensure that the information on the product labels was complete, accurate, and met FSIS labeling requirements. The OAs are to conduct labeling verification activities daily and the OVs are to conduct these activities on a monthly basis in accordance with *SGIA-CMAI-17*. The FSIS auditors verified the frequencies that each of these verification activities were conducted to verify that FSIS labeling requirements were being met on a shipment that was prepared for export. Through a records review, the FSIS auditors confirmed that the OAs conduct label verification on representative samples of each shipment destined for export to the United States and document the results of their verification.

SENASA conducts official verification of species in accordance with Section 5(e) of the 2019 National Residue Plan. The species testing for beef products is performed on a monthly basis with a commercial kit, ELISA-TEK ™. The FSIS auditors reviewed results of the species testing from 2020 and 2021 and confirmed that all results confirmed accurate species identification.
SENASA ensures that its meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website in addition to FSIS’ product eligibility chart for individual countries, which also considers current APHIS restrictions. When changes occur, SENASA is notified through the APHIS regional office located in Guatemala and the USDA’s Foreign Agricultural Service offices in Tegucigalpa, Honduras. Pre-printed export certificates issued by SENASA for a given country are specific to species and commodity. Consequently, only those products previously identified by SENASA as meeting both FSIS and APHIS requirements can be certified for export to the United States. The electronic export certification system includes validation controls to ensure only eligible products are certified. The OVI oversees the signing of certificates for every export and is responsible for verifying that the attestations comply with the requirements set by APHIS regarding animal health.

Within Section VIII of SGIA-GIPC-05, SENASA maintains a definition of SRMs, which is consistent with that outlined in 9 CFR 310.22. This document also includes requirements for slaughterhouses and beef processing plants implement and maintain documented procedures for the removal, segregation, and disposal of SRMs within the scope of their HACCP system. Through records review, the FSIS auditors verified that the OVI verifies monthly control of SRMs per Section D, Number 6 of SGIA-CMAI-17. In addition, OAIAs verify the control of SRMs every two hours on form Monitoreo de MRE’s (Matanza). The form is stamped by the OVI on a daily basis to confirm that the OAIAs performed verification. The OVI reviews the records, observes the employees, and conducts an on-site verification (the observation of carcasses) in order to ascertain whether the plant is in compliance with the activities relating to the execution, monitoring, and verification of the pertinent corrective actions, as well as the re-evaluation of the program designed to control the SRMs. Additionally, these requirements are verified by the SOV every month and by documenting the results on form FIMEC-01.

SENASA maintains adequate official control over condemned materials. Articles 120 and 144 of Regulation No. 552-05 (poultry) stipulate that receptacles used for storing inedible material must not be used for storing any edible product and bear conspicuous and distinctive marking to identify permitted uses. Article 120 of the same regulation also requires inedible materials be denatured or destroyed under direct supervision of the official inspector. Lastly, Article 290 of Regulation No. 078-00 (meat) requires the denaturing of carcasses and parts condemned at post-mortem. Through records review, the FSIS auditors verified that the OVIAs performed daily verification to ensure condemned and inedible materials are destroyed or denatured before leaving the establishment for final disposal in rendering facilities. Additionally, the FSIS auditors verified that during periodic supervisory visits the SOV also assesses compliance with requirements for the control of condemned and inedible products and then document the results on form FIMEC-01.

The FSIS auditors concluded that SENASA continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over meat and poultry establishments that export or are interested in exporting their products to the United States using statutory authority consistent with criteria established for this component.
VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that SENASA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions; to include requirements for sanitation performance standards (SPS); and sanitary dressing.

The FSIS auditors verified that SENASA requires establishments certified to export to the United States to develop and adhere to written programs that prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions by complying with the requirements consistent with 9 CFR 416. Additionally, SENASA has the authority to take formal enforcement action when a noncompliance has been identified and verify corrective actions have been implemented.

Articles 163 and 200–215 of Regulation No. 078-00 set the requirements for sanitary dressing of livestock throughout the slaughter operation. SENASA provides guidance to inspection personnel on official controls for slaughter sanitary dressing verification activities and ongoing assessment of the establishment’s compliance with sanitary dressing of livestock requirements in Section VII of SGIA-GIPC-05. The in-plant inspection personnel verify that the establishment implements sanitary dressing procedures throughout the slaughter process daily. Additionally, these requirements are verified by the SOV every month.

Section VII of SGIA-GIPC-05, SENASA requires verification of establishment HACCP plan controls for fecal material, ingesta, and milk during the slaughter operations. SENASA has established procedures for verifying the control of fecal material, ingesta, and milk (i.e., “zero-tolerance”) during cattle slaughter. In addition to 100 percent monitoring of the zero-tolerance critical control point (CCP), additional documented control points employed by establishments included bung tying, weasand (esophagus) rodding, hide removal, and evisceration. Inspection verification activities include review of establishment records, direct observation of monitoring (of establishment employees), and hands-on verification. Inspection personnel document daily verification of zero-tolerance based on each establishment’s CCPs on form FCVT-01. The FSIS auditors conducted a random review of government records generated over the past 3 months, for which no concerns were identified.

Section VII (1) of SGIA-GIPC-05 describes the procedures for the offline verification of livestock carcasses for visible fecal material, ingesta, and milk. Verification is conducted by the OVIIs based on the number of animals slaughtered: four carcasses are selected if ≤100 animals are slaughtered, and eight carcasses are selected if 101 to 250 animals are slaughtered. Section VII (2) of SGIA-GIPC-05 indicates that the zero-tolerance verification is to be conducted prior to any wash intervention. The OVIIs document the offline zero-tolerance verification using form Puesto de Inspección Visual de Canales (Cero Tolerancia para Materia Fecal, Ingesta y Leche) – Code: FVCT-01.

Regulation No. 552-05 establishes a zero-tolerance policy for fecal material and ingesta contamination in poultry. Article 123 of Regulation No. 552-05 indicates that carcasses
contaminated during the process with gastrointestinal contents are to be sent for re-processing under inspection control and supervision, when the affected parts are separated and condemned. Section IX of SGIA-GIIP-17 describes the procedures for zero-tolerance verification activities and how to conduct verification of the adequacy of the establishments’ procedures. The OVIs are to conduct sanitary verification activities, verification of the establishment’s sampling programs, and verification for the control of visible fecal contamination and process control on a weekly basis in accordance with Sections A, B, D-2 and D-8 of SGIA-CMAI-17. At least twice a day, the inspection personnel are to select and examine 10 poultry carcasses off the line at a location assigned by the establishment for these tasks or at the inspection station prior to the chilling tank. Additionally, these requirements are to be verified by the SOV quarterly by completing form SI-PA-05 (poultry).

Requirements related to construction, facilities, and equipment for beef establishments are detailed in Chapter IV (Articles 30-121) and Chapter VII (Articles 174-221) of Regulation No. 078-00. Similar requirements regarding poultry establishments are detailed in Chapter V (Articles 58-75) and Chapter IX (Articles 148-157) of Regulation No. 552-05. The SENASA inspection system verifies compliance of establishment construction, facilities, and equipment as described in inspection guidance Section VI, Part 2 of SGIA-GIPC-05 for beef establishments and Section VI, Part 2 of SGIA-GIIP-17 for poultry establishments. These requirements are verified by the SOV every month by completing Sections I–XI of form FIMEC-01 (meat) and quarterly by completing form SI-PA-05 (poultry). Additionally, the inspection personnel at the establishment verify these requirements as per the frequencies indicated in Sections A and B of SGIA-CMAI-17.

The FSIS auditors verified that SENASA requires that establishments certified to export product to the United States develop, implement, and maintain sanitation SOPs. Honduras requires compliance with the Central American Technical Regulation (RTCA) 67.06.55:09, Good Hygiene Practices for Unprocessed and Semi Processed Foods. Section 6.2 defines requirements for written procedures and controls sufficient to ensure sanitary operations, including cleaning and sanitizing procedures prior to operations for beef establishments. Chapter IV, Article 27 of Regulation No. 552-05 sets the same requirements for poultry establishments.

The sanitation SOP requirements in RTCA 67.06.55:09 and Regulation No. 552-05 are consistent with sanitation standards applied in the United States in accordance with 9 CFR 416.11–416.16. These documents require each establishment to develop and implement a written sanitation SOP program. The establishments must have written procedures to require that food contact surfaces are cleaned prior to the start of operations and to maintain sanitary conditions during operations to prevent product adulteration.

Section VI, Part III of SGIA-GIPC-05 for beef establishments and Section VI, Part III of SGIA-GIIP-17 for poultry establishments provide instructions to the inspection personnel on how to verify compliance with the sanitation SOP requirements. The inspection personnel at the establishment verify the pre-operational requirements on a daily basis prior to the operations and the operational requirements at least once a month as per Sections A, Number 13 and B, Number 5 of SGIA-CMAI-17. Daily, the OVI is responsible for reviewing establishment
records documenting the implementation of its programs, including the implemented corrective actions after instances of noncompliance. Additionally, these requirements are to be verified by the SOV every month by completing Section XII, Numbers 67 and 68 of form *FIMEC-01* (meat) and quarterly by completing form *SI-PA-05* (poultry).

The FSIS auditors’ verification activities included review of inspection verification records of sanitation for all three audited establishments and interviews of government inspection personnel. The FSIS auditors reviewed the inspection personnel’s daily verification records, documentation of DACs, and supervisory reviews. This review included the evaluation of corrective action verification records associated in response to documented noncompliance. The FSIS auditors verified inspection personnel took official regulatory control actions sufficient to ensure sanitary conditions were restored and product was protected from contamination.

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

The FSIS auditors verified that SENASA requires establishments certified to export to the United States to meet requirements consistent with 9 CFR 417 for the implementation of HACCP. SENASA, through Article 136 of *Regulation No. 078-00* and Article 25 of *Regulation No. 552-05* outlines regulatory requirements, consistent with those of FSIS, for establishments exporting to the United States to develop, implement, and maintain a HACCP system that incorporates the seven principles of HACCP.

Section VI of *SGIA-GIPC-05* and Section IV of *SGIA-GIIP-17* provide instructions to the inspection personnel on how to verify compliance with the HACCP requirements, including monitoring, verification, recordkeeping, and adequacy of corrective actions taken in response to a deviation from a CCP. These sections also describe how the inspection personnel are to verify that establishments properly identify hazards reasonably likely to occur and develop CCPs. Section VII (2) of *SGIA-GIPC-05* requires verification of establishment HACCP plan controls for fecal material, ingesta, and milk during the slaughter operations. The inspection personnel at the establishment are to verify these requirements at least once a month as per Section C, Number 1 of *SGIA-CMAI-17*. Additionally, these requirements are to be verified by the SOV, every month by completing Section XV of form *FIMEC-01* (meat) and quarterly by completing form *SI-PA-05* (poultry).

Before any product is exported to the United States, a pre-shipment review is conducted by the establishment, which includes a review of records associated with the production of the product
to ensure that all critical limits have been met and any necessary corrective actions were taken. Section VI, Part IV of SGIA-GIPC-05 and Section IV of SGIA-GIIP-17 describe that the inspection personnel at the establishment are to verify this requirement at least once a week (four times a month) as per Section C, Number 7 of SGIA-CMAI-17. Additionally, the “pre-shipment review” requirement is to be verified by the SOV every month by completing Section XV, Number 107 of form FIMEC-01 (meat) and quarterly by completing form SI-PA-05 (poultry).

The FSIS auditors verified that SENASA requires that establishments certified to export to the United States address the hazard of contamination of carcasses with STEC (O157:H7, O26, O45, O103, O111, O121, and O145) within the context of their HACCP system. Establishments have implemented controls including zero-tolerance critical control points, organic acid spray, and additional controls to ensure that carcasses are chilled in a manner sufficient to prevent the outgrowth of microbial pathogens.

The FSIS auditors conducted a remote review of the HACCP inspection verification records of in-plant inspection verification activities, supervisory reviews, and interviews of inspection personnel for all three audited establishments. The actions to be taken by in-plant inspection personnel at establishments certified to export to the United States are identified in Section VI of SGIA-GIPC-05 and Section IV of SGIA-GIIP-17. The inspection personnel conducted verification of HACCP plans consistent with FSIS Directive 5000.1, Verifying an Establishment’s Food Safety System.

The inspection personnel verification procedure encompasses the evaluation of written HACCP programs and verification of HACCP prerequisites and plan monitoring, corrective actions, and recordkeeping. In-plant inspection personnel adequately documented and verified the adequacy of the establishments’ corrective actions. The establishments’ corrective actions in response to deviations from critical limits, identified by the establishment or the government inspectors, met all four parts of corrective action requirements cited in 9 CFR 417.3(a), which have been adopted by Honduras. Additionally, at least once a year the SOV is to conduct an audit of the establishment’s HACCP system to verify its effectiveness and document the results using form FIA-006, Guide for the Verification of Compliance with the Hazard Analysis and Critical Control Points (HACCP).

The FSIS auditors determined that SENASA requires operators of establishments 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 of six equivalence components 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 products inspection authorities or by FSIS as potential contaminants.
Prior to the remote audit, FSIS’ residue experts reviewed the Honduras National Residue Program (NRP) for 2021 (and 2020 results), associated methods of analysis, and additional SRT responses outlining the structure of Honduras’ chemical residue testing program. Methods of analysis are consistent with those outlined in the FSIS Chemistry Laboratory Guidebook or other internationally recognized organization. There have not been any POE violations related to this component since the previous FSIS audit in 2018.

*Phytosanitary Law (Decree No. 157-94)*, modified by *Decree No. 344-2005*, states that SENASA must verify and enforce compliance of the levels for chemical compounds and food contaminants established in the NRP for food products intended for consumers. The NRP establishes tolerance levels for the compounds of interest according to the Honduran regulations; *Codex Alimentarius* Commission standards; regulations of the United States Food and Drug Administration and the United States Environmental Protection Agency; and the Directorate General for Health and Consumers of the European Commission requirements.

The FSIS auditors verified that personnel from SENASA, in cooperation with LANAR, develop and implement the annual residue-monitoring plan. SENASA ensures the implementation and maintenance of their national residue program by having full oversight over the residue program and LANAR. SENASA verifies and requires compliance of the tolerance levels established in the NRP and provides technical guidance to LANAR for the analysis required by the program. The program is developed on an annual basis using the *Codex Alimentarius Commission Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals*. The program is based on banned substances and those that are of public health concern, analytical methods available, history of results, primary production practices, approved veterinary products, and requirements of trading partners. The number of scheduled samplings in establishments is based on the production numbers of the preceding year. In addition to routine sampling, sample collections may be generated by the inspectors whenever they have a reason to suspect that a sample is needed.

The official monitoring is conducted according to the NRP, which is developed every year. The NRP includes the species, analytes, analytical methods, matrix, number of samples, and the detection and action limits. The FSIS auditors verified the implementation of the NRP remotely at the three slaughter and processing establishments. A review of the sample records maintained at the inspection offices within the establishments indicated that the 2020 sampling program was adhered to as scheduled.

The FSIS auditors verified that the OVIs follow the instructions outlined in the NRP (2020 *SGIA-PNRAC-05* (meat) and 2019 *SGIA-PNAR-05* (poultry)). The NRP indicates that samples are collected by the OVI, who is responsible for identifying, preparing, storing, and submitting samples to LANAR in a safe cooler with the submission form duly signed and sealed. The inspection personnel of the establishment are to attach the current submission sheet, and the samples must be sent in a cooler properly sealed to LANAR. LANAR’s personnel ensure that the samples comply with the requirements such as temperature, sample integrity and sufficient quantity for the analysis. The information in the submission form is reviewed and approved for
Regulation No. 330-13 describes the prohibition for producers, breeders, or intermediaries to deliver cattle that have received treatments such as avermectins, hormones or antibiotics without complying with the required withdrawal period. Regulation No. 330-13 further provides the authority to SENASA to perform regulatory actions described in Decree No. 157-94 when cattle suppliers deliver animals to national establishments that do not comply with the withdrawal period for veterinary drugs detected in the meat and poultry products and are found to be over the Maximum Residue Levels (MRL) established by SENASA.

While there have been no residue violations in recent history, the FSIS auditors verified that SENASA has developed the necessary enforcement procedures should a violative result be reported. Residue results are communicated to SENASA headquarters through email. Section 8 of the NRP states that LANAR is to convey violative results directly to SENASA headquarters, the SOV, and the local OVI assigned to the establishment. The report from LANAR includes the result of the sample and the MRL or action level that has been determined in the NRP. In addition, LANAR immediately notifies the OVI whenever a suspect or confirmatory violative result is detected. The establishment’s residue results are verified by the SOV every month by completing Section XIII, Number 82 of form FIMEC-01. Whenever SENASA detects a residue violation, SGIA and LANAR will perform follow-up activities over results that are reported above the established levels (tolerances) in the meat products from the national establishments.

Section 4 of the 2020 NRP (SGIA-PNRAC-05) states that sampled carcasses must be held under official control pending the receipt of acceptable results from LANAR are obtained. Through interviews and records review, the FSIS auditors confirmed that in the event of a violative sample, the violations are reported immediately as a Health Alert with the product being disqualified for export from the establishment until the source of the problem has been determined and corrected. The affected product cannot be exported under any circumstances, and destruction of the product must be documented. The analytical reports include expected information, such as the establishment from which the samples were obtained, dates and identification. In the event of a violation, the establishment prepares a written record of the short and long-term preventive actions taken to prevent a recurrence. In all cases that test positive for the various compounds, SENASA and LANAR follow up on case notifications describing where the problem arose. These notifications allow SENASA to better control the movement of animals to slaughter establishments, and better control the collection of tissue samples for residue testing. The specifics are outlined in Section 8 of the 2020 SGIA-PNRAC-05 (meat) and Section 7 of the 2019 SGIA-PNAR-05 (poultry).

The FSIS auditors verified that analysts assigned to LANAR have completed academic work and specialized training that qualify them to conduct the analytical methods for detection and quantification of chemical residues in their scope of accreditation. The FSIS auditors verified that LANAR ensures traceability throughout sample receipt, analysis, and reporting per their laboratory quality control manual. The FSIS auditors verified that LANAR performs timely analysis of samples and reports the number of analyzed samples and the results to SENASA headquarters in a timely manner. The FSIS auditors also verified that the quality control manual
included organization, staff, qualifications, credentials, and training. No concerns arose from the records reviewed.

The FSIS auditors verified that Honduras’ meat and poultry 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 residues of veterinary drugs and contaminants in meat and poultry products destined for export to the United States. FSIS has not identified any POE violations related to this component since the previous FSIS audit in 2018.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

SENASA has implemented establishment sampling and testing requirements for generic E. coli that are consistent with those listed in 9 CFR Part 310.25(a) in order to verify process control during cattle slaughter and carcass dressing. Section II of the Program of Reduction of Pathogens (SGIA-PRPPC-05) requires the establishments to perform the microbiological evaluation for generic E. coli to ensure that process control systems are sufficient to prevent fecal contamination. NOTA.SGIA.16O.2017 sets the requirements for establishments to have documented procedures to prevent poultry carcasses with visible fecal contamination from entering the chiller, procedures to prevent contamination of carcasses by enteric pathogens, microbial testing requirements at pre-and post-chill locations, and monitoring records.

The FSIS auditors verified the microbiological sampling and testing programs of the three audited slaughter establishments through remote document reviews. The FSIS auditors confirmed that the OVIIs and SOVs (during monthly supervisory reviews) verify that slaughter establishments comply with SENASA’s regulatory requirements regarding generic E. coli testing of cattle carcasses, including sampling frequency, technique, and methodology; maintaining records of analytical results; and sampling requirements. The FSIS auditors’ review of inspection records identified no concerns.

The FSIS auditors confirmed that government inspectors were verifying that the poultry slaughter establishment monitored the effectiveness of their process control procedures by testing chicken carcasses for indicator organisms at pre-chill and post-chill. The FSIS auditors also verified through SOV inspection record review that the poultry establishment had developed, implemented, and maintained written microbiological sampling procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operations, as required by SENASA.
SENASA has established *Salmonella* performance standards for livestock and poultry as described in Article 260 of *Regulation No. 078-00*, Section III, Number 18 of *SGIA-PRPPC-05* (beef) and Section XI of *SGIA-GIIP-17* (poultry). The FSIS auditors reviewed SENASA’s *Salmonella* sampling and testing program which is consistent with those listed in 9 CFR 310.25(b) for beef.

The FSIS auditors verified that the implementation of the program in the audited cattle and poultry slaughter establishments met SENASA’s requirements outlined in *Regulation No. 078-00*. In the beef slaughter establishments, inspection personnel use swabs or sponges to collect a 100-cm² surface area from the flank, rump, and brisket at a frequency of once per every 300 carcasses. Performance standards for cows and bulls consist of a moving window of 58 consecutive carcass samples, for which the maximum number of positive samples is two. Samples are submitted to LANAR. SENASA uses the *FSIS Microbiology Laboratory Guidebook* (MLG) method 4.10 for confirmation for official analysis of *Salmonella* in beef and poultry.

In the poultry slaughter establishment, chicken carcasses are to be collected after chilling by inspection personnel. Carcasses are randomly selected and sampled completely with rinsing techniques, using 400 ml of sterilized peptonated water. A portion of at least 30 ml of the liquid of the wash must be sent to the laboratory for *Salmonella* analysis. Performance standards consist of a moving window of 51 consecutive samples (one weekly sample) by carcass rinse method for which the maximum number of positive samples is five. SENASA uses the FSIS-MLG 4.10, without modifications for official analysis of *Salmonella* in chicken.

Within its official *Program for the Control of STEC (DIA-PCEC-08)*, SENASA stipulates a zero-tolerance policy and identifies *E. coli* O157:H7, O26, O45, O103, O111, O121, and O145 to be adulterants in raw beef products intended for grinding or other non-intact product exported to the United States. This document includes instructions for government sample collection (sixty pieces, i.e., N-60) and submission procedures; interpretation of results; and outlines an enforcement strategy that includes immediate corrective actions, HACCP reassessment, and follow-up testing. Chapter VI of *DIA-PCEC-08* states that when official samples for any lot are reported as positive by LANAR, establishments will immediately fall into an intensified sampling procedure, which consists of the double sampling for sub lots of beef manufacturing trimmings until 16 consecutive negative samples have been collected. The program specifically designates LANAR as the only laboratory that performs screening and confirmation analyses of official samples.

LANAR uses the FSIS methods for official analysis of *E. coli* O157:H7 (MLG 5A.04 for screening and 5.10 for confirmation) and non-O157 (MLG 5B.05 for screening) in raw beef. LANAR does not perform confirmatory analyses for non-O157 STEC. If the screen test is positive, the result is reported as positive. The number of verification samples collected is proportional to production volume, with a minimum frequency of 12 samples per month (increased to 14 times per month during the rainy season that consists of six months out of the year) to analyze for *E. coli* O157:H7 and non-O157 STEC. In Chapter VII of *DIA-PCEC-08* states that all official positive results associated with product processed in establishments certified to export to the United States will be immediately communicated to FSIS.
audit of two beef establishments indicated that inspection personnel were adhering to the sampling plans established by SENASA and implemented test and hold protocols, retaining sampled product pending acceptable results, for each lot of product destined for export to the United States.

SENASA requires that establishments certified to export to the United States design a written program for implementing verification testing for *E. coli* O157:H7 and non-O157 STECs. The FSIS auditors reviewed the following specific inspection verification activities related to implementation of the establishments’ sampling program, for which no concerns were identified. On a routine basis, official inspection personnel conduct direct observation of the establishment’s sample collection procedures and review prior testing results. OVIs record these verification activities on form *SGIA-CMAI-17*. On a monthly basis, SOVs review the verification activities of the OVI and record the results on form *SGIA-CMAI-17*. The SOV also performs direct observation of the establishment’s procedures for sample collection and reviews the results of the sampling performed by the establishment. The results of this review are recorded on form *FIMEC-01*. On a yearly basis, the official government laboratory (LANAR) performs audits of the private laboratories used in conjunction with establishment testing. The FSIS auditors’ review of *Salmonella* and STEC testing procedures indicated that the appropriate MLG methods were implemented as prescribed.

The FSIS auditors determined that SENASA 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. There have not been any POE violations related to this component since the previous FSIS audit in 2018.

**X. CONCLUSIONS AND NEXT STEPS**

An exit meeting was held April 9, 2021, by videoconference with SENASA in Tegucigalpa, Honduras. The FSIS auditors concluded that Honduras’ raw beef and raw poultry products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has verified the implemented sanitation and HACCP system requirements to ensure controls of hazards in raw beef and raw poultry products. In addition, the CCA has implemented microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety system. An analysis of each component did not identify any findings that represented an immediate threat to public health.
Appendix: Foreign Country Response to the Draft Final Audit Report
Tegucigalpa, M.D.C.
August 31st, 2021

MICHELLE CATLIN  
INTERNATIONAL COORDINATION EXECUTIVE  
OFFICE OF THE ADMINISTRATOR  
FOOD SAFETY AND INSPECTION SERVICE  
U.S. DEPARTMENT AGRICULTURE  
WASHINGTON, D.C., USA

Subject: FSIS Draft Final Audit Report to Honduras’ Inspection System

Dear Dr. Catlin:

I hope this letter finds you doing well. By this means, we would like to follow-up your letter from July 21st, 2021, with the draft final audit report regarding the remote ongoing equivalence verification audit conducted by the United States Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) to the Honduras raw beef and raw poultry products Inspection System.

Please find our comments of the draft final report attached to this letter.

Should you have further questions or comments please contact us: jvelasquez@senasa.gob.hn and mbueno@senasa.gob.hn

Sincerely,

Cc: Dra. Mirian Bueno Almendarez, Directora Técnica de Inocuidad Agroalimentaria, DIA/SENASA  
Dra. María Eugenia Sevilla, Gerente Técnico de Inocuidad Agroalimentaria, DIA/SENASA  
Dra. Irma Esperanza Barahona, Jefe Departamento de Productos Cárnicos, SGIA/SENASA  
Archivo 2021 ☐
Comment #1:

Page 9 paragraph #1

The FSIS auditors verified that LANAR conducts analyses of raw beef products exported to the United States in compliance with ISO/IEC 17025 standards and prepared to conduct analyses of raw poultry products for export to the United States. All methods of analysis used by LANAR are ISO-accredited and are scientifically validated. SENASA’s Top Management team through SGIA conducts bi-annual reviews of the microbiological and residue sections of the laboratory to verify that they use scientifically validated and approved methods for the analysis of products destined for export to the United States. The Costa Rican Accreditation Entity (Ente Costarricense de Acreditación - ECA) also audits the LANAR laboratory annually. ECA is an organization in Costa Rica that provides third party accreditation in accordance with ISO/IEC 17025:2017 standards. The FSIS auditors reviewed the accreditation certificate, scope of accreditation, and accreditation audit reports and did not identify any concerns.

Specific comment from SENASA:

Not all methods of analysis used by LANAR are ISO-accredited, but all of them are scientifically validated and are under the Quality Management System that is in place at the laboratory. We suggest minor rewording to this paragraph.

Comment #2:

Page 15 paragraph #5:

Section VI, Part III of SGIA-GIPC-05 for beef establishments and Section VI, Part III of SGIAGIIP-17 for poultry establishments provide instructions to the inspection personnel on how to verify compliance with the sanitation SOP requirements. The inspection personnel at the establishment verify the pre-operational requirements at least once a week and the operational requirements at least once a month as per Sections A, Number 13 and B, Number 5 of SGIACMAI-17.

Specific comment from SENASA:

Pre-operational inspections are conducted on a daily basis and prior to the operations of each working shift. We suggest minor rewording to this paragraph.

Comment #3:

Page 21 paragraph #2:

The FSIS auditors verified that the implementation of the program in the audited cattle and poultry slaughter establishments met SENASA’s requirements outlined in Regulation No. 078-00. In the beef slaughter establishments, inspection personnel use swabs or sponges to collect a 100-cm² surface area from the flank, rump, and brisket at a frequency of once per every 300 carcasses. Performance standards for cows and bulls consist of a moving window of 58 consecutive carcass
samples, for which the maximum number of positive samples is two. Samples are submitted to LANAR. SENASA uses the *FSIS Microbiology Laboratory Guidebook* (MLG) method 4.09 for confirmation for official analysis of *Salmonella* in beef.

**Specific comment from SENASA:**

SENASA uses the *FSIS Microbiology Laboratory Guidebook* (MLG) method 4.10 for confirmation for official analysis of *Salmonella* in beef and poultry. We suggest minor rewording to this paragraph.