



United States Department of Agriculture

Food Safety and
Inspection Service

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Dr. Ileana Duarte
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Managua, Nicaragua, C.A.

Dear Dr. Duarte,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote ongoing verification audit of Nicaragua's meat inspection system July 13 through August 9, 2021. Enclosed is a copy of the final audit report. Comments received from the Government of Nicaragua 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 Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF
NICARAGUA

JULY 13–AUGUST 9, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

January 26, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a routine equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) July 13–August 9, 2021. Due to the global COVID-19 pandemic, FSIS conducted the audit remotely using a combination of videoconferences and records review. The purpose of the audit was to determine whether Nicaragua's 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 correctly labeled and packaged. Nicaragua currently exports raw beef products to the United States.

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

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

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- The Institute of Agricultural Protection and Health (Instituto de Protección y Sanidad Agropecuaria (IPSA)) Directorate of Laboratories has not ensured that proficiency testing plans are established to ensure that laboratory personnel are proficient in the microbiological analyses performed.
 - The Central Veterinary Diagnostic and Food Microbiology Laboratory (Laboratorio Central de Diagnóstico Veterinario y Microbiología de Alimentos (LCDVMA)) has not conducted proficiency testing for Shiga toxin-producing *Escherichia coli* (STEC) analysis.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Nicaragua's food safety inspection system July 13–August 9, 2021. The audit began with an entrance meeting on July 13, 2021, held via videoconference with representatives from the Central Competent Authority (CCA) – the Institute of Agricultural Protection and Health, (Instituto de Protección y Sanidad Agropecuaria (IPSA)). Representatives from IPSA participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that FSIS conducted remotely. The audit objective was to determine whether Nicaragua's food safety inspection system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Nicaragua 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 Nicaragua as free of foot-and-mouth disease and negligible risk for bovine spongiform encephalopathy (BSE).

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed Nicaragua's self-reporting tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether Nicaragua's food safety inspection system governing raw beef products is being implemented as documented in the country's SRT responses and supporting documentation.

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

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the 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 auditors reviewed administrative functions at the CCA headquarters, including the supervisory office, and records from three local inspection offices providing inspection of eligible establishments. The FSIS auditors evaluated the CCA's implementation of control systems that ensure the national system of inspection, verification, and enforcement is functioning as intended.

The FSIS auditors selected a sample of three establishments from a total of seven establishments certified to export to the United States. This included three beef slaughter and processing establishments. The products these establishments produce and export to the United States include raw intact and raw non-intact beef products.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include 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.

The FSIS auditors also conducted interviews and reviewed records associated with two official government laboratories to verify that these laboratories can provide adequate technical support to the food safety inspection system.

| Remote Audit Scope | | # | Locations |
|---------------------|---------|---|--|
| Competent Authority | Central | 1 | <ul style="list-style-type: none"> Institute of Agricultural Protection and Health, (Instituto de Protección y Sanidad Agropecuaria (IPSA)), Managua |
| Laboratories | | 2 | <ul style="list-style-type: none"> National Laboratory of Chemical and Biological Residue (Laboratorio Nacional De Residuos Químicos y Biológicos (LNRQB)), government residue, Managua |

| | | |
|--|---|--|
| | | <ul style="list-style-type: none"> Central Veterinary Diagnostic and Food Microbiology Laboratory (Laboratorio Central de Diagnóstico Veterinario y Microbiología de Alimentos (LCDVMA)), government microbiological, Managua |
| Beef slaughter and processing establishments | 3 | <ul style="list-style-type: none"> Establishment No. 3, MAINCA, El Rama Establishment No. 5, Nuevo Carnic S.A., Managua Establishment No. 8, MACESA, Juigalpa |

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

The audit standards applied during the review of Nicaragua's 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 December 1, 2017 to November 30, 2020, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 402,595,995 pounds of raw beef from Nicaragua. This included 350,508,064 pounds of raw intact beef and 52,087,931 pounds of raw non-intact beef exported by Nicaragua to the United States. Of these amounts, FSIS performed additional types of inspection on 30,108,058 pounds of beef, including testing for chemical residues and Shiga toxin-producing *Escherichia coli* (STEC). As a result of this additional reinspection, FSIS rejected 7,810 pounds of beef offal for ingesta contamination of raw beef tripe.

The last FSIS audit in 2019 identified the following systemic finding:

| Summary of Findings from the 2019 FSIS Audit of Nicaragua |
|--|
| Component 3: Government Sanitation |
| The Central Competent Authority's (CCA) in-plant inspection officials failed to identify, document, and enforce compliance with sanitation performance standards and sanitation standard operating procedures requirements in one of five slaughter and processing facilities. The overhead structures in several beef carcass coolers exhibited condensation and extensive rust directly above exposed beef carcasses which may lead to direct product contamination. The severity of the degraded conditions led the CCA to retain the beef carcasses, reject the coolers, and trim all carcasses within these coolers. In addition, the overhead structures |

throughout the fabrication areas of the facility exhibited rust directly above exposed beef product. However, no direct product contamination was observed in any of these instances.

Prior to the audit, FSIS verified that the corrective actions for the previously reported findings were acceptable and addressed the findings. Due to the format of the current audit, on-site observations could not confirm the effectiveness of the corrective actions in preventing recurrence.

The most recent FSIS final audit reports for Nicaragua's 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 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 auditors verified that the national government of Nicaragua organizes and administers the inspection system. Law No. 862, Law Creating the Institute of Agricultural Protection and Health (IPSA), created and designated IPSA as the CCA for the meat inspection system. The law established the organizational structure of IPSA. There have been no major changes in IPSA's organizational structure since the last FSIS audit.

IPSA has one central office in Managua that is comprised of three separate directorates: the Directorate General of Agricultural Health, the Directorate General of Agricultural Traceability, and the Directorate General of Agrifood Safety and Laboratories (Dirección General de Inocuidad Agroalimentaria y Laboratorios (DGIAL)). DGIAL comprises the Directorate of Agrifood Safety (Dirección de Inocuidad Agroalimentaria (DIA)) and the Directorate of Laboratories.

DIA includes the Department of Food Safety Surveillance (Departamento de Vigilancia e Inocuidad de Alimentos), the Department of Inspection of Establishments and Agribusiness (Departamento de Inspección a Establecimientos y Agroindustriales, (DIEA)), and the Department of Registration and Certification (Departamento de Registro y Certificación (DRC)). The DIA is responsible for the safety of meat products, promulgation of food safety regulations, and has the sole authority to enforce the laws and regulations of the meat inspection system.

Within DIEA is the Meat Safety Section (Sección de Inocuidad Carne (SIC)) that provides inspection of establishments. Management of the SIC is coordinated from the IPSA headquarters in Managua, and there are no regional offices. The Chief Veterinary Officer of DIA provides direct oversight of SIC management. The SIC Manager and Assistant Manager are responsible for oversight of the official activities of inspection personnel. The Official Veterinarians (OV)

stationed at establishments certified to export to the United States are responsible for oversight including managing and supervising teams of Auxiliary Inspectors (AI). Inspection personnel conduct ante-mortem and post-mortem inspection as well as daily verification of the establishments' compliance with the sanitation, HACCP, chemical residue, and microbiological requirements.

The Meat Inspection Regulations give IPSA the authority and ability to take enforcement actions when an establishment fails to prevent product adulteration, does not comply with regulations, interferes with inspection, or fails to humanely handle or slaughter livestock. In addition, the regulations provide inspection personnel the authority to suspend inspection temporarily, in whole or in part, when an establishment fails to comply with regulatory requirements. The Meat Inspection Procedures Manual describes the regulatory control actions inspection personnel may use including slowing or stopping lines, retaining of product, rejecting of facilities, and denying use of the mark of inspection. The FSIS auditors verified that there have been no suspensions or withdrawals of inspection for cause since the last FSIS audit.

IPSA ensures that meat products are not adulterated or misbranded prior to certification for export to the United States. The Meat Inspection Regulations define adulterated product, including but not limited to: product contaminated with chemical pesticides; product consisting, in whole or in part of any dirty, putrid, or decomposed substance, or for any reason unhealthy or otherwise unsuitable for food; and product prepared, packaged, or maintained under unhygienic conditions including product contaminated with filth or otherwise harmful to health. The regulations define misbranded product as product with a false or misleading label, product not conforming to a recognized standard of identity, and product not labeled in compliance with labeling regulations. The regulations require all inspected and passed product to bear an official inspection legend. IPSA requires that official inspection personnel retain all product sampled for veterinary drug residues, pesticides, and microbiological pathogens pending acceptable analytical results.

The Central American Technical Regulations RTCA 67.06.55.09, Good Hygiene Practices for Unprocessed and Semi-processed Foods, Section 6.6, requires establishments to have effective procedures to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of finished food from the market. The Product Removal Guide, an annex in the Meat Inspection Procedures Manual, provides the authorized establishments with the terminology, responsibilities, and public notification procedures regarding the recall of inspected meat products. IPSA requires each establishment to have a written, detailed recall plan. In the event a recall is initiated, IPSA verifies that the procedures are conducted in an adequate manner. Additionally, the establishments are required to conduct a "mock" recall once a year as part of their recall procedure. The FSIS auditors verified that no recalls have been issued since the last FSIS audit.

The Meat Inspection Regulations require that product eligible for export includes an official meat inspection certificate, issued by a veterinary inspector, testifying that all requirements have been met prior to export. The Meat Inspection Procedures Manual, Procedure No. 10, describes the export certification procedures, including the review and confirmation of acceptable testing results prior to certification.

Establishments provide the OV a written export request detailing the lot(s) intended for export, including acceptable HACCP records, acceptable analytical results, and documentation of the cleaning and sanitizing of export containers. The official inspection personnel perform a preshipment review and verify that each lot staged for export meets requirements, has acceptable analytical results, and that the container is sanitary. Official inspection personnel document verification results on Form F-SIC-30, Shipment Control Report for Export. If the OV verifies compliance, the OV proceeds to issue an official meat inspection certificate and apply an official seal to the shipping container. The FSIS auditors reviewed export certification records for the three audited establishments and did not identify any concerns.

The Meat Inspection Procedures Manual, Procedure No. 19, describes procedures to ensure secure government control over the official meat inspection certificates, stamps, and seals. The FSIS auditors verified that the official meat inspection certificates are pre-printed with unique sequential numbers and distributed from IPSA headquarters to OVs. All certificates, seals, and stamps are controlled items secured by official inspection personnel and subject to records documenting use. The FSIS auditors verified implementation of controls and records as described in the SRT.

The FSIS auditors verified that certified establishments only slaughter cattle raised in Nicaragua. Each establishment processes beef originating from cattle slaughtered at the same facility. Nicaragua does not import raw meat to further process product for export to the United States.

IPSA ensures that the same set of laws, regulations, and policies are consistently applied to all certified establishments eligible to export meat to the United States. Official inspection personnel are required to follow procedures in the Meat Inspection Procedures Manual to ensure that establishments comply with all requirements.

The DRC is responsible for conducting audits to determine initial and annual approval of official establishments and those eligible for export to the United States. The Meat Inspection Regulations detail requirements for establishment approval and the authority for the approval of authorized establishments. The IPSA website includes a list of requirements for establishments seeking initial approval. Following DRC review of written establishment food safety programs and required documentation, DRC performs an on-site inspection. The FSIS auditors reviewed the written records documenting the audit results for an establishment certified after the last FSIS audit. The DRC audit report documented elements verified and identified both compliant and noncompliant aspects. The OV verified establishment corrective actions were acceptable. The DRC reviewed the corrective actions, determined they were acceptable, and proceeded to certify the establishment by issuing a HACCP certificate. Once the establishment was certified, IPSA provided written notification to FSIS that the establishment was eligible to export to the United States.

IPSA conducts annual audits to evaluate establishment compliance according to the Procedure for the Audit of the Hazard Analysis and Critical Control Points (HACCP) System (2017), documenting audit results using the checklist in the procedure. Approximately three months before annual certification each year, each establishment must submit their written food safety programs to the DRC. The DRC reviews each establishment's written food safety programs for

compliance with Nicaraguan and United States requirements. Next, the DRC Director and SIC Manager conduct an on-site audit to verify compliance. If the audit identifies noncompliance, IPSA provides written notification to the establishment and the OV assigned to the establishment verifies compliance. IPSA will only re-certify an establishment eligible for export to the United States if it meets all requirements at the completion of this process. The FSIS auditors reviewed the annual audit records for each of the three audited establishments. The audit reports demonstrated that IPSA evaluated the written food safety programs, audited the facilities, and evaluated their compliance with FSIS requirements before granting certification of eligibility to export meat to the United States.

The SIC Manager is responsible for providing updated information, including FSIS import requirements, to the inspection personnel at certified establishments. The FSIS auditors verified that the SIC Manager issues memoranda to OVs notifying them of new information, instructions, and other updated information. In addition, SIC schedules monthly meetings with all OVs from certified establishments for the purpose of correlation, discussion of revised processes or procedures, and other relevant topics. The FSIS auditors reviewed records documenting monthly meetings and verified the process as described.

The national government funds IPSA, including through fees assessed to meat establishments as provided under the authority of Law No. 291, Basic Law on Animal Health. The law states that fees for services are calculated based on the need to cover necessary operating expenses and expansion and modernization of the sanitary and phytosanitary services, to ensure effectiveness. The government bills establishments for provided services and the establishments pay the fees to the Financial Administrative Delegation (Delegación Administrativa Financiera (DAF)), within IPSA. The DAF processes the transactions and releases funds as necessary to maintain ongoing operations of IPSA and to pay for the services provided by the laboratories. The FSIS auditors reviewed the ministerial decree describing fees as well as an example contract between IPSA and an establishment documenting the fees for service. The FSIS auditors also reviewed billing documentation from IPSA for establishment fees and records documenting receipt of payment by IPSA.

All IPSA personnel are employees of the government of Nicaragua and subject to administrative policies that apply to all government officials. The Meat Inspection Regulations, Article 23, lists and describes the official inspection personnel positions under the direct authority of the government, including veterinary inspectors and auxiliary inspectors. The regulations also include ethical provisions including controls on purchase of product from establishments, precluding assignment of inspection personnel to an establishment in which any member of the family is employed by the establishment, and preventing any SIC employee from requesting employment for any other person in an establishment.

The FSIS auditors verified that official inspection personnel assigned to certified establishments are government employees paid by the Nicaraguan government. The FSIS auditors reviewed the official list of government inspection personnel assigned to each audited establishment. The FSIS auditors verified documents demonstrating direct deposit payment by the government's Ministerio de Hacienda y Crédito Público directly into IPSA employee accounts.

IPSA ensures that government inspection occurs continuously during slaughter operations including inspection of every carcass and during each meat processing shift. The Meat Inspection Regulations require that all livestock and all products that enter any authorized establishment and all products generated there in whole or in part, will be inspected in the manner established in the regulation. The regulations state that no establishment may conduct operations requiring inspection unless they are under the supervision of official inspection personnel. The regulations also require establishments to notify the official inspection personnel of hours of operation and to provide advance notice any time they request operations requiring inspection during weekends, holidays, or overtime periods.

The FSIS auditors verified that inspection staffing levels vary among establishments, but always include one OV providing oversight at the establishment level and AIs responsible for conducting post-mortem inspection, sampling, and other assigned verification activities. Staffing is sufficient to conduct all government inspection duties. At least two of the AIs assigned to each establishment are veterinarians, authorized to perform OV duties in the event of staffing emergencies. In the event of staffing shortages, SIC has established procedures for ensuring assignment of official inspection personnel as needed. The FSIS auditors reviewed official staffing rosters, monthly staffing calendars, weekly assignments, and weekly attendance records for each establishment and concluded staffing was sufficient to ensure inspection throughout slaughter and processing. Review of additional verification records throughout the audit provided evidence of continuous inspection throughout slaughter and processing operations.

IPSA ensures that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to carry out their inspection tasks. The OVs assigned to certified establishments must have a veterinary degree from an accredited university, have two years of experience in the specialty of meat inspection, and knowledge of the law and its regulations. AIs must have an education background and experience in fields including veterinary medicine, agriculture, and similar careers.

The Training Manual for Official Medical Inspectors for Meat Inspection describes the training of new OVs, including ante-mortem and post-mortem inspection, carcass marking, off-line inspection, deboning inspection, shipping inspection, sanitation, HACCP, good manufacturing practices, specified risk material (SRM) controls, humane handling, sampling procedures, and FSIS requirements. The FSIS auditors reviewed records documenting the initial training of an OV assigned to an establishment certified after the last FSIS audit. The records documented extensive training details, including assignment to the establishments already certified for export to the United States for mentoring and training by experienced OVs.

IPSA provides for ongoing training of all official inspection personnel. The OV at each certified establishment is responsible for developing an annual training plan for AIs. The SIC Manager reviews and approves annual AI training plans. The FSIS auditors reviewed annual training records for AIs at each audited establishment and verified ongoing training including, but not limited to, post-mortem inspection, sanitation, HACCP, SRMs, food microbiology, sampling, traceability, and animal welfare. OVs attend ongoing training courses as opportunity allows and attend the monthly correlation sessions at headquarters as previously described.

The Functions Manual of the Meat Inspection Department includes the job duties and responsibilities for each position. The SIC Manager and Assistant Manager are required to perform quarterly evaluations for each official veterinarian assigned to the certified establishments and document results on Form F-SIC-50, Evaluation of Official Veterinarians. The quarterly OV evaluation includes reviewing performance in ante-mortem inspection, post-mortem inspection, humane handling verification activities, sanitation standard operating procedures (sanitation SOP), HACCP verification, labeling verification, export certification, sampling programs (*Salmonella* and *E. coli*), supervision of AIs, and control over condemned material, including SRM control. The OV is responsible for supervising and performing a monthly performance assessment of AIs. IPSA implemented a change since the last FSIS audit and the OV now documents individual assessment results for each AI on Form F-SIC-43, Evaluation of Auxiliary Inspectors. The FSIS auditors reviewed performance assessment records for OVs and AIs at the audited establishments and verified that IPSA is implementing the processes as described.

IPSA maintains adequate administrative and technical support to operate its laboratory system. Law No. 862, Law Creating the Institute of Animal and Plant Health Protection (IPSA), Article 4, gives IPSA the legal authority and responsibility to approve laboratories conducting testing of official government samples of product destined for export to the United States. The official laboratories are under the immediate authority of the Directorate of Laboratories. The National Laboratory of Chemical and Biological Residue (Laboratorio Nacional de Residuos Químicos y Biológicos (LNRQB)) is the government laboratory conducting chemical analyses and the Central Veterinary Diagnostic and Food Microbiology Laboratory (Laboratorio Central de Diagnóstico Veterinario y Microbiología de Alimentos (LCDVMA)) is the government laboratory conducting microbiological analyses.

The National Accreditation Office (Oficina Nacional de Acreditación (ONA)) is the national accreditation organization. ONA conducts annual surveillance audits and certification audits every four years. ONA audits laboratories against the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2017, General requirements for the competence of testing and calibration laboratories standards and issues accreditation certificates when ONA verifies compliance with ISO standards. The FSIS auditors reviewed the most recent ONA accreditation reports, associated corrective actions, and acceptance by ONA of laboratory corrective actions.

DIA conducts an annual inspection of the official laboratories to verify compliance with the designated analytical methods and compliance with ISO/IEC 17025:2017 standards. The FSIS auditors reviewed the most recent DIA audit reports of each laboratory. In addition, the FSIS auditors reviewed the most recent internal laboratory audits and associated corrective action plans.

IPSA ensures that analytical methods are scientifically validated or approved and adopted by a recognized international organization. The FSIS auditors determined that the Director of Laboratories is the bridge between the official laboratories and IPSA management in headquarters. The Director attends the ONA audit exit meeting at each laboratory, receives the ONA audit reports, and informs IPSA management of results. The Director of Laboratories is

also responsible for purchasing proficiency testing, reviewing results, and correlating with the technical staff at each laboratory.

The FSIS auditors reviewed the current accreditation certificates and scopes of accreditation for each laboratory and determined that the LCDVMA has not yet obtained accreditation for the STEC analytical methods. Therefore, ONA has not included the STEC methods in the accreditation audits. IPSA personnel explained the intent to have the STEC methods accredited within the forthcoming year. The FSIS auditors also reviewed proficiency testing records for each laboratory and identified the following finding:

- The IPSA Directorate of Laboratories has not ensured that proficiency testing plans are established to ensure that laboratory personnel are proficient in the microbiological analyses performed.
 - The LCDVMA has not conducted proficiency testing for STEC analysis.

IPSA develops annual sampling plans and programs for microbiological and chemical residue sampling. At the beginning of each calendar year, SIC distributes the plans to the OV of each establishment to ensure chemical residue and microbiological sampling in every establishment certified to export to the United States.

The FSIS auditors reviewed the process and records at each laboratory for sample receipt, sample traceability, and anonymity of samples during the analytical process. The FSIS auditors also reviewed calibration plans and records at each laboratory as well as internal quality controls for analytical methods. In addition, the FSIS auditors reviewed the process for laboratory management review and approval of analytical results prior to generating the analytical report. Lastly, the FSIS auditors reviewed the process for issuance of analytical reports and reporting methods. The official laboratories provide analytical results reports to the OV at the establishment from which a sample originated. In the event of unacceptable analytical results, the laboratory manager provides immediate notification via e-mail to the OV and IPSA headquarters personnel, including the SIC Manager. The FSIS auditors further verified that when official laboratory test results are unacceptable (e.g., residue exceeding allowable levels, detection of pathogens) they do not repeat the analyses and original results are final. The FSIS auditors did not identify any concerns after reviewing records and conducting interviews with laboratory personnel.

The FSIS auditors determined that the Nicaraguan government organizes and administers the country's food safety inspection system to provide ultimate control, supervision, and enforcement of regulatory requirements. IPSA officials enforce laws and regulations governing production and export of raw beef at establishments certified to export to the United States. However, IPSA needs to address the audit finding described above.

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

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

IPSA ensures the humane handling and welfare of livestock. The Meat Inspection Regulations detail requirements to ensure the humane handling and slaughter of livestock. The requirements include facility construction and maintenance to minimize the potential for inflicting injury to livestock. The regulations also address water, feed, and pens for suspect livestock and humane handling requirements to ensure establishment personnel handle livestock with minimum stress and discomfort. Lastly, the regulations specify stunning methods and procedures.

The Meat Inspection Procedures Manual provides instructions to inspection personnel for verifying humane handling and slaughter requirements in certified establishments. The OV performs weekly verification of humane handling requirements and records the results on Form F-SIC-40, Verification of Humane Handling and Slaughter of Animals. Official inspection personnel also perform daily verification of humane handling and humane slaughter requirements. At the time of this audit, official inspection personnel did not document the daily verification results. However, during this audit IPSA designed and implemented use of Form F-SIC-40.1, Verification of Welfare and Humane Slaughter of Animals to document daily humane handling and slaughter verification results. Official inspection personnel document humane handling and slaughter noncompliance on Form F-SIC-44, Demand for Corrective Actions. The FSIS auditors reviewed monthly verification records and noncompliance records for each audited establishment.

IPSA ensures that official inspection personnel perform ante-mortem inspection of livestock prior to slaughter. Chapter VIII of the Meat Inspection Regulations includes requirements for condemnation of livestock that show signs of a disease or condition that would result in the carcasses being condemned at post-mortem inspection. The regulations also describe the disposition of livestock identified with clinical signs of toxic, metabolic, infectious, parasitic, and other disorders and require condemnation of dead, dying, injured, sick, or similarly affected livestock. The regulations require that official inspection personnel mark condemned livestock with a tag or stamp that can only be removed by program employees. Condemned animals may not move into an authorized establishment or any food product area and must be destroyed in the presence of an inspector by incineration or denaturing.

The Meat Inspection Procedures Manual, Procedure No. 9, describes procedures for performing ante-mortem inspection. OVs perform ante-mortem inspection and document results on Form F-SIC-11, Ante-mortem Inspection, including the date and time of inspection, pen number, number

of livestock approved for slaughter, and any identified suspect animals. The OV performing ante-mortem inspection utilizes Form F-SIC-10, Approved Animals (i.e., pen cards) to document the date, lot, corral number, time of ante-mortem inspection, and number of livestock in each class approved for slaughter, and one copy accompanies each lot to slaughter. When the OV identifies a suspect animal, the OV documents the details on Form F-SIC-09, Ante-mortem Inspection Suspect Animals, and the record accompanies the livestock to slaughter. The OV performs a post-mortem examination on all suspects and documents disposition on the same Form F-SIC-09. Official inspection personnel also verify traceability during ante-mortem inspection according to the Meat Inspection Procedures Manual, Procedure No. 2. IPSA requires establishments to document the traceability of every lot at receiving and throughout all subsequent processes. The FSIS auditors reviewed multiple records for each audited establishment and verified IPSA implemented the procedures as described.

The Meat Inspection Procedures Manual, Procedure No. 7, Procedure for Sampling Bovine Spongiform Encephalopathy (BSE) requires that non-ambulatory cattle be slaughtered, condemned, and transported to an incinerator on vehicles or receptacles used solely for that purpose. Following condemnation, the OV submits a central nervous system sample to the official LCDVMA laboratory for BSE analysis. The FSIS auditors verified the submission, laboratory results, and the condemnation certificate for a cow that was dead in the corrals.

IPSA ensures that government inspection personnel perform post-mortem inspection for every carcass. The Meat Inspection Regulations, Chapter IX, identifies regulatory requirements for the post-mortem inspection of livestock carcasses and parts including examination of the bovine heads, viscera, and carcasses using incision, observation, and palpation of required organs and lymph nodes. The regulations state that veterinary inspectors are responsible for meat inspection and that assistant inspectors assist in post-mortem inspection and must have sufficient experience and capacity in the branch of meat inspection to carry out these tasks.

The Meat Inspection Regulations, Chapter X, detail the diseases and conditions of livestock that render a carcass adulterated and those requiring removal or condemnation of carcasses and parts. Carcasses and parts with lesions or other conditions that might make them unfit for human consumption or otherwise adulterated are required to be withheld pending a final inspection by the OV. The identification of all carcasses and parts must be maintained until the final inspection is complete. The OV is responsible for determining the final disposition of ante-mortem suspects and any carcasses identified during post-mortem as requiring veterinary inspection in certified establishments. The OV documents results of the examination of suspects on Form F-SIC-09, Ante-mortem Inspection Suspect Animals.

The Meat Inspection Procedures Manual, Procedure No. 9, provides instructions to inspection personnel on conducting post-mortem inspection activities. The AIs conduct post-mortem inspection activities under the supervision of the OV. AIs perform examination of bovine heads, viscera, and carcasses using incision, observation, and palpation of required organs and lymph nodes in accordance with the procedures. The FSIS auditors verified line speeds and staffing levels for each audited establishment are adequate to ensure continuous inspection throughout slaughter. The remote audit format precluded FSIS auditor observation of post-mortem inspection.

For each day of slaughter, the AIs maintain Form F-SIC-22, Control of Condemned Viscera and Other Parts to document the number and reasons for condemnation of viscera. At the conclusion of every slaughter day, the OV completes the post-mortem report Form F-SIC-37, Post-mortem Report which contains information on how many animals were inspected, approved, condemned, or suspect along with the numbers and conditions for condemned viscera using data from Form F-SIC-22. Each day the OV verifies that the numbers and class of cattle during post-mortem inspection align with the numbers approved for slaughter during ante-mortem inspection before finalizing the record with signature and stamp. The OV also completes Form F-SIC-13, Operational Control of Slaughter that documents the numbers, age class, and sex of cattle slaughtered as well as the lots and carcass numbers sampled for residue analyses. The FSIS auditors reviewed the slaughter records, including condemnation certificates, for each audited establishment and verified IPSA implements the procedures as described.

The SIC Manager and Assistant Manager are responsible for oversight of the official activities of inspection personnel and for conducting monthly supervisory visits at establishments eligible to export to the United States. The scope of these supervisory visits is consistent with those identified in 9 CFR Part 327.2(a)(2)(ii) and includes ante-mortem and post-mortem inspection, official controls over sanitation, humane handling verification activities, sanitation SOP, HACCP, labeling, export certification, sampling programs (*Salmonella* and STEC testing verification), and control over condemned material. Supervisory visit results are documented on the Form F-SIC-57, Supervision Form for Authorized Establishments that Slaughter and Process Bovine Meat and Other Species. The SIC Manager provides the completed supervisory report to the OV who then provides a copy to the establishment. The establishment provides written corrective actions to the OV. The OV reviews and verifies the corrective actions and provides a copy of the corrective actions to the SIC Manager. The FSIS auditors reviewed multiple supervisory reports for each establishment and verified that SIC is implementing the process as described.

In addition, SIC requires the OV for each certified establishment to submit monthly and annual summary reports to the SIC Manager that include slaughter volume, condemnations, all residue and microbiological sampling and results, and issuance of official meat inspection certificates by export market. The SIC Manager utilizes the reports, in part, to ensure official sampling and analysis according to the annual plans. The FSIS auditors reviewed multiple records from each establishment including the monthly and annual reports.

IPSA considers Nicaragua requirements to be consistent with those of the United States. Therefore, IPSA considers that each certified establishment is always operating under requirements that meet those for export to the United States. The Meat Inspection Regulations, Article 13, requires each authorized establishment to be separate and distinct from non-authorized establishments. The regulations require establishments that distribute meat nationally to separate meat products destined for export markets from meat products that are destined for national consumption (“local sale”) including separation during cold storage. IPSA has not authorized every establishment for local sales.

Official inspection personnel verify daily that operators comply with the requirement for separation of product destined for the United States and document results on Form F-SIC-52,

Inspection of Local Sale Areas and Local Sale Stores. The OV may allow diversion of products ineligible for export to the United States to local sale, most commonly for quality reasons. The Meat Inspection Regulations require products eligible for local sale to be marked “Local” and the OV certifies all local sales products on Form F-SIC-36, Certificate for Local Sale. The FSIS auditors verified records documenting controls of local sales as described. In addition, the FSIS auditors verified that each establishment has identified and labeled designated freezers for storage of products intended for export to the United States. Lastly, the FSIS auditors verified use of product codes with designated codes for export to the United States for each audited establishment.

The Meat Inspection Regulations include the requirement that establishments must conduct labeling activities under the supervision of a SIC employee. The regulations also describe the requirements for the official control and application of marking devices. The Meat Inspection Procedures Manual, Procedure No. 2 describes official verification procedures, including verification of labeling at deboning and in the shipping area. Procedure No. 15 includes the verification procedures for net weight and labeling. The frequency of verification is weekly, and results are documented on Form F-SIC-42, Verification of Weights and Contents of Boxes According to their Label. Official inspection personnel also verify proper labeling of products during the export certification process. The FSIS auditors reviewed verification records for each establishment and verified that SIC is following the process as described.

In addition, IPSA requires each slaughter establishment to have procedures and records to ensure that carcasses do not gain weight during carcass chilling, consistent with FSIS Directive 6330.1, Carcass Spraying During Chilling. The FSIS auditors reviewed establishment records, verified by the OVs, that demonstrate hot and cold carcass weights and lack of gain.

The Animal Health Directorate of IPSA maintains close communication with APHIS regarding livestock disease status. IPSA ensures that beef exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website for current restrictions. APHIS has determined that Nicaragua is a region of negligible risk for BSE and free of foot-and-mouth disease. The OVs at certified establishments verify that products meet APHIS requirements prior to signing the official meat inspection certificate.

IPSA ensures that all beef products are free of infectious materials associated with BSE. Administrative Resolution No. 099-2019, Surveillance of BSE, defines SRMs consistent with the World Organization for Animal Health Terrestrial Animal Health Code and, specifically, tonsils and distal ileum in cattle of all ages and brain, skull, eyes, spinal cord, and spinal column of cattle 30 months of age or older. Any non-ambulatory cattle, those showing central nervous system signs, or cattle found dead are condemned and sent to incineration. The resolution bans the use of air injection during stunning. Article 21 of the resolution requires establishments to address SRMs in their HACCP systems, have written food safety programs for removal of SRMs, and procedures to avoid contamination of other products. Establishments are required to keep records documenting removal and destruction of SRMs.

The Meat Inspection Procedures Manual, Procedure No. 16, provides verification procedures for inspection personnel to ensure that the establishment appropriately identifies, removes, and

disposes of SRMs to prevent contamination of products destined for consumption. AIs verify the establishment's determination of the age of cattle based on dentition during slaughter and document those carcasses less than 30 months of age on Form F-SIC-18, Cattle Younger than 30 Months. AIs also verify proper removal of SRMs hourly and record results on Form F-SIC-19, Verification of Separation and Elimination of SRM. Official inspection personnel also verify the proper destruction of SRMs daily and document results on Form F-SIC-19-1, Verification of the Destruction of SRMs. In addition, the OV performs weekly verification of handling of dead and non-ambulatory cattle, collection of samples for BSE testing, segregation and disposal of SRMs in the establishment, and destruction of SRMs. The OV documents weekly verification results on Form F-SIC-41, Verification of Elimination and Destruction of SRMs. The FSIS auditors reviewed verification records described above and documented noncompliance and corrective actions for each audited establishment. The FSIS auditors concluded that IPSA implements the verification procedures as described.

IPSA ensures control over condemned animals, carcasses and parts, and inedible materials until they are denatured or otherwise destroyed. The Meat Inspection Regulations include requirements for denaturing agents and denaturing procedures, including the requirement that establishment personnel thoroughly slash all inedible material prior to the application of the denaturant. The regulations also include requirements for the clear labeling and segregation of condemned and inedible products and containers and the requirement that all condemned materials remain in the custody of SIC until destruction. If a certified establishment fails to adequately destroy condemned product, IPSA has the authority and responsibility to suspend inspection activities.

Inspection personnel verify proper handling of inedible material three times per shift and record the results on Form F-SIC-21, Operational SSOP Verification, that includes a line item for "Handling of edible and inedible product." The FSIS auditors reviewed verification records for each audited establishment.

The FSIS auditors concluded that Nicaragua's food safety inspection system provides for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and part; controls over condemned materials; and periodic supervisory visits to official establishments.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

The Meat Inspection Regulations require that carcasses and carcass components be handled in a sanitary manner to prevent contamination with fecal matter, urine, bile, hair, dirt, or foreign matter. If contamination does occur, the contaminant must be immediately removed in a way that

is satisfactory to the inspector. Additional regulatory requirements include sanitation of personnel and equipment that handle carcasses or diseased parts.

Official inspection personnel verify that carcasses and parts are free of contamination during post-mortem inspection activities, including final carcass inspection and during verification of the establishments' zero tolerance critical control point (CCP) for milk, ingesta, and feces at a frequency of 10 carcasses per hour. AIs document verification results on Form F-SIC-15.1, Verification CCP1 Zero Tolerance. The FSIS auditors reviewed verification records for each audited establishment.

IPSA requires establishments have HACCP system procedures to prevent contamination of livestock carcasses and parts by enteric pathogens, fecal matter, ingesta, and milk. The OV performs a detailed assessment of process control and sanitary dressing once every month consistent with FSIS Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age. Results are documented on Form F-SIC-57, Checklist of Process Control and Sanitary Slaughter. During the remote audit, the SIC Manager advised the FSIS auditors that IPSA is currently incorporating the written instructions for the verification process into the Meat Inspection Procedures Manual. Official inspection personnel also verify operational sanitation, including employee hygiene, three times a day. The FSIS auditors reviewed verification records for each audited establishment, including documented noncompliance for sanitary dressing deficiencies.

IPSA has official controls over establishment construction, facilities, and equipment. The Meat Inspection Regulations, Chapters VI and VII, are consistent with the requirements found in 9 CFR Sections 416.2 - 416.6. In addition, the Central American Technical Regulations RTCA 67.06.55.09, Good Hygiene Practices for Unprocessed and Semi-processed Foods, describe the requirements for general hygienic practices at different stages of production including receiving of raw materials, processing, packaging, storage, and transportation to ensure the safety of the products for human consumption.

The Meat Inspection Procedures Manual includes verification procedures conducted by government inspection personnel for sanitary requirements in Procedures No. 11, 12, and 13. Procedure No. 11 provides instructions for pre-operational verification including the physical inspection of installations, equipment, and sanitary condition of the processing areas. Procedure No. 12 provides instructions for operational sanitation verification three times daily including employee hygiene; sanitary condition of walls, floors, and ceilings; condensation; hot and cold-water availability; and inedible product handling, among other sanitation requirements. Procedure No. 13 describes the responsibility of the establishment to execute a pest control plan and provides instructions for verification of pest and rodent control.

The Meat Inspection Regulations describe authorities for inspection personnel regulatory control actions including rejecting insanitary utensils, equipment, or rooms and suspending inspection temporarily or ordering the withdrawal of products. When inspection personnel identify noncompliance, they either issue the establishment Form F-SIC-44, Demand for Corrective Actions, which records the type of noncompliance, corrective actions, and preventive measures or document noncompliance on the back of the verification form, including corrective actions and preventive measures. For example, the FSIS auditors determined that official inspection

personnel document sanitation SOP pre-operational noncompliance on the reverse of the verification form whereas operational sanitation SOP noncompliance was documented on Form F-SIC-44. During the audit, the SIC Manager recognized this inconsistency and verbally stated they were implementing a change to ensure all identified noncompliance is documented on Form F-SIC-44, Demand for Corrective Actions.

Official inspection personnel document daily sanitation verification results on Form F-SIC-31, SSOP Pre-Operational Verification and Form F-SIC-21, SSOP Operational Verification. Inspection personnel conduct pest control verification activities twice a week and document results on Form F-SIC-32, Verification of Rodent Control. Inspection personnel perform daily verification of the chlorine levels (three times daily) and pH (once daily) of water with results documented on Form F-SIC-47, Monitoring Chlorine and pH of Water. Once a month official inspection personnel verify sanitation of lockers, documenting results on Form F-SIC-48, Monitoring of Lockers. Additional forms document daily verification results for monitoring temperatures of cold rooms and carcasses, processing rooms, viscera rooms and sterilizer temperatures in slaughter and processing rooms. The FSIS auditors reviewed verification records, documented noncompliance, and corrective actions for each audited establishment.

The FSIS auditors concluded that IPSA 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; and procedures to ensure sanitary dressing.

Prior to the audit, FSIS verified that the corrective actions for the previously reported systemic finding under the sanitation component were acceptable and addressed the finding. The FSIS auditors reviewed additional records including supervisory visit reports following implementation of the corrective actions.

The FSIS auditors concluded that IPSA's food safety inspection system continues to maintain sanitation requirements and verification procedures that meet the core requirements for this component.

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

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

IPSA requires establishments to develop, implement, and maintain HACCP systems. Nicaragua's Law No. 291, Basic Law on Animal Health, designates IPSA as responsible for regulating the requirements for HACCP according to national, regional, and international standards. The Guidelines for Implementation of the Hazard Analysis and Critical Control Points System (NTON 03 001-98) includes mandatory requirements of a HACCP system. The Meat Inspection Procedures Manual requires that establishments develop HACCP systems consistent with national regulations and 9 CFR Part 417. The CCA requires certified slaughter

establishments to develop a minimum of four CCPs that include zero tolerance for fecal material, ingesta and milk; antimicrobial intervention; carcass chilling; and metal detection.

The Meat Inspection Procedures Manual, Procedure No. 12 describes the daily HACCP verification activities conducted by the official inspection personnel. Verification of CCP No. 1, zero visible contamination by ingesta, feces, and milk on carcasses, is conducted for ten carcasses each hour of slaughter and results are documented on Form F-SIC-15.1. Verification of CCP No. 2, Antimicrobial interventions, is conducted every 50 carcasses during slaughter and results are documented on Form F-SIC-15.2. Inspection personnel verify CCP No. 3, temperature of carcasses, daily prior to the deboning process and document results on Form F-SIC-15.3. Verification of CCP 4, metal detection, is conducted prior to production and every two hours during production and inspection personnel document verification results on Form F-SIC-15.4. Verification methods include inspection personnel obtaining their own measurements and observation of establishment monitoring procedures. The FSIS auditors reviewed HACCP verification records for each audited establishment, including identified noncompliance. The FSIS auditors identified that official inspection personnel were documenting noncompliance on the reverse of the respective verification form. During the audit IPSA developed and implemented Form F-SIC-58, Corrective Actions for a Deviation from a Critical Control Point, for documenting noncompliance associated with CCP requirements. The FSIS auditors determined IPSA implements verification activities as described.

The Meat Inspection Procedures Manual also describes monthly verification of HACCP requirements by the OV. The OV is responsible for verifying supporting documentation, establishment monitoring records, establishment ongoing verification activities, direct observation of monitoring, corrective actions, and reevaluation of the HACCP plan. The OV documents monthly verification results on Form F-SIC-39, Verification of HACCP Plan and document noncompliance on Form F-SIC-44, Demand for Corrective Actions. The FSIS auditors reviewed monthly HACCP verification records and documented noncompliance for each audited establishment.

The Meat Inspection Procedures Manual, Procedure No. 10, describes the official inspection personnel verification procedures for the establishment's preshipment review. Official inspection personnel are responsible for verifying HACCP preshipment review requirements, including assurance that the results of any establishment or official testing program are acceptable prior to certifying product for export. Official inspection personnel document the verification results on Form F-SIC-30, Shipment Control Report for Export. The FSIS auditors reviewed records for each audited establishment and verified the procedures are implemented as described.

Lastly, as noted in Component One, DRC personnel conduct annual comprehensive reviews of all written food safety programs and perform an annual on-site audit to ensure HACCP compliance. In addition, the monthly SIC supervisory reviews also assess HACCP compliance.

The FSIS auditors conclude that IPSA requires that each official establishment develop, implement, and maintain a HACCP system and provides multiple levels of verification activities to ensure compliance with HACCP requirements.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Prior to the audit, FSIS' residue experts reviewed Nicaragua's 2020 Residue Program, associated methods of analysis, and additional SRT responses outlining the structure of Nicaragua's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

The objective of Nicaragua's National Residue Plan (NRP) is to verify the safety of food products to minimize risks and ensure an adequate level of protection for the consumer. The NRP provides for the detection of residues and contaminants that exceed allowed quantities in food products destined for human consumption. Development of the NRP is a collaborative effort between DIA, DGIAL, and the LNRQB Director. DGIAL is responsible for the implementation and maintenance of the NRP and has full oversight of the national residue program. The majority of NRP samples are collected at establishments certified to export to the United States but the NRP also includes samples collected at other authorized slaughter establishments in Nicaragua.

Nicaragua's laws and resolutions provide the legal basis for control of veterinary drugs, pesticides, and other chemicals. Law No. 291, Basic Law on Animal Health designates IPSA as the authority for regulating the use, handling, and manufacture of chemicals including pharmaceutical, biological, and related substances. Law No. 274, Basic Law for the Regulation and Control of Pesticides, Toxic, Dangerous and Other Similar Substances, designates the Ministry of Agriculture responsible for managing the national registry of pesticides and other toxic substances for agricultural use and controlling the use and marketing of such substances. Administrative Resolution No. 001-2018 consolidates earlier resolutions and lists banned substances. The Nicaraguan Technical Standard on Maximum Veterinary Medicine Limits (NTON 03087-09) establishes allowable levels for veterinary drugs and other substances.

Official inspection personnel are responsible for the collection of meat samples for residue analyses and IPSA has the authority to enforce maximum residue limits in meat. The LNRQB is the official government laboratory that conducts residue analyses. IPSA requires that a letter of guarantee from the livestock owner accompany every lot of cattle to slaughter. The owner is required to affirm proper use of all veterinary drugs and adherence to withdrawal periods according to label.

The DIA Director approves annual sampling plans for each certified establishment. The NRP apportions samples between establishments based on the prior year slaughter volume. The SIC Manager distributes sampling plans, detailed for each month, to the OV's in each establishment. The SIC Manager ensures that OV's collect and submit scheduled samples by reviewing the

monthly OV reports documenting residue sampling and results for each certified establishment. In addition, at the end of the year the SIC Manager compares an annual report from the LNRQB against the annual reports submitted by the OVs. The FSIS auditors reviewed sampling plans, monthly and annual OV reports, and the annual LNRQB summary of results and verified implementation as described.

The Meat Inspection Procedures Manual, Procedure No. 1 describes the procedures and responsibilities for residue sampling. AIs perform residue sampling and use random sample selection procedures. Records document the sampled lot and carcass and associated traceability details. The AI completes Form F-SIC-03, Remittance of Samples to Laboratory, documenting sample details and places it inside the outer of double-bags containing the sample. The AI also completes Form F-SIC-01, Remission of Samples to the National Laboratory of Chemical and Biological Residue, documenting all details of the sample including sample seal numbers. Samples are frozen and placed into coolers, secured with an official seal, for transport to the laboratory. All residue samples are frozen and transported to the LNRQB by authorized establishment couriers. The FSIS auditors reviewed sampling schedules, sampling forms, and photographic evidence of the sampling process and concluded that IPSA ensures sample integrity and chain of custody for delivery to the LNRQB.

The AI places Form F-SIC-04, Withhold Pending Laboratory Test, on the carcasses at the time of sampling. IPSA requires that official inspection personnel retain the entire sampled lot pending laboratory results. Following deboning, each box from the sampled lot is identified with Form F-SIC-04 and the official inspection personnel document the details of retained product, including number of boxes per lot, on Form F-SIC-06, Record of Retained Pending Laboratory Result. IPSA requires establishments to segregate retained product in specific and labeled cold storage units.

The Meat Inspection Procedures Manual, Procedure No. 1, describes procedures for retention of samples pending laboratory results, including condemnation of carcasses, organs, and other parts any time the result exceeds established tolerance levels, consistent with Article 134 of the Meat Inspection Regulations. If a sample result exceeds allowable levels the OV provides an official written memorandum to establishment management documenting the sample details and informing them the sampled lot is not approved for human food and condemned according to requirements. The OV documents the condemned product on Form F-SIC-35, Official Condemnation Certificate, including final disposition of the product. DIA informs the Animal Health Directorate, which is responsible for conducting regulatory investigations and activities at the source farm. The OV documents all IPSA actions on Form F-SIC-05, Nonconformity Report (exceeds allowable limit) for internal purposes. In addition, the OV verifies establishment corrective actions including on-farm visits informing suppliers of good agricultural practices and regulatory requirements associated with the proper use of veterinary drugs. The FSIS auditors reviewed documents detailing IPSA actions in response to an official ivermectin sample collected from a certified establishment in 2020 that exceeded allowable levels and verified that IPSA implemented the processes as described, including condemnation of the entire lot.

The FSIS auditors reviewed the process for sample receipt at the LNRQB. Designated establishment couriers deliver official samples to the LNRQB. Laboratory personnel at receiving

verify the integrity of the official seal on the sample container and the information documented on official sampling documents accompanying each sample. In addition, laboratory personnel verify and document that sample condition (e.g., temperature) meets requirements. The laboratory software assigns a unique sample identification number that is also recorded on the Form F-SIC-01 and the sample reception record. Once admitted, a sample proceeds to the sample preparation area where assigned personnel verify the documentation for completion and accuracy, weigh the sample, and add the sample identification number to each sample. From this point samples are anonymous and identified only by sample identification number prior to delivery to the analyst.

The LNRQB procedures require supervisory review and approval of analyst reports to ensure validity of results prior to finalizing the results. The LNRQB Director and SIC Manager stated that analytical results are final and never retested in the event of an unacceptable result. Laboratory personnel prepare analytical results reports for delivery to the OV at the certified establishment by the authorized establishment courier. LNRQB provides immediate e-mail notification to IPSA headquarters and the OV at the establishment for all unacceptable results. The FSIS auditors reviewed LNRQB documentation demonstrating analyst records, supervisory review, analytical reports, and associated records and no concerns were identified.

The FSIS auditors concluded that IPSA continues to meet the core criteria for a chemical residue testing program, organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

IPSA requires the use of generic *E. coli* as an indicator organism to verify slaughter process control. IPSA requires each establishment to have a written generic *E. coli* testing program. Procedure No. 8 of the Meat Inspection Procedures Manual describes the requirements for generic *E. coli* testing. Establishment personnel collect samples under the direct observation of the AI, using the sponge technique to sample 100 cm² from the flank, brisket, and rump. The generic *E. coli* samples are analyzed using 3M™ Petrifilm™ at the LCDVMA or approved establishment laboratory. The establishment is responsible for evaluating results using statistical process control and charting the most recent 13 results. Official inspection personnel perform weekly verification of generic *E. coli* requirements and record verification results on Form F-SIC-45, Verification of Generic *E. coli*. The FSIS auditors reviewed records, including statistical process control charts, for each audited establishment and confirmed that IPSA is implementing the procedures as described.

IPSA provides for an official government microbiological sampling and testing program for *Salmonella* in raw meat as a measure of process control in slaughter establishments. The IPSA *Salmonella* requirements mirror the FSIS *Salmonella* Performance Standards in 9 CFR

310.25(b). The Meat Inspection Procedures Manual, Procedure No. 3, describes the requirements for *Salmonella* testing. AIs perform all *Salmonella* sampling, collecting samples each day of slaughter in carcass coolers after 12 hours of refrigeration. A three-site sponge sampling method is used for collecting the samples from the flank, brisket, and the rump from 100 cm² at each of the three locations on the carcass (300 cm² total area). AIs document sample collection on Form F-SIC-51, Submission of Microbiologic Samples to the Central Veterinary Diagnostic and Food Microbiology Laboratory. The LCDVMA analytical method follows the FSIS Microbiology Laboratory Guidebook Chapter 4.05 for detection of *Salmonella*.

The OV at each certified establishment is responsible for documenting each sample set to provide ongoing evaluation against the standards. The OV provides documentation for each completed sample set, including individual sample result reports, to the SIC Manager and the LCDVMA laboratory. IPSA implements ongoing *Salmonella* performance standards and once a sample set is complete, OVs initiate a new sample set, again collecting one sample daily for each day of slaughter. The FSIS auditors reviewed the most recent *Salmonella* sampling set records for each audited establishment.

IPSA has established a zero tolerance policy for STEC (*E. coli* O157:H7, O26, O45, O103, O111, O121, and O145) in raw beef products intended for export to the United States. Notice No 08 SIC-1 includes requirements and instructions for government verification sample collection and submission procedures and outlines an enforcement strategy that includes immediate corrective actions, HACCP reassessment, and follow-up testing for any STEC detection.

IPSA requires that establishments identify STECs as a hazard reasonably likely to occur in their hazard analysis. In addition, IPSA requires each establishment to implement zero tolerance (fecal material, ingesta, milk), carcass chilling, and organic acid critical control points (CCP) to prevent and control STEC. IPSA also requires that establishments perform daily STEC sampling, conducted by AIs, of every subplot (10,500 pounds) of boneless beef. Establishment samples are analyzed in authorized establishment laboratories, accredited by ONA and audited annually by LCDVMA personnel. The OVs receive and review daily analytical results reported by the establishment laboratories. In addition, the monthly supervisory review includes review of establishment results. In the event of a positive STEC result the OV condemns the sampled lot.

Official inspection personnel collect all STEC samples, both official and establishment, using the N60 method. AIs have a dedicated STEC sampling station and utilize a stainless template to collect thin slices of surface tissue approximately one inch by three inches in size. AIs collect official STEC samples once a week. The AI retains all sampled lots using Form F-SIC-04, Withhold Pending Laboratory Test, pending acceptable analytical results and documents the retained product on Form F-SIC-06, Record of Retained Pending Laboratory Result. IPSA requires the establishment to segregate retained product in a specific identified cage or section of cold storage. The OV provides an official written memorandum to establishment management advising of the retention of the products pending acceptable analytical results. AIs complete Form F-SIC-08, Submission of Microbiologic Samples to the Central Veterinary Diagnostic and Food Microbiology Laboratory, Sampling program for *E. coli* O157:H7 and *E. coli* non-O157 (STECs), for STEC samples submitted to the LCDVMA for analysis.

The LCDVMA analyzes samples using the Assurance GDS® MPX Top 7 STEC method and FSIS MLG 5C.00 as the confirmatory method. The LCDVMA sample receipt procedures ensure sample integrity and chain of custody through verification that official seals are intact and match sample forms. Laboratory personnel assess sample condition and ensure the appropriate chilled temperature of product, with discard of any frozen samples. The laboratory ensures analysis of all 60 sampled pieces. The LCDVMA Director and SIC Manager affirmed that all analytical results are final with no retesting performed. The laboratory reports results to the OV at the sampling establishment through delivery of analytical reports by authorized establishment courier. In the event of a positive STEC result, the LCDVMA immediately reports results via e-mail to IPSA headquarters and the OV at the establishment. The FSIS auditors reviewed an example documenting the immediate communications for a positive STEC sample. The FSIS auditors also reviewed sample receipt records, analyst reports, internal laboratory audits, and annual SIC Manager audits of the LCDVMA.

When the OV receives acceptable analytical results, they notify the establishment through issuance of Form F-SIC 08-1, Product Release, notifying the establishment that IPSA has released the products for distribution. Official inspection personnel remove the retention tags, allowing products to be further distributed.

The FSIS auditors reviewed all records associated with identification of STEC O103 during official sampling of a certified establishment in 2020. IPSA demonstrated immediate communications from LCDVMA to IPSA headquarters and the OV notifying them of the initial positive result and subsequent serotyping result. The OV documented an official memorandum to establishment management notifying them of the sampled lot details, sample result, condemnation of the product, and requirement for corrective and preventive actions. The official memorandum serves as documentation that the establishment failed to meet requirements. The OV also issued Form F-SIC-35, Official Condemnation Certificate, documenting condemnation of the sampled lot. The OV verified product destruction, as evidenced by the OV's seal and signature on establishment rendering records. The establishment provided written corrective and preventive actions, including all supporting documents, to the OV. In addition, official inspection personnel implemented 16 follow-up samples. The OV verified the establishment corrective actions and when the additional sampling was complete, the OV sent the SIC Manager a memorandum documenting the sampling results. The FSIS auditors verified that IPSA is implementing their STEC procedures as described.

The FSIS auditors verified that Nicaragua's food safety inspection system continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system aimed at controlling the presence of microbiological pathogens in beef products exported to the United States, and that those beef products are unadulterated, safe, and wholesome in accordance with FSIS requirements. The CCA's meat inspection system continues to meet the FSIS requirements for this component. There have not been any POE violations related to microbiological testing conducted by FSIS since the last FSIS audit. However, the CCA should address the finding in Component One and implement proficiency testing for the STEC analytical method.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held with IPSA on August 9, 2021. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following finding:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- The Institute of Agricultural Protection and Health Directorate of Laboratories has not ensured that proficiency testing plans are established to ensure that laboratory personnel are proficient in the microbiological analyses performed.
 - The LCDVMA has not conducted proficiency testing for STEC analysis.

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

Appendix: Foreign Country Response to the Draft Final Audit Report

Managua, January 10, 2022
DIA/IDC/0032/01/2022

Michelle Catlin, PhD.

International Coordination Executive.
Office of International Coordination.
Food Safety and Inspection Service-USDA.
Washington D.C.

Dear Ms. Catlin.

In response to your communication dated October 18, 2021, which refers the draft of the final report of the remote verification audit of the Nicaraguan meat inspection system carried out from July 13 to August 9, 2021, I would like to make the following comment:

The Instituto de Protección y Sanidad Agropecuaria **IPSA**, expresses its agreement with the terms and procedures with which the remote audit was carried out.

Likewise, after reading the draft report of each of the six components of the audit, we accept the findings identified and commit ourselves to their correction and continuous improvement in our institution to guarantee the equivalence of our Official Meat Inspection System and consequently the eligibility as a country to export meat products of bovine origin to the United States of America.

Enclosed is the corrective actions plan to be implemented as well as updated evidence from the process carried out by the Central Laboratory of Veterinary Diagnostics and Food Microbiology, in response to the finding of component number one.

We appreciate the recommendations resulting from the audit.

Best regard,


Dra. Ileana Georgina Duarte Campos.
Director of Agri-Food Safety.
DIA-IPSA.

Cc. Dra. Martha Hernández
Dr. Julio Guadamuz L
Archivo

- Responsable DIEA/DIA
- Responsable SIC/DIA

TODOS JUNTOS, VAMOS ADELANTE...!
FUERZA DE PUEBLO QUE VENCE...!
UNIDAD PARA LA PROSPERIDAD...!
CON DANIEL, EL FRENIÉ, EL PUEBLO PRESIDENTE...!

 **FE,
FAMILIA
Y COMUNIDAD!**

CRISTIANA, SOCIALISTA, SOLIDARIA!

INSTITUTO DE PROTECCIÓN Y SANIDAD AGROPECUARIA IPSA.
Dirección de Inocuidad Agroalimentaria DIA-IPSA.
Km. 5 Carretera Norte, Contiguo a ENACAL Portezuelo.
Correo: ileana.duarte@ipsa.gob.ni
Tel: (505)22981330 ext178. web: www.ipsa.gob.ni

| | | | |
|------------------------------------|----------------------------|---|-------------------------|
| A: Ubicada en: LCDVMA | | Proceso: Aseguramiento de la calidad | |
| NC #01 | | | |
| Fuente de la No Conformidad | Auditoria USDA 2021 | Fecha: | 04/ agosto /2021 |

No Conformidad Real

☐

No conformidad Potencial

☐

Acción de mejora

☒

Definición de la no conformidad real o potencial (definir lo más detallado posible), incluyendo el requisito o documento que se incumple

Hallazgo:

El Laboratorio Central de Diagnóstico Veterinario y Microbiología de Alimentos (LCDVMA) no ha realizado pruebas de aptitud para el análisis de *Escherichia coliproducedora* de toxina Shiga (STEC).

B: Análisis de las causas del problema o la no conformidad real o potencial (no aplica para acción de mejora)

En el Sistema de Gestión de Calidad (SGC) del laboratorio tiene diseñado un Plan de Ensayo de Aptitud Anual, que responde en su mayoría a los requisitos de la Oficina Nacional de Acreditación (ONA), integrando las otras actividades con las cuales no hay compromiso con ONA de manera parcial, lo cual ha dejado por fuera la participación de *E. coli* O 157 H:7 STEC.

Análisis de extensión a otras actividades o procesos donde la No Conformidad pueda ocurrir (En casos de detectarse casos de extensión, definir acciones a tomar).

Se puede extender el hallazgo a otros ensayos requeridos por USA.

Corrección

☒

| Actividad | Responsable de la acción | Fecha Inicial | Fecha Final |
|--|--------------------------|---------------|-------------|
| Inscribirse para participar en una ronda de Ensayo de Aptitud de <i>E. coli</i> O 157 H:7 STEC, 2022 en base a la disponibilidad de los proveedores de ensayo de aptitud | Coordinador SGC | 10/01/2022 | 28/01/2022 |

Acción Correctiva

☒

| Acción | Responsable de la acción | Fecha Inicial y Fecha Final |
|--|--------------------------|-----------------------------|
| Revisión del P 7.7 Aseguramiento de la Calidad de tal forma que se declare la participación de ensayo de aptitud no solo con los requisitos del Oficina Nacional de Acreditación (ONA) | Coordinador SGC | 10/01/2022 13/01/2022 |
| Integrar Ensayos que no han sido tomado en cuenta en el F 7.7.0.2 Plan de participación de EA | Coordinador SGC | 12/01/2022 |

Acciones para corregir desviaciones surgidas en el análisis de extensión

☒

| Acción | Responsable de la acción |
|--|--------------------------|
| Revisar los diferentes ensayos requeridos por USDA, de tal forma que se asegure implementar la participación de Ensayos de Aptitud de dichos ensayos | Coordinador SGC |

Ubicada en:

Fuente de la NC:

NC #

| Responsable de Seguimiento (Nombre y Cargo) | Resultado del Seguimiento | Fecha |
|---|---|-------|
| | Seguimiento 1 | |
| | Seguimiento 2 | |
| | Seguimiento 3 | |
| Verificación de la eficacia 1 Fecha: | Realizada por: Comentarios: | |
| Verificación de la eficacia 2 Fecha: | Realizada por: Comentarios: | |
| Las actividades tomadas fueron eficaces (responsable de Seguimiento) Sí <input type="checkbox"/> No <input type="checkbox"/> | Estado de la Gestión de Acción Correctiva y/o Preventiva Cerrada <input type="checkbox"/> Abierta <input type="checkbox"/> | |

Verificada por:

Wendy Fortalez
Coordinador de Gestión de la Calidad
Nombre y Apellido / Fecha 07/10/22


Jefe de Departamento del LCDVMA
Nombre y Apellido / Fecha 07-Enero-2022