

Food Safety and Inspection Service

1400 Independence Avenue, SW. Washington, D.C. 20250 Dr. Ileana Duarte Food Safety Director Nicaraguan Institute of Agricultural Protection and Health (IPSA) Gobierno De Nicaragua Managua, Nicaragua, C.A.

Dear Dr. Duarte,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Nicaragua's meat inspection system October 29–November 13, 2024. Enclosed is a copy of the final audit report. The comments received from the Government of Nicaragua are included as an attachment to the report.

Sincerely,

PARRISH ENDY Digitally signed by PARRISH ENDY Date: 2025.04.15 06:10:52 -04'00'

On behalf of Margaret Burns Rath, JD, MPH Assistant Administrator Office of International Coordination

Enclosure

April 15, 2025

FINAL REPORT OF AN AUDIT CONDUCTED OF

NICARAGUA

OCTOBER 29–NOVEMBER 13, 2024

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

RAW BEEF PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

April 14, 2025

Food Safety and Inspection Service U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Nicaragua conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) October 29–November 13, 2024. The purpose of the audit was to verify 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 properly 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.

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

TABLE OF CONTENTS

| I. | INTRODUCTION |
|-------|---|
| II. | AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY1 |
| III. | BACKGROUND |
| IV. | COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION) |
| 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) |
| VI. | COMPONENT THREE: GOVERNMENT SANITATION |
| VII. | COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM11 |
| VIII. | COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS |
| IX. | COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS |
| X. | CONCLUSIONS AND NEXT STEPS |
| APPI | ENDICES16 |
| Ap | pendix A: Individual Foreign Establishment Audit Checklists |

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

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Nicaragua's food safety inspection system October 29–November 13, 2024. The audit began with an entrance meeting October 29, 2024, in Managua, Nicaragua, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the Institute of Agricultural Protection and Health (IPSA). Representatives from IPSA accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted November 13, 2024.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. 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 beef imported from Nicaragua as subject to bovine spongiform encephalopathy (BSE) requirements specified in Title 9 of the U.S. Code of Federal Regulations (9 CFR) 94.18 or 9 CFR 94.19.

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

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Nicaragua's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify 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.

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 capabilities of laboratories. The review process included an analysis of data collected by FSIS over a 3-year period, in addition to information obtained directly from IPSA 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 IPSA headquarters and six local inspection offices within the establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the country's SRT responses and supporting documentation.

All six beef slaughter and processing establishments were selected from a total of six establishments certified to export to the United States. The products these establishments produce and export to the United States include raw intact and non-intact beef.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed IPSA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also visited two government laboratories (one microbiology and one chemical residue) to verify that these laboratories can provide adequate technical support to the food safety inspection system.

| Competent Authority | Visits | # | Locations |
|---|---------|---|---|
| Competent Authority | Central | 1 | • Institute of Agricultural Protection and Health, Managua |
| Laboratories Beef slaughter and processing establishments | | 2 | National Laboratory of Chemical and Biological Residue, Managua Central Veterinary Diagnostic and Food Microbiology Laboratory, Managua |
| | | 6 | Establishment No. 1, Ganadería Integral Nicaragua S.A., Managua Establishment No. 2, Novaterra S.A., Managua Establishment No. 4, Industrial Comercial San Martín S.A., Nandaime Establishment No. 5, Nuevo Carnic S.A., Managua Establishment No. 8, Matadero Central S.A., Chontales Establishment No. 109, Nica Beef Packers S.A., Estelí |

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

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); 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 July 1, 2021, to June 30, 2024, FSIS inspection personnel performed 100 percent reinspection for labeling and certification on 388,066,077 pounds of meat from Nicaragua. This included 317,204,618 pounds of raw intact beef and 70,861,459 pounds of raw non-intact beef exported by Nicaragua to the United States. Of these amounts, additional types of inspection were performed on 23,473,398 pounds of meat, including physical examination, chemical residue analysis, and testing for microbiological pathogens (i.e., *Salmonella* and Shiga toxin-producing *Escherichia coli* [STEC] serogroups O26, O45, O103, O111, O121, O145, and O157 in beef). As a result of this additional testing, no products were rejected for issues related to public health. An additional 220,158 pounds of beef were refused for other issues not related to public health, including shipping damage, labeling, or other miscellaneous issues.

The previous FSIS audit in 2023 identified the following finding:

Summary of the Finding from the January/February 2023 FSIS Audit of Nicaragua Component 1: Government Oversight (e.g., Organization and Administration)

• IPSA's Directorate of Laboratories has a provision that allows official chemical residue samples with violative test results to be retested. IPSA has not provided written procedures to ensure that these retested products cannot be exported to the United States.

The FSIS auditors verified that corrective actions for the previously reported finding were implemented and effective in resolving the finding.

The most recent audit reports for Nicaragua's food safety inspection system are available on the FSIS website at: <u>www.fsis.usda.gov/foreign-audit-reports</u>.

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 inspection system is organized and administered by the national government of Nicaragua. IPSA is the CCA of Nicaragua's raw beef products inspection system and has direct authority over the government inspection personnel in establishments certified to export products to the United States. In accordance with Nicaragua's Law No. 862, IPSA 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 (DGIAL). DGIAL is comprised of the Directorate of Agrifood Safety (DIA) and the Directorate of Laboratories.

Nicaragua's raw beef inspection system is organized into two levels: the headquarter offices and government inspection offices in establishments. At the headquarter level, DIA is responsible for the safety of meat products, promulgation of food safety regulations, and has sole authority to enforce the laws and regulations of the meat inspection system. DIA's Meat Safety Section (SIC) provides direct supervision over government inspection personnel at establishments certified to export raw beef products to the United States. These responsibilities include ensuring that establishments certified to export raw beef products to the United States are staffed by at least two official veterinarians (OV) and auxiliary inspectors (AI) who perform official government verification activities.

When government inspection personnel observe any noncompliance, they document the noncompliance on the Demand for Corrective Actions form (DCA) and require corrective actions from establishments. The FSIS auditors reviewed a sample of DCAs generated by inplant government inspection personnel. The in-plant government inspection personnel closed the DCAs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. In addition, the DCAs and associated corrective actions are reviewed during supervisory visits and annual audits. Nicaragua's Regulations for Health Inspection of Meat for Authorized Establishments (hereafter referred to as Meat Inspection Regulations) provide IPSA with the legal authority and responsibility to take enforcement actions, as appropriate, including suspension and withdrawal of export certification of establishments certified for export to the United States. The FSIS auditors verified IPSA has enforcement procedures in place and understands how and when to document noncompliance and take enforcement actions when appropriate.

Within DIA, the Department of Registration and Certification (DRC) is responsible for conducting audits to determine initial and annual approval of certified establishments. The FSIS auditors reviewed a sample of IPSA's approval process for certified establishments which included government inspection personnel's evaluation of an establishment's written programs and onsite follow-up audits to determine the establishment's compliance with IPSA's requirements. The FSIS auditors verified through interviews and record reviews that government inspection personnel followed IPSA's approval process and made their determination based on the outcome of the record reviews and onsite inspection verification. No concerns arose regarding implementation of this process.

The OVs are responsible for reviewing and signing export health certificates of beef products intended for export to the United States. Government inspection personnel conduct an official pre-shipment verification that includes reviewing all associated traceability documents and food safety records for each lot, observing the staged products, and verifying the weight declaration, shipping marks, and labels prior to applying the official export stamp and signature on the export health certificate. In addition, OVs verify that all official verification samples and establishment samples are within acceptable analytical results for microbiological pathogens and chemical residues prior to signing an export health certificate. The FSIS auditors confirmed through interviews and record reviews that OVs maintain pertinent verification documents for each production lot intended for export to the United States. The FSIS auditors review of IPSA's export certification process did not identify any concerns.

IPSA requires that each certified establishment maintain written recall and traceback procedures which are consistent with FSIS requirements defined in 9 CFR 418.3–418.4. The FSIS auditors noted that certified establishments maintain these procedures as well as records sufficient to conduct traceback activities if adulterated product were produced or exported. IPSA only allows raw beef products produced in certified establishments to be exported to the United States. The FSIS auditors verified through interviews and record reviews that certified establishments only slaughter cattle that were raised in Nicaragua and were not receiving any raw materials from other establishments or other countries for use in the production of products intended for export to the United States.

IPSA's headquarters personnel provide instructions including any new FSIS import requirements to government inspection personnel located at certified establishments during their monthly supervisory visit. Additionally, instructions can be given to government inspection personnel through letters, memos, or by telephone communication. SIC management is responsible for translating newly issued policies concerning FSIS import requirements into Spanish and sending the translated documents to the OVs at establishments certified to export products to the United States. At the establishment level, OVs are responsible for conveying the new policy to AIs and verifying implementation with new FSIS import requirements.

The FSIS auditors verified through interviews and record reviews that all government inspection personnel assigned to certified establishments are government employees who are hired and paid by the national government. IPSA ensures that government inspection personnel have the appropriate educational credentials, disciplinary backgrounds, and experience to carry out their inspection tasks. IPSA has established initial and ongoing training sessions for OVs and AIs to ensure that they have the appropriate training to conduct inspection activities. The FSIS auditors verified that the SIC manager conducts quarterly performance appraisals for each OV to assess their knowledge, skills, and abilities. The OV is responsible for supervising and performing performance appraisal of AIs. Each performance appraisal includes interviews, review of inspection-generated records, and direct observation of government inspection personnel performance while conducting their assigned inspection activities. The FSIS auditors reviewed inspection records associated with government inspection personnel educational credentials, payment of salaries, initial and ongoing trainings, and performance evaluations without any concerns.

IPSA has the legal authority and responsibility to approve or remove the approval of laboratories conducting analytical testing of products intended for export to the United States. The FSIS auditors visited the National Laboratory of Chemical and Biological Residue (LNRQB) and the Central Veterinary Diagnostic and Food Microbiology Laboratory (LCDVMA). These are government laboratories under direct authority of IPSA's Directorate of Laboratories. LNRQB conducts official government chemical residue testing and LCDVMA conducts all microbiological (*Salmonella* and STEC) testing of official verification samples for raw beef products intended for export to the United States.

The Nicaraguan National Accreditation Office (ONA) has the authority for accrediting laboratories in accordance with International Organization for Standardization/International Electrotechnical Commission 17025 standards. ONA conducts annual surveillance audits and certification audits of the government laboratories every four years. The FSIS auditors reviewed the accreditation certificates, scope of accreditation, and the most recent ONA accreditation reports and associated corrective actions. The FSIS auditors noted that DIA also conducts an annual audit of these laboratories as part of IPSA's oversight functions over government laboratories that perform analyses of official government verification sampling and testing programs. The FSIS auditors reviewed the most recent DIA audit reports and associated corrective action plans of each laboratory. The FSIS auditors verified that DIA and ONA annual audits and related follow-up activities have been conducted in accordance with IPSA's requirements.

The FSIS auditors reviewed the qualifications of technicians, training records, proficiency testing, and laboratory quality control records. The FSIS auditors verified that IPSA does not allow retesting of samples with violative or unacceptable results for products intended for export to the United States. Additionally, the FSIS auditors verified that the laboratory maintains sample integrity and sample traceability throughout the entire process from sample receipt to reporting of the results. In addition to reviewing documentation, the FSIS auditors interviewed laboratory personnel and reviewed records of analysis. The FSIS auditors did not identify concerns with Nicaragua's government oversight of laboratories.

The FSIS auditors verified that Nicaragua's meat inspection system is organized and administered by the national government, and that IPSA inspection personnel are assigned to enforce the laws and regulations governing these meat products.

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

The second equivalence component the FSIS 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 its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once-per-shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified that in-plant government inspection personnel are required to conduct daily verification of humane handling and slaughter procedures. The Meat Inspection Procedures Manual provides instructions to in-plant government inspection personnel for verifying humane handling and slaughter requirements in certified establishments. This includes verification of proper repair and maintenance of holding pens and alleyways, proper handling of livestock prior to slaughter, and evaluation of the proper stunning and sticking procedures in accordance with IPSA's regulatory requirements. The FSIS auditors review of inspection records, including in-plant inspection verification of humane handling and slaughter and periodic supervisory review records, in conjunction with FSIS observation of humane handling and slaughter practices in the audited establishments did not identify any concerns.

The FSIS auditors verified that in-plant government inspection personnel are required to conduct ante-mortem inspection of all livestock prior to slaughter. The Meat Inspection Procedures Manual provides instructions to in-plant government inspection personnel for performing ante-mortem inspection. The FSIS auditors observed that in-plant government inspection personnel conduct ante-mortem inspection on the day of slaughter, including reviewing required documentation accompanying the livestock to ensure that all required information is accurately documented in ante-mortem records, and observing all animals at rest and in motion from both sides in designated holding pens to determine whether they are fit for slaughter. The FSIS auditors observed that all animals had access to water in all holding pens, and that feed was available for animals held longer than 24 hours. The FSIS auditors confirmed that each audited slaughter establishment provided a separate holding pen designated for observation and further

examination of suspect animals. The Meat Inspection Procedures Manual provides instructions for handling of suspect animals including identification of reportable and condemnable disease conditions. The FSIS auditors verified that non-ambulatory disabled cattle and those showing signs of central nervous system disorders are condemned during ante-mortem inspection. No concerns arose regarding IPSA's ante-mortem inspection procedures.

The FSIS auditors verified that each audited establishment is staffed with enough government inspection personnel to ensure an inspector is present during all slaughter operations, and at least once per shift during processing operations. The Meat Inspection Procedures Manual provides instructions to in-plant government inspection personnel for performing post-mortem inspection of every carcass and all parts. This included in-plant inspection verification of proper presentation, identification, examination, and disposition of affected carcasses and parts. The FSIS auditors observed that proper post-mortem inspection methodology for incision, observation, and palpation of required organs and lymph nodes are performed in accordance with IPSA's requirements. The FSIS auditors observed implementation of post-mortem inspection and concluded that IPSA has provided enough government inspection personnel to effectively implement post-mortem inspection procedures. The FSIS auditors reviewed government inspection records, daily disposition reports, and periodic supervisory reviews, and observed implementation of post-mortem inspection personnel without identifying any concerns.

IPSA's official control and labeling requirements for raw beef products intended for export to the United States are described in the Meat Inspection Procedures Manual. The Meat Inspection Procedures Manual provides instructions to in-plant government inspection personnel for performing labeling verification activities to ensure proper labeling of products during the entire production including the export certification process. The export health certificate for raw beef products intended for export to the United States requires raw beef products be processed, stored, and transported in a manner to preclude them from being commingled with products not eligible for export to the United States. The FSIS auditors verified that raw beef products intended for export to the United States are stored separately by time or space from products intended for other markets. The FSIS auditors confirmed that government inspection personnel routinely verify labeling requirements, in particular, prior to issuing an export health certificate, to ensure that information on the product label is complete, accurate, and meets FSIS labeling requirements.

The SIC manager or assistant manager are responsible for conducting periodic (monthly) supervisory reviews at establishments certified to export to the United States. The scope of these supervisory reviews includes humane handling and slaughter requirements; ante-mortem inspection; post-mortem inspection; labeling verification procedures; microbiological and chemical residue sample collection methodology and results; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities, including verification of critical control points (CCP) in certified slaughter and processing establishments. The FSIS auditors reviewed several periodic supervisory review records and associated corrective actions for each audited establishment and noted that SIC personnel conducted these reviews in accordance with IPSA requirements.

IPSA remains aware of U.S. animal health restrictions by subscribing to APHIS notifications. APHIS has determined that Nicaragua is a region of negligible risk for BSE and free of foot-andmouth disease. The export health certificates indicate that only those raw beef products that have been identified by IPSA as meeting both FSIS and APHIS requirements can be certified for export to the United States.

IPSA's BSE Procedures Manual defines specified risk materials (SRM) consistent with FSIS' definition in 9 CFR 310.22. The Meat Inspection Procedures Manual provides instructions to inplant government inspection personnel for performing verification procedures concerning identification, removal, segregation, and disposal of SRMs. The in-plant government inspection personnel verification activities include reviewing of establishments' SRM control records, observing establishments' SRM monitoring procedures, and direct observation of beef carcasses to ensure the establishments' SRM control procedures comply with IPSA's SRM control requirements. The FSIS auditors reviewed inspection verification records, observed implementation of SRM controls and disposal of SRMs without identifying any concerns.

The FSIS auditors verified that IPSA maintains official control over segregation, removal, and destruction of product that is condemned and considered inedible or not fit for human consumption. The Meat Inspection Regulations include requirements for denaturing agents and denaturing procedures, including the regulatory requirement that establishment personnel must thoroughly slash all inedible material prior to the application of the denaturant. The FSIS auditors observed the disposal process of condemned and inedible materials at each audited establishment without identifying any concerns.

FSIS onsite audit verification activities indicate that IPSA maintains the legal authority and responsibility to establish regulatory controls to operate its inspection system consistent with criteria established for this component. FSIS concludes that IPSA continues to meet the core requirement for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The food safety inspection system is to require that each official establishment develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOPs) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

IPSA has official control over establishment construction, facilities, and equipment. The Meat Inspection Regulations provide requirements consistent with FSIS requirements in 9 CFR 416. In addition, IPSA has 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. Government inspection personnel verify that certified establishments implement and maintain sanitation procedures sufficient to prevent direct product contamination through procedures detailed in the Meat Inspection Procedures Manual. IPSA requires certified slaughter and processing establishments to develop, implement, and maintain written Sanitation SOPs and SPS, to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing. The certified 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.

The FSIS auditors verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or creation of insanitary conditions. Each audited establishment's Sanitation SOPs included maintenance and improvement of sanitary conditions through ongoing evaluation of the establishment's hygienic practices. The FSIS auditors confirmed that in-plant government inspection personnel conduct daily verification procedures in accordance with IPSA's requirements. Inspection verification activities consist of a combination of document reviews, observations, and hands-on inspection verification.

The FSIS auditors observed in-plant government inspection personnel conduct pre-operational sanitation verification inspection in one of the audited establishments. The verification inspection was performed after the establishment had conducted its pre-operational sanitation procedures and determined that the facility was ready for production. The FSIS auditors also observed the in-plant government inspection personnel perform hands-on operational sanitation verification in all visited establishments. The FSIS auditors noted that inspection verification activities included direct observation of the actual sanitary conditions and review of the establishments' associated records. The FSIS auditors also examined government inspection personnel's documentation of sanitation noncompliance records and verified that government inspection personnel took regulatory enforcement control actions sufficient to ensure that sanitary conditions were restored and product was protected from contamination. The FSIS auditors' observations and record reviews of establishments' sanitation monitoring, verification, and corrective action records showed no systemic concerns. Similarly, review of in-plant government inspection personnel records documenting inspection verification results and periodic supervisory reviews showed that government inspection personnel were adequately verifying establishments' compliance with IPSA's sanitation regulatory requirements.

IPSA's Meat Inspection Regulations require carcasses and parts be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter. If visible contamination occurs, the contaminant must be immediately removed. The FSIS auditors evaluated daily verification of establishment sanitary dressing procedures by in-plant government inspection personnel in all audited slaughter and processing establishments. This included verification of sanitary practices to prevent potential carcass contamination during hide removal, direct contact between carcasses during dressing procedures, and carcass contamination with gastrointestinal contents during evisceration, including tying the bung and esophagus. The FSIS auditors verified that in-plant government inspection personnel maintain sanitation records sufficient to document their verification activities and any corrective actions taken by the establishment.

FSIS onsite audit verification activities indicate that IPSA maintains sanitation programs that are consistent with criteria established for this component. The FSIS auditors identified isolated

noncompliances related to the inspection verification of sanitation requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

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

The fourth equivalence component 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 certified slaughter and processing establishments to develop, implement, and maintain HACCP systems in accordance with Nicaragua's Law No. 291, Basic Law on Animal Health, and the Guidelines for Implementation of the Hazard Analysis and Critical Control Points System, which are consistent with FSIS requirements in 9 CFR 417.

The FSIS auditors verified that certified establishments' HACCP programs include written hazard analysis; flow charts; supporting documentation for hazard analysis decisions and critical limits, monitoring, and verification activities for CCPs; documentation of validation and reassessments; and records supporting the implementation of the HACCP system. The FSIS auditors reviewed establishment records for monitoring, verification, corrective actions, and validation, as well as inspection daily verification records for all CCPs. The FSIS auditors verified that audited establishments took appropriate corrective actions in response to any critical limit deviations and in-plant government inspection personnel adequately documented and verified the effectiveness of the establishments' corrective actions.

IPSA requires that establishments apply an intervention to control STEC as part of their HACCP plan. The FSIS auditors confirmed that each audited establishment considers STEC, including serogroups O157, O26, O45, O103, O111, O121, and O145, as a hazard reasonably likely to occur in their HACCP system. The FSIS auditors noted that each audited establishment has established a minimum of three CCPs to address STEC that include zero tolerance contamination by fecal material, ingesta, and milk; a validated antimicrobial intervention (organic acid spray); and carcass chilling procedures in a manner sufficient to prevent the outgrowth of microbiological pathogens.

The Meat Inspection Procedures Manual provides instructions to in-plant government inspection personnel for performing HACCP verification activities that include direct observation of establishment employees' monitoring procedures, hands-on verification, and review of establishment records, with the results of verification being entered in the associated inspection records. The FSIS auditors observed in-plant government inspection personnel verification procedures for all CCPs in all audited establishments. No concerns arose from these observations. The FSIS auditors also confirmed that physical location of the zero tolerance CCP verification for both the establishment personnel and in-plant government inspection personnel is before the final carcass wash in all audited slaughter establishments.

The Meat Inspection Procedures Manual also describes monthly verification of HACCP requirements by OVs. They are responsible for verifying supporting documentation,

establishment monitoring records, establishment ongoing verification activities, direct observation of monitoring, corrective actions, and reevaluation of the HACCP plan. In addition, DRC conducts a review of HACCP requirements at each establishment as part of IPSA's annual approval of certified establishments. The FSIS auditors review of HACCP verification records generated by government inspection personnel, including daily, weekly, and annual reviews, did not raise any concerns.

FSIS onsite audit verification activities indicate that IPSA maintains HACCP systems that are consistent with criteria established for this component. As noted above, the FSIS auditors identified isolated noncompliance related to the inspection verification of HACCP record-keeping requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

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

Nicaragua's 2024 National Program of Residues for Authorized Establishments includes IPSA's chemical residue sampling requirements for the year. The plan includes the species, classes of compounds and specific chemical compounds to be analyzed, tissue matrix, analytical methodology, action level or maximum residue level (MRL) for evaluating the results, number of samples to be analyzed, and location of the sampling (farm/establishment).

IPSA has the legal authority and responsibility to regulate, plan, and execute Nicaragua's National Residue Plan (NRP) in accordance with Nicaragua's Law No. 291. The NRP provides for the detection of residues and contaminants that exceed allowed quantities in food products intended for human consumption. The Technical Standard on Maximum Veterinary Medicine Limits (NTON 03087-09) establishes allowable levels for veterinary drugs and other substances. These MRLs are consistent with U.S. requirements in 21 CFR part 556 for veterinary drugs and 40 CFR part 180 for pesticides. Development of the NRP is a collaborative effort between DIA, DGIAL, and the LNRQB Director. The FSIS auditors verified government inspection personnel at each establishment compares the results of chemical residue testing against the U.S. MRLs prior to signing each export certificate. When there is no established tolerance in the United States, the MRL is determined to be zero.

The DIA director approves annual sampling plans for each certified establishment. The NRP apportions samples among establishments based on the slaughter volume for the prior year. The SIC manager distributes monthly sampling plans to OVs in each certified establishment, and the OVs are responsible for ensuring the proper implementation of the sampling program in accordance with IPSA's requirements. The FSIS auditors verified through record reviews, interviews, and observation that trained in-plant government inspection personnel collect,

prepare, and send sealed samples to LNRQB in accordance with IPSA instructions. The LNRQB is the official government chemical residue laboratory that conducts chemical residue analyses. The SIC manager provides overall oversight by reviewing the OV's monthly and annual reports documenting chemical residue sampling and laboratory results for each certified establishment. The FSIS auditors reviewed chemical residue sampling plans, monthly and annual OV reports, and the annual LNRQB summary of results for each audited establishment and identified no concerns.

FSIS onsite audit verification activities indicate that IPSA maintains the regulatory requirements for an official chemical residue testing program that is organized and administered by the national government to prevent and control the presence of veterinary drugs and contaminants in beef products intended for export to the United States. FSIS concludes that IPSA continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component 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 prepared for export to the United States is safe and wholesome.

IPSA requires that certified establishments develop written sampling procedures for monitoring process control through testing of beef carcasses for generic *Escherichia coli* (*E. coli*). IPSA sets criteria for the required frequency, the locations and methods of sampling on the carcass, and evaluation of the results using statistical process control. IPSA also ensures that establishments take appropriate actions to reestablish process control of the slaughter operation if sample results indicate a loss of process control. The FSIS auditors verified through observations, interviews, and record reviews that generic *E. coli* sampling and testing programs are conducted by establishment personnel at all six audited establishments in accordance with IPSA's requirements. The FSIS auditors confirmed that OVs and the SIC manager, during monthly supervisory reviews, verify that slaughter establishments comply with IPSA's regulatory requirements. The FSIS auditors reviewed government inspection personnel verification records of generic *E. coli* sampling, observed the establishments sampling procedures, and testing results without identifying any concerns.

IPSA implements official verification sampling for control of *Salmonella* in chilled beef carcasses. The Meat Inspection Procedures Manual provides instruction to government inspection personnel concerning the sample collection technique and methodology. After collection, samples are sealed by government inspection personnel prior to submission to the LCDVMA laboratory for *Salmonella* testing. The OVs are responsible for providing proper documentation for each completed sample set, including individual sample result reports, to the SIC manager and the LCDVMA laboratory. IPSA requires an ongoing *Salmonella* verification sampling through continuous set-based sampling. Once a sample set is complete, OVs initiate a new sample set by collecting one sample daily for each day of slaughter. IPSA implements an enforcement strategy when the number of positive samples exceeds the permitted limits. The

enforcement strategy includes inspection verification of establishments' immediate corrective actions (first failure), HACCP reassessment (second failure), and suspension of inspection activities (third failure). The FSIS auditors reviewed *Salmonella* official verification sampling records, testing results, and observed implementation of government inspection sampling without identifying any concerns.

IPSA considers STEC an adulterant in raw beef products intended for export to the United States. IPSA requires in-plant government inspection personnel to conduct official verification sampling of beef manufacturing trimmings for STEC using the N60 sampling method. The FSIS auditors verified the proper implementation of N60 sample collection techniques and methodology in all audited establishments by observing in-plant government inspection personnel collecting STEC samples for both the establishments' testing and official government verification testing programs.

IPSA requires that certified establishments perform daily STEC sampling, collected by AIs, for every sublot of beef manufacturing trimmings. Establishment samples are analyzed in authorized establishment laboratories, which are accredited by ONA and audited annually by LCDVMA personnel. OVs receive and review daily analytical results reported by the establishment laboratories. AIs also conduct official government verification sampling of beef trimmings with a minimum frequency of one sample per week. The official verification samples are sealed and sent to the LCDVMA for analysis. IPSA requires certified establishments to hold the production lot associated with both the establishments' samples and official government verification samples tested for STEC until acceptable analytical test results have been obtained. When OVs receive acceptable analytical test results, a Product Release Form is issued, and the establishment is notified that IPSA has officially released the products for distribution. When positive test results are received from either the establishment's testing or official government verification testing, IPSA's enforcement strategy includes performing Sanitation SOPs and HACCP verification activities, verifying the proper implementation of the establishment's corrective actions, and conducting follow-up sampling activities. The FSIS auditors reviewed in-plant government inspection personnel official government verification sampling records for STEC testing, including test results and implementation of IPSA's hold and test policy, and identified no concerns.

The FSIS auditors verified that IPSA maintains the legal authority to implement its official microbiological sampling and testing programs to ensure that raw beef products intended for export to the United States are safe and wholesome, meeting the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held November 13, 2024, by videoconference with IPSA. FSIS concluded that Nicaragua's raw beef products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. IPSA has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, IPSA has implemented official microbiological and chemical residue testing programs that are organized

and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

| United States Department of Agriculture |
|---|
| Food Safety and Inspection Service |

Foreign Establishment Audit Checklist

| 1. ESTABLISHMENT NAME AND LOCATION | 2. AUDIT D | ATE | 3. ES | STABLISHMENT NO. | 4. NAME OF COUNTRY | |
|---|--------------|------------------|----------------------------------|----------------------------|--------------------------------|------------------|
| Ganadería Integral Nicaragua S.A.(GINSA) 11/07/20 Km. 34.5 Carretera vieja a León. | | 7/2024 1 | | 1 | Nicaragua | |
| Managua | 5. AUDIT ST | TAFF | | | 6. TYPE OF AUDIT | |
| OIEA St | | tate and Ir | nterna | tional Audit Staff | X ON-SITE AUDIT DOCUMEN | |
| Place an X in the Audit Results block to i | indicato nor | nomel | iona | with roquirom | | |
| Part A - Sanitation Standard Operating Procedure | | · · | | • | rt D - Continued | |
| Basic Requirements | s (330F) | Audit Results | | | onomic Sampling | Audit Results |
| 7. Written SSOP | | | 33. | Scheduled Sample | | |
| 8. Records documenting implementation. | | | 34. | Species Testing | | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | | 35. | Residue | | |
| Sanitation Standard Operating Procedures (SSC Ongoing Requirements | DP) | | | Part E - | Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of imple | mentation. | | 36. | Export | | |
| 11. Maintenance and evaluation of the effectiveness of SSO | | | 37. | Import | | |
| 12. Corrective action when the SSOP's have failed to preven product contamination or adulteration. | t direct | | 38. | Establishment Grounds | and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | | | 39. | Establishment Construc | tion/Maintenance | |
| Part B - Hazard Analysis and Critical Control | | | 40. | Light | | |
| Point (HACCP) Systems - Basic Requirements 14. Developed and implemented a written HACCP plan . | 5 | | 41. | Ventilation | | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective | e actions. | | _ | Plumbing and Sewage | | |
| Records documenting implementation and monitoring of HACCP plan. | the | | | Water Supply | | |
| The HACCP plan is signed and dated by the responsible establishment individual. | | | | Dressing Rooms/Lavato | | |
| Hazard Analysis and Critical Control Point | | | 10. | | · | |
| (HACCP) Systems - Ongoing Requirements | | | 46. | Sanitary Operations | | |
| 18. Monitoring of HACCP plan. | | X | 47. | Employee Hygiene | | |
| 19. Verification and validation of HACCP plan. | | | 48. | Condemned Product Co | pntrol | |
| 20. Corrective action written in HACCP plan. | | | | Dout E | expection Poquiromente | |
| 21. Reassessed adequacy of the HACCP plan. | | | Part F - Inspection Requirements | | | |
| 22. Records documenting: the written HACCP plan, monitori critical control points, dates and times of specific event of | | | 49. Government Staffing | | | |
| Part C - Economic / Wholesomeness 23. Labeling - Product Standards | | | 50. | Daily Inspection Covera | ge | |
| 23. Labeling - Product Standards | | | 51. | Periodic Supervisory Revie | ews | |
| 24. Labeling - Net Weights | | | 52. | Humane Handling | | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins | /Moisture) | | 53. | Animal Identification | | |
| Part D - Sampling Generic <i>E. coli</i> Testing | | | 54. | Ante Mortem Inspection | | |
| 27. Written Procedures | | | 55. | Post Mortem Inspection | l | |
| 28. Sample Collection/Analysis | | | 1 | | | |
| 29. Records | | | 1 | Part G - Other Regu | Ilatory Oversight Requirements | |
| Salmonella Performance Standards - Basic Re | quirements | | 56. | European Community Di | rectives | 0 |
| 30. Corrective Actions | | | 57. | | | |
| 31. Reassessment | | | 58. | | | |
| 32. Written Assurance | | | 59. | | | |

FSIS- 5000-6 (04/04/2002)

| Prepared Products: Raw Intact and Raw Non-Intact | |
|--|--|

60. Observation of the Establishment

18-CCP 2 monitor is required to verify the application of an antimicrobial intervention (e.g., organic acid) as part of the monitoring procedure. While implementing monitoring procedures the record entry was documented as acceptable when the cabinet was not spraying organic acid on the first carcass.

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
|--|---------------------------------|
| OIEA State and International Audit Staff | 11/07/2024 |

| United States Department of Agriculture |
|---|
| Food Safety and Inspection Service |

Foreign Establishment Audit Checklist

| 1. ESTABLISHMENT NAME AND LOCATION | 2. AUDIT D | ATE | 3. ES | TABLISHMENT NO. | 4. NAME OF COUNTRY | |
|--|----------------|------------------|----------|----------------------------|-------------------------------------|------------------|
| Novaterra S.A. 10/30/20 Km 42. Carretera Panamericana Norte | | 024 2 | | 2 | Nicaragua | |
| Km 42, Carretera Panamericana Norte Municipio Tipitapa, Managua | 5. AUDIT S | TAFF | | | 6. TYPE OF AUDIT | |
| | OIEA S | tate and Ir | nternati | ional Audit Staff | | |
| | | | | | | IENT AUDIT |
| Place an X in the Audit Results block t | | lcompl | liance | • | | e. |
| Part A - Sanitation Standard Operating Proced Basic Requirements | ures (SSOP) | Audit Results | | | rt D - Continued onomic Sampling | Audit Results |
| 7. Written SSOP | | TCOULD | 33 | Scheduled Sample | | |
| 8. Records documenting implementation. | | | - | Species Testing | | |
| 9. Signed and dated SSOP, by on-site or overall authority | 1 | | - | Residue | | |
| Sanitation Standard Operating Procedures (S | | | 35. | | | |
| Ongoing Requirements | , | | | Part E - | Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of in | plementation. | X | 36. | Export | | |
| 11. Maintenance and evaluation of the effectiveness of S | | | 37. | Import | | |
| 12. Corrective action when the SSOP's have failed to pre product contamination or adulteration. | event direct | | 38. | Establishment Grounds | and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | | | 39. | Establishment Construc | tion/Maintenance | |
| Part B - Hazard Analysis and Critical Cont Point (HACCP) Systems - Basic Requireme | | | | Light | | |
| 14. Developed and implemented a written HACCP plan . | | X | 41. | Ventilation | | X |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corre | ctive actions. | | 42. | Plumbing and Sewage | | |
| Records documenting implementation and monitoring HACCP plan. | g of the | X | | Water Supply | | |
| 17. The HACCP plan is signed and dated by the response establishment individual. | ible | | | Dressing Rcoms/Lavato | | |
| Hazard Analysis and Critical Control Poin | | | | | | |
| (HACCP) Systems - Ongoing Requirement | ts | | 46. | Sanitary Operations | | |
| 18. Monitoring of HACCP plan. | | | 47. | Employee Hygiene | | |
| 19. Verification and validation of HACCP plan. | | | 48. | Condemned Product Co | ontrol | |
| 20. Corrective action written in HACCP plan. | | | | | | |
| 21. Reassessed adequacy of the HACCP plan. | | | _ | Part F - Ir | nspection Requirements | |
| 22. Records documenting: the written HACCP plan, mon critical control points, dates and times of specific even | | | 49. | Government Staffing | | |
| Part C - Economic / Wholesomeness | 5 | | 50. | Daily Inspection Covera | ige | |
| 23. Labeling - Product Standards | | | 51. | Periodic Supervisory Revie | ws | |
| 24. Labeling - Net Weights | | | 52 | Humane Handling | | |
| 25. General Labeling | | | _ | | | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Si | (Ins/Moisture) | | 53. | Animal Identification | | |
| Part D - Sampling Generic <i>E. coli</i> Testing | | | 54. | Ante Mortem Inspection | | |
| 27. Written Procedures | | | 55. | Post Mortem Inspection | | |
| 28. Sample Collection/Analysis | | | | | | |
| 29. Records | | | | Part G - Other Regu | llatory Oversight Requirements | |
| Salmonella Performance Standards - Basic | Requirements | | 56. E | European Community Di | rectives | 0 |
| 30. Corrective Actions | | | 57. | | | |
| 31. Reassessment | | | 58. | | | |
| 32. Written Assurance | | | 59. | | | |
| | | | | | | |

FSIS- 5000-6 (04/04/2002)

| Establishment Operations: | Beef slaughter and processing. |
|---------------------------|--------------------------------|
| Prepared Products: | Raw Intact and Raw Non-Intact |
| | |

60. Observation of the Establishment

10 and 41-Condensation was observed upon entering the cutting room on the underside of the refrigeration unit and in the carcass cooler in multiple spots over carcasses.

10-A sterilizer was not functioning properly in the hallway prior to entering the carcass cooler.

No product contamination was observed.

14-The HACCP plans did not identify the frequency that direct observations and record keeping verifications are being performed.

16-For zero tolerance CCP (number 1) the HACCP monitoring records did not include a time for each monitoring event that occurred. Additionally, the HACCP verification records did not include the time the verification event occurred.

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
|--|---------------------------------|
| OIEA State and International Audit Staff | 10/30/2024 |

| United States Department of Agriculture |
|---|
| Food Safety and Inspection Service |

Foreign Establishment Audit Checklist

| I. ESTABLISHMENT NAME AND LOCATION 2. AUDIT DA | | ATE | 3. ESTABLISHMENT NO. | 4. NAME OF COUNTRY | | | |
|--|----------------------------|------------------|---|-------------------------------------|------------------|--|--|
| Industrial Comercial San Martín S.A., Km. 11/05/202 | | 024 | 4 | Nicaragua | | | |
| 67 1/2, Carretera Panamericana Sur, | namericana Sur, 5. AUDIT S | | | 6. TYPE OF AUDIT | | | |
| Nandaime, Granada OIEA Sta | | tate and Ir | nternational Audit Staff | | | | |
| | | | | | T AUDIT | | |
| Place an X in the Audit Results block to inc | | lcompl | | •• | | | |
| Part A - Sanitation Standard Operating Procedures (Basic Requirements | SSOP) | Audit Results | | rt D - Continued onomic Sampling | Audit Results | | |
| 7. Written SSOP | | | 33. Scheduled Sample | | | | |
| 8. Records documenting implementation. | | | 34. Species Testing | | | | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | | 35. Residue | | | | |
| Sanitation Standard Operating Procedures (SSOP) | | | | | | | |
| Ongoing Requirements | | | Part E - | Other Requirements | | | |
| 10. Implementation of SSOP's, including monitoring of impleme | | | 36. Export | | | | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | | 37. Import | | | | |
| 12. Corrective action when the SSOP's have failed to prevent di product contamination or adulteration. | rect | | 38. Establishment Grounds | and Pest Control | | | |
| 13. Daily records document item 10, 11 and 12 above. | | | 39. Establishment Construc | tion/Maintenance | X | | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | | 40. Light | | | | |
| 14. Developed and implemented a written HACCP plan . | | | 41. Ventilation | | | | |
| Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective and | ctions. | | 42. Plumbing and Sewage | | | | |
| Records documenting implementation and monitoring of the HACCP plan. |) | | 43. Water Supply | | | | |
| The HACCP plan is signed and dated by the responsible establishment individual. | | | 44. Dressing Rooms/Lavato 45. Equipment and Utensils | | | | |
| Hazard Analysis and Critical Control Point | | | | | | | |
| (HACCP) Systems - Ongoing Requirements | | | 46. Sanitary Operations | | | | |
| 18. Monitoring of HACCP plan. | | | 47. Employee Hygiene | | | | |
| 19. Verification and validation of HACCP plan. | | | 48. Condemned Product Co | ontrol | | | |
| 20. Corrective action written in HACCP plan. | | | Davi E Jr | | | | |
| 21. Reassessed adequacy of the HACCP plan. | | | Part F - Inspection Requirements | | | | |
| Records documenting: the written HACCP plan, monitoring critical control points, dates and times of specific event occ | | | 49. Government Staffing | | | | |
| Part C - Economic / Wholesomeness | | | 50. Daily Inspection Covera | ge | | | |
| 23. Labeling - Product Standards | | | 51. Periodic Supervisory Revie | ws | | | |
| 24. Labeling - Net Weights 25. General Labeling | | | 52. Humane Handling | | | | |
| 25. General Labeling 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo | oisture) | | 53. Animal Identification | | | | |
| Part D - Sampling | , | | | | | | |
| Generic <i>E. coli</i> Testing | | | 54. Ante Mortem Inspection | | | | |
| 27. Written Procedures | | | 55. Post Mortem Inspection | | | | |
| 28. Sample Collection/Analysis | | | Bart C. Other D.c. | laton (Nomight Possiersents | | | |
| 29. Records | | | Part G - Other Regu | latory Oversight Requirements | | | |
| Salmonella Performance Standards - Basic Requ | irements | | 56. European Community Di | rectives | 0 | | |
| 30. Corrective Actions | | | 57. | | | | |
| 31. Reassessment | | | 58. | | | | |
| 32. Written Assurance | | | 59. | | | | |

FSIS- 5000-6 (04/04/2002)

| | Establishment Operations: | Beef slaughter and processing. |
|--|---------------------------|--------------------------------|
| Prepared Products: Kaw Intact and Kaw Non-Intact | Prepared Products: | Raw Intact and Raw Non-Intact |

60. Observation of the Establishment

30-In the cutting room the floors surface was breaking up and at times in spots, water would seep out when stepping on the floor.

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
|--|---------------------------------|
| OIEA State and International Audit Staff | 11/05/2024 |

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| 1. ESTABLISHMENT NAME AND LOCATION | 2. AUDIT D | ATE | 3. EST | ABLISHMENT NO. | 4. NA | ME OF COUNTRY | | |
|--|-------------|------------------|---|----------------------------|---------|--------------------------|-------------|------------------|
| Nuevo Carnic S.A. | 11/04/2 | 024 | | 5 Nicaragua | | | | |
| Km. 10 1/2 Carretera Norte, Managua | 5. AUDIT ST | ΓAFF | | | | 6. TYPE OF AUDIT | | |
| | | ate and In | e and International Audit Staff X ON-SITE AUDIT | | | | | |
| | | | | | | ON-SITE AUDIT | | T AUDIT |
| Place an X in the Audit Results block to in | | lcompl | liance | • | | | applicable. | |
| Part A - Sanitation Standard Operating Procedures Basic Requirements | (SSOP) | Audit Results | | | | Continued ic Sampling | | Audit Results |
| 7. Written SSOP | | | 33. S | cheduled Sample | | le camping | | |
| 8. Records documenting implementation. | | | 34. S | pecies Testing | | | | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | | 35. Residue | | | | | |
| Sanitation Standard Operating Procedures (SSOP) | | | | Part F - | Othe | r Requirements | | |
| Ongoing Requirements | | | 00 F | | othe | Requiremente | | |
| 10. Implementation of SSOP's, including monitoring of implem | | | 36. E | • | | | | |
| 11. Maintenance and evaluation of the effectiveness of SSOP' 12. Corrective action when the SSOP's have failed to prevent | | | 37. Import | | | | | |
| product contamination or adulteration. | uncor | | 38. E | stablishment Grounds : | and Pe | st Control | | |
| 13. Daily records document item 10, 11 and 12 above. | | | 39. E | stablishment Construct | tion/Ma | aintenance | | |
| Part B - Hazard Analysis and Critical Control | | | 40. Li | ght | | | | |
| Point (HACCP) Systems - Basic Requirements | | | 41. V | entilation | | | | |
| 14. Developed and implemented a written HACCP plan . 15. Contents of the HACCP list the food safety hazards, | | | 42. P | lumbing and Sewage | | | | |
| critical control points, critical limits, procedures, corrective actions. 16. Records documenting implementation and monitoring of the | | | 43. W | /ater Supply | | | | |
| HACCP plan. | | | 44. D | ressing Rooms/Lavato | ries | | | |
| The HACCP plan is signed and dated by the responsible establishment individual. | | | 45. E | quipment and Utensils | | | | X |
| Hazard Analysis and Critical Control Point | | | 40.0 | | | | | |
| (HACCP) Systems - Ongoing Requirements 18. Monitoring of HACCP plan. | | | 46. S | anitary Operations | | | | |
| 19. Verification and validation of HACCP plan. | | | 47. E | 47. Employee Hygiene | | | | |
| · · · · · · · · · · · · · · · · · · · | | | 48. C | ondemned Product Co | ntrol | | | |
| 20. Corrective action written in HACCP plan. 21. Reæssessed adequacy of the HACCP plan. | | | Part F - Inspection Requirements | | | | ; | |
| 22. Records documenting: the written HACCP plan, monitoring | | | 49. G | 49. Government Staffing | | | | |
| critical control points, dates and times of specific event of Part C - Economic / Wholesomeness | courrences. | | 50 D | | | | | |
| 23. Labeling - Product Standards | | | | aily Inspection Covera | | | | |
| 24. Labeling - Net Weights | | | 51. Pe | eriodic Supervisory Review | WS | | | |
| 25. General Labeling | | | 52. H | umane Handling | | | | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/M | loisture) | | 53. A | nimal Identification | | | | |
| Part D - Sampling Generic <i>E. coli</i> Testing | | | 54. A | nte Mortem Inspection | | | | |
| 27. Written Procedures | | | 55 D | ost Mortem Inspection | | | | |
| 28. Sample Collection/Analysis | | | | ost mortan inspection | | | | |
| 29. Records | | | P | art G - Other Regu | latory | / Oversight Requir | ements | |
| Salmonella Performance Standards - Basic Req | uirements | | 56. Eu | uropean Community Dir | rective | s | | 0 |
| 30. Corrective Actions | | | 57. | | | | | |
| 31. Reassessment | | | 58. | | | | | |
| | | | | | | | | |
| 32. Written Assurance | | | 59. | | | | | |

FSIS- 5000-6 (04/04/2002)

| Establishment Operations | Beef slaughter and processing. |
|--------------------------|--------------------------------|
| Prepared Products | Raw Intact and Raw Non-Intact |
| | |

60. Observation of the Establishment

45-Two plastic containers were observed to have loose slivers that could potentially contaminate products.

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
|--|---------------------------------|
| OIEA State and International Audit Staff | 11/04/2024 |

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| 1. ESTABLISHMENT NAME AND LOCATION | 2. AUDIT D | ATE | 3. ESTABLISHMENT NO. | 4. NAME OF COUNTRY | | |
|--|---|------------------|----------------------------------|---------------------------------|------------------|--|
| Matadero Central S.A. (MACESA) | , | | 8 | Nicaragua | | |
| CARRETERA A JUIGALPA - RAMA KM. 130 JUIGALPA- CHONTALES | 5. AUDIT ST | TAFF | | 6. TYPE OF AUDIT | | |
| | OIEA St | tate and Ir | ternational Audit Staff | | | |
| | | | | | ENT AUDIT | |
| Place an X in the Audit Results block to inc | | lcompl | | | ə. | |
| Part A - Sanitation Standard Operating Procedures (| SSOP) | Audit Results | | Part D - Continued | Audit Results | |
| Basic Requirements 7. Written SSOP | | Tresuits | 33. Scheduled Sample | conomic Sampling | Tresuits | |
| 8. Records documenting implementation. | | | | | | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | | 34. Species Testing | | | |
| Sanitation Standard Operating Procedures (SSOP) | | | 35. Residue | | | |
| Ongoing Requirements | | | Part E | - Other Requirements | | |
| 10. Implementation of SSOP's, including monitoring of implement | ntation. | | 36. Export | | | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | | 37. Import | | | |
| 12. Corrective action when the SSOP's have failed to prevent di product contamination or adulteration. | rect | | 38. Establishment Ground | is and Pest Control | | |
| 13. Daily records document item 10, 11 and 12 above. | | | 39. Establishment Constru | uction/Maintenance | | |
| Part B - Hazard Analysis and Critical Control | | | 40. Light | | | |
| Point (HACCP) Systems - Basic Requirements 14. Developed and implemented a written HACCP plan . | | | 41. Ventilation | | | |
| Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective ac | ctions. | | 42. Plumbing and Sewage | e | | |
| Records documenting implementation and monitoring of the HACCP plan. | 9 | | 43. Water Supply | | | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | | 44. Dressing Rooms/Lava | | | |
| Hazard Analysis and Critical Control Point | | | 45. Equipment and Utens | lis | | |
| (HACCP) Systems - Ongoing Requirements | | | 46. Sanitary Operations | | | |
| 18. Monitoring of HACCP plan. | | | 47. Employee Hygiene | | | |
| 19. Verification and validation of HACCP plan. | | | 48. Condemned Product (| Control | | |
| 20. Corrective action written in HACCP plan. | | | | | | |
| 21. Reassessed adequacy of the HACCP plan. | | | Part F - Inspection Requirements | | | |
| Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | | 49. Government Staffing | | | |
| Part C - Economic / Wholesomeness | | | 50. Daily Inspection Cove | erage | | |
| 23. Labeling - Product Standards | | | 51. Periodic Supervisory Rev | views | | |
| 24. Labeling - Net Weights | | | 52. Humane Handling | | | |
| 25. General Labeling 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo | oisture) | | 53. Animal Identification | | | |
| Part D - Sampling | , | | | | | |
| Generic E. coli Testing | | | 54. Ante Mortem Inspectio | on | | |
| 27. Written Procedures | | | 55. Post Mortem Inspection | on | | |
| 28. Sample Collection/Analysis | | | Bart G. Other Des | nulaton (Nomight Paguimmarte | | |
| 29. Records | | | Part G - Other Reg | gulatory Oversight Requirements | | |
| Salmonella Performance Standards - Basic Requi | irements | | 56. European Community | Directives | 0 | |
| 30. Corrective Actions | | | 57. | | | |
| 31. Reassessment | | | 58. | | | |
| 32. Written Assurance | | | 59. | | | |

FSIS- 5000-6 (04/04/2002)

| Establishment Operations: | Beef slaughter and processing. |
|---------------------------|--------------------------------|
| Prepared Products: | Raw Intact and Raw Non-Intact |

60. Observation of the Establishment

No findings observed

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
|--|---------------------------------|
| OIEA State and International Audit Staff | 11/06/2024 |

| United States Department of Agriculture |
|---|
| Food Safety and Inspection Service |

Foreign Establishment Audit Checklist

| 1. ESTABLIS | SHMENT NAME AND LOCATION | 2. AUDIT D | ATE | 3. E | STABLISHMENT NO. | 4. NAME OF COUNTRY | |
|---|--|----------------|------------------------|-------------------------|----------------------------|-------------------------------------|------------------|
| Nica Beef | Packers arretera Panamericana Norte | 11/01/20 | 024 | 109 | | Nicaragua | |
| Condega, | | 5. AUDIT STAFF | | 6. TYPE OF AUDIT | | 6. TYPE OF AUDIT | |
| OIEA Inte | | ternationa | onal Audit Staff (IAS) | | | | |
| | | 1 | | | | | I AUDII |
| | X in the Audit Results block to inc | | · · | land | • | | |
| Part A - Sa | nitation Standard Operating Procedures (Basic Requirements | SSOP) | Audit Results | | | rt D - Continued onomic Sampling | Audit Results |
| 7. Written S | SOP | | | 33. | Scheduled Sample | | |
| 8. Records documenting implementation. | | | 34. | Species Testing | | | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | | 35. | Residue | | | |
| Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements | | | | Part E - | Other Requirements | | |
| 10. Impleme | entation of SSOP's, including monitoring of impleme | ntation. | | 36. | Export | | |
| 11. Mainten | ance and evaluation of the effectiveness of SSOP's. | | | 37. | Import | | |
| | ve action when the SSOP's have failed to prevent di contamination or adulteration. | irect | | 38. | Establishment Grounds | and Pest Control | |
| 13. Daily red | cords document item 10, 11 and 12 above. | | | 39. | Establishment Construc | tion/Maintenance | |
| | - Hazard Analysis and Critical Control HACCP) Systems - Basic Requirements | | | 40. | Light | | |
| | bed and implemented a written HACCP plan . | | Х | 41. | Ventilation | | |
| | s of the HACCP list the food safety hazards, control points, critical limits, procedures, corrective a | ctions. | | 42. | Plumbing and Sewage | | |
| 16. Records HACCP | documenting implementation and monitoring of the plan. |) | X | | Water Supply | | |
| | CCP plan is signed and dated by the responsible hment individual. | | | | Dressing Rooms/Lavato | | |
| | rd Analysis and Critical Control Point | | | | | | |
| • | CP) Systems - Ongoing Requirements | | | 46. | Sanitary Operations | | |
| 18. Monitoring of HACCP plan. | | | 47. Employee Hygiene | | | | |
| 19. Verification and validation of HACCP plan. | | | 48. | Condemned Product Co | ontrol | | |
| 20. Corrective action written in HACCP plan. | | | | | | | |
| 21. Reassessed adequacy of the HACCP plan. | | | | nspection Requirements | | | |
| | s documenting: the written HACCP plan, monitoring control points, dates and times of specific event occ | | | 49. Government Staffing | | | |
| | Part C - Economic / Wholesomeness | | | 50. | Daily Inspection Covera | ge | |
| 23. Labeling | g - Product Standards | | | 51. | Periodic Supervisory Revie | WS | |
| | - Net Weights | | | 52 | Humane Handling | | |
| 25. General | • | | | | | | |
| 26. Fin. Pro | od. Standards/Boneless (Defects/AQL/Pork Skins/Mo | oisture) | | 53. | Animal Identification | | |
| | Part D - Sampling Generic <i>E. coli</i> Testing | | | 54. | Ante Mortem Inspection | | |
| 27. Written | Procedures | | | 55. | Post Mortem Inspection | | |
| 28. Sample | Collection/Analysis | | | | | | |
| 29. Records | 5 | | | 1 | Part G - Other Regu | latory Oversight Requirements | |
| Salmon | ella Performance Standards - Basic Requ | irements | | 56. | European Community Di | rectives | 0 |
| 30. Correcti | ve Actions | | | 57. | | | |
| 31. Reasses | ssment | | | 58. | | | |
| 32. Written | | | | 59. | | | |
| | | | 1 | | | | 1 |

FSIS- 5000-6 (04/04/2002)

| Establishment Operations: | Beef slaughter and processing. |
|---------------------------|--------------------------------|
| Prepared Products: | Raw Intact and Raw Non-Intact |
| | |

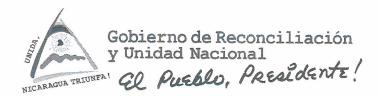
60. Observation of the Establishment

14-When applying the lactic acid spray to carcasses the establishment was not applying the lactic acid to the entire surface of carcass, as required by the establishment's procedure.

16-For zero tolerance CCP (number 1) the HACCP monitoring records did not include a time for each monitoring event that occurred. Nor did the records review verification activity include a time the event occurred.

| 61. AUDIT STAFF | 62. DATE OF ESTABLISHMENT AUDIT |
|--|---------------------------------|
| OIEA State and International Audit Staff | 11/01/2024 |

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





Managua, April 10th, 2025 DIA/IDC/0437/04/2025

Margaret Burns-Rath, JD, MPH Assistant Administrator Office of International Coordination Food Safety and Inspection Service-USDA Washington D.C. United States of America

Dear Ms. Burns-Rath:

In response to your letter of February 13, 2025, submitting a draft of the final audit report conducted between October 29 and November 13, 2024.

In this regard, I inform you that this Authority expresses its agreement with the findings identified by the FSIS-USDA Auditors, and therefore we are submitting reports on the corrective actions implemented by the audited establishments. These were verified by our official personnel, who determined that they were satisfactory in addressing the observed non-compliances.



Director de **Inocuidad** Agroalimentaria DIA-IPSA.

CC. Ing. Ricardo Somarriba Reyes, Executive Director IPSA. Ing. Jimmy A. Bolaños, Agricultural Specialist, USDA/FAS. Dra. Martha Hernández García, Responsible DIEA/DIA/IPSA. Dr. Julio Guadamuz Lara, Responsible SIC/DIA/IPSA. Archive.

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