United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
20250

July 12, 2023

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 January 30–February 16, 2023. 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,

MICHELLE CATLIN

Digitally signed by MICHELLE CATLIN
Date: 2023.07.12 10:40:10 -04'00'

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

NICARAGUA

JANUARY 30–FEBRUARY 16, 2023

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

RAW BEEF PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

July 11, 2023

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) January 30–February 9, 2023. 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.

An analysis of the audit findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following finding related to laboratory oversight by the Central Competent Authority (CCA)—the Institute of Agricultural Protection and Health (IPSA):

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.

FSIS held an exit meeting February 16, 2023, by videoconference, with representatives from IPSA. During the exit meeting, IPSA committed to address the preliminary finding as presented. FSIS will evaluate the adequacy of IPSA's documentation of proposed corrective actions once received and base future equivalence verification activities on the information provided.

TABLE OF CONTENTS

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 January 30–February 9, 2023. The audit began with an entrance meeting held January 30, 2023, in Managua, Nicaragua, 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 accompanied the FSIS auditor throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference February 16, 2023.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective 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 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; Beef Patty Product; Finely Textured Beef; Ground Beef; Hamburger; Partially Defatted Chopped Beef; Partially Defatted Beef Fatty Tissue; 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 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 auditor 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 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 3-year period, in addition to information obtained directly from IPSA through the SRT.

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

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

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

The FSIS auditor visited six beef slaughter and processing establishments currently certified as eligible to export to the United States. During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor assessed IPSA'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 auditor 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
Central Competent Authority	1	• Institute of Agricultural Protection and Health, Managua
Laboratories	2	• National Laboratory of Chemical and Biological Residue, Managua • Central Veterinary Diagnostic and Food Microbiology Laboratory, Managua
Beef slaughter and processing establishments	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 Nicaragua's food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);

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

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

III. BACKGROUND

From November 1, 2019, to October 31, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 439,030,462 pounds of raw beef from Nicaragua. This included 371,944,544 pounds of raw intact beef and 67,085,918 pounds of raw non-intact beef exported by Nicaragua to the United States. Of these amounts, FSIS performed additional types of inspection on 28,383,890 pounds of beef, including testing for chemical residues and Shiga toxin-producing *Escherichia coli* (STEC). As a result of this additional reinspection, FSIS rejected 36,552 pounds of exported beef products for various issues including leaking vacuum packages, shipping damage, export certification, labeling verification failures, or other miscellaneous issues. No point-of-entry violations were identified during the reinspection.

The last FSIS audit in 2021 identified the following systemic finding:

Summary of Findings from the 2021 FSIS Audit of Nicaragua
Component 1: Government Oversight (e.g., Organization and Administration)
• IPSA's Directorate of Laboratories had not established proficiency testing for STEC to ensure that laboratory personnel are proficient in the microbiological analyses performed.

During the current audit, the FSIS auditor verified that the corrective actions for the above finding reported in 2021 were implemented and effective in resolving the finding.

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

IPSA is the CCA of Nicaragua's raw beef products inspection system in accordance with Law No. 862, Law Creating the Institute of Animal and Plant Health Protection, which provides for

overall responsibility for regulating raw beef inspection and production activities related to the export of raw beef products to the United States. The FSIS auditor confirmed through interviews and record reviews that there have been no major changes in IPSA's organizational structure since the last FSIS audit conducted in 2021. 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 (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.

IPSA's raw beef inspection system consists of two levels: central and establishment. At the central level, DIA is responsible for the safety of raw beef products and the promulgation of food safety regulations. DIA also has the sole authority to enforce the laws and regulations of the raw beef inspection system in accordance with national legislation and FSIS import requirements. DIA's Meat Safety Section (Sección de Inocuidad Carne (SIC)) provides direct supervision over government inspection personnel at certified establishments eligible to export raw beef products to the United States. At the establishment level, each certified beef slaughter and processing establishment is staffed by at least two official veterinarians (OV) and several auxiliary inspectors (AI) who conduct inspection verification tasks in accordance with IPSA's prescribed procedures and frequencies.

The FSIS auditor verified through interviews and record reviews that all 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 auditor verified that the SIC manager conducts quarterly performance appraisals for each OV to assess his or her knowledge, skills, and abilities. The OV is responsible for supervising and performing a monthly 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 in the following areas: ante-mortem inspection; post-mortem inspection; humane handling verification activities; verification of sanitation standard operating procedures (Sanitation SOP) and sanitation performance standards (SPS); HACCP verification; labeling verification; chemical residue and microbiological sampling methodology; export certification; and official control over condemned materials, including specified risk materials (SRM) control. The FSIS auditor reviewed inspection records associated with government inspection personnel educational credentials, payment of salaries, initial and ongoing trainings, and performance evaluations. No concerns arose regarding these reviews.

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 when an establishment does not meet Nicaragua's regulatory requirements. At the establishment level, regulatory control actions taken by government inspection personnel include detaining products, rejecting equipment or facilities,

or stopping or slowing the line speed. The FSIS auditor verified through interviews and record reviews that IPSA has provided instructions to its government inspection personnel to identify and document any noncompliance findings on the Demand for Corrective Actions (DCA) form, F-SIC-44. The FSIS auditor verified that government inspection personnel had identified and documented noncompliance findings on DCAs in accordance with IPSA's requirements. In-plant government inspection personnel closed the DCAs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures, when applicable.

IPSA has provided regulatory definitions for adulterated and misbranded products that are consistent with FSIS requirements. Nicaragua's Meat Inspection Regulations defines adulterated product as 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 government inspection personnel retain all product sampled for veterinary drug residues, pesticides, and microbiological pathogens pending acceptable analytical results.

IPSA requires that each certified establishment maintains written recall and traceback procedures in accordance with the Central American Technical Regulations (RTCA) 67.06.55.09, Good Hygiene Practices for Unprocessed and Semi-processed Foods, which is consistent with FSIS requirements defined in 9 CFR 418.2–418.4. The FSIS auditor noted that each audited establishment maintained these procedures as well as records sufficient to conduct traceback activities if adulterated product were produced or exported.

Nicaragua's Meat Inspection Procedures Manual provides instructions and standards verification activities to government inspection personnel to ensure that the same set of laws, regulations, and policies are applied consistently to all establishments certified to export raw beef products to the United States. Within DIA, the Department of Registration and Certification (Departamento de Registro y Certificación (DRC) is responsible for conducting audits to determine initial and annual approval of certified establishments. The FSIS auditor reviewed a newly certified establishment's approval process which included government inspection personnel's evaluation of establishment written programs and onsite follow-up audits to determine the establishment's compliance with IPSA requirements. The FSIS auditor 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.

IPSA only allows raw beef products produced in certified establishments to be exported to the United States. The FSIS auditor 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 products exported to the United States. The OVs are responsible for reviewing and signing export health certificates of

beef products destined for export to the United States. Government inspection personnel conduct a pre-shipment verification review 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 also verify that all official verification samples and establishment self-monitoring samples are within acceptable analytical results for microbiological pathogens and chemical residues prior to signing an export health certificate. The FSIS auditor 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 auditor's review of IPSA's export certification process did not identify 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 auditor visited the National Laboratory of Chemical and Biological Residue (Laboratorio Nacional de Residuos Químicos y Biológicos (LNRQB)) and the Central Veterinary Diagnostic and Food Microbiology Laboratory (Laboratorio Central de Diagnóstico Veterinario y Microbiología de Alimentos (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 that are destined for export to the United States.

The Nicaraguan National Accreditation Office (Oficina Nacional de Acreditación (ONA)) has the authority for accrediting laboratories in accordance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2017 standards. ONA conducts annual surveillance audits and certification audits of the government laboratories every four years. The FSIS auditor reviewed the accreditation certificates, scope of accreditation, and the most recent ONA accreditation reports and associated corrective actions. The FSIS auditor 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 auditor reviewed the most recent DIA audit reports and associated corrective action plans of each laboratory. The FSIS auditor verified that DIA and ONA annual audits and related follow-up activities have been conducted in accordance with IPSA requirements.

The FSIS auditor's scope in each laboratory included review of sample receipt, sample traceability, timely analysis, analytical methodologies, analytical controls, analyst qualifications and trainings, proficiency testing, and recording and reporting of results. The FSIS auditor identified the following finding related to IPSA's oversight of LNRQB:

- 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 retested products cannot be exported to the United States.

The FSIS auditor reviewed recent inspection records and did not identify any circumstances where retested samples with violative test results had been exported to the United States.

With the exception of the laboratory finding described above, the FSIS auditor concluded that IPSA continues to organize, administer, and enforce its raw beef food safety inspection system in a manner that meets the core requirements for this component.

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

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

The FSIS auditor 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 regulatory requirements. The FSIS auditor's 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 did not identify any concerns.

The FSIS auditor verified that in-plant government inspection personnel are required to conduct ante-mortem inspection of livestock prior to slaughter. The Meat Inspection Procedures Manual provides instructions to in-plant government inspection personnel for performing ante-mortem inspection. The FSIS auditor observed that in-plant government inspection personnel conduct ante-mortem inspection on the day of slaughter, including: (1) reviewing required documentation accompanying the livestock to ensure that all required information is accurately documented in ante-mortem records, and (2) 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 auditor 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 auditor 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 auditor verified that non-ambulatory disabled cattle and those showing signs of central nervous system disorders are condemned during ante-mortem inspection and that related samples are collected for BSE testing in the official LCDVMA laboratory, as warranted. No concerns arose regarding IPSA's ante-mortem inspection procedures.

The FSIS auditor verified that each audited establishment is staffed with a sufficient number of government inspection personnel to ensure continuous inspection coverage during 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. This included in-plant inspection verification of proper presentation, identification, examination, and disposition of affected carcasses and parts. The FSIS auditor observed that the 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 auditor correlated the number of in-plant government inspection personnel who conduct post-mortem inspection examination in each audited establishment with the maximum slaughter rate and concluded that IPSA has provided enough government inspection personnel for the existing production volume and slaughter line speed. The FSIS auditor's review of inspection records, including in-plant inspection post-mortem daily disposition reports and periodic supervisory review records, in conjunction with FSIS observation of post-mortem inspection activities by in-plant government inspection personnel did not identify any concerns.

IPSA's official control and labeling requirements for raw beef products eligible for export to the United States are described in the Meat Inspection Procedure 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 destined 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 auditor verified that raw beef products eligible to export to the United States are stored separately by time or space from products for other markets. The FSIS auditor confirmed that government inspection personnel routinely verify labeling requirements, in particular, prior to issuing an export health certificate, to ensure that the information on the product labels is complete, accurate, and meets FSIS labeling requirements.

The FSIS auditor 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 auditor observed the disposal process of condemned and inedible materials at each audited establishment and verified: (1) appropriate identification of inedible or condemned materials; (2) segregation in specially marked or otherwise secure containers; and (3) documentation of final disposal of these materials at rendering facilities. The FSIS auditor did not identify any concerns.

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-and-mouth 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 to export to the United States.

IPSA's BSE Procedures Manual defines SRMs consistent with FSIS' definition, specifically, tonsils and distal ileum in cattle of all ages and brain, skull, eyes, trigeminal ganglia, spinal cord, dorsal root ganglia, and spinal column of cattle 30 months of age or older. The Meat Inspection Procedures Manual provides instructions to in-plant 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 auditor's review of inspection verification records concerning removal, segregation, and disposal of condemned animals, inedible materials, and SRM controls did not identify any concerns.

IPSA has official controls over establishment construction, facilities, and equipment. The Meat Inspection Regulations provide requirements consistent with those found in 9 CFR 416.2–416.6. In addition, RTCA 67.06.55.09, describes the regulatory 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 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 is consistent with FSIS requirements in 9 CFR 327.2(a)(2)(ii) and 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 auditor 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.

FSIS analysis and 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 auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

IPSA requires certified slaughter and processing establishments to develop, implement, and maintain written Sanitation SOPs and SPS, and implement sanitary dressing procedures to prevent direct product contamination or the creation of insanitary conditions. These

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 auditor verified that each audited establishment maintained 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 auditor confirmed that in-plant government inspection personnel conduct daily verification procedures in accordance with IPSA requirements. Inspection verification activities consist of a combination of document reviews, observations, and hands-on inspection verification.

The FSIS auditor 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 auditor also observed the in-plant government inspection personnel perform hands-on operational sanitation verification in all visited establishments. The FSIS auditor noted that the inspection verification activities included direct observation of the actual sanitary conditions and review of the establishments' associated records. The FSIS auditor 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 auditor's 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 inspection personnel were adequately verifying establishments' compliance with 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 auditor 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 auditor verified that in-plant government inspection personnel maintain sanitation records sufficient to document their verification activities and any corrective actions taken.

FSIS analysis and onsite audit verification activities indicate that IPSA maintains sanitation programs that are consistent with criteria established for this component. The FSIS auditor 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 auditor reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

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 (NTON 03 001-98), which are consistent with FSIS requirements in 9 CFR 417.

The FSIS auditor 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 auditor reviewed establishment records for monitoring, verification, corrective actions, and validation, as well as inspection daily verification records for all CCPs. The FSIS auditor 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.

The FSIS auditor 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 auditor 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; 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 auditor observed in-plant government inspection verification procedures for all CCPs in all audited establishments. No concerns arose from these observations. The FSIS auditor also confirmed that the 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, as noted in Component One of this report, DRC conducts annual review of HACCP requirements as part of IPSA's annual approval of certified establishments. The FSIS auditor's review of

HACCP verification records generated by government inspection personnel, including daily, weekly, and annual reviews, did not raise any concerns.

FSIS analysis and onsite audit verification activities indicate that IPSA maintains HACCP systems that are consistent with criteria established for this component. The FSIS auditor identified isolated noncompliances 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 auditor reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, or muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

IPSA has the legal authority and responsibility to regulate, plan, and execute Nicaragua's National Residue Plan (NRP) in accordance with Law No. 291. The NRP provides for the detection of residues and contaminants that exceed allowed quantities in food products destined for human consumption. The Technical Standard on Maximum Veterinary Medicine Limits (NTON 03087-09) establishes allowable levels for veterinary drugs and other substances. These limits are consistent with U.S. requirements in 21 CFR Part 556 (veterinary drugs) and 40 CFR Part 180 (pesticides). IPSA's NRP includes the specific chemical compound to be analyzed, the matrix analyzed, the analytical methodology for regulatory decision making, the action level or maximum residue level, number of samples to be analyzed, and location of the sampling (farm/establishment). Development of the NRP is a collaborative effort between DIA, DGIAL, and the LNRQB Director.

The DIA Director approves annual sampling plans for each certified establishment. The NRP apportions samples between establishments based on the slaughter volume for the prior year. The SIC manager distributes monthly sampling plans to OVs in each certified establishment. The OVs are responsible to ensure the proper implementation of the sampling program in accordance with IPSA's requirements. The FSIS auditor verified through records review, 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 auditor 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.

The FSIS auditor verified that IPSA implements a hold and test policy to ensure that in-plant government inspection personnel retain the entire sampled lot pending laboratory results when a

carcass or its parts are sampled as part of the NRP. The Meat Inspection Procedures Manual describes procedures for retention of samples 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, IPSA notifies the establishment's management of the violative result, determines the disposition of the retained product, and conducts regulatory investigations at the source farm. The FSIS auditor observed the designated veterinary retained cold storage units in each audited establishment and reviewed associated inspection verification records to confirm that IPSA's hold and test policy was being implemented as documented. No concerns arose from these observations and reviews.

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

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 auditor verified through observations, interviews, and records review that generic *E. coli* sampling and testing programs are conducted by establishment personnel at all six audited establishments in accordance with IPSA requirements. The FSIS auditor confirmed that OVs and the SIC manager, during monthly supervisory reviews, verify that slaughter establishments comply with IPSA's regulatory requirements. The FSIS auditor's review of government inspection personnel verification records of generic *E. coli* sampling and testing results identified no 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, *Salmonella* samples are sealed by government inspection personnel prior to submission to the LCDVMA laboratory. The OVs are responsible to provide 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 auditor's review of *Salmonella* official verification sampling records, including testing results for each audited establishment, identified no concerns.

IPSA considers STEC an adulterant in raw beef products intended for export to the United States. IPSA requires certified slaughter and processing establishments to develop a minimum of three CCPs that include zero tolerance for fecal material, ingesta, or milk, antimicrobial interventions, and carcass chilling to prevent and control STEC. 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 auditor 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' self-monitoring 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 N60 official government verification sampling 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' self-monitoring 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 self-monitoring or official government verification testing, IPSA's enforcement strategy includes performing Sanitation SOP and HACCP verification activities, verifying the proper implementation of the establishment's corrective actions, and conducting follow-up sampling activities. The FSIS auditor reviewed in-plant government inspection personnel N60 sampling records, including test results and implementation of IPSA's hold and test policy, and identified no concerns.

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

X. CONCLUSIONS AND NEXT STEPS

FSIS held an exit meeting February 16, 2023, by videoconference, with representatives from IPSA. At this meeting, the FSIS auditor presented the preliminary finding related to IPSA's oversight of LNRQB:

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 retested products cannot be exported to the United States.

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

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 DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Ganaderia Integral Nicaragua, S.A. (GINSA) Km. 34.5 Carretera vieja a Ledn. (Highway 12) Managua, Nicaragua	01/31/2023	1	Nicaragua
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance w ith req uirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Bovine Slaughter and Processing
Prepared Products:	Raw Intact Beef and Raw Ground, Comminuted, or Otherwise Non-intact Beef

60. Observation of the Establishment

22 -The establishment's HACCP verification records (direct observation and record review) did not include the results of the verification activities.

39 -The FSIS auditor observed deteriorated ceiling surfaces and rusted areas on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	01/31/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Novatrra, S.A. Km 42 Carretera Panamericana Norte Municipio Tipitapa, Managua, Nicaragua	02/09/2023	2	Nicaragua
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Bovine Slaughter and Processing
Prepared Products:	Raw Intact Beef and Raw Ground, Comminuted, or Otherwise Non-intact Beef

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	02/09/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Industrial Comercial San Martin, S.A. Km. 67 1/2, Carretera Panamericana Sur P.O. Box 5 Nandaime, Granada	02/03/2023	4	Nicaragua
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Bovine Slaughter and Processing
Prepared Products:	Raw Intact Beef and Raw Ground, Comminuted, or Otherwise Non-intact Beef

60. Observation of the Establishment

22-The establishment’s HACCP verification records for calibration of monitoring instruments (thermometers) did not include the times of the calibration activities.

40-The establishment did not meet Nicaragua's regulatory lighting requirements, minimum of 50-footcandles of shadow-free lighting, at the inspector's post-mortem inspection stations (viscera and carcass).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	02/03/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Nuevo Carnic, S.A. Km. 10 1/2 Carretera Norte P.O. Box 1251 Managua	02/08/2023	5	Nicaragua
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Bovine Slaughter and Processing
Prepared Products:	Raw Intact Beef and Raw Ground, Comminuted, or Otherwise Non-intact Beef

60. Observation of the Establishment

22- The establishment’s HACCP plan did not address its return product procedures in its hazard analysis or flow chart.
22- The establishment’s HACCP verification records did not include the types of the verification activities.

39-The FSIS auditor observed an extensive application of silicone type caulking over exposed products in the production areas. It was applied to cover holes or cracks on the ceiling panel joints or attached overhead equipment. There were several areas of cracked or peeled off silicone which made it difficult to wash or clean properly. Nicaragua's Annex 05 Decree 40-90 of Meat Inspection Regulation states that " the floors, walls, ceilings, partitions, columns, doors and other parts of all buildings must be made of such materials, constructions and finish as to permit easy and complete cleaning". The auditor did not observe any direct products contamination. However, this condition may lead to product adulteration.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	02/08/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Matadero Central, S.A. (MACESA) Km. 130 1/2 Carretera a Juigalpa Ramo	02/06/2023	8	Nicaragua
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Bovine Slaughter and Processing
Prepared Products:	Raw Intact Beef and Raw Ground, Comminuted, or Otherwise Non-intact Beef

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	02/06/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Nica Beef Packers S.A. Esteli, Nicaragua	02/01/2023	109	Nicaragua
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57.	
58.	
59.	

Establishment Operations:	Bovine Slaughter and Processing
Prepared Products:	Raw Intact Beef and Raw Ground, Comminuted, or Otherwise Non-intact Beef

60. Observation of the Establishment

22 - The establishment’s HACCP verification records (record review) did not include the dates, the times, or the results of the verification activities.
22 - The establishment’s HACCP verification records for calibration of monitoring instruments (thermometers) did not include the times of the calibration activities.

40 -The establishment met Nicaragua's regulatory lighting requirements, minimum of 50-footcandles of shadow-free lighting, at the inspector's post-mortem inspection stations for head, viscera, and carcass (high rail/hindquarter). However, the quality and positioning of lighting at the inspector's carcass inspection (low rail/forequarters) was not optimum and below 50-footcandles.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	02/01/2023

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

Gobierno de Reconciliación y Unidad Nacional
El Pueblo, Presidente!

2023 TODOS JUNTOS Vamos Adelante!

Managua June 28, 2023
DIA/IDC/1331/06/2023

Michelle Catlin, PhD.
International Coordination Executive.
Office of International Coordination.
Food Safety and Inspection Service-USDA.
Washington D.C. United States of America.

Dear Dra. Catlin:

I am hereby writing to you in order to inform you that in response to the non-conformity detected during the FSIS-USDA audit of the National Laboratory of Chemical and Biological Residues, which reads: "IPSA Laboratories Directorate has a Provision that allows official samples of chemical residues with violative test results to be reanalyzed. IPSA has not provided written procedures to ensure that retested products cannot be exported to the United States."

In this regard, I am pleased to inform you that the IPSA Official Laboratories Directorate has been notified that results that violate any type of chemical residue must be notified to this Directorate, in order to proceed with the destruction of the product as established by our Official Procedures. of Meat Inspection for Authorized Establishments (procedure No. 1) and article 134 of the Meat Inspection Regulation of the Republic of Nicaragua, regardless of the results obtained in the re-testing practiced as internal evaluations and quality control.

Attached official notification addressed to the Director of Official Laboratories, Procedures Manual and Meat Inspection Regulations of the Republic of Nicaragua.

I hope that the information provided is satisfactory.

Best,

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

Cc. Dra. Martha Hernández - Responsable DIEA/DIA
Dr. Julio Guadamuz L - Responsable SIC/DIA

SOMOS PUEBLO QUE VENCE!

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. www.ipsa.gob.ni