USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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Dr. Cesar Lacayo
Food Safety Director
Nicaraguan Institute of Agricultural Protection and Health (IPSA)
Gobierno De Nicaragua
Managua, Nicaragua, C.A.

Dear Dr. Lacayo,

The USDA Food Safety and Inspection Service (FSIS) onsite audit conducted from September 20 through October 5, 2016, supports that Nicaragua's meat inspection system continues to remain equivalent to that of the United States. 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.

If you have any questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

NICARAGUA

SEPTEMBER 20 – OCTOBER 5, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT

EXPORTED TO THE UNITED STATES OF AMERICA

February 9, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 20 – October 5, 2016. The purpose of the audit was to determine whether Nicaragua's food safety system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. Nicaragua currently is eligible to export beef within the following product categories: raw intact; and raw ground, comminuted, or otherwise non-intact beef.

The audit focused on six system equivalence components: Government Oversight (Organization and Administration); Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (Inspection System Operation, Product Standards and Labeling, and Humane Handling); Government Sanitation; Government Hazard Analysis and Critical Control Points (HACCP) System; Government Chemical Residues Testing Programs; and Government Microbiological Testing Programs.

The FSIS auditors identified the following findings.

Government Oversight:

- The Central Competent Authority (CCA) has not provided adequate policies and written procedures for conducting verification procedures for verifying sanitation, HACCP, and other United States food safety requirements.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations:

- The CCA in-plant inspection personnel failed to ensure that all livestock in ante-mortem pens had access to water.
- The CCA does not require appropriate documentation for failure to meet Sanitary Performance Standards (SPS) and Sanitation Standard Operating Procedures (SSOP) requirements when an establishment takes immediate corrective actions.

Government Sanitation:

- The CCA in-plant officials failed to identify, document, and enforce compliance with SPS and SSOP requirements at multiple audited establishments.

Government Microbiological Testing Programs

- The CCA does not have a process for identification and tracking of samples comprising *Salmonella* Performance Standard sets.
- The CCA procedures for confirmation of establishment Shiga-toxin producing *E. coli* (STEC) test results are not adequate to ensure chain of custody and confirm results of the same sample.

The analysis did not identify any significant findings representing an immediate threat to public health for those products that Nicaragua is currently eligible to export to the United States. During the audit exit meeting, the CCA committed to addressing the FSIS audit findings. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Nicaragua's food safety system governing meat from September 20 – October 5, 2016. The audit began with an entrance meeting held on September 20, 2016, in Managua, Nicaragua with the participation of the FSIS auditors and representatives from the Central Competent Authority (CCA), the Institute of Animal and Plant Health Protection (IPSA).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

FSIS applied a risk-based procedure, which 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) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a 3-year timeframe in addition to information obtained directly from the CCA through a self-reporting process.

Representatives from the CCA, including headquarters and local inspection office personnel, accompanied the FSIS auditors throughout the entire audit. 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 Points (HACCP) System; (5) Government Chemical Residues Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at the CCA headquarters. The FSIS auditors examined the Government Oversight of establishments performed through the CCA headquarters, and five local inspection offices, during which the FSIS auditors evaluated the implementation and effectiveness of in-place control systems that ensure the national system of inspection, verification, and enforcement is implemented and effective in meeting United States requirements.

The FSIS audit also included two government laboratories. The National Laboratory of Chemical and Biological Waste (LNRQB, *Laboratorio Nacional De Residuos Químicos Y Biológicos*), located in Managua, is the government laboratory conducting chemical residue analyses for the national residue plan. The Central Laboratory for Veterinary Diagnostics and Food Microbiology (LCDVMA, *Laboratorio Central de Diagnostico Veterinario y Microbiología de Alimentos*), located in Managua, is the government laboratory conducting

generic *Escherichia coli*, *Salmonella* Performance Standard and Shiga-toxin producing *E. coli* (STEC) analyses from certified establishments. FSIS audited both laboratories to verify their ability to provide technical support to Nicaragua's food safety system governing meat.

Nicaragua has six establishments certified as eligible to export raw beef products to the United States. Of these, FSIS audited five beef slaughter and processing establishments. During the establishment visits, the auditors paid particular attention to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety. Additionally, the auditors focused on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) § 327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	IPSA/Managua
Government Laboratories:		2	• National Laboratory of Chemical and Biological Waste/Managua • Central Veterinary Diagnostic and Food Microbiology Laboratory/Managua
Establishments: Beef Slaughter/Processing		5	• Managua District (2) • Juigalpa • Nandaime • Tipitapa

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, et seq.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Nicaragua's inspection system for meat 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 Sanitary/Phytosanitary Agreement. Currently Nicaragua does not have any individual sanitary measure equivalence determinations.

III. BACKGROUND

Nicaragua is eligible to export meat products to the United States. The establishments are currently certified as eligible to export to the United States within the following product categories: raw intact; and raw ground, comminuted, or otherwise non-intact beef.

From January 1, 2013, through December 31, 2015, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 255,028,773 pounds of raw beef products

exported directly from Nicaragua to the United States. FSIS also performed additional Type-of-Inspection (TOI) on 19,383,351 pounds at POE and Nicaragua had a total of 26 lots fail FSIS reinspection due to TOI failures. However, 8 of 26 failed due to public health TOIs and were refused entry to the United States. Six lots failed POE reinspection due to the presence of ethion, an organophosphate pesticide with no current United States tolerance.

Another lot failed due to avermectins exceeding tolerance, resulting in seven lots failing reinspection due to the failure to meet United States residue tolerance requirements. FSIS refused entry on an additional eight lots after FSIS identified a trend of products testing positive for ethion. In addition, one lot of raw intact beef failed physical exam reinspection due to the presence of zero tolerance (e.g., fecal, ingesta, or milk) contamination. The remainder of TOI failures was due to reasons other than public health including certification and labeling.

FSIS last audited Nicaragua in 2014 and reported that Nicaragua's meat inspection system remained equivalent while the audit identified findings within the HACCP system component. The FSIS auditors identified a failure to meet sanitary operations and SSOP requirements at multiple establishments. The CCA did not send any comments in response to the draft final audit report.

The FSIS final audit reports for Nicaragua's food safety system are available on the FSIS Web site at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign 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 inspection system is organized and administered by the national government of Nicaragua. There have been no major changes in the CCA's organizational structure since the last FSIS audit. At the national level, the IPSA is Nicaragua's CCA. *Law No. 862, Law Creating the Institute of Animal and Plant Health Protection (IPSA)*, dated May 20, 2014, created and designated the IPSA as the CCA for the meat inspection system. These laws and regulations are applicable to all certified establishments. The laws and regulations provide IPSA with the authority and ability to take enforcement actions as appropriate, including suspension of operations and removing eligibility for export to the United States. The CCA has the legal authority and responsibility to develop and oversee the implementation of inspection procedures in accordance with national standards, in addition to those standards imposed by importing countries.

IPSA is a government agency funded by the national government and whose revenue includes fees assessed to meat establishments as provided under the authority of *Law No. 291, Article 67,* which states fees for services are calculated based on the need to cover necessary operating expenses and expansion and modernization of the sanitary and phytosanitary services, in order to ensure effectiveness. All IPSA personnel are employees of the government of Nicaragua and subject to administrative policies that apply to all government officials.

The government bills establishments for provided services and the establishments pay the fees to the *Delegación Administrativa Financiera* (DAF), within IPSA. The DAF processes the transactions and releases funds as necessary to maintain ongoing operations of IPSA and to pay for the services provided by the laboratories. The audit verified documents demonstrating direct deposit payment by the government's *Ministerio de Hacienda Y Crédito Publico* into IPSA employee accounts. The FSIS auditors verified that IPSA personnel are government employees directly paid by the government.

The CCA has one central office that is comprised of three separate directorates, the General Directorate of Agricultural Health; the Directorate General of Agricultural Traceability; and, the Directorate General of Agrifood Safety and Laboratories (DGIAL, *Dirección General de Inocuidad Agroalimentaria y Laboratorios*). The DGIAL is organized into the Directorate of Agrifood Safety (DIA, *Dirección de Inocuidad Agroalimentaria*) and the Directorate of Laboratories. The DIA is comprised of the Department of Food Safety Surveillance (DVIA, *Departamento de Vigilancia E Inocuidad de Alimentos*), the Department of Inspection of Establishments and Agribusiness (DEIA, *Departamento de Inspección a Establecimientos y Agroindustrias*), and the Department of Registration and Certification (DRC, *Departamento de Registro y Certificación*). 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. At the central level within IPSA, the Chief Veterinary Officer (CVO) is the head of DIA and is responsible for the meat inspection system.

The DEIA includes the Meat Safety Section (i.e., *Sección de Inocuidad Carne (SIC*)) that provides delivery of services in the field and reports directly to the CVO. Management of the SIC is coordinated from the IPSA headquarters in Managua and there are no regional offices. The Manager and Assistant Manager of the SIC are responsible for oversight of the official activities of inspection personnel and for conducting supervisory visits at establishments certified eligible to export to the United States as well as official government laboratories.

- It was determined, through record review and interviews with CCA officials and in-plant inspection personnel, that the CCA has not always provided sufficient written instruction to SIC personnel for conducting verification procedures for verifying sanitation, HACCP, and other food safety requirements. As described in Component 2, the CCA places a certain reliance on FSIS issuances without highlighting specific procedures that SIC personnel should follow. The *IPSA Meat Inspection Procedure Manual* sometimes includes general instructions and frequencies but does not provide specific instructions regarding verification objectives and methods.

At the local government (establishment) level, one Official Veterinarian (OV) has the responsibility to implement and enforce inspection requirements at the certified establishment. Each official establishment also includes Auxiliary Inspectors (AIs), including veterinarians, under the supervision of the OV. The SIC in-plant personnel are responsible for carrying out all daily inspection activities. In the event of staffing shortage the OV contacts the SIC Manager who then assigns a government employee from a local establishment. All local establishment employees are direct employees of the government and receive the same training as personnel at certified establishments. Each OV reviews, stamps, and signs official daily records that document inspection activity. The FSIS auditors' reviews of these records confirm that an OV was at each audited establishment each day of the week that inspection was required.

The audit of the CCA headquarters included an examination of its oversight activities, including verification of periodic supervisory visits of certified establishments. The SIC Manager performs supervisory visits to meet 9 CFR Part 327.2 requirements once each month at every certified establishment. The FSIS auditors reviewed multiple supervisory visit reports conducted over the prior 12 months that confirmed a monthly frequency of supervisory visits at each certified establishment. The SIC Manager transmits electronically a memorandum documenting the findings resulting from each supervisory review to the OV assigned to the establishment. The OV issues the establishment a request for corrective actions where appropriate and for each identified supervisory finding documents the immediate corrective actions and measures to prevent recurrence. Once the OV has verified the findings were corrected, this report is returned to the SIC Manager.

In addition, the CCA conducts annual audits that provide an additional layer of verification beyond the periodic supervisory visit. The DRC is responsible for conducting audits to determine initial and annual approval of official establishments and those eligible for export to the United States. *Chapter III and Chapter IV of the Nicaraguan Meat Inspection Regulations* provide written requirements for application of inspection and detail the authority for the approval of authorized establishments. Approximately 3 months before annual certification each year, each establishment is required to submit documentation of their food safety programs to the DRC.

The DRC reviews each establishment's written food safety programs for compliance with Nicaraguan and the United States requirements. Following the written program review, the DRC Director and SIC Manager verifies compliance via an onsite audit. If the audit identifies noncompliance, the CCA provides written notification to the establishment and the OV assigned to the establishment verifies compliance and communicates the results back to DRC. The CCA will only certify an establishment eligible for export if they meet all requirements at the completion of this process. Following completion of this process, the CVO notifies FSIS in writing of the list of establishments certified eligible for export to the United States. The CCA has the sole authority to grant final certification of a new establishment and determine annual eligibility to export to the United States.

The FSIS auditors verified elements of the annual review process including annual audit reports of the establishments that included sanitation requirements, facility maintenance, Sanitation Standard Operating Procedures (SSOPs), HACCP programs, and microbial testing. The yearly audit reports demonstrated that the CCA evaluated the written food safety programs, audited the facilities, and evaluated their compliance with FSIS requirements before granting certification of eligibility to export meat to the United States.

The FSIS auditors verified that the CCA has implemented and conducted ongoing training programs intended to ensure that in-plant inspection personnel are aware of specific food safety and inspection requirements. The CCA conducted training sessions in 2015 including Good Manufacturing Practices; HACCP; N60 sampling; ante-mortem and post-mortem inspection; and collection of *Salmonella spp.* and residue samples. The FSIS auditors verified the training records of OVs and observed in-plant inspection personnel while they were conducting their inspection activities. Each OV is responsible for training the AIs under their supervision.

The CCA assesses the technical competence and performance of individual in-plant inspection personnel conducting official inspection activities at certified establishments. The OV evaluates AIs on a monthly basis and documents results for AIs as a whole, not individually, on form *Evaluación de Inspectores Auxiliares*. The OV documents any identified performance deficiency on the form along with corrective actions. The OV also documents an official memorandum to the individual AI that had the identified performance deficiency. The SIC Manager evaluates performance of OVs every 3 months and results are documented on form *Evaluación a Medicos Veterinarios Oficiales*. The FSIS auditors' verification of documents associated with these evaluations identified no issues of concern.

The CCA maintains adequate administrative and technical support to operate its laboratory system. The laboratories are under the immediate authority of DGIAL. Coordination and communication occur between DIA and DGIAL to develop the National Residue Plan and microbial sampling plans to ensure that IPSA meets United States requirements. The CCA includes two government laboratories that perform official chemical residue and microbiologic analyses. Since the last FSIS audit, the Nicaraguan National Accreditation Office (NAO) has received international accreditation recognition and accredited some of the methods utilized by the laboratories. Both laboratories operate in accordance with criteria aligned with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standard. In addition to the NAO accrediting audits, the CCA performs an annual audit including observation of methods.

The FSIS audit included onsite visits to both official laboratories to verify the functions and oversight provided by the CCA. The FSIS auditors reviewed the CCA, internal laboratory, and NAO audit reports generated for the previous year at CCA Headquarters and at the audited laboratories. No concerns arose as the result of these reviews.

The audit determined that the Nicaragua government organizes and administers the country's meat inspection system, and that CCA officials enforce laws and regulations governing production and export of meat at certified establishments.

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

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock, ante-mortem inspection of animals, post-mortem inspection of carcasses and parts, controls over condemned materials, controls over establishment construction, facilities, and equipment, daily inspection, and, periodic supervisory visits to official establishments.

FSIS auditors verified that the CCA maintains regulatory authority as outlined in official legislation, regulations, decrees, and policies. *Law No. 291, Basic law on Animal and Plant Health*, was amended by *Decree No. 59/03* in October 2014 to provide that IPSA, in part, regulate and facilitate sanitary and phytosanitary (SPS) activities in the production, import and export of animal products and ensure official IPSA laboratories support programs of inspection, SPS certification and verification of the quality and safety of food. The *Nicaragua Meat Inspection Regulations* (*Reglamento de Inspección Sanitaria de la Carne para Establecimientos Autorizados de la República de Nicaragua*) detail requirements for meat inspection systems in all official establishments eligible for export to the United States. The *IPSA Meat Inspection Procedure Manual* provides instructions to SIC in-plant personnel. Since the last audit, there have been no regulatory changes associated with the export of meat products to the United States that would have required changes by the CCA.

The FSIS auditors performed onsite observations, interviewed CCA personnel, and reviewed records maintained by inspection personnel at CCA headquarters and SIC inspection offices in each audited establishment. The FSIS auditors verified whether the CCA provides appropriate oversight and direction to inspection personnel for them to use their regulatory authority to enforce requirements for Nicaragua's meat food safety system. The FSIS auditors, accompanied by the CCA representatives, observed the performance of verification activities by the in-plant inspection personnel.

The verification activities observed included ante-mortem inspection; humane handling and slaughter verification; post-mortem inspection; zero-tolerance verification of establishment's procedures for controlling of feces, ingesta, and milk contamination; N60 STEC sample collection; *Salmonella* Performance Standard sample collection; analysis of establishment generic *E. coli* sample results; verification of pre-operational and operational sanitation verification procedures; and HACCP verification activities. Additionally, the FSIS auditors assessed the performance evaluation of in-plant inspection personnel and the completion of supervisory reviews of establishments certified eligible to export to the United States.

The FSIS auditors verified through direct observation, onsite record reviews, and interview that in-plant inspection personnel's ante-mortem inspection activities complied with *Nicaragua's Meat Inspection Regulations, Chapter VII.* The inspection personnel observe all animals from both sides while at rest and in motion in a designated IPSA ante-mortem inspection pen before

slaughter in order to determine whether the animals are fit for slaughter. For each inspected lot the SIC personnel document the results of ante-mortem inspection and numbers of livestock on pen cards with one copy accompanying each lot to slaughter.

Each establishment audited maintained a designated holding pen for further examination of sick or suspect animals. The OV examines any suspect livestock, identified with conditions that may preclude slaughter, and documents results on form *Inspección ante-mortem*. Additionally, the OV documents livestock condemned on either ante-mortem or post-mortem inspection on a condemnation form. The implementation of ante-mortem inspection complies with United States requirements for ante-mortem inspection of livestock.

The FSIS auditors verified through direct observation, onsite record reviews, and interviews whether the inspection system ensures United States requirements are met for livestock facilities and humane handling and slaughter. In-plant inspection personnel verify that operators comply with humane handling and humane slaughter requirements. The FSIS auditors observed the stunning process at audited establishments and verified that each establishment utilized captive bolt stunning and verified adequate stunning prior to shackling and hoisting. The SIC personnel also verify through observation the loss of consciousness and accompanying indicative signs of adequate stunning before cattle are shackled and bled.

The SIC personnel document results of humane handling and humane slaughter verification on form *Verificación De Manejo Y Sacrificio Humanitario de Los Animales. IPSA's Procedure N^{o} 14* and *Annex Procedure N^{o} 11* state that all establishments producing meat and meat products for export to the United States must meet the same requirements as United States establishments regarding humane handling and humane slaughter of livestock, including direct reference to 9 CFR 313.2(e) that animals will have access to water in all the pens. The FSIS auditors identified findings associated with lack of water in some ante-mortem pens at two separate slaughter establishments:

- At one establishment, cattle held in the ante-mortem inspection pen had no access to water and there was no structure to accommodate providing water to the cattle. Review of ante-mortem inspection records identified that SIC performed ante-mortem inspection on this specific lot 2 hours prior to the observation. At a second slaughter establishment, there were cattle present in two separate ante-mortem pens without access to water. At each facility, water was present in all other pens. Nicaragua has documented requirements that animals have access to water in all pens yet the FSIS auditors identified a lack of consistent verification because the FSIS auditors at two separate establishments identified the same finding when IPSA personnel present during, and before, the audit failed to identify the noncompliance.

The CCA has defined the number of SIC personnel required for each establishment. The FSIS auditors verified that the SIC Manager and SIC OV at each establishment were aware of the required staffing, and that the number of AIs conducting post-mortem inspection activities is sufficient for the existing production volume and line speed in all audited establishments. The staffing levels varied between establishments, but always included one OV, at least one head inspector, one viscera inspector, and one carcass inspector. Personnel was also assigned to

perform marking of all carcasses approved for food and selected verification activities such as ante-mortem inspection, collection of samples for laboratory analyses and verification procedures in the deboning rooms.

The FSIS auditors verified through direct observation the post-mortem inspection by SIC personnel to verify implementation of proper presentation, identification, examination, and disposition of carcasses and parts. The FSIS auditors observed AIs perform examination of bovine heads, viscera, and carcasses using incision, observation, and palpation of required organs and lymph nodes. IPSA post-mortem examinations are the same as, or in some cases exceed, those utilized by FSIS. For example, AIs incised the pre-scapular, tracheobronchial, and other lymph nodes of every animal.

The FSIS auditors also observed procedures and records for control of specified risk materials (SRMs). Every animal is aged using dentition, consistent with FSIS methods to identify cattle 30 months of age or older. At each audited establishment, the FSIS auditors verified sanitation controls including the use of different colored utensils and sanitation of equipment between every carcass. Following removal, establishment personnel place all SRMs into clearly labeled containers. Each establishment had written programs describing their procedures and records documenting controls. SIC personnel verify implementation of establishment programs to ensure proper identification, removal, and disposition of SRMs to ensure the CCA precludes their export to the United States. The FSIS auditors did not identify any concerns.

The FSIS auditors observed the off-line AIs conduct daily inspection and verification activities in all five audited establishments. The standard SIC verification procedures and instructions are documented in the IPSA Meat Inspection Procedure Manual, including reference to specific FSIS policies by name only. The IPSA Meat Inspection Procedure Manual lacks specific instructions for verification of United States requirements.

The verification activities include direct observation and record review procedures related to SSOP, Sanitation Performance Standards (SPS), HACCP, N60 STEC sampling, residue sampling, and *Salmonella ssp.* sampling. The CCA has not developed specific verification schedules but each OV ensures that inspection personnel perform procedures at the frequency identified on each verification form.

At each audited establishment, the FSIS auditors observed the sanitary dressing processes to verify implementation of practices that maximize the prevention of contamination during hide and viscera removal. The FSIS auditors also observed in-plant inspection personnel conduct verification of monitoring of the critical control point (CCP) for zero-tolerance of feces, ingesta, and milk contamination and reviewed documented inspection verification results. The FSIS auditors did not observe any sanitary dressing concerns or zero tolerance deviations during the audit.

The FSIS onsite audit verified through direct observation, record review, and interviews the separation of product eligible for export to the United States from product not meeting requirements. In-plant inspection personnel verify that operators comply with the requirement for separation of product destined for the United States. The OV may allow diversion of

products ineligible for export to the United States to local sale. The Nicaragua regulations require products eligible for local sale to be marked "Local" and the OV certifies all local sale products on document *Certificado a Venta Local*. In-plant personnel verify requirements for separation of products and document results on *Inspección a Las Area de Venta Local y Bodega de Venta Local*. The FSIS auditors verified use of product codes with designated codes for export to the United States and segregation of final boxed product. The FSIS auditors verified that some establishments had written programs to define separation of products destined for export to the United States.

The 2016 FSIS audit identified some repetitive findings from the 2014 FSIS audit including the following:

- The IPSA requirements and policies do not require SIC personnel in certified establishments to document each establishment failure to meet requirements if the establishment, upon notification from the OV, immediately corrects the finding. For example, review of official verification records showed that areas and surfaces identified during pre-operational sanitation inspection as insanitary are documented in the records as acceptable if immediate corrective actions were implemented. Nicaragua's regulations, *Article 42*, states that walls, ceilings and overheads shall be free of moisture to prevent dripping and product contamination yet the FSIS audits in 2014 and 2016 identified findings associated with dripping condensation directly over or involving product.

  The failure to document noncompliance results in an inability to identify trends of noncompliance within establishments as well as throughout the system. There is no mechanism to ensure that each establishment implements corrective actions based on root cause and implement measures to prevent recurrence. Furthermore, lack of documentation precludes management oversight and the ability to implement changes in response to data analysis.

- In one establishment, the inspection personnel did not take adequate official regulatory control action when the FSIS auditors identified insanitary conditions, dripping condensation over the carcass rail at the entry to the deboning room, during production. The OV observed an establishment employee use a mop to remove condensation without first moving carcasses immediately beneath the area with dripping condensation. Further, the OV concluded the establishment's actions were adequate and proceeded to leave the area despite the fact that dripping condensation remained and that carcasses were still on the rail immediately below the dripping. The SIC Manager was also present at the time and failed to step in or give any indication that the establishment or OV actions were inadequate.

The FSIS auditors identified that the CCA has inadequate verification procedures to ensure United States requirements are met. In addition, the CCA has not consistently ensured official regulatory control actions sufficient to prevent products from contamination are implemented when insanitary conditions or practices are present.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide requirements for general sanitation, sanitary handling of products, and development and implementation of SSOP.

The FSIS auditors reviewed the legislation, regulations, official instructions, decrees, and guidelines of the CCA and verified that the IPSA uses its legal authority in the *Basic Law on Animal and Plant Health* to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. The *Nicaragua Meat Inspection Regulations, Chapter VII, Establishments: Sanitary Conditions; General Requirements,* largely mirror 9 CFR Part 416.1 through 416.6 requirements for Sanitation Performance Standards. The *IPSA Manual of Procedures, Procedure N^{o} 17, Verification of SSOP and HACCP*, states that the purpose of verification is to ensure national requirements and 9 CFR Part 416 and Part 417 are met.

The CCA demonstrated that it enforces these requirements at certified establishments conducting verification of sanitary conditions in accordance with the aforementioned documents, including the evaluation of written sanitation programs, verification of both pre-operational and operational sanitation implementation and monitoring of sanitation procedures including hands-on verification inspection, and records review. The FSIS auditors verified that the verification frequency of most SPS requirements is 3 times daily except verification of pest and rodent control that is twice weekly. The SIC personnel conduct verification of operational SSOP requirements three times daily and verify pre-operational sanitation daily. In addition, once a month the OV evaluates the establishment's written SSOP program and records to verify compliance.

The FSIS auditors assessed the adequacy of pre-operational sanitation by observing SIC personnel conducting pre-operational verification of the establishment's sanitation program at two of the audited establishments. The in-plant inspection personnel conducted this activity in accordance with the established procedures at least once daily including a pre-operational record review of the establishment monitoring results and an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils; as well as an assessment of sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity).

In addition, the FSIS auditors observed SIC in-plant inspection personnel's verification of operational sanitation procedures in all five audited establishments, comparing the overall sanitary conditions of all audited establishments to the SIC inspection verification documentation. The FSIS auditors' verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records over a 3-month period at all establishments. The FSIS auditors also examined the SIC documentation of inspection verification results documented on *SIC Verification SSOP Pre-operational, Verification SSOP,* and *SIC Demand for Corrective Actions* records. The FSIS auditors noted that the inspection and establishment records do not necessarily reflect the actual sanitary conditions of the establishment.

The FSIS auditors identified SPS and SSOP findings at several audited establishments reflective of the CCA's ability to identify insanitary conditions and exercise appropriate regulatory control to ensure sanitary conditions and operations. Furthermore, as noted earlier in the report SIC personnel do not document each failure to meet regulatory requirements if they determine that the establishment immediately corrected the finding. The 2014 FSIS audit identified condensation at multiple establishments resulting in direct product contamination. This FSIS audit identified similar findings associated with condensation, including one establishment with similar findings in 2014. The FSIS auditors reviewed the SIC and establishment records and identified multiple instances of undocumented noncompliance as described in the following deficiencies:

- In one establishment, the FSIS auditors identified extensive rusted overhead rails covered with grease throughout the carcass coolers, transfer hallways, and slaughter floor and rail switch locations with thick smears of black, discolored grease in large accumulations. In one establishment, leaks at joints of water supply lines in the carcass coolers resulted in slow drips from insanitary surfaces directly over carcasses.
- In two establishments, beaded, dripping condensation involved the overhead structures and ceiling. The findings included multiple carcass coolers in two establishments and the entry to the deboning room, red viscera room, and one freezer at one establishment. In one establishment, the FSIS auditors identified a very strong odor of paint in one carcass cooler used for carcass chilling. According to the OV, the establishment painted the cooler the previous week and the OV approved its use despite the strong odor, with distinct potential to taint carcasses.
- In one establishment, bovine heads that had received post-mortem inspection and on a head rail destined for processing were observed to have edible product directly contact and drag across an insanitary air line fixture that was not a contact surface. Multiple SIC personnel were present and failed to identify direct product contamination or take any corrective action.
- In one establishment, the faceplate of the zero tolerance stand in the slaughter room had trimmings accumulated over the inner and outer surfaces of the faceplate so that subsequent carcasses were in contact with these potentially adulterated trimmings.
- In one establishment, the front shanks of a carcass were observed to contact and drag across a condemned/inedible gondola resulting in direct product contamination.

These findings included inspection personnel failing to identify inadequate ventilation (condensation, odors), facility maintenance (dripping water, grease, rusty rails), and insanitary operational conditions (head chain, inspection stand, inedible gondola) resulting in actual or potential product contamination. The CCA provided the FSIS auditors with immediate corrective actions taken by the establishments and will verify implementation of those actions to ensure compliance with United States requirements. However, the CCA did not always take adequate official regulatory control actions sufficient to ensure sanitary conditions were restored and product was protected from contamination.

The FSIS auditors' analysis and onsite verification activities indicate that the CCA requires operators of certified establishments to develop, implement, and maintain sanitation programs, including SSOPs.

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

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP Systems. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP plan.

The CCA requires establishments exporting to the United States develop, implement, and maintain HACCP programs. As previously, described, the DRC within DIA performs annual review and approval of all establishment HACCP plans. The *IPSA Manual of Procedures, Procedure N^{o} 17, Verification of SSOP and HACCP*, states that the purpose of verification is to ensure national requirements and 9 CFR Part 416 and Part 417 are met. IPSA requires that each establishment implement zero tolerance, antimicrobial, and carcass chilling CCPs.

At the five slaughter and processing establishments audited, the FSIS auditors conducted an onsite review of establishment HACCP hazard analyses, HACCP plans, and CCP records. The FSIS auditors observed the SIC personnel conducting HACCP hands-on verification activities at each audited establishment. In addition, the FSIS auditors reviewed the in-plant inspection HACCP verification records associated with CCPs documented on the *Verification HACCP* records. The review of the establishments' corrective actions in response to a few deviations from critical limits establishment corrective actions were adequately documented and verified by SIC personnel as meeting all HACCP corrective action requirements in 9 CFR 417.3(a). For each corrective action, SIC personnel also documented the elements of the corrective action and SIC verification results on the *Verification HACCP* form.

The FSIS auditors' review of documents pertaining to the hazard analysis, HACCP plan, monitoring, verification, and corrective actions implementation by establishments as well as onsite observation of the inspection personnel conducting inspection tasks and associated inspection verification records, revealed an adequate HACCP food safety system in the audited establishments.

The FSIS auditors' analysis and onsite verification activities indicate that the CCA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs for each processing category.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUES TESTING PROGRAMS

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

FSIS based its verification of Nicaragua's chemical residue testing program on information contained in Nicaragua's Annual Residue Control Plan (2016), in association with the previous two year's (2014 and 2015) testing results. *Nicaragua Law N^{o} 291* and related Regulations provide the legal basis for the annual residue plan. Nicaragua's *Law No. 274, Basic Law for the Regulation and Control of Pesticides, Toxic, Dangerous and Other Similar Substances,* prescribes conditions of chemicals used in the production of meat, including animal feed; provides authority to prohibit the use of compounds that may present public health risks; and, provides the ability to control and monitor industrial and environmental chemicals. Following repetitive FSIS POE violations involving ethion in beef, IPSA's *Administrative Resolution N^{o} 018-2015* cancelled the manufacture, import, registration, endorsement, marketing, and use of veterinary products containing ethion. These documents indicate that IPSA maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The Office of Control and Registry of Veterinary Products within DIA has responsibility for approval of veterinary drugs. The Office for the Control and Regulation of Pesticides and Toxic Substances within the Directorate of Plant Protection and Seed (*Dirección de Sanidad Vegetal y Semilla*) has responsibility for licensing the distributors of pesticides. The DIA is responsible for collection of meat samples for residue analyses, verifies establishments' food safety programs, and has the authority to enforce maximum residue limits in meat. The LNRQB conducts residue analyses. Lastly, the *Departamento de Vigilancia e Inocuidad de Alimentos* (DVIA) in DIA conducts regulatory follow-up investigations of confirmed residue violations. Development of the annual residue plan is a collaborative effort between DIA, DGIAL, and the LNRQB Director.

Within IPSA the DIA CVO maintains oversight of the LNRQB through an annual audit of the residue laboratory conducted by the SIC Manager. The FSIS auditors reviewed the most recent CCA audit report for the residue laboratory as documented on *Auditoria Para Laboratorios Oficiales y Autorizados* conducted on July 23, 2016. The scope of the audits conducted by the CVO included administrative and technical controls of the laboratory that analyze samples from certified establishments.

The FSIS auditors verified implementation of the national residue plan at the audited establishments. The *IPSA Manual of Procedures, Procedure N^{o} 1,* provides instructions to SIC personnel collecting samples for residue analyses, including a scheduled sampling plan. The plan lists the residue group, frequency of sampling, and number and day(s) of sampling each month. The individual OVs randomly select the carcass to sample. The SIC personnel complete the laboratory submission form, *Remisión de Muestras al Laboratorio,* and a copy is packaged in the sample shipment cooler which SIC secures with a numbered seal to maintain integrity. The CCA's prescribed sampling protocol mandates test and hold practices to ensure that SIC verifies acceptable residue results prior to issuing certification for export to the United States. The FSIS auditors verified official records documenting condemnation of sampled lots that IPSA identified with violative levels of doramectin. In the event any sampled lot has violative levels of a chemical compound, the OV also issues a nonconformity report, (*Reporte de No Conformidad)* to the establishment.

In addition, the FSIS auditors verified implementation of Nicaragua's corrective actions in response to repetitive FSIS POE residue violations associated with detection of ethion in 2015 and early 2016. At the certified establishment that exported products containing ethion to the United States, the FSIS auditors verified implementation of corrective actions. In 2016, IPSA has identified detectable ethion and each case the entire production lots were condemned and destroyed. As noted, Nicaragua has banned the use of ethion and they continue to perform onsite investigations to ensure removal of ethion from use. FSIS has not identified POE violations attributed to ethion since early 2016.

The FSIS auditors also performed an onsite audit of the IPSA official LNRQB residue laboratory. The FSIS auditors verified the NAO scope of accreditation, equivalent to ISO/IEC 17025, for the LNRQB is currently for avermectins and heavy metals including lead and cadmium. The laboratory is validating methods for hormones, benzimidazoles, and pesticides and, once complete, the laboratory intends to expand their scope of accreditation. The LNRQB has also participated in FAPAS® proficiency tests for avermectins in bovine liver and implemented changes to improve performance. The most recent accrediting body audit was by NAO on September 20, 2016, and the laboratory was still developing an action plan for submission to NAO. The laboratory performs internal audits and implements an annual audit plan. The LNRQB develops an action plan to address each internal audit finding and improve the laboratory. Associated with the action plan is the *Registros De Acciones Correctivas 2016*, which the FSIS auditors verified included individual corrective actions for each finding including verification signatures and dates from the laboratory personnel responsible for implementation.

The FSIS auditors verified receipt of samples in the LNRQB. At sample receipt, the laboratory verifies the seal is intact and matches the number on the laboratory submission form. The laboratory verifies and documents the temperature of the sample and, once verification confirms sample integrity, the laboratory assigns a unique laboratory sample number. LNRQB rejects the sample if requirements are not met or sample integrity is not maintained. The laboratory sample number alone accompanies the sample through the analytical process to eliminate any potential bias during the analytical process.

The LNRQB reports results on an official form to the OV at the establishment. In the event a sample exceeds tolerances, the LNRQB notifies the CVO and OV via electronic mail. The CVO communicates with the DVIA who initiates an investigation of the supplier. In addition, IPSA intensifies sampling by implementing sampling of the next five lots from the same supplier.

The FSIS auditors verified that IPSA has implemented the national residue plan in accordance with *Nicaragua's Basic Law on Animal and Plant Health*. The program contains provisions that ensure any product with residues exceeding established tolerances is condemned and ineligible for use as human food. In addition, to prevent the violations from recurring, the cause of the residue violation is investigated by the DVIA via site visits to suppliers, and intensified sampling from the same supplier is initiated. IPSA provides written notification to source suppliers.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

The FSIS audit included direct observation, record review, and interviews of IPSA personnel to verify microbial process control. Nicaragua has adopted "same as" United States requirements found in 9 CFR 310.25(a) for generic *E. coli.* The CCA conducts verification activities that verify written generic *E. coli* testing programs meet requirements including the location of sampling, randomness of sampling, and sample integrity. The SIC personnel also verify establishment sampling methodology through direct observation and securely submit each sample to the LCDVMA official laboratory for analysis. The CCA uses the test results to verify establishment slaughter dressing controls for fecal contamination. Furthermore, the in-plant inspectors verify that each establishment documents and correctly evaluates test results, and takes appropriate corrective actions if the upper control limits are exceeded.

The FSIS auditors verified through document reviews and direct observation that the five audited slaughter establishments had implemented a generic *E. coli* testing program to verify process control of livestock carcasses in accordance with 9 CFR 310.25(a). The FSIS auditors also reviewed testing results for the last year showing that the establishments routinely met their limits, and that there has not been any identified loss of process control. The FSIS auditors' review of the establishments' generic *E.coli* testing programs and of the establishments' records did not reveal any noncompliance or concerns. The testing program complies with FSIS's equivalence criteria.

The CCA has a *Salmonella spp.* sampling and testing program in raw product that mirrors FSIS's *Salmonella* Performance Standards requirements in 9 CFR 310.25(b). The FSIS auditors reviewed implementation of the program within certified establishments along with results and records documenting performance standards. Sampling and testing of carcasses for *Salmonella spp.* occurs in all certified establishments that slaughter livestock. In-plant inspection personnel collect sponge samples from chilled bovine carcasses without prior notice to the establishments. The SIC personnel submit all samples to the official LCDVMA microbiology laboratory for analysis for presence of *Salmonella spp*. The CCA utilizes 9 CFR 310.25(b), Table 2, regulatory requirements to evaluate *Salmonella* Performance Standards.

The FSIS auditors reviewed records, including *Salmonella spp.* results, at the five slaughter establishments audited. In addition, the FSIS auditors accompanied and observed the in-plant inspection verification activities for sponge sampling collection from bovine carcasses for *Salmonella* testing in one of the audited establishments. The demonstrated methodology is consistent with FSIS's method.

The FSIS auditors identified several findings associated with oversight and implementation of *Salmonella* Performance Standards.

- The CCA's implemented procedures do not include a procedure for documenting the samples comprising a *Salmonella* performance standard set. In one establishment, there were two positive *Salmonella spp.* results within the prior 3 months but the CCA could not identify the beginning or ending of the set to determine whether a set passes or fails using 9 CFR 310.25(b) Table 2. Results are retained in the SIC office of each certified establishment. There is no process for data review or compilation and management control oversight of *Salmonella* Performance Standard results at the headquarters level. The CCA cannot compile data across the system to evaluate the performance standards and consider tightening of standards when warranted. Further, without management oversight of performance standards there is no mechanism to ensure appropriate actions, including triggering of additional sets and verification of establishment corrective actions, are implemented.

The CCA provides a sampling and testing program for the seven STEC adulterants (026, 045, 0103, 0111, 0121, 0145, and O157) and has established a zero tolerance policy for STEC in raw beef exported to the United States. The CCA's *Notice No. 08 SIC-1* describes the requirements and inspection procedures for control of STEC, including verification sampling. The analytical methods used to analyze samples are those deemed equivalent by FSIS. FSIS has previously evaluated the STEC program and determined it to be equivalent. The sampling program includes daily samples for establishment laboratory analysis and weekly samples for official laboratory analysis.

Establishment laboratories are required to use methodology approved by the CCA. The CCA approves, and LCDVMA personnel perform annual audits, of establishment laboratories. The establishment is responsible for reporting results to SIC personnel.

The in-plant SIC AIs perform the N60 sample collection for both establishment and official government sampling programs. The AI collects establishment verification samples daily from every sub-lot of boneless beef. The FSIS auditors observed the N60 sampling stations and N60 sampling. Methods are consistent with FSIS excision methodology except that the inspector obtains two samples from each piece of meat with one destined for analysis in the establishment laboratory while the "contra" sample is retained under the control of SIC personnel. In the event of a positive STEC screen test, the SIC OV reportedly submits the establishment enriched sample along with the "contra" sample to the official LCDVMA laboratory for confirmatory analysis.

- Submitting establishment laboratory enriched samples for confirmation by the CCA laboratory is inadequate to ensure sample security and integrity because the samples were outside the control of official government personnel. In addition, the use of "contra" samples for confirmatory analysis may misrepresent the true status of the product sampled due to small numbers of pathogens present and unequal distribution of pathogens.

The FSIS auditors performed an onsite audit of the LCDVMA laboratory in Managua, the government microbiological laboratory. The laboratory performs inspection system analyses for

water supplies (microbiologic and chemical), generic *E. coli*, *Salmonella spp*., and STEC. For food microbiology, the laboratory charges fees for service in accordance with *Ministerial Decree 00-6-2012*. The FSIS auditors verified that NAO has accredited the laboratory as meeting Norma Técnica Nicaragüense (NTN) 04 001-05 requirements, equivalent to ISO/IEC 17025 criteria, for calibration and five microbiologic analyses. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support IPSA's inspection program for certified establishments eligible to export to the United States.

NAO, the accrediting authority, audits the LCDVMA laboratory annually. Each NAO audit is partial so that it takes 4 years to complete an audit of the entire laboratory system. The FSIS auditors reviewed the most recent audit report, *FOR-ONA-03.007*, performed by the accrediting authority. The laboratory also performs internal audits according to their Quality Manual. Additionally, the SIC Manager and Assistant Manager audit the lab annually to verify United States equivalent methods used for samples from certified establishments as well as administrative and technical controls. During the CCA headquarters audit the FSIS auditors reviewed the last annual audit report of the laboratory. There were no findings from the document review.

The laboratory methods for STEC analysis include the Assurance GDS® MPX Top 7 STEC for screening, FSIS Microbiology Laboratory Guidebook (MLG) 5.B.05 for non-O157 confirmation and FSIS MLG 5.09 for *E. coli* O157:H7 confirmation. The LCDVMA's *Salmonella spp.* analytical method is based on the FSIS MLG 4.05 method and is one of the methods accredited by NAO. Generic *E. coli* are analyzed using 3M™ Petrifilm™. The laboratory has procedures for proficiency testing.

In addition, the FSIS auditors observed and verified sample receipt and handling. The FSIS auditors verified that the laboratories do a timely analysis of samples, and that they report data to the CCA in a timely manner, apply approved analytical methodologies, and have quality assurance programs. No concerns arose because of these observations and reviews. The FSIS auditors verified that DIA auditors conduct the prescribed annual audit of the laboratory quality system to ensure United States requirements are met.

Nicaragua's meat inspection system includes requirements for a microbiological sampling and testing program that is organized and administered by the national government in accordance with FSIS's equivalence criteria.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on October 5, 2016, in Managua, Nicaragua with IPSA. At this meeting, the FSIS auditors presented the preliminary findings from the audit. The CCA accepted the findings.

The FSIS auditors identified the following findings.

Government Oversight:

- The CCA has not provided adequate policies and written procedures for conducting verification procedures for verifying sanitation, HACCP, and other United States food safety requirements.

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations:

- The CCA in-plant inspection personnel failed to ensure that all livestock in ante-mortem pens had access to water.
- The CCA does not require appropriate documentation for failure to meet SPS and SSOP requirements when an establishment takes immediate corrective actions.

Government Sanitation:

- The CCA in-plant officials failed to identify, document, and enforce compliance with SPS and SSOP requirements at multiple audited establishments.

Government Microbiological Testing Programs

- The CCA does not have a process for identification and tracking of samples comprising *Salmonella* Performance Standard sets.
- The CCA procedures for confirmation of establishment STEC test results are not adequate to ensure chain of custody and confirm results of the same sample.

The analysis did not identify any significant findings representing an immediate threat to public health for those products that Nicaragua is currently eligible to export to the United States. During the audit exit meeting, the CCA committed to addressing the FSIS audit findings. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Ganaderia Integral Nicaragua, S.A (GINSA) Km 34.5 carretera vieja a león (Highway 12), Managua, Nicaragua	09/28/2016	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 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	O
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.	X	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. Enforcement	X
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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment: Ganaderia Integral Nicaragua, S.A (GINSA), Est. 1, Slaughter/Processing, 09/28/2016

10/51 SSOP Implementation

Bovine heads that had received post-mortem inspection and on a head rail destined for processing were observed to have edible product directly contact an air line fixture that was insanitary and not a contact surface. This resulted in direct contamination of product. Immediate corrective actions were implemented including repositioning the equipment to provide adequate clearance for inspected and passed heads. The official veterinarian failed to identify this deficiency.
[Regulatory Reference: 416.13(c)]

61. NAME OF AUDITOR	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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
NOVATERRA S.A Km. 42 carretera Norte via a Matagalpa Tipitapa, Nicaragua	09/27/2016	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.	X
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	O
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	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	X
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment: NOVATERRA S.A, Est. 2, Slaughter/Processing, 09/27/2016

41, 46/ 51 Ventilation; Sanitary Operations

There was beaded, dripping condensation involving the overheads and ceiling in two carcass coolers, the entry to the deboning room, and in the red viscera room. The condensation and drips were not observed to directly contaminate carcasses but due to extent there was high probability carcasses were affected. The official veterinarian failed to identify these deficiencies and failed to effectively verify immediate corrective actions. Subsequent corrective actions were initiated to retain all affected carcasses for trimming, application of lactic acid, and performance of microbiologic sampling.
[Regulatory Reference: 416.1, 416.2(d), and 416.2(e)]

39/51 Establishment Construction and Maintenance

There were extensively rusted overhead rails throughout the carcass coolers, transfer hallways, and slaughter floor. Additionally, rails had a thick smear of grease applied which was discolored black and accumulating in globs at rail switch locations. The rust and grease on the overhead rails resulted in insanitary conditions with potential to directly contaminate products. The official veterinarian failed to identify these deficiencies.
[Regulatory Reference: 416.2(b)]

10/51 SSOP Implementation

The faceplate to the zero tolerance stand in the slaughter room had trimming accumulated over the inner and outer surfaces of the faceplate so that subsequent carcasses were in contact with these potentially adulterated trimmings. In addition, immediately below the stand was a vestibule with a condemned/inedible gondola with accumulated trimmed product and blood on the surface that the front shanks of a carcass were observed to contact and drag across the gondola. This resulted in direct contamination of product. The official veterinarian failed to identify this deficiency.
[Regulatory Reference: 416.13(c)]

52/51 Humane Handling

There were cattle present in two separate ante-mortem pens without access to water. The official veterinarian failed to identify this deficiency. Immediate corrective actions were implemented.
[Regulatory Reference: 313.2(e)]

22/51 HACCP Recordkeeping (Corrective Actions)

The establishment's HACCP corrective actions records for the zero tolerance (fecal, ingesta, milk) CCP, implemented in response to deviation from a critical limit, failed to document or identify product identity such as carcass numbers or slaughter production lot. Therefore, there was no means for associating the corrective action record with the affected product. The official veterinarian failed to identify this deficiency.
[Regulatory Reference: 417.3(c), 417.5(a)(3)]

61. NAME OF AUDITOR	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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, Nandaime, Granada, Nicaragua	09/26/2016	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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	O
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	X
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	X
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. Enforcement	X
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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment: Industrial Comercial San Martin S.A., Est. 4, Slaughter/Processing, 09/26/2016

41, 46/ 51 Ventilation; Sanitary Operations

1. There was condensation involving the overheads and ceiling in two carcass coolers and one freezer. Additionally, there were leaks involving some of the PVC joints in the carcass coolers resulting in slow drips. The condensation and drips were not observed to directly contaminate carcasses but due to multiple locations there was high probability carcasses were affected. The official veterinarian failed to identify these deficiencies. Immediate corrective actions were initiated to retain all affected carcasses for trimming, application of lactic acid, and performance of microbiologic sampling.
[Regulatory Reference: 416.1, 416.2(d), and 416.2(e)]

2. One carcass cooler was noted to have a very strong odor of paint upon entry and the cooler was being used for carcass chilling. The official veterinarian and plant management stated the cooler had been painted the previous week. Inadequate time and insufficient ventilation resulted in strong odors with the potential to impact the exposed carcasses.
[Regulatory Reference: 416.1, 416.2(d)]

46/51 Sanitary Operations (Separation of Product)

One carcass marked "Local Sale" due to failure to meet United States requirements was observed on the rail in the carcass cooler adjacent to a carcass eligible for export to the United States. The establishment lacked a written program adequate to ensure separation of United States-eligible product from that destined for the local market.
[Regulatory Reference: 416.4(d)]

61. NAME OF AUDITOR	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	

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. 10.5 Carretera Norte 1,000 metros al lago Managua, Nicaragua	09/22/2016	5	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	O
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.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment: Nuevo Carnic, S.A., Est. 5, Slaughter/Processing, 09/22/2016

22/51 HACCP Verification

Calibration of process monitoring instruments (thermometers), records do not include all results. Establishment is only documenting results for thermometers requiring adjustment. A review of official records and interviews of CCA personnel revealed that the CCA had not identified this deficiency.
[Regulatory Reference: 9 CFR 417.5(a)(3) and 417.8]

61. NAME OF AUDITOR	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	Enter Date Here

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. Km 130 Carretera Juigalpa-Rama Juigalpa, Nicaragua	09/23/2016	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	O
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	X
19. Verification and validation of HACCP plan.	X	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. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	X
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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment: Matadero Central, S.A., Est. 8, Slaughter/Processing, 09/23/2016

46/51 Sanitary Operations

The slaughter floor split saw sterilizer water tank had the flow turned off precluding a constant flow of fresh water and resulting in water that was opaque and greenish-tan in color. The official veterinarian failed to identify this deficiency until it was pointed out by the FSIS auditors. Immediate corrective actions were implemented by the establishment to include opening the flow-through valve and turning over the water in the sterilizer.
[Regulatory Reference: 416.1]

19/51 HACCP Verification

The establishment employees were using hand-held spray nozzles to apply lactic acid to each carcass at Critical Control Point 2 (CCP 2). One employee was shorter and repeated observations consistently identified the failure to apply acid to the upper eight (8) to ten (10) inches of each rear leg. Additionally, review of the establishment's written HACCP plan identified that lactic acid was to be applied to all surfaces of the carcass. The establishment took immediate corrective actions by providing two-step stands for the employees responsible for application of lactic acid. The official veterinarian and other CCA personnel failed to identify this deficiency during observations on the slaughter floor and review of establishment and government verification records identified that the CCA failed to identify the failure to properly implement the antimicrobial intervention at CCP 2.
[Regulatory Reference: 417.2(c)(4), 417.4(a)(2)(ii) and 417.8]

52/51 Humane Handling

The ante-mortem inspection pen was being used to hold cattle and there was no access to water in the pen. Review of ante-mortem inspection records identified that ante-mortem inspection on this specific lot was performed approximately two hours prior to the observation. The official veterinarian failed to identify this deficiency.
[Regulatory Reference: 313.2(e)]

61. NAME OF AUDITOR	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	

Appendix B: Foreign Country Response to Draft Final Audit Report

[Image: United, Nicaragua succeeds!]

Government of Reconciliation and National Unity
The people are the president!

2017
Times of victories!
By the grace of God

Managua, January 17, 2017
DIA/CLW/0040/01/17

Mrs. Jane H. Doherty
Office of International Coordination
Food Safety and Inspection Service
United States Department of Agriculture
Washington, District of Columbia
FSIS-USDA
Your communiqué -

Dear Mrs. Doherty:

Greetings.

I wish to hereby submit to you the corrective actions and preventive measures adopted by Nicaragua regarding the findings from the audit conducted by the Food Safety and Inspection Service (FSIS) during the period from September 20, 2016, through October 5, 2016, on the meat inspection system under the Administration of the Institute of Agricultural Health and Safety (Instituto de Protección y Sanidades Agropecuarias, IPSA).

Reports attached.

There being nothing further.

Sincerely,

[Signature]
[Seal: Institute of Agricultural Health and Safety / Department of Food Safety and Plant and Animal Health / Division of Food Safety, Plant and Animal Health and Laboratories (DGAL) / DIA Director / Republic of Nicaragua/ Central America]

Dr. César Lacayo Whitford
Food Safety Director
DIA-IPSA

CC:	Mr. Ricardo Somarriba	-	IPSA Trustee
	Dr. Martha Hernandez	-	DIEA Representative
	Dr. Henry Pérez Leiva	-	Meat Inspection Service Representative
	File/PM	-	

Faith, Family and Community!
CHRISTIAN, SOCIALIST, UNITED!
INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY
Department of Food Safety and Plant and Animal Health DGIAL-DIA-IPSA
Bolonia, Antiguo Banco Aval Card, across from the SUMEDICO Hospital
Email: inocuidad.agroalimentaria@ipsa.gob.ni Tel.: (505)22981330 ext 178

[Image: United, Nicaragua succeeds!]	Government of Reconciliation and National Unity The people are the president!	2017 Times of victories! By the grace of God

INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY

IPSA

Report on the Corrective Actions and Preventive Measures by the Central Competent Authority (CCA) and the Meat Processing Establishments in the Republic of Nicaragua, in response to the Noncompliance Report specified in the FSIS-USDA Audit, conducted from September 20, 2016 through October 5, 2016.

DEPARTMENT OF FOOD SAFETY AND PLANT AND ANIMAL HEALTH

DIA

JANUARY 2017

Faith, Family and Community!	CHRISTIAN, SOCIALIST, UNITED! INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY Department of Food Safety and Plant and Animal Health DGIAL-DIA-IPSA Bolonia, Antiguo Banco Aval Card, across from the SUMEDICO Hospital Email: inocuidad.agroalimentaria@ipsa.gob.ni Tel.: (505)22981330 ext 178

[Image: United, Nicaragua succeeds!]	Government of Reconciliation and National Unity The people are the president!	2017 Times of victories! By the grace of God

CONTENTS OF THE REPORT

Faith, Family and Community!	CHRISTIAN, SOCIALIST, UNITED! INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY Department of Food Safety and Plant and Animal Health DGIAL-DIA-IPSA Bolonia, Antiguo Banco Aval Card, across from the SUMEDICO Hospital Email: inocuidad.agroalimentaria@ipsa.gob.ni Tel.: (505)22704121 ext 178

I. EXECUTIVE SUMMARY

Faith, Family and Community!

CHRISTIAN, SOCIALIST, UNITED!
INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY
Department of Food Safety and Plant and Animal Health DGIAL-DIA-IPSA
Bolonia, Antiguo Banco Aval Card, across from the SUMEDICO Hospital
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I. Executive summary

This report describes in detail the corrective actions implemented in chronological order in response to the noncompliance issues identified by **FSIS/USDA** auditors upon the meat inspection service of the Republic of Nicaragua (Central Competent Authority, CCA) and the authorized Meat Processing Establishments —**Ganadería Integral, S.A. (GINSA, Est. #1); NOVATERRA (Est. #2); Industrial Comercial San Martin, S.A. (Est. #4); NUEVO CARNIC (Est. #5); and Matadero Central, S.A. (MACESA, Est. #8)**— during the period of *September 20, 2016, through October 5, 2016.*

Below is an outline of the structure of this report based on the six equivalence components for systems:

1. Action plan implemented by the Central Competent Authority (CCA) with the respective date of implementation.

2. Corrective actions taken by the five meat processing establishments authorized for export to the United States. I am attaching written documentation and photographs of the execution and verification of the implementation at the establishments by the Official Veterinarian assigned to each one of the establishments.

3. Documentation of communication via *Memorandum* issued by the Central Competent Authority (CCA) to the Official Veterinarians assigned to each one of the authorized meat processing establishments, which were audited in the Republic of Nicaragua, is submitted in the annexes.

II. ACTION PLAN IN RESPONSE TO THE FINDINGS DISCOVERED DURING THE FSIS-USDA AUDIT IN NICARAGUA

II. Action plan in response to the findings discovered during the FSIS-USDA audit in Nicaragua from September 20 to October 5, 2016.			
Deficiency observed/finding	Actions implemented	Date of implementation	Comments
The CCA is not assessing the requirements of the U.S. or policy documents to determine whether relevant changes, if any, are needed in the inspection system, and no corresponding instructions are given to IPSA personnel. FSIS policies that are applied at each establishment vary and do not necessarily reflect the most current U.S. requirements.	IPSA's CCA has notified the Official Veterinarians of the most current versions of the directives, notices, and notifications of the FSIS-USDA, and they have been adopted within the standards and legislation applied to IPSA's Inspection System.	October 7, 2016	The updated directives, notices, and news of the FSIS-USDA were translated into Spanish and sent to the Official Veterinarian of each establishment for their proper implementation. CCA personnel are continuously monitoring for any changes or modifications to FSIS directives to keep the Official Veterinarians of the establishments that export to the United States updated. (See Annex No. 1.)

The CCA does not have a process for the identification and tracking of samples that contain sets of Performance Standards for *Salmonella*.	At the meat processing establishments approved for export to the United States of North America, at the beginning of each year, a set or group of analyses are conducted, beginning with analysis number 1 and ending with 58 analyses, which correspond to a set or cycle. At each establishment, *Salmonella spp* standards are conducted per year. The acceptance level for positive results is ≤ 2. As of October 7, 2016, the *Salmonella spp.* set or standards are sent to the CCA and Official Central laboratory of IPSA.	As of October 7, 2016, the *Salmonella spp.* set or standards were sent to the CCA and Official Laboratory.	In the samples of *Salmonella spp.* submitted, the sample number corresponding to the set in effect is placed. (See attached the *Salmonella spp.* sets of one of the audited establishments as an example, and the official communication sent to official inspectors at each one of the establishments.) (See Annex No. 2.)

The central competent authority (CCA) does not require appropriate documentation for noncompliance with the requirements of the Sanitation Performance Standards (SPS) and Standard Operating Procedures (SSOP) when an establishment takes immediate corrective measures.	As of October 8, 2016, the Official Veterinarians assigned to authorized establishments were instructed to record in a timely and proper fashion all noncompliance issues (regardless of the degree of severity) that have been detected and corrected immediately.	October 8, 2016	See attached official communication sent to the Official Veterinarians of the authorized establishments. At each one of the establishments, the official inspection team has the Pre-operational and Operational inspection forms designed to record any identified noncompliance. (See Annex No. 3 as an example.)

CCA procedures for confirming an establishment's results for Shiga toxin-producing E. coli (STEC) are not sufficient to safeguard the chain of custody or confirm the results of the sample.	As of October 8, 2016, all samples found to be positive for E. coli O157:H7 and E. coli Non O157 (STECs) at authorized laboratories and located at authorized establishments will not send the counter sample to the Official Central Laboratory for confirmation. The sub-batches with this condition will be separated and sent to rendering, as well as the sub-batches sampled by the official party and tested at the Food Microbiology and Veterinary Diagnostics Central Laboratory (Laboratorio Central de Diagnóstico Veterinario y Microbiología de los Alimentos, LCDVMA). These sub-batches are retained pending results. All samples with presumptive positive result taken by the Official Inspection Service will be confirmed by the Official Central Laboratory. If the result is found to be positive, then the sampled sub-batch will be sent to rendering. If the result is negative, it will be sent for local sale and separated from the sub-batches intended for the United States of America.	October 8, 2016	An official communication was sent to the Official Veterinarians at the authorized meat processing establishments, with a copy to the Official Central Laboratory representative. (See Annex No. 4.)

The central competent authority (CCA) has not provided adequate policies or written procedures for conducting verification procedures to verify HACCP sanitation requirements and other United States safety requirements.	There are written procedures for verifying sanitation, HACCP, and SSOP requirements, updated on January 4, 2016. These are shown in the *Mean Inspection Procedures Manual* (*Manual de procedimientos para la inspección de carne)* for Nicaragua.	As of the issuance and effective date of the *Meat Inspection Procedures Manual* (Jan. 4, 2016).	The following procedures, per the table of contents of the **Meat Inspection Procedures Manual**, contain the requirements for sanitation verification under HACCP, SSOP, and other safety requirements: Pre-operational control (Item 13, pages 100–105), Operational verification (Item 14, pages 106–114), Rodent control (Item 15, pages 115–119), Animal welfare verification (Item 16, pages 120–125), SSOP and HACCP verification (Item 19, pages 137–146). (See attached official verification forms for HACCP and SSOP as an example.) (See Annex No. 5.)

Officials at the CCA plant failed to identify, document, and implement requirements per the SPS and SSOP at the various establishments audited.	As of October 8, 2016, all Official Veterinarians of IPSA assigned to authorized establishments were advised to improve the identification, documentation, and implementation of SPS and SSOP requirements in a timely and proper fashion. The CCA will maintain strict monitoring of this during supervisions.	October 8, 2016	See attached official communication addressed to the Official Veterinarians located at each one of the authorized establishments. (See Annex No. 6).
Animals without access to water (troughs) at ante-mortem inspection pens at two authorized meat processing plants.	On October 8, 2016, an official communication was sent to the Official Veterinarians regarding the verification of the permanent availability of water at the ante-mortem inspection pens at the authorized meat processing establishments.	October 8, 2017 [sic]	See attached official communication to the Official Veterinarians located at each one of the authorized meat processing establishments. (See Annex No. 7.)

Formation of condensation	An official communication dated October 8, 2016, was sent to the Official Veterinarians for proper compliance regarding the verification and control of the formation of condensation during the pre-operational and operational procedures, recording the findings and the respective corrective actions on the official verification forms found in the *Meat Inspection Procedures Manual.*	October 8, 2017 [sic]	See attached official communication addressed to the Official Veterinarians located at each one of the authorized meat processing establishments. (See Annex No. 8.)

IV. ANNEXES (CCA)

ANNEX No. 1

INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY
Department of Food Safety and Plant and Animal Health DGIAL-DIA-IPSA
Bolonia, Antiguo Banco Aval Card, across from the SUMEDICO Hospital
Email: inocuidad.agroalimentaria@ipsa.gob.ni Tel.: (505)22704121 ext 178

[Image: United, Nicaragua succeeds!]	Government of Reconciliation and National Unity The people are the president!	2016 Moving forward! With hope and victory!

MEMORANDUM

DIA/DIEA/SC/0304/10/16

To:	Dr. Francisco Ramírez	- Official Veterinarian Est. #1
	Dr. Julio Guadamuz	- Official Veterinarian Est. #2
	Dr. Norman Castellón	- Official Veterinarian Est. #4
	Dr. Etdaly Fuentes	- Official Veterinarian Est. #5
	Dr. Gerardo Treminio	- Official Veterinarian Est. #8
	Dr. Erick Díaz	- Official Veterinarian Est. #109

From: [Signature]
[Seal: Institute of Agricultural Health and Safety (IPSA) / Department of Food Safety and Plant and Animal Health / Division of Food Safety, Plant and Animal Health and Laboratories (DGAL) / Meat Area / Republic of Nicaragua/ Central America]

Dr. Henry Erick Pérez Leiva
Meat Safety Section Representative, SIC

Date: October 7, 2016

Subject: Delivery of FSIS-USDA directives

I am writing this memorandum to you all to deliver and notify you of the updated FSIS-USDA equivalent directives, the Spanish translations of which are attached so that you may be informed of the requirements for exporting to the United States.

I take this opportunity to send you all greetings.

CC: Dr. Cesar Lacayo, Director, DIA
Dr. Martha Hernández G., DIEA Rep.
Dr. Adriana Ibarra, Meat Section Deputy Rep.
File

ANNEX No. 2

[Image: United, Nicaragua succeeds!]	Government of Reconciliation and National Unity The people are the president!	2016 Moving forward! With hope and victory!

MEMORANDUM

DIA/DIEA/SC/0305/10/16

To:	Dr. Francisco Ramírez	- Official Veterinarian Est. #1
	Dr. Julio Guadamuz	- Official Veterinarian Est. #2
	Dr. Norman Castellón	- Official Veterinarian Est. #4
	Dr. Etdaly Fuentes	- Official Veterinarian Est. #5
	Dr. Gerardo Treminio	- Official Veterinarian Est. #8
	Dr. Erick Díaz	- Official Veterinarian Est. #109

From: [Signature]
[Seal: Institute of Agricultural Health and Safety (IPSA) / Department of Food Safety and Plant and Animal Health / Division of Food Safety, Plant and Animal Health and Laboratories (DGAL) / Meat Area / Republic of Nicaragua/ Central America]

Dr. Henry Erick Pérez Leiva
Meat Safety Section Representative, SIC

Date: October 7, 2016

Subject: Request for *Salmonella spp.* set report

I am writing this memorandum to you all to instruct that, as of today, you must send the set report for the official monitoring of *Salmonella* to these offices and to the IPSA Microbiology and Food laboratory. Should the results indicate the presence of the bacteria, the corrective actions implemented by the establishment must also be sent. It should be noted that the set number and the consecutive number of the sample must also be noted in the submittal of the samples.

There being nothing further, I send you greetings.

CC: Dr. Cesar Lacayo, Director, DIA
Dr. Martha Hernández G., DIEA Rep.
Dr. Adriana Ibarra, Meat Section Deputy Rep.
File

ANNEX No. 3

[Image: United, Nicaragua succeeds!]	Government of Reconciliation and National Unity The people are the president!	2016 Moving forward! With hope and victory!

MEMORANDUM

DIA/DIEA/SC/0303/10/16

To:	Dr. Francisco Ramírez	- Official Veterinarian Est. #1
	Dr. Julio Guadamuz	- Official Veterinarian Est. #2
	Dr. Norman Castellón	- Official Veterinarian Est. #4
	Dr. Etdaly Fuentes	- Official Veterinarian Est. #5
	Dr. Gerardo Treminio	- Official Veterinarian Est. #8
	Dr. Erick Díaz	- Official Veterinarian Est. #109

From: [Signature]
[Seal: Institute of Agricultural Health and Safety (IPSA) / Department of Food Safety and Plant and Animal Health / Division of Food Safety, Plant and Animal Health and Laboratories (DGAL) / Meat Area / Republic of Nicaragua/ Central America]

Dr. Henry Erick Pérez Leiva
Meat Safety Section Representative, SIC

Date: October 7, 2016

Subject: Instruction

I am writing this memorandum to you all to instruct that any noncompliance issues identified in routine inspections and that are immediately corrected, regardless of the degree of severity, must always be documented on the appropriate form, as well as the corrective actions taken by the establishment.

I take this opportunity to send you all greetings.

CC: Dr. Cesar Lacayo, Director, DIA
Dr. Martha Hernández G., DIEA Rep.
Dr. Adriana Ibarra, Meat Section Deputy Rep.
File

ANNEX No. 4

[Image: United, Nicaragua succeeds!]	Government of Reconciliation and National Unity The people are the president!	2016 Moving forward! With hope and victory!

MEMORANDUM

DIA/DIEA/SC/0306/10/16

To:	Dr. Francisco Ramírez	- Official Veterinarian Est. #1
	Dr. Julio Guadamuz	- Official Veterinarian Est. #2
	Dr. Norman Castellón	- Official Veterinarian Est. #4
	Dr. Etdaly Fuentes	- Official Veterinarian Est. #5
	Dr. Gerardo Treminio	- Official Veterinarian Est. #8
	Dr. Erick Díaz	- Official Veterinarian Est. #109

From: [Signature]
[Seal: Institute of Agricultural Health and Safety (IPSA) / Department of Food Safety and Plant and Animal Health / Division of Food Safety, Plant and Animal Health and Laboratories (DGAL) / Meat Area / Republic of Nicaragua/ Central America]

Dr. Henry Erick Pérez Leiva
Meat Safety Section Representative, SIC

Date: October 8, 2016

Subject: Instruction

I am writing this memorandum to you all to instruct the following, as of today:

1. For any presumptive positive result for *E. coli O157:H7* and *E. coli non O157* (STECs) at the laboratories located at the authorized establishments, no sample shall be sent to the central laboratory for confirmation. Sub-batches with presumably positive results shall be separated and sent to rendering.

2. Any presumptive positive result for *E. coli O157:H7* and *E. coli non O157* (STECs) from samples sent to the IPSA official laboratory shall be confirmed. If after confirmation the result is positive, then the sub-batch sampled will be sent to rendering. If the result is negative, the sub-batch sampled will be sent for local sale, but in no circumstance intended for the United States of America.

3. All sub-batches sampled by the official inspection service and the authorized meat processing establishment must be withheld pending results.

There being nothing further, I send you greetings.

CC: Dr. Cesar Lacayo, Director, DIA
Dr. Martha Hernández G., DIEA Rep.
Dr. Adriana Ibarra, Meat Section Deputy Rep.
Dr. Nohemí Pineda – Responsible for the Official Central Laboratory (LCDVMA)
File

ANNEX No. 5

[Image: Republic of Nicaragua / Central America]

INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY
IPSA
DEPARTMENT OF FOOD SAFETY AND PLANT AND ANIMAL HEALTH
MEAT INSPECTION SERVICE

Date: _____ **HACCP Verification** Est. No.: _____

Concentration of organic acid solution	Time	Temperature	Area	No. of Carcasses	PCC	Deviation	Corrective Actions	Time of Correction	Preventive Measure	Verifier's Signature

Comments:

Official Veterinarian

PCC1: Zero visual contamination of stomach contents, manure, or milk in carcasses (10 carcasses per hour).
PCC2: Solution concentration between 2.5% (every 50 carcasses)
PCC3: Temperature of carcasses ≤ 47ºF. In 24 hours of [TN: remainder cut off]

Area Manager

[Image: Republic of Nicaragua / Central America]

INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY

DEPARTMENT OF FOOD SAFETY AND PLANT AND ANIMAL HEALTH

MEAT INSPECTION SERVICE

OPERATIONAL SSOP VERIFICATION

FREQUENCY: THREE TIMES PER DAY

ROOM: _____ CODES

START TIME: _____ C: IN COMPLIANCE

END TIME: _____ NC: NONCOMPLIANCE

NA: NOT APPLICABLE

Date: _____ Est. No.: _____

	Description	Time	Time	Time	Deficiency Observed
1	Washing and sanitizing of hands.				
2	Clothing, gloves, mask, and hairnet.				
3	Washing and sterilization of work equipment.				
4	Cleaning and sanitizing of walls and floors.				
5	Cleaning and sanitizing of containers.				
6	Handling of edible and non-edible product.				
7	Handling of packing material.				
8	Condensation.				
9	Cleaning of refrigeration units.				
10	Cleaning and sanitizing of chillers.				
11	Washing of jowls.				
12	Cleaning and sanitizing area of contact.				
13	Ventilation and lighting.				
14	Concentration of chlorine in potable water.				
15	Hot and cold water.				
16	Drainage and pipes.				
17	Insect control.				
18	Foot bath.				
19	Water pressure – steam.				
20	Other.				

Comments:

_____ _____

Verifier's Name Signature

_____

Official Veterinarian

F-SIC-21

ANNEX No. 6

MEMORANDUM

DIA/DIEA/SC/0313/10/16

To:	Dr. Francisco Ramírez	- Official Veterinarian Est. #1
	Dr. Julio Guadamuz	- Official Veterinarian Est. #2
	Dr. Norman Castellón	- Official Veterinarian Est. #4
	Dr. Etdaly Fuentes	- Official Veterinarian Est. #5
	Dr. Gerardo Treminio	- Official Veterinarian Est. #8
	Dr. Erick Díaz	- Official Veterinarian Est. #109

From: [Signature]
[Seal: Institute of Agricultural Health and Safety (IPSA) / Department of Food Safety and Plant and Animal Health / Division of Food Safety, Plant and Animal Health and Laboratories (DGAL) / Meat Area / Republic of Nicaragua/ Central America]

Dr. Henry Erick Pérez Leiva
Meat Safety Section Representative, SIC

Date: October 8, 2016

Subject: Instruction

I am writing this memorandum to you all to instruct that, as of today, the identification, documentation, and implementation of the requirements to comply with the Sanitation Performance Standards (SPS) and Sanitation Standard Operating Procedures (SSOP) must be improved.

There being nothing further, I send you all greetings.

CC: Dr. Cesar Lacayo, Director, DIA
Dr. Martha Hernández G., DIEA Rep.
Dr. Adriana Ibarra, Meat Section Deputy Rep.
File

Nicaragua succeeds!]

The people are the president!

Times of victories!
By the grace of God

ANNEX No. 7

Faith, Family and Community!

CHRISTIAN, SOCIALIST, UNITED!
INSTITUTE OF AGRICULTURAL HEALTH AND SAFETY
Department of Food Safety and Plant and Animal Health DGIAL-DIA-IPSA
Bolonia, Antiguo Banco Aval Card, across from the SUMEDICO Hospital
Email: inocuidad.agroalimentaria@ipsa.gob.ni Tel.: (505)22704121 ext 178

[Image: United, Nicaragua succeeds!]

Government of Reconciliation and National Unity
The people are the president!

2016
Moving forward!
With hope and victory!

MEMORANDUM

DIA/DIEA/SC/0314/10/16

To:
Dr. Francisco Ramírez - Official Veterinarian Est. #1
Dr. Julio Guadamuz - Official Veterinarian Est. #2
Dr. Norman Castellón - Official Veterinarian Est. #4
Dr. Etdaly Fuentes - Official Veterinarian Est. #5
Dr. Gerardo Treminio - Official Veterinarian Est. #8
Dr. Erick Díaz - Official Veterinarian Est. #109

From: [Signature]
[Seal: Institute of Agricultural Health and Safety (IPSA) / Department of Food Safety and Plant and Animal Health / Division of Food Safety, Plant and Animal Health and Laboratories (DGAL) / Meat Area / Republic of Nicaragua/ Central America]

Dr. Henry Erick Pérez Leiva
Meat Safety Section Representative, SIC

Date: October 10, 2016

Subject: Instruction

I am writing this memorandum to you all to instruct that, as of today, it must be verified that there is an availability of water (troughs) at the ante-mortem inspection pens at each one of the authorized meat processing establishments.

There being nothing further, I send you all greetings.

CC: Dr. Cesar Lacayo, Director, DIA
Dr. Martha Hernández G., DIEA Rep.
Dr. Adriana Ibarra, Meat Section Deputy Rep.
File

ANNEX No. 8

[Image: United, Nicaragua succeeds!]	Government of Reconciliation and National Unity The people are the president!	2016 Moving forward! With hope and victory!

MEMORANDUM

DIA/DIEA/SC/0315/10/16

To:	Dr. Francisco Ramírez	- Official Veterinarian Est. #1
	Dr. Julio Guadamuz	- Official Veterinarian Est. #2
	Dr. Norman Castellón	- Official Veterinarian Est. #4
	Dr. Etdaly Fuentes	- Official Veterinarian Est. #5
	Dr. Gerardo Treminio	- Official Veterinarian Est. #8
	Dr. Erick Díaz	- Official Veterinarian Est. #109

From: [Signature]
[Seal: Institute of Agricultural Health and Safety (IPSA) / Department of Food Safety and Plant and Animal Health / Division of Food Safety, Plant and Animal Health and Laboratories (DGAL) / Meat Area / Republic of Nicaragua/ Central America]

Dr. Henry Erick Pérez Leiva
Meat Safety Section Representative, SIC

Date: October 8, 2016

Subject: Instruction

I am writing this memorandum to you all to instruct that, as of today, the formation of condensation during the pre-operational and operational procedures must be verified and controlled. Moreover, the official auxiliary inspectors must be trained in BPM and BPH, and the management of the meat processing establishments must train their personnel on the topics mentioned.

There being nothing further, I send you all greetings.

CC: Dr. Cesar Lacayo, Director, DIA
Dr. Martha Hernández G., DIEA Rep.
Dr. Adriana Ibarra, Meat Section Deputy Rep.
File