



United States Department of Agriculture

Food Safety and
Inspection Service

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Cesar Lacayo
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Managua, Nicaragua, C.A.

Dear Mr. Lacayo:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Nicaragua's meat inspection system from September 8 through September 19, 2014. No comments were received from the Government of Nicaragua within 60 days. Enclosed is a copy of the final audit report.

For technical questions regarding the FSIS audit report, please contact Dr. Shaukat H. Syed, Director, International Audit Staff, Office of Investigation, Enforcement and Audit (OIEA) at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or by electronic mail at international.audit@fsis.usda.gov.

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

Sincerely,

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
NICARAGUA

September 8 –19, 2014

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
THE PRODUCTION OF MEAT AND POULTRY PRODUCTS
INTENDED FOR EXPORT TO
THE UNITED STATES OF AMERICA

August 11, 2015
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 8 to September 19, 2014. The audit was to determine whether Nicaragua's food safety system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products that are unadulterated, safe, wholesome, and properly labeled.

The focus of the audit was on the ability of the Central Competent Authority (CCA), *Direccion General de Inocuidad Agroalimentaria y Laboratorios* (DGIAL), to regulate meat products production. This audit was designed to determine the equivalence of Nicaragua's meat inspection system and focused on six main system components: Government Oversight (Organization & Administration), Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), Sanitation, Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residues Control Program, and Government Microbiological Testing Programs. Prior to the on-site audit, FSIS reviewed the self-reporting tool (SRT) provided by Nicaragua; and reports of corrective actions that Nicaragua implemented to address findings of FSIS 2012 audit and Point-of-Entry (POE) violations since the last audit.

The audit results indicate that Nicaragua's food safety inspection system continues to maintain equivalence with the United States' system and is operating at an "average" level of performance. The CCA meets the core criteria for all six equivalence components. However, the FSIS auditor identified a need for improvement within the HACCP systems component.

During the exit meeting, the CCA noted that it had begun taking actions to address the audit observations. FSIS will evaluate any information provided by Nicaragua, including the submittal of the CCA's proposed corrective actions, in response to the audit findings to assess the effectiveness of the corrective actions through its ongoing equivalence verification methodology.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	AUDIT GOAL AND OBJECTIVES	1
III.	AUDIT METHODOLOGY	2
IV.	COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION & ADMINISTRATION)	3
V.	COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATIONS AND PRODUCT STANDARDS)	5
VI.	COMPONENT THREE: SANITATION	8
VII.	COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS	10
VIII.	COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUES CONTROL PROGRAM...	12
IX.	COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	14
X.	CONCLUSIONS AND NEXT STEPS	15
	APPENDICES	17
	APPENDIX A: Nicaragua's Establishment Audit Checklists	
	APPENDIX B: Nicaragua's Response to Draft Final Audit Report	

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site equivalence verification audit of Nicaragua's meat inspection system from September 8 to September 19, 2014.

Nicaragua is eligible to export beef products to the United States. From October 1, 2012, to April 30, 2014, Nicaragua exported 118,679,504 pounds of products to the United States, of which 8,418,658 pounds were re-inspected at United States Point of Entry (POE). A total of 52,354 pounds were refused at POE (e.g., labeling issues or packaging/transportation damage). Nicaragua exports the following categories of beef products; raw intact beef, which includes subcategories such as boneless manufacturing trimmings, cuts, edible offal, other intact, and primal and sub-primal. No ground beef is exported to the United States.

This audit was conducted pursuant to the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations.

The audit standards applied during this audit of Nicaragua's meat inspection system included (1) all applicable legislation originally determined by FSIS as part of the initial equivalence process, and (2) any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement.

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Nicaragua's food safety system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six equivalence components with the objective of determining whether each component continues to be equivalent to that of the United States. The six equivalence components are the following: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residues Control Program, and (6) Government Microbiological Testing Programs. In addition, FSIS verified that the corrective actions proffered by the Central Competent Authority (CCA) in response to the March 2012 FSIS audit were being implemented.

The focus of the audit was on the ability of the Central Competent Authority (CCA), *Direccion General de Inocuidad Agralimentaria y Laboratorios* (DGIAL), to regulate meat products production. The first special area of emphasis was to conduct a follow up examination of the CCA's corrective action in response to the previous FSIS audit, which was conducted from March 13 to March 22, 2012. During that audit, no notice of intent to delist (NOID) or delistment was issued.

III. AUDIT METHODOLOGY

In conducting this on-going equivalence verification audit, FSIS utilized its established four-phase process: planning; execution (on-site); evaluation; and feedback. Each phase is described below.

The first phase involved document and data review and analysis of previous audit findings and other available information. Therefore, prior to conducting the 2014 on-site audit, the FSIS auditor examined CCA's performance within the six equivalence components using data for exported product types and volumes, POE testing results, and other data collected by FSIS since the last FSIS on-site audit in 2012. In addition, FSIS reviewed information obtained directly from the CCA, through a self-reporting process, outlining the current structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit. This comprehensive analysis served as the basis for first determining the performance level of the CCA's equivalent system and then planning the on-site audit itinerary.

The second phase of the audit was the on-site or execution phase. FSIS conducted this on-site audit to verify the CCA's oversight activities through on-site document reviews, interviews, observations, and site visits. The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA-DGIAL of the Ministry of Agriculture – former MAGFOR, which was re-named to Institute of Animal and Health Protection (*Instituto de Proteccion y Sanidad Agropecuaria-IPSA*), including members from the establishment inspection offices.

Auditor reviewed management, supervision, and administrative functions at the CCA headquarters in Managua and visited four slaughter/processing establishments to determine whether the national system of inspection, verification, and enforcement is being implemented as required. During the establishment visits, particular attention was paid to the extent to which the CCA ensures the control of hazards and prevents non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with Title 9 CFR 327.2.

The FSIS auditor assessed the CCA's oversight activities for approved chemical residue and microbiology laboratories during the planning phase and this execution phase. FSIS reviewed laboratory-related data collected prior to the 2014 audit through analysis of documents in the self-reporting tool (SRT). Second, FSIS conducted on-site interviews of inspection personnel and reviewed the CCA's laboratory audit reports at the CCA's headquarters and in the laboratory.

The third phase of the audit was an evaluation. FSIS conducted a post-audit evaluation of all data collected on-site to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents. FSIS conducted an exit meeting with the CCA representatives to convey all findings and discuss next steps.

The final phase of the audit was feedback, which begins with this draft audit report providing the CCA with an opportunity for submitting comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report. Then, FSIS and the CCA mutually develop an action plan to address any issues raised by the audit. These issues will be tracked by FSIS until resolution and will be automatically included as areas of special emphasis in the next on-site verification audit.

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

The first of the six equivalence components reviewed was Government Oversight. FSIS import eligibility requirements state that the foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the system of meat inspection in the United States.

The evaluation of this component includes a review and analysis of documentation previously submitted by the CCA as support for the responses and corrective actions provided in the SRT, as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices and audited establishments.

In accordance with Chapter II of Law 291, Basic Plant and Animal Health, Article 5 and Chapter V, section 20, articles 22 and 23 of the regulations of the meat inspection system of Nicaragua, the CCA inspects the production activities of establishments that intend to export beef products to the United States. The CCA conducts initial and ongoing evaluations of establishments authorized to export beef products to the United States. Establishments requesting certification to export to the United States must present, among others, HACCP, SSOP, SPS, and GMP programs. The establishment is approved to export to the United States for one (1) year, after which the establishment must be re-certified. Official certification is only granted to establishments that fulfill requirements for construction of facilities, food safety controls, and sanitary requirements stipulated in the regulations of the system. Records reviewed by the FSIS auditor showed that certified slaughter establishments have been evaluated annually by the CCA. Additionally, DGIAL has direct authority over the official Government Chemical Residue and Microbiological laboratories of the system that perform analysis of meat products exported to the United States.

FSIS verified that the DGIAL oversees the Direccion de Inocuidad Agroalimentaria (DIA), which manages Nicaragua's Meat Inspection Service (SIC). DIA is responsible for the safety of meat products and promulgation of food safety regulations, and it has sole authority to enforce the laws and regulations of the meat products inspection system. The SIC provides delivery of services in the field.

All individuals who work for the Nicaraguan meat inspection system, from the CCA Headquarters office level down to in-plant officials and laboratory personnel are employees of the Government of Nicaragua (GON), and are subject to administrative policies that apply to all government officials.

The CCA provided documents that indicate that inspection, certification, and laboratory services provided to establishments are paid with funds generated from the collection of fees for service paid by establishments in accordance with a statutory fee for service schedule administered by the GON. Establishments are billed for provided services and the fees paid are received by the Delegacion Administrativa Financiera (DAF) which processes the transactions and releases funds as necessary to maintain ongoing operations of the SIC and to pay for the services provided by the laboratories.

FSIS assessed the hierarchical organization of the SIC and verified that it is staffed with government officials who accomplish administrative and regulatory functions under the coordination of a Chief Veterinary Officer (CVO). The CVO reports to the Director of the DIA and supervises the Veterinary Medical Officers (VMO) stationed at the five establishments certified as eligible to export to the United States. VMOs serve as veterinarians in charge and supervise the performance of teams of auxiliary inspectors (AI) at their duty stations. These inspectors conduct inspection duties including ante and post-mortem inspection as well as daily verification of the establishments' compliance with the sanitary, HACCP, chemical and microbiological requirements of the system.

The meat inspection system of Nicaragua recruits its veterinarians from government-approved universities and supplements their academic training with expertise that they gain while stationed at certified establishments as interns within SIC. After being selected to serve as officials, participants receive general training on the different aspects of veterinary meat inspection. This training is provided to the veterinarians through the on-the-job training exercises and classroom sessions. Non-veterinary personnel are also trained at the time of their joining the service and receive additional training as needed. FSIS reviewed records that indicate that in-plant inspection personnel have successfully completed training that includes enforcement of United States requirements for slaughter inspection, sampling methodology, HACCP, SSOP, food microbiology, meat technology, meat inspection, and specified risk materials (SRM) handling. FSIS verified that in-plant inspection personnel staffing levels are consistent with established CCA protocols requiring full operational coverage.

The CCA has provided several instructions to inspection personnel stationed at certified establishments. The main sources of instructions that the CCA has distributed to the field, are manuals of procedures entitled Manual of Procedures of the Directorate of Animal Industry (MPDAI), Official Meat Inspection Procedures for Authorized Establishments of Nicaragua (OMIPAEN), and the official General Procedure for Audits of HACCP Systems (GPAHS), documents that include procedures to be followed by inspection personnel in conducting uniform inspection of the production activities and adequacy of food safety controls at establishments certified to export beef products to the United States.

The procedures are designed to enforce Law 291, Basic Law of Animal and Plant Health and its Regulations (BLAPHR) and the Sanitary Meat Inspection Regulations for Certified Establishments (SMIRCE). The instructions contained in the MPDAI are supplemented with

updated procedures and notifications that are transmitted via electronic mail, standard mail, and telephone. FSIS verified that inspection personnel were knowledgeable with the sources of regulatory guidance provided by the CCA.

The FSIS auditor verified that the CCA exercises its legal authority to require that the United States-eligible establishments develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or insanitary conditions. The slaughter, processing, and refrigeration storage establishments with official Veterinary Medical Officers that have been authorized by the CCA have implemented a Good Manufacturing Practices (GMP) system.

After a review of official documents, on-site observations, and interviews with government personnel, FSIS verified that Nicaragua's government has maintained an equivalent organizational structure for performing oversight. The FSIS auditor interviewed inspection personnel at CCA headquarters and at four audited establishments and reviewed daily inspection records generated by in-plant inspection personnel for the previous three months.

The auditor verified, through document review at the CCA and at audited establishments, that inspection personnel assigned to the United States-eligible establishments are employees of the national government. The national government employs inspection personnel at all levels. All United States-eligible slaughter and processing establishments are staffed with at least one full-time veterinarian and at least three to four inspectors.

FSIS found that the CCA provides HACCP requirements equivalent to those of FSIS' SSOP, SPS, and HACCP regulatory requirements, performs periodic supervisory reviews, and does *Salmonella* spp. and generic *E. coli* testing. In-plant veterinary officials and supervisors monitor, verify, and enforce the implementation of most of the SSOP, SPS, and HACCP regulatory requirements in the audited establishments.

The CCA maintains competent and qualified personnel to ensure the production of safe, wholesome, and accurately labeled product in certified establishments.

The audit confirmed that Nicaragua's meat inspection system is organized and administered by the government, and that the CCA officials are assigned to enforce laws and regulations governing meat inspection in official establishments. However, the auditor made a finding in the sanitation component that indicates a need for the CCA to improve its oversight activities. The verification activities of Nicaragua's inspection system as designed and implemented showed that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component, as articulated by the FSIS import regulations (9 CFR 327.2). FSIS has determined that Nicaragua's inspection system and the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component and operates at an "average" level of performance.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATIONS AND PRODUCT STANDARDS)

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits in the United States-eligible establishments.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the on-site audit of the system. The FSIS auditor verified by reviewing manuals and procedures at IPSA that official inspection and verification activities are in accordance with the responses in the SRT and supporting documentation, and that the CCA continues to maintain equivalent legislative controls for this component.

During the CCA's headquarters audit, the FSIS auditor verified the CCA's regulatory authority as outlined in official legislation, circulars, and other instructions issued in accordance with Law 291, Meat Inspection Regulations, and Manual of Inspection Procedures. The auditor confirmed that the CCA provides inspection offices located at United States-eligible establishments with the appropriate regulatory authority and guidance to enforce requirements for HACCP, sanitation, chemical residue and microbiological sampling, humane handling, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits. There are no regulatory changes associated with the export meat products in the United States since the last audit that would have required changes by the CCA.

During the on-site audit of one bovine slaughter/processing establishment, the FSIS auditor observed the in-plant inspection verification activities for pre-operational sanitation, and in all four establishments, he observed operational sanitation procedures (described under Component Three); HACCP verification activities including the zero tolerance Critical Control Point (CCP) verification (described under Component Four); ante-mortem/humane handling inspection examination; post-mortem examination; and *Salmonella* spp. and generic *E. coli* sample collection (described under Component Six).

The SMIRCE portion of the system provides requirements that apply to slaughter and processing activities, control of inedible and condemned materials, delivery of daily inspection, and periodic supervisory reviews of certified establishments. On-site observations and government and plant records reviews conducted by FSIS demonstrated that, from the point of arrival, all cattle are identified and inspected in accordance with established procedures that ensure that only animals that are inspected and that pass ante-mortem inspection continue to the slaughter operation, which is performed in accordance with humane slaughter including examination of the corneal reflex of the stunned animal. The FSIS auditor verified the adequacy of ante-mortem facilities and compliance of operators with humane handling requirements imposed by the Nicaraguan government.

In accordance with procedures outlined in the SRT, the Veterinary Medical Officer (VMO) observes all animals at rest and in motion from both sides in designated holding pens in order to determine whether they are fit for slaughter. Each establishment has a designated observation pen for further examination of suspect animals. The FSIS auditor observed and verified that all animals have access to water in all holding pens, including the pens used for suspect animals; and that if animals are held overnight, feed and water are provided.

FSIS observed inspection personnel implementing the procedure for oversight of health assessment and the monitoring of suspect animals. The procedure ensures that animals that display overall poor condition or signs of disease are slaughtered under special conditions, separated from the rest.

The FSIS auditor also reviewed records that demonstrate that in accordance with the regulations of the Nicaraguan meat inspection system, production of meat products is only conducted when government officials are present at certified establishments. Certified establishments provide adequately furnished stations to government inspectors and consistently present properly identified heads, viscera, and carcasses for post mortem inspection with proper line synchronization. Government inspectors were observed conducting post mortem inspection in an appropriate manner in accordance with official procedures with proper disposition of suspects and verification of acceptability of the final product by removing cases of pathology condition. On-site audit and documents reviewed by FSIS during the audit reflect that certified establishments maintain a consistent and adequate delivery of official ante- and postmortem inspection.

FSIS assessed post-mortem inspection examinations through on-site record review, interviews, and observations of inspection activities, which demonstrated that in accordance with the regulations of the Nicaraguan meat inspection system, production of meat products is only conducted when government officials are present at certified establishments. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented. The objective of post-mortem inspection control is to ensure the hygiene of the operative processes, preventing visible contamination, and reducing the probability of non-visible contamination to the extent possible. Ensuring that meat, organs and viscera are fit for human consumption occurs through systematic post-mortem inspection management and the identification of meat, organs and viscera based on their fitness determination.

Both in-plant veterinary and non-veterinary inspectors were adequately trained in their on-line post-mortem inspection duties. The design of the post-mortem inspection stations, including proper lighting and the number of online inspectors, are in accordance with inspection requirements. The FSIS auditor also observed the functions of the offline veterinary inspectors who have an in-plant supervisory role to ensure continuous daily inspection and to conduct daily inspection verification activities in all audited establishments. These daily verification activities include direct observation and review of the establishment's records, including its HACCP, SSOP and SPS, and generic *E. coli* and *Salmonella* carcass sampling records.

The CCA representatives, such as the CVO and VMOs, conduct periodic reviews of certified establishments to evaluate efficacy of food safety systems, adequacy of inspection and official verification activities, and performance of in-plant inspection personnel. The auditor found that the records of reviews conducted at the establishments, the records of periodic supervisory reviews, and the records of evaluations of sanitary conditions at establishments are properly maintained. The FSIS auditor observed VMOs as they evaluated the design and maintenance of the facilities, their sanitary conditions, the monitoring of food safety systems, official verification activities, and the technical competence of in-plant officials. The observations made by the auditor were that government officials periodically assess the functions of inspection personnel and establishment operators, document findings, verify adequacy of corrective actions, and provide guidance to officials and establishments.

The FSIS auditor verified that the CCA exercises its legal authority to require that the United States-eligible establishments develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or insanitary conditions. The CCA has adopted FSIS sanitation regulatory requirements prescribed in 9 CFR Part 416.

FSIS verified that the meat inspection system of Nicaragua has statutory authority to deliver inspection to all establishments certified to slaughter and process meat products as described in Law 291, Basic Law of Animal and Plant Health and its Regulations which provides instructions to the official inspection personnel to conduct a continuous and systematic assessment of establishment activities during routine verifications of sanitation issues, including maintenance of the facilities and industrial equipment; dressing rooms and restrooms; illumination; ventilation; water supply; waste water; pest control; cleaning and sanitization; hygiene, hygienic habits, and workers' health; and operational sanitary procedures. The auditor also assessed the adequacy of HACCP program verification activities conducted by inspection officials at the establishment by observing verification activities and reviewing monitoring and verification records generated by establishment and in-plant inspection personnel at all audited establishments.

Nicaragua's meat inspection system has legal authority and a regulatory framework to implement requirements equivalent to those governing the United States' system of meat inspection. The analysis and on-site verification activities indicate that the CCA continues to maintain equivalence. FSIS has determined that Nicaragua's inspection system and the CCA continue to demonstrate the ability to meet the core equivalence requirements for this component and operates at an "average" level of performance.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components the FSIS auditor reviewed was sanitation. To be considered equivalent to FSIS' program, the CCA must provide requirements for all areas of sanitation, sanitary handling of products, and SSOP.

The evaluation of this component included a desk review and analysis of the responses provided by the CCA in the Sanitation component portions of the SRT covering Sanitation Performance Standards and SSOP's. The information reviewed indicates that the CCA has legal authority to

require that operators develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions, and that the in-plant official inspection personnel perform duties to verify the adequacy of implementation of plant sanitation programs.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at all audited establishments. In one of the audited establishments, the FSIS auditor verified the pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspection personnel's hands-on verification procedures begin after the establishment personnel conducted its pre-operational sanitation and determined that the facility is ready for in-plant inspector pre-operational sanitation verification activities. The in-plant inspection personnel conduct this activity in accordance with the CCA's established procedures.

The FSIS auditor followed the off-line inspector and observed in-plant inspection verification of operational sanitation procedures at all four audited establishments. These verification activities include direct observation of operations and review of the establishments' associated records. The FSIS auditor reviewed the establishment's sanitation monitoring and corresponding inspections' verification records for the same time period. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures authenticated these records with initials or signatures and the date.

The FSIS auditor noted that the CCA has several documents that clarify establishment and inspection personnel responsibilities to prevent product contamination. References to the responses provided included Law 291, Basic Law of Animal and Plant Health and its Regulations, Sanitary Meat Inspection Regulations for Certified Establishments (SMIRCE), Manual for Control of Implementation of SSOPs, OMIPAEN, GPAHS, and samples of government daily sanitation monitoring records.

The FSIS auditor determined that the CCA's inspection system provides requirements equivalent to those of the FSIS system for sanitary handling of products, as well as for development and implementation of SSOPs. In-plant veterinary officials, under the CCA's oversight, enforce the regulatory requirements and monitor the ability of establishments to maintain sanitary conditions.

FSIS analysis and audit verification activities of Nicaragua's inspection system indicated that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component. FSIS determined that Nicaragua's inspection system does support that the CCA operates at an "average" level of performance.

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

The fourth of the six equivalence components reviewed was HACCP. The inspection system must demonstrate a HACCP plan or a similar preventative control plan.

The CCA's headquarters and four establishments were visited to determine whether the DGIAL and inspection offices maintained effective government oversight for the implementation of the CCA's meat food inspection system's HACCP requirements. In addition to focusing on the HACCP plan design and implementation, the FSIS auditor verified the CCA's oversight activities through on-site record review, interviews, and observations of the implementation of the SRM Control Program at four audited bovine slaughter establishments.

The evaluation of this component included a desk review and analysis of the responses provided by the CCA in the HACCP portion of the SRT and documents submitted as support for the responses given including Law 291, official operational procedures OMIPAEN and GPAHS, and copies of official monitoring records. Additionally, FSIS conducted on-site observations to assess the operations of the establishments and local government offices of the system.

The auditor verified that the regulations of the system require establishments to develop, implement, and maintain HACCP programs. Only establishments that operate with a government approved HACCP program can be certified as eligible to export meat products to the United States. Additionally, establishments are required to be located in an area free of environmental food safety hazards, to hold a current sanitary license, to be in good food safety performance standing, and to have written manuals to implement food safety control systems that include HACCP, Good Manufacturing Practices (GMP), and Sanitation Standard Operating Procedures (SSOPs) programs. The DIA is the government agency that certifies establishments producing meat products for export to the United States. In that capacity, and in accordance with Law 291, Articles 17 and 22, and Decree No. 59-2003, Chapter VII, Article 40, the HACCP Technical Unit (HTU) of the DIA conducts evaluations of the design of establishments' written HACCP programs. As part of those evaluations, the HTU verifies that the HACCP programs presented by the industry meet official requirements. To assist reviewing officials in the performance of those duties, the CCA developed a standardized procedure, herein identified as GPAHS, that reviewers must follow to ensure uniform evaluation of HACCP programs and enforcement of the HACCP regulatory requirements.

The FSIS auditor verified through record review and observation that the in-plant inspection personnel conducted daily verification of HACCP monitoring activities, including evaluation of written HACCP programs, monitoring, verification, corrective actions, record keeping, and hands-on verification inspection. The in-plant inspection personnel verification of HACCP plans include verification of CCPs for all production shifts.

At the four slaughter establishments audited, the FSIS auditor conducted an on-site review of the zero tolerance (feces, ingesta, and milk) CCP records generated over the past three months. The review of the establishment's corrective actions in response to deviations from zero tolerance critical limits indicated that all four parts of the corrective actions, in accordance with 9

CFR 417.3, were addressed by slaughter establishment employees and verified by the inspection personnel. No non-compliance trends were detected as the result of these document reviews. Furthermore, the FSIS auditor verified the physical CCP monitoring location by observing inspection personnel conducting HACCP hands-on verification activities, as well as performing an independent direct monitoring examination of livestock carcasses. The inspection personnel or the FSIS auditor observed no deviation from the critical limits. The FSIS auditor also verified that the zero tolerance CCP monitoring location meets the CCA's requirement, including the adequate illumination for proper examination.

The FSIS auditor visited four bovine slaughter establishments to review the CCA's SRM control program. The auditor toured these slaughter establishments in their entirety to observe and verify actual operations concerning removal, segregation, and disposal of SRM. In particular, the FSIS auditor reviewed and verified the CCA's verification and control program for SRMs at both ante-mortem and post-mortem inspection examinations. The CCA has developed strategies to address the separation of cattle in accordance with their age to remove SRMs. Accordingly, age determination of cattle presented for slaughter is based on records or by dentition examination in the kill floor.

In addition, the FSIS auditor reviewed relevant documents and records generated by the slaughter establishments and in-plant inspection personnel, as well as conducted interviews with in-plant personnel. The auditor noted that the CCA has requirements for removal, segregation, and disposal of SRM in cattle and requires that all SRM be removed prior to export to the United States. However, one establishment was not following its written SRM procedures in that the colors of the knives its employees used were different from those described in the procedure.

In the four bovine slaughter establishments audited, the FSIS auditor verified through review of verification records and direct observation of inspection activities that the in-plant veterinarians identified and secured all animals exhibiting clinical signs of central nervous system (CNS) disorders at the ante-mortem inspection station. At each establishment visited, the auditor confirmed that the on-site veterinarians could appropriately identify the clinical signs associated with CNS disorders which include, but are not limited to: excitement or depression; deviation or rotation of the head; drooping of the lips, eyelids, cheeks, and ears; convulsions and tremors; paralysis; sudden onset of fainting; head pressing; aimless walking; ataxia; and blindness.

The CCA continues to demonstrate the ability to satisfy equivalence for this component as articulated in FSIS import regulations (9 CFR 327.2). Therefore, the FSIS has determined that Nicaragua's inspection system and the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component and operates at an "adequate" level of performance.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUES CONTROL PROGRAM

The FSIS auditor reviewed Government Chemical Residues Control Program as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that carries out effective regulatory

activities to prevent chemical residue contamination of food products. To be considered equivalent to FSIS' residue control program, the CCA's program needs to include random sampling of internal organs, muscles, and carcass fats for chemical residues identified by the exporting countries and FSIS as potential contaminants. In addition, the CCA needs to identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of the program; provide a description of its residue sampling and testing plan and the process used to design the plan; describe the actual operation of its residue plan and actions taken to deal with unsafe residues as they occur; and provide oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

FSIS assessed the Nicaraguan residue control program by analyzing information provided by the CCA during the audit of its central offices and by observing operations at the official chemical residue laboratory and four certified slaughter establishments. This evaluation made evident that the program is organized and administered by the CCA.

The FSIS auditor verified that the CCA in cooperation with DIA and SIC develops the annual residue monitoring plan and distributes instructions for random collection of samples to in-plant officials, indicating in the instructions the matrix and time period when samples are to be collected. Furthermore, FSIS verified that Chapter XVII, Articles 192 and 193, of the SMIRCE of Nicaragua provides requirements for chemical residue analysis, and the OMIPAEN describes the procedures that in-plant officials, plant personnel and the official laboratory are to follow to ensure effective monitoring of chemical residues at establishments certified to produce meat products for export to the United States. The records maintained by the meat inspection system show that Nicaragua tests tissues from slaughtered cattle destined for the United States market at certified establishments for the presence of nine classes of compounds using FSIS methods of analysis. Polychlorinated biphenyl (PCB) is included in the class of chlorinated hydrocarbons (CHC) which brings the number of compounds to nine. For analysis of CHC, a compositing sample method is performed.

The sample receiving area of the residue analysis laboratory distributes samples to the micro or chemistry laboratory based on the analysis request. A received sample is registered in the "Log book," and the temperature must be below 4°C. In case of a spoiled sample, a new sample is taken. Residue samples are tested monthly to complete the national residue plan. Residue violative results are sent to a coordinator who informs the IIC.

At the official residue analysis laboratory, the FSIS auditor reviewed training records and certifications associated with the qualifications of the analysts. The documents reviewed made evident that analysts had successfully completed intra-lab evaluations administered by the laboratory manager and possessed the competence necessary to conduct the analysis assigned to them by the manager.

The FSIS auditor verified that the sampling protocol included in the residue control program applies to certified establishments that export meat products and that comply with the SMIRCE. The prescribed sampling protocol mandates test and hold practices to ensure that only products that have tested negative for the analytes of interest are released for export to the United States. Furthermore, violative results are reported by the laboratory directly to the CCA, DIA, and in-

plant SIC personnel, who initiate follow-up that includes identification and segregation, under official control, of the involved product, which, in accordance with the regulations of the system, is then only eligible for sale in the local market. Additionally, SIC officials report the occurrence to the IPSA/DGIAL, which in turn issues notification to the involved cattle supplier and follows up with outreach activities to provide guidance to the identified rancher to prevent recurrence of noncompliant use of veterinary pharmaceuticals.

FSIS determined that the Government Chemical Residue Control Programs component includes a national program managed by the CCA. The inspection system has appropriate laws, circulars, and other decrees that serve as the legal authority for the implementation of this program. The CCA has access to and supervises the activities of analytical laboratories that have testing capabilities to ensure the validity and reliability of test data.

The meat inspection system of Nicaragua has regulatory requirements for a chemical residue control program that is organized and administered by the national government. The program includes random sampling of internal organs and fat of carcasses for chemical residues. The program is adjusted on a yearly basis to address emerging concerns. Testing conducted by FSIS at United States POE has not detected violative chemical residues in meat products produced by Nicaraguan certified establishments.

FSIS analysis and audit verification activities of Nicaragua's chemical residue testing program found that the CCA continues to demonstrate the ability to meet the equivalence requirements for this component. FSIS determined that Nicaragua's chemical residue testing program operates at an "average" level of performance.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components the FSIS auditor reviewed was Government Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

FSIS auditor evaluated the microbiological raw beef products sampling and testing programs implemented by establishments and follow up with laboratories within the meat inspection system of Nicaragua. The evaluation also included a review of the responses provided by the CCA in the Pathogen Reduction Standards (Testing of Generic *E. coli* and *Salmonella*) and *E. coli* O157:H7 control programs sections of its SRT.

The FSIS auditor accompanied and observed the in-plant inspection verification activities for *Salmonella* and generic *E. coli* sample collection in all four-slaughter establishments. The generic *E. coli* program places the responsibility for collection of samples upon the establishments and SIC officials to verify that this activity is performed in accordance with the official procedure. Analysis of the collected samples is conducted at the official microbiology laboratory or at the CCA's approved laboratories that are evaluated to verify that they use approved rapid methods of analysis for the quantification of generic *E. coli*, and that they have

the proper equipment to conduct the tests. The results of the testing are evaluated using statistical process control criteria to determine the adequacy of process controls and dressing procedures. The FSIS auditor observed that testing is being conducted at the audited establishments with results that were within acceptable parameters associated with adequate process control.

The auditor reviewed the *E. coli* O157:H7 testing program and records and made observations that support that SIC officials collect samples from each lot of ground beef components destined to the United States. Samples are analyzed daily at accredited establishment laboratories and weekly at the official microbiological laboratory, while the tested lots remain on hold waiting the results of the microbiological testing. The FSIS auditor also evaluated the ability of SIC officials to collect samples following N-60 methodology and observed that they perform their functions in accordance with the written protocol. Beef products from Nicaraguan certified establishments have not tested positive for the presence of *E. coli* O157:H7 in Nicaragua and at POE in the United States in the last two years.

The Director of the official government-testing laboratory, the Laboratorio Central de Diagnostico Veterinario y Microbiologia de Alimentos, was interviewed regarding the performance of the laboratory. The collection and testing of samples for *E. coli* O157:H7 and STECs is performed daily by the establishment laboratory using the PCR and MLG 5.08. The FSIS MLG 5.04 method is used for the *E. coli* STECs analysis. Government officials collect and analyze *E. coli* O157:H7 and STECs in the official government laboratory on a weekly basis. The positive sample results are reported by the official laboratory to the CVO who reports it to the IIC, and he in turn reports the results to the establishment. The CCA performs verification at the private laboratories annually.

The CCA has identified *E. coli* O157:H7 in beef trimmings and components and six additional non-O157 STECs (O26, O45, O103, O111, O121 and O145) in beef manufacturing trimmings as adulterants and has established a zero-tolerance policy.

Additionally, the FSIS auditor verified that the CCA has implemented sampling and testing of beef carcasses for the presence of *Salmonella* at slaughter establishments certified to export beef products to the United States and considers any carcass that tests positive as inedible. Random samples are collected daily by CCA officials following standardized sampling methodology. The samples are then analysed at the official government microbiological laboratory following the FSIS MLG 4.05 method to detect *Salmonella* in raw meat products. Corrective actions that are implemented when carcasses test positive include rendering the affected carcass and intensifying sampling frequency. An additional positive during intensified sampling triggers additional measures that require that the establishment reassess its HACCP program and additional testing. The occurrence of a third positive result would lead to suspension of eligibility of the establishment, which would be reinstated after implementation of demonstrable effective controls. None of the certified establishments in Nicaragua has been suspended because of repetitive *Salmonella* positive results in the last two years.

FSIS concludes that based on the results of the overall microbiological component assessment, the CCA continues to meet the core equivalence requirements for this component. FSIS finds that the CCA operates at an “average” level of performance.

X. CONCLUSIONS AND NEXT STEPS

The audit results show that Nicaragua’s inspection system is performing at an “average” level in maintaining its equivalence. FSIS concluded that the CCA is meeting the core requirements for all components. However, the FSIS auditor identified a need for improvement within the HACCP systems component.

The audit finding was conveyed by the FSIS auditor to the IPSA inspection officials at an exit meeting on September 18, 2014, in Managua. The CCA understood and accepted the need to address this finding to maintain its equivalence. FSIS will evaluate the adequacy of the CCA’s proposed corrective actions once received, and base future equivalence verification activities on the information provided.

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 Matadero Nuevo Carnic Managua Nicaragua	2. AUDIT DATE 09/9/2014	3. ESTABLISHMENT NO. 5	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
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/Park 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. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 09/09/2014 Est #: 5 [S/B] (Nicaragua)

58/51 The FSIS auditor observed that an employee performing the SRM tonsil removal did not follow the written SRM procedures as the color of the knives being used was different than that described in the procedure. This non-compliance was corrected immediately by the establishment management.

61. NAME OF AUDITOR
Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 9/9/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Industrial Commercial San Martin, Km 67.5 Carratera Pan Americana Nicaragua	2. AUDIT DATE 09/10/2014	3. ESTABLISHMENT NO. 4	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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	X	33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
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/Park 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. SRM	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 09/10/2014 Est 4 #: [S/B] (Nicaragua)

7/51 During the on-site audit of the boning room the FSIS auditor observed that there has not been written sanitation program for handling of the fallen equipment (knives, knife sharpener) on the floor. Currently performed corrective action includes the verbal instruction to employees to sanitize their equipment and wash their hands. Additionally, there is a twenty minutes sound signal requiring employees to sanitize knives. This non-compliance was scheduled for corrective action.

10/51 During the on-site audit of the establishment, the over-product condensation from pipes and over-head railing structure were observed in the carcass chiller. This condensation was wiped off by the establishment employee without removing carcasses. Immediate corrective action performed by establishment employees included to remove carcasses from affected chiller, rewash the affected carcasses, spray them with lactic acid and send collected samples for laboratory testing.

61. NAME OF AUDITOR

Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 9/10/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Novaterra, Municipio Tipitapa, Nicaragua	2. AUDIT DATE 09/11/2014	3. ESTABLISHMENT NO. 2	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
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.		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. SRM	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 09/11/2014 Est #: 2 [S/B] (Nicaragua)

46/51 The operator of the splitting saw was observed to set the handle portion of the equipment on the floor of the moving platform he was perched on after every carcass. Immediate corrective action was taken by the establishment employee to use the metal stand for affected portion of the split saw (handle).

61. NAME OF AUDITOR
Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 9/11/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Central Juigalpa Km 130 Route to Juigalpa, Comarca San Estebon Nicaragua	2. AUDIT DATE 09/12/2014	3. ESTABLISHMENT NO. 8	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
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.		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/Park 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. SRM	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 09/12/2014 Est # 8 [S/B] Nicaragua)

10/51 During the on-site audit of the establishment, the over-product condensation from pipes and over-head railing structure were observed in the carcass chiller. This condensation was wiped off by the establishment employee without removing carcasses.

Immediate corrective action was performed by establishment employees, and included the removal of carcasses from the affected chiller, rewash of the affected carcasses, spray them with lactic acid and send the collected samples for laboratory micro testing.

46/51 The one of the knife sterilizers in the slaughter room did not have sufficient amount of sanitizing water. This non-compliance was immediately corrected by the establishment management.

61. NAME OF AUDITOR

Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

 9/12/2014

APPENDIX B: Nicaragua's Response to the Draft Final Audit Report – The Government of Nicaragua did not send any comments to the Draft Final Report.