



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

FEB 25 2013

Dr. Norman Valdivia Quijano
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Dear Dr. Valdivia,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Nicaragua's meat inspection system from March 13 to March 22, 2012. FSIS has received your comments and has incorporated the information received into the report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at Shaukat.Syed@usda.gov.

Sincerely,

Dr. Shaukat H. Syed, Director
International Audit Staff
Office of International Affairs

Enclosure

FEB 25 2013

FINAL REPORT OF AN AUDIT CONDUCTED IN
NICARAGUA
MARCH 13-22, 2012

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

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 13 through March 22, 2012, to determine if 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 which are safe, unadulterated, and properly labeled.

The focus of the audit was on the ability of the Central Competent Authority (CCA), Direccion General de Proteccion y Sanidad Agropecuaria (DGPSA), to regulate meat products production. FSIS reviewed and verified the information provided by the CCA in the Self Reporting Tool (SRT 2009 Version) during an onsite audit, which included one central and three local government offices; three bovine slaughter establishments; and government chemical residues and microbiology laboratories. Determinations concerning the effectiveness of Nicaragua's meat inspection system focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points Systems, (5) Chemical Residue Control Programs and (6) Microbiological Testing Programs.

The audit outcome made evident that the CCA must implement improvements to several components of its meat inspection system to ensure ongoing equivalence of the Nicaraguan meat inspection system with FSIS. The CCA implemented immediate and adequate corrective actions and proposed long term activities to further address the reported audit findings, which are summarized below:

- Government Oversight Component
 - Implementation of the procedure for evaluation of written HACCP programs and in-plant verification activities related to facility maintenance require the attention of the CCA. Officials need additional training and/or supervisory feedback to improve the level of knowledge and/or execution of their duties.
 - Official recordkeeping is not maintained uniformly by in-plant inspection personnel at all certified establishments.
 - CCA oversight has not ensured that the two official laboratories fully meet the FSIS general criteria for testing laboratories provided in ISO/IEC Guide 17025
- Sanitation
 - The CCA must improve the ability of in-plant officials to evaluate compliance of establishments with the regulatory requirements for construction and maintenance of facilities.
- HACCP
 - The CCA was unable to demonstrate that the review process provided an adequate assessment of the HACCP plans used by certified establishments
- Chemical Residue Program Component
 - The residue control plan does not include measures that are to serve as deterrent against the slaughtering of animals with violative residues

Nicaraguan government officials instituted immediate corrective actions to address the audit findings and proposed additional long term corrective actions. The CCA has sent to FSIS information that documents the implementation of the long term corrective measures that the CCA had proposed to ensure ongoing equivalence of the Nicaraguan system with FSIS.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AI	Auxiliary Inspector
BLAPHR	Law 291, Basic Law of Animal and Plant Health and its Regulations
CCA	Central Competent Authority (DGPSA)
DIA	Direccion de Inocuidad Agroalimentaria
DGPSA	Direccion General de Proteccion y Sanidad Agropecuaria
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
GPHAS	General Procedure for Audits of HACCP Systems
HTU	HACCP Technical Unit
IAS	International Audit Staff
MAGFOR	Ministerio Agropecuario y Forestal (Ministry of Agriculture and Forestry)
MPDAI	Manual of Procedures of the Directorate of Animal Industry
MVO	Medico Veterinario Oficial (Veterinary Medical Officer)
OMIPAEN	Official Meat Inspection Procedures for Authorized Establishments of Nicaragua
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Points
<i>Salmonella</i>	<i>Salmonella</i> species
SIC	Servicio de Inspeccion de Carnes (Meat Inspection Service)
SMIRCE	Sanitary Meat Inspection Regulations for Certified Establishments
SPS	Sanitation Performance Standards
SRM	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures
USDA	United States Department of Agriculture

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Nicaragua's meat inspection system from March 13 through March 22, 2012.

The audit began with an entrance meeting held on March 13, 2012, in Managua with the participation of representatives from the Central Competent Authority (CCA) – General Directorate for the Protection of Plant and Animal Health (DGPSA), Directorate for Agricultural Food Safety (DIA) and the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS).

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to verify that Nicaragua's food safety system governing meat continues to be equivalent to that of the United States of America (U.S.), with the resultant capacity to produce products which are safe, unadulterated, and properly labeled.

In pursuit of this objective, FSIS conducted an analysis of information provided by Nicaragua in the FSIS document entitled Self Reporting Tool (SRT), U.S.'s port-of-entry (POE) testing results, other data collected by FSIS and findings reported from onsite audits conducted in the last three years, prior to conducting this audit.

The FSIS auditor was accompanied throughout the entire audit by representatives from the DIA and the Meat Inspection Service (SIC).

Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government oversight, (2) Statutory authority and food safety regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical residues control programs, and (6) Microbiological testing programs.

Administrative functions of the system were reviewed at CCA headquarters and at three local inspection offices, during which the auditor evaluated the management control systems in place which ensure that the national system of inspection, verification, and enforcement is implemented as intended.

A sample of three establishments was selected from a total of five, currently certified to export meat products to the U.S. During the establishment visits, particular attention was given to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

Additionally, the two official laboratories that conduct microbiological and chemical residues analyses were audited to verify their ability to provide adequate technical support to the inspection system and the oversight that the CCA provides to their functions.

Sectors Visited During the Audit		No. Sites	Locations
Competent Authority Offices	Central	1	Managua
	Local	3	Managua, Juigalpa and Tipitapa
Laboratories		2	Managua
Slaughter Establishments		3	<ul style="list-style-type: none"> • Est. 5, Nuevo Carnic, S. A. (bovine) • Est. 8, Matadero Central, S. A. (bovine) • Est. 2, Matadero Novaterra, S. A. (bovine)

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

The audit standards included all applicable legislation and procedures originally determined by FSIS as equivalent as part of the initial review process, and any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Nicaragua has equivalence determinations in place for the following:

- The method used to analyze samples for diethylstilbesterol J.A.O.A.C., 56, No. 4, 1973
- National Residue Program
- National program for *E. coli* O157:H7
- Neogen Reveal analytical Method for *E. coli* O157:H7

4. BACKGROUND

Nicaragua is eligible to export meat products to the U.S. and in fiscal year 2011, it exported 233,074,736 pounds of raw-not ground beef products. FSIS re-inspected 18,884,696 pounds of that volume and rejected 235,327 pounds at POE due to findings that were not of public health significance.

The last audit conducted by FSIS of the Nicaragua's meat inspection system was conducted in 2009. Reported findings for that audit pertained to the Sanitation and HACCP components, which Nicaraguan officials promptly addressed during the completion of that audit. Records, i.e. Informe de Acciones Correctivas, provided by the CCA for FSIS review, documented that in-plant inspection officials appropriately verified and documented corrective actions implemented by the establishment. FSIS verified that past findings had been corrected.

The FSIS final audit reports for Nicaragua's meat inspection system are available on the FSIS' website at:

http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

5. GOVERNMENT OVERSIGHT

The first of the six equivalence components of the meat inspection system of Nicaragua that FSIS reviewed was Government Oversight. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT (2009 Version) and onsite observations made by the FSIS auditor at government offices, establishments and laboratories of the system.

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 oversees production activities of establishments that intend to export beef products to the U.S. The CCA therefore, conducts initial and ongoing evaluations of establishments authorized to export beef products to the U.S. 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 by the CCA yearly. Additionally, DGPSA has direct authority over the official Chemical Residue and Microbiological laboratories of the system that perform analyzes of meat products exported to the U.S.

FSIS verified that the DGPSA oversees the DIA, which manages Nicaragua's Meat Inspection Service (SIC). 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 products inspection system and the SIC provides delivery of services in the field.

All individuals who work for the Nicaraguan meat inspection system, from the CCA down to in-plant officials and laboratory personnel are employees of the Government of Nicaragua (GON), who 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 services rendered and the fees paid are received by the Delegacion Administrativa Financiera (DGPSA-MAGFOR) 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 U.S. VMOs serve as veterinarians in charge and supervise the performance of teams of auxiliary inspectors (AI) at their duty stations. AI's conduct inspection duties including ante and post mortem inspection as well as daily verification of the establishments' compliance with the sanitary 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. Once selected to serve as officials, they receive general training on the different aspects of veterinary meat inspection. This supplemental training is provided to the veterinarians via on the job training exercises and in-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 include enforcement of U.S. export requirements, slaughter inspection, sampling methodology, HACCP, SSOP, food microbiology, meat technology, meat inspection, and specified risk materials (SRM) handling.

During the onsite evaluation of the establishments, FSIS verified that in-plant inspection personnel staffing levels are consistent with established protocols that address normal manpower requirements and manpower shortages.

The CCA provides uniform 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 which include procedures to be followed by inspection personnel to conduct uniform inspection of production activities and verification of adequacy of food safety controls at establishments certified to export beef products to the U.S. 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 annexed updated procedures and notifications that are transmitted via electronic mail, standard mail and telephone

communications. During the audit of the local government offices activities, FSIS verified that inspection personnel were familiar with the sources of regulatory guidance provided by the CCA. However, observations of the actual conditions of the establishments and documents reviews indicated that the evaluation of written HACCP programs and the adequacy of construction and maintenance of the facilities had not been adequately conducted as described in the portions of this report that address the HACCP and Sanitation components of the system.

FSIS reviewed records maintained by in-plant inspection personnel and conducted onsite observations at the establishments to assess the adequacy of official food safety regulatory activities being performed at all establishments audited. FSIS verified that government officials use their legal authority to enforce the rules of the meat inspection system, identify and document non compliances and verify the adequacy of corrective actions. However, FSIS observed that official recordkeeping maintained at local offices lacks uniformity.

- Forms that in-plant inspection officials use to document daily monitoring results, sample shipping and government seals control, vary in design. Entries made in the forms are not consistent among establishments, e.g. forms used to ship samples to the microbiological laboratory from one certified establishment did not have a space to enter the date of shipment of the sample. The design of the forms used to record SSOP and HACCP monitoring results at two of the three audited establishment differ in design and did not bear any official markings that could identify them as government records, and at one of the three establishments audited, the log of controlled government seals did not identify the official issuing those seals. This lack of uniformity could limit the ability of supervisory reviewers to accurately evaluate official recordkeeping activities and identification of developing non-compliance trends.

In response to this finding, the CVO stated that in April of 2012, his office would initiate and coordinate the revision of official forms to obtain uniformity in their design and use. This finding, therefore, required that the CCA provide to FSIS evidence that the planned corrective measures were adequately implemented. The CCA reported to the FSIS that the official forms used by certified establishments had been revised, and harmonized and included copies of the revised forms with the report.

FSIS assessed the laboratory oversight procedures by conducting onsite observations at the laboratories and by reviewing records of laboratory personnel qualifications and training, as well as written operational procedures. The assessment revealed that the CCA ensured that analysts stationed at both laboratories possessed relevant academic credentials and that analysts had received training on analytical methodology and current laboratory procedures. In addition, records maintained at the laboratories indicate that analysts have successfully completed intra and inter-laboratory proficiency evaluations necessary to gradually expand the scope of their analytical qualifications as the needs of the laboratories demand.

FSIS also evaluated the government oversight provided to the two official laboratories that conduct analysis of products to be exported to the U.S. from certified establishments. One laboratory conducts analysis of samples as part of the microbiological control

programs. The other laboratory performs analysis of tissues for the detection of chemical residues. Verification testing frequencies, development of sampling protocols, and training programs related to the scope of responsibilities of the technical support are designed with the participation of the CVO, the laboratory managers, and DIA and DGPSA officials. The CCA oversees the overall administrative functions of the two laboratories and has delegated the responsibility of the auditing of the performance of the meat products analysis sections of both laboratories to the CVO. FSIS was notified that the auditing of the laboratories was recently implemented as a regular practice and is scheduled to take place on an annual basis. The scope of the audits conducted by the CVO includes administrative and technical controls maintained by managers over the sections of their laboratories that analyze samples from certified establishments. FSIS reviewed records of analyses, laboratory audit reports, and conducted onsite observations of the laboratories' facilities; and verified that the CVO conducted audits of both laboratories and had reported audit findings to both laboratories. However, corrective actions to address the reported findings had not been fully implemented.

- The CVO conducted an audit of the chemical residue laboratory on April 19, 2011. But, FSIS observed that the required corrective actions had not been implemented. For instance, reagent containers were not properly labeled, laboratory personnel used different versions of forms to record results of analysis, and unauthorized forms that did not include all information required for inclusion in the official records. In addition, personnel at the laboratory operated without written, operational procedures. The laboratory manager indicated that under the current conditions, quality assurance standards are communicated orally. However, these findings indicate that this laboratory does not meet fully the general criteria for testing laboratories provided in ISO/IEC Guide 17025, which includes requirements for laboratories to establish quality control procedures and ensure that these procedures are followed.
- The audit conducted by the CVO of the microbiological analysis laboratory took place in February 2012, and in a similar situation to the one observed at the residues laboratory, corrective actions had not been implemented. FSIS also identified that reagent containers and growth media were not properly labeled. The FSIS auditor also observed that official samples arrive to the laboratory accompanied by forms that contain inaccurate and unclear sample shipping dates and lab personnel at receiving do not report these errors. Requests for specific analyses are at times not presented in writing but via a telephone call without generating documentation of the request made. In addition, personnel that prepare solutions and manage the stock of reagents rely on their memory to recognize when solutions have been prepared and for what purpose. These findings indicate that this laboratory does not meet fully the FSIS general criteria for testing laboratories provided in ISO/IEC Guide 17025, which includes requirements for laboratories to establish quality control procedures and ensure that these procedures are followed.

The CVO and laboratory managers, implemented immediate corrective actions to address the findings reported during this audit and indicated that as a long term corrective

measures, the CCA had planned a gradual implementation of ISO/IEC 17025 to be initiated in April 2012, which would be fully implemented as the two laboratories are moved to their new locations. Furthermore, they indicated that a compilation of operational procedures has been initiated to address the CVO audit findings and the findings reported by FSIS during this audit. In response to the findings reported above, the CCA should confirm the implementation of measures that meet ISO/IEC 17025 at both laboratories. The CCA has sent to FSIS information that further addresses the status of implementation of the proposed long term corrective measures.

In conclusion, the meat inspection system is organized and administered by the national government and provides standards equivalent to those of the Federal system of meat inspection in the United States. However, FSIS identified areas of government oversight that require the attention of the CCA. As discussed above the evaluation of written HACCP programs and verification activities related to facility maintenance conducted by government officials need improvement, official recordkeeping is not uniform and the laboratories do not fully meet the FSIS general criteria for testing laboratories provided in ISO/IEC Guide 17025.

However, regardless of the HACCP program's design errors, quality assurance personnel effectively control food safety hazards through other good manufacturing practices or standard operating procedures. Field personnel instituted immediate corrective actions to address the findings reported for this component of the system, but the CCA must provide to the FSIS verifiable documentation to demonstrate that the proposed long term corrective actions have been adequately implemented and verified as effective. The CCA provided to FSIS information that documents implementation of the proposed long term corrective actions.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework utilized by the CCA to impose upon producers, requirements equivalent to those governing the system of meat inspection of the U.S.

The evaluation of this component included an analysis of information provided by the CCA in the SRT (2009 version) and observations of the functions of government offices, establishments and laboratories, gathered during the onsite audit of the system. 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 (BLAPHR). The system has also developed sanitary meat inspection regulations for certified establishments (SMIRCE) that provide requirements that apply to the design and construction of establishments and the pieces of equipment used in the meat production processes, and require that producers adopt sanitary measures that ensure that meat products are safe, wholesome, properly labeled and properly packaged. Additionally, the

SMIRCE of the system provide 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. Onsite observations, and government and plant records reviews conducted by FSIS, demonstrated that from the point of arrival to the establishments, all cattle are identified and inspected in accordance with established procedures that ensure that only animals that pass ante-mortem inspection continue to slaughter. The FSIS auditor verified the adequacy of ante-mortem facilities and compliance of operators with humane handling requirements imposed by the Nicaraguan government.

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. Government inspectors were observed conducting post mortem inspection in an appropriate manner in accordance with official procedures. Dispositions of suspects and verification of acceptability of the final product was conducted by the resident veterinarian, who prepares daily post-mortem disposition reports and has the legal authority to condemn carcasses and adjust production rates in accordance with the characteristics of the livestock being inspected and the incidence of pathology. Documents reviewed by FSIS during the audit reflect that a consistent and adequate delivery of official ante and post mortem inspection is maintained at certified establishments.

CCA representatives, the CVO and MVOs 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 respectively. During this audit, FSIS reviewed reports of the reviews conducted at the establishments, records of periodic supervisory reviews and records of evaluations of sanitary conditions at establishments. Additionally, FSIS conducted observations of supervisory officials as they evaluated design and maintenance of the facilities, sanitary conditions, monitoring of food safety systems, official verification activities and technical competence of in-plant officials. The observations made by FSIS indicate 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. However, FSIS findings described in sections of this report, that relate to government oversight, sanitation, and HACCP components of the system, indicate that it is necessary for the CCA to make an assessment of the knowledge and/or execution of the duties of supervisory personnel to ensure that opportunities for improvement of the ability of officials to enforce the regulation of the program are appropriately recognized, acted upon and resolved. The CCA has responded to this concern by training inspection personnel stationed at the certified establishments. Information concerning implementation of the training program was sent to FSIS.

In conclusion, the meat inspection system of Nicaragua has legal authority from which it has developed a regulatory framework to impose requirements equivalent to those governing the system of meat inspection organized and maintained by the United States. Inspection personnel provide daily inspection and verification services at certified establishments and supervisory officials periodically assess the technical expertise of inspection personnel and the ability of the establishments to comply with the regulations of the system.

SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures.

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 (2009 Version) covering Sanitation Performance Standards and Sanitation Standard Operating Procedures (SSOP's). References to the responses provided included Law 291, Basic Law of Animal and Plant Health and its Regulations (BLAPHR), Sanitary Meat Inspection Regulations for Certified Establishments (SMIRCE), Manual for Control of Implementation of SSOP's, OMIPAEN, GPAS and samples of government daily sanitation monitoring records. 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, in-plant, official inspection personnel perform duties to verify the adequacy of implementation of plant sanitation programs.

During the onsite audit, FSIS verified the adequacy of verification and inspection functions of the SIC by reviewing monitoring records for pre-operational and operational sanitation maintained by the establishment and in-plant inspection personnel and by observing inspection personnel as they performed pre-operational and operational sanitation inspection and verification of the adequacy of the establishments' sanitation programs. Records reviewed onsite, showed that inspection personnel identify and document sanitary deficiencies and verify adequacy of corrective actions. Furthermore, FSIS verified that inspection personnel framed their inspection work within the regulatory authority provided by Chapter VII, Section 26, Articles 37, 42, and Chapter XVI, Section 45, Articles 89, 190 and 191 of the SMIRCE and used the MIPOAN for that effect. However, at two of the three audited establishments, FSIS noted that in-plant inspection personnel had failed to identify deficiencies in construction and maintenance of establishments' facilities that had the potential to create insanitary conditions.

- There were openings along exterior walls and overhead structures through which vermin and insects could enter the production areas, paint flakes falling on the vicinity of uncovered product, and water droplets falling down from the ceiling in

the production area. In-plant inspection officials had conducted daily evaluations of the structures and facilities at the establishments, but had failed to identify the above described deficiencies. The findings indicate that the CCA has not adequately implemented Chapter VII, Section 26, article 37(h) and (k) of the SMIRCE that pertain to design, construction and maintenance of facilities to prevent the creation of insanitary conditions. The FSIS auditor did not observe evidence of direct product contamination in the production rooms. However, these deficiencies in construction, and maintenance of the establishment's facilities, even when they don't represent an immediate risk to the safety of the meat products, must be corrected to prevent the creation of insanitary conditions which could cause adulteration of product. Accordingly, the CCA must ensure that in plant inspection personnel adequately execute verification activities that result in the identification and correction of deficiencies within the establishments.

In conclusion, the results of the assessment of the sanitation programs conducted by FSIS, demonstrates that the Nicaraguan meat inspection system provides requirements equivalent to those of the U.S. system for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. However, the CCA must ensure that in-plant officials improve their ability to evaluate adequacy of maintenance of the establishments' facilities to verify regulatory compliance. The CCA has responded to this concern by training inspection personnel stationed at the certified establishments. Information concerning implementation of the training program was sent to FSIS.

7. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require that each official establishment develop, implement and maintain a HACCP plan.

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 (2009 Version) and documents submitted as support for the responses given including Law 291-BLAPHR, official operational procedures OMIPAEN and GPHAS and copies of official monitoring records. Additionally, FSIS conducted onsite 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 become certified as eligible to export meat products to the U.S. 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 (SSOP's) programs. The DIA is the government agency that certifies establishments producing meat products for export to the U. S. 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 GPHAS that reviewers, must follow to ensure uniform evaluation of HACCP programs and enforcement of the HACCP regulatory requirements.

FSIS evaluated onsite, the design and execution of HACCP programs at three certified slaughter establishments and verified that the CCA exerts its legal authority to require that operators comply with the HACCP System rules. In addition, the FSIS auditor reviewed documentation generated and maintained onsite that made evident that in plant and supervisory government officials regularly verify the adequacy of HACCP programs. Government records reviewed showed that in-plant officials conduct daily verification of the adequacy of implementation of HACCP plans by conducting hands on, daily monitoring procedures at the critical control points (CCP) and reviewing the HACCP records being generated by the establishments. FSIS also verified that establishments maintain documentation that include flow of product charts, written hazard analysis and associated documents that support decisions made to establish CCP's and critical limits. The establishments also generate and maintain records documenting the results of CCP monitoring activities and corrective actions implemented when deviations occurred and records that document the monitoring of the adequacy of prerequisite programs and implementation of other programs that support their HACCP system. Documents reviewed made evident that establishments adequately monitor food safety controls in operation, documenting deviations from the critical limits and implementing adequate corrective actions that include effective preventive measures. The FSIS auditor observed that Government officials and establishments operators work cooperatively to ensure that implementation of process controls ensures food safety. However, examinations of the HTU approved written HACCP programs in use at the audited establishments, revealed that their design did not meet the requirements specified in the GPHAS.

- The GPHAS, officials approved HACCP programs that inappropriately described in the hazard analysis, potential hazards at several steps of the process; e.g., microbial contamination rather than microbial growth was considered as the biological hazard controlled by chilling of products. In addition, the hazard analysis at two establishments did not consider among all likely hazards, the chemical hazards associated with the application of a chemical intervention to carcasses and meat products. HACCP plans did not include verification procedures for the calibration of devices nor provided a reference to the procedure to be used by plant personnel to calibrate the instruments used to measure critical limits such as pH, temperature and organic acid concentration.

FSIS verified that the reported flaws in the design of the HACCP program did not have an impact on the safety of the meat products due to the fact that, certified establishments operate using multiple prerequisite programs that include temperature controls of product and production rooms, control of chemical substances and calibration of instruments, which are closely monitored by the establishment and government officials. However, the CCA must ensure that HACCP program evaluators adequately verify that written HACCP programs presented for approval by the industry meet the regulatory requirements of the Nicaraguan meat inspection system.

The CVO indicated that as part of the corrective actions, the HACCP expert would conduct in-depth assessments of adequacy of HACCP programs at all certified establishments. In the meantime, establishments were to revise their HACCP programs to make immediate corrections and needed revisions to address the reported findings. Prior to the exit conference, SIC officials provided documentation to the FSIS auditor that demonstrated that the identified flaws in the design of the HACCP programs of the three audited establishments had been adequately addressed.

In conclusion, the Nicaraguan meat inspection system has the legal authority to impose requirements equivalent to those governing the system of meat inspection organized and maintained by the U.S. However, the CCA was unable to demonstrate that the review process provided an accurate assessment of the HACCP plans. Immediate corrective actions have been implemented to address the reported findings. The CCA must ensure a comprehensive evaluation of the HACCP plans is conducted and that reviewing officials of certified establishment HACCP plans possess the knowledge, skills and ability required to adequately perform their duties. The CCA has responded to this concern by training inspection personnel stationed at the certified establishments. Information concerning implementation of the training program was sent to FSIS.

8. CHEMICAL RESIDUES CONTROL PROGRAMS

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residues Control Programs. This component pertains to regulatory requirements for the inspection system to have a chemical residue control program that is organized and administered by the national government. The program must include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

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 three certified slaughter establishments. This evaluation made evident that the program, is organized and administered by the DGPSA which serves as CCA for the system. The FSIS auditor verified that the CCA in cooperation with DIA and SIC develop the annual residue monitoring plan and distribute 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 provide requirements for chemical residue analysis, and the OMIPAEN, describes the procedures to be followed by in-plant officials, plant personnel and the official laboratory, to ensure effective monitoring of chemical residues at establishments certified to produce meat products for export to the U.S. The records maintained by the meat inspection system indicate that currently, Nicaragua tests tissues from slaughtered cattle destined for the U.S. market, at certified establishments for the presence of nine classes of compounds, using FSIS methods of analysis.

FSIS reviewed the residue monitoring plan being implemented by the Nicaraguan meat inspection system and observed that the sampling results for 2010 showed an increase in positive violative results for macrocyclic lactones (ML) (Avermectins). In response to that event, the Nicaraguan authorities increased the number of samples collected in 2011 to 156 per establishment. But, results of sampling for ML for year 2011 were again in the increase and the CCA responded to the observed continued increase of positives by adjusting again the sampling frequency for year 2012. Accordingly, 318 samples are to be collected from each certified establishment during 2012. As stated by Nicaraguan officials, an increase in the number of samples collected, would translate into a greater level of confidence of the sampling protocol for the detection of macrocyclic lactones in products destined for the U.S.

FSIS verified that the sampling protocol included in the residue control program applies only to certified establishments that export meat products and that in accordance 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 U.S. Furthermore, violative results are reported by the laboratory directly to the CCA, DIA, in-plant SIC personnel, who initiate follow-up that includes identification and segregation, under official control, of the involved product, that in accordance with the regulations of the system is only eligible for sale in the local market. Additionally, SIC officials report the occurrence to the MAGFOR, 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. Currently there are no mechanisms to deter recurrence, but the CVO indicated that regulatory measures applicable to the use of ML have been developed by the MAGFOR and are being currently presented to ranchers and other parties prior to their official approval and dissemination for enforcement.

Testing conducted by FSIS at U.S. POE has not detected violative chemical residues in meat products produced by Nicaraguan certified establishments. However, in order for the Nicaraguan residue control program to be considered equivalent, it must meet the full set of applicable FSIS equivalence criteria that requires the following:

V. Compliance and Enforcement

The country must provide a description of the actions taken to deal with unsafe residues as they occur. The program must:

A. Describe the enforcement actions taken when positive or violative results occur.

FSIS food safety measure: *FSIS, as appropriate, condemns product, withholds the mark of inspection, and requests prosecution when meat, poultry or egg products are adulterated with chemical residues.*

Objective: *To ensure that regulatory action serves as a deterrent against the slaughter of animals with violative residues and the processing of adulterated product.*

Criteria: *Criteria for reaching equivalence decisions regarding the capability of a government to take regulatory actions against individuals or firms for food safety violations are as follows.*

- 1. The government has the authority and resources to remove violative product from the human food chain, to take regulatory action against violative meat, poultry or egg products, to take regulatory action against individuals who introduce violative meat, poultry or egg products in to the human food chain.*
- 2. The government takes appropriate regulatory action as required.*

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. However, as described previously in the Government Oversight portion of this report, the official residues laboratory operates without adequately meeting quality control requirements.

In conclusion, 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 and the program is adjusted on a yearly basis to address emerging concerns. However, in order to be considered equivalent, this component must meet all applicable FSIS criteria. Specifically, the Nicaraguan meat inspection system must implement regulatory actions that are to serve as deterrent against the slaughtering of animals with violative residues. Additionally, the laboratory must establish and follow quality control procedures to ensure reliability of analytical activities performed by laboratory personnel. In response, the CCA has sent to FSIS documents that describe the measures that the MAGFOR will enforce to control chemical residues at certified slaughter establishments in Nicaragua and the measures implemented by the residues laboratory to address the above reported findings.

9. MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to microbiological analysis

programs that the Nicaraguan meat inspection system administers to verify that products for export to the U.S. are safe and wholesome.

During this audit, FSIS evaluated the microbiological raw beef products sampling and testing programs for generic *E. coli*, *Salmonella* and *E. coli* O157:H7 as they are being implemented by establishments and 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 (Version 2010). Documents reviewed included Law 291-BLAPHR, OMIPAEN, Control of Analysis and Detection of *E. coli* Programs Manual (CADECMP) and the Protocol for Routine Sampling of *E. coli* O157:H7.

The FSIS auditor verified that officials of the SIC maintain monitoring and verification activities following standardized instructions for collection, handling and shipping of samples to the official laboratory. The generic *E. coli* program places the responsibility for collection of samples upon the establishments and SIC officials 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 CCA's approved laboratories which 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. During this audit, FSIS observed that testing being conducted at the audited establishments yielded results that were within acceptable parameters associated with adequate process control. However, as it was indicated in the Government Oversight portion of this report, the fact that the official microbiological laboratory does not implement an adequate quality control program requires the attention of the CCA to prevent the creation of conditions that could compromise the analysis conducted.

In reference to *E. coli* O157 testing program, records reviewed and observations made indicate that SIC officials collect samples from each lot of ground beef components destined to the U.S. Samples are then analyzed daily at accredited establishment's laboratories and weekly at the official microbiological laboratory while the tested lots remain on hold. The FSIS auditor also evaluated the ability of SIC officials to collect samples following N-60 methodology and observed that they performed their functions in accordance with the protocol. Beef products from Nicaraguan certified establishments have not tested positive for the presence of *E. coli* O157 in Nicaragua and at POE in the U.S. in the last three years.

During the audit, FSIS also verified that the CCA has implemented a sampling and testing of beef carcasses for the presence of *Salmonella* at slaughter establishments certified to export beef products to the U.S. and considers any carcass that tests positive, as inedible. Random samples are collected daily by SIC officials following standardized sampling methodology. The samples are then analyzed at the official microbiological laboratory following the FSIS method to detect and quantify *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 further testing. The occurrence of a third positive result would lead to suspension of eligibility of the establishment, which would be reinstated upon implementation of demonstrable effective controls. None of the certified establishments in Nicaragua has been suspended due to repetitive *Salmonella* positive results

FSIS reviewed records and documents maintained at the laboratory that pertained to the qualifications of personnel assigned to work in the laboratory and verified that analysts are periodically evaluated to verify that their level of expertise is appropriate for the scope of their assignments. In addition, the laboratory maintains records of results of the analyses conducted for the establishments and for the government.

All analytical work performed by the sectors of the CCA that are involved in the administration of the microbiological testing programs is fully reimbursable by establishment operators who pay for services rendered to the treasury of the MAGFOR.

In conclusion, the meat inspection system of Nicaragua administers microbiological analysis programs to verify that products for export to the U.S. are safe and wholesome. However, the CCA must ensure that the official microbiological laboratory implements an effective quality control program to prevent the creation of conditions that could compromise the accuracy of the analytical results.

10. EXIT MEETING

An exit meeting was held on March 22, 2012 in Managua with representatives of the DGPSA, DIA and SIC. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

The CCA understood the findings and indicated that upon receipt of the draft final report they would provide further information that documents implementation of corrective actions to the findings of this audit.

11. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The audit outcome made evident that the current level of government oversight provided by the CCA requires improvement to ensure that ongoing equivalence of the Nicaraguan meat inspection system is maintained. The CCA addressed the findings that FSIS identified within the several components of its meat inspection system by implementing immediate and adequate corrective actions and proposed long term activities to further address the findings of this audit which are summarized below:

- Government Oversight Component
 - There is a Lack of uniformity of official recordkeeping at local government offices. The CCA must ensure that forms used by inspection officials to record the results of daily monitoring activities, to control microbiological sample shipping, and to control government seals do not vary in design and recorded content. In response to the draft audit report the CCA should provide the expected completion date that forms will be uniform in format.
 - Inspection personnel require additional training to remedy deficiencies of knowledge and/or execution. Observations conducted by FSIS indicate that there exists a need for an improvement of the verification activities of applicable sanitation and HACCP plans.
 - Government oversight must also ensure that the laboratories of the system meet FSIS equivalence criteria. The CCA must therefore provide additional information to demonstrate that the laboratories that support the system meet FSIS' equivalence criteria and documentation indicating that the laboratories' concerns have been corrected including implementation of the general criteria, for testing laboratories provided in ISO/IEC Guide 17025 that includes requirements for laboratories to establish quality control procedures and ensure that these procedures are followed.

- Sanitation Component
 - The CCA must develop strategies to ensure that in plant officials effectively evaluate sanitary conditions at certified establishments in accordance with the portions of the regulations of the system and the GPHAS that apply to construction and maintenance of the facilities. Accordingly, the CCA must ensure that the establishments adequately correct identified deficiencies and must provide additional guidance to in-plant officials on daily monitoring of the implementation of sanitation programs.

- HACCP Component
 - The CCA must provide additional information in order for the FSIS to verify that an adequate, comprehensive evaluation of the design of the HACCP programs used by certified establishments was conducted and that officials assigned to verification of the adequacy of the design of HACCP programs possess the level of competency required to adequately perform their duties

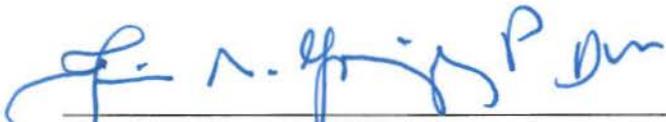
- Chemical Residue Program Component
 - The Nicaraguan meat inspection system must implement regulatory actions that are to serve as deterrent against the slaughtering of animals with violative residues. Additionally, the residues laboratory serving the system must establish and follow quality control procedures to ensure reliability of analytical activities performed by laboratory personnel

- Microbiological Testing Component

- The Microbiological laboratory serving the system must establish and follow quality control procedures to ensure reliability of analytical activities performed by laboratory personnel

The above summarized findings were promptly addressed by the CCA and immediate and adequate corrective actions were implemented. However, the need for the CCA to provide verifiable information concerning implementation of long term corrective measures remains. Therefore, the CCA must provide to the FSIS, additional documentation pertaining to the effective implementation of the long term corrective actions that were proposed by Nicaragua to address the findings of this audit as presented in this report.

The CCA has sent to FSIS information that documents the implementation of the long term corrective measures that the CCA had proposed to ensure ongoing equivalence of the Nicaraguan system with FSIS.



Francisco Gonzalez, DVM
Senior Program Auditor

13. ATTACHMENTS TO THE AUDIT REPORT

Establishments Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Carnic SA Managua	2. AUDIT DATE 3/14/2012	3. ESTABLISHMENT NO. Est. 5	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Francisco Gonzalez, 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	
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.	X	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.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	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	
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

Est. 5

15/51 The regulations of the Nicaraguan meat inspection system require that written HACCP programs be approved by the CCA prior to the granting of certification of eligibility to export meat products. FSIS observed that the head official at this establishment had approved as correct the written HACCP program of this establishment. However, the evaluation overlooked several flaws in the design of the hazard analysis, flow of product charts and CCP monitoring records. The hazard analysis mistakenly identified at several steps in the process, microbial contamination as a biological hazard where bacterial growth should be in fact the concern. The hazard analysis also identifies a physical hazard at the injection step, but the documented thought process entered in the form does not correspond to the actual controls that are in place to prevent such hazard.

51 Inventory control of official seals applied to samples sent to the laboratory and transported by company employees is not being maintained by inspection personnel at this establishment.

Past supervisory reviews had not detected the flaws noted by FSIS. The CVO indicated that as part of the corrective actions, the HACCP expert for the Ministry of Agriculture, Livestock and Forestry, MAGFOR by its initials in Spanish, would conduct in-depth assessments of adequacy of HACCP programs at all certified establishments. In the meantime, the establishment would review its program to make the pertinent revisions.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Novaterra Tipitapa, Nicaragua	2. AUDIT DATE 3/16/2012	3. ESTABLISHMENT NO. Est. 2	4. NAME OF COUNTRY Nicaragua
5. NAME OF AUDITOR(S) Francisco Gonzalez, 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	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	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	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	
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

Est. 2

51 There is no inventory control of official seal applied to the samples transported to the official laboratory by a company employee. The plant veterinarian does not keep the program for sampling of tissues distributed by the technical support confidentially. This practice could cause other individuals from becoming aware of the scheduled sampling dates.

Forms used to record result of verification activities of adequacy of SSOP and HACCP programs are not the same as used by officials at other establishments audited. Forms at this establishment do not have indicators of their being official documents.

10/51 Supervisory personnel were observed conducting operational sanitation verification in a less than adequate manner. FSIS auditor brought to the attention of the officials, areas that required attention. There were flakes of paint on the surfaces of structures located in the proximity of areas where uncovered raw products were handled and one overhead cooling unit with organic residue accumulation on its surfaces.

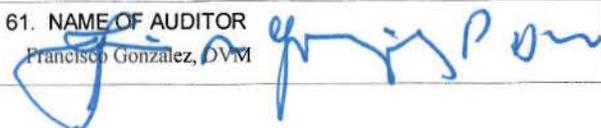
15/51 The hazard analysis documented erroneously that diseased animals were slaughtered under government control and did not recognize the application of a chemical to carcasses as a potential chemical hazard. Inspection personnel that had reviewed the HACCP program maintained by the establishment had not identified these inadequacies in the hazard analysis.

38/51 Openings in the roofing of the viscera processing area that could allow entrance of vermin and pests. Inspection personnel had not identified this problem with the roof.

61. NAME OF AUDITOR

Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE



United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Central SA Juigalpa, Nicaragua	2. AUDIT DATE 3/15/2012	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Francisco Gonzalez, 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
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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	X
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.	X	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	
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26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
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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

51. Government forms used to record sanitation non-compliances are not uniform. Two different versions are in use at this establishment.

Inspection personnel make entries in government forms in a manner that is not consistent with their design. CVO indicated that all forms used by officials at certified establishments will be revised to develop uniformity in design and instructions will be issued to ensure that in-plant officials properly complete the forms.

15/51 There are flaws in the design of the HACCP plan and hazard analysis used by the establishment. The verification section of the HACCP slaughter plan maintained by the establishment, does not describe the calibration of instruments used to measure the limits of the critical control points and does not indicate how that task will be accomplished. In addition, carcasses are sprayed with a chemical substance, an antimicrobial intervention, but the hazard analysis did not identify the application of a chemical to the carcasses as a potential chemical hazard. However, there are multiple controls from the point of receiving to application where the chemical is identified and controlled. Reviews of the written HACCP program conducted by in-plant personnel and supervisory reviews had not identified the above described flaws in the program.

38/51 There were areas in the outer walls of the building where screening placed to prevent insects and other pests from entering the building, did not fit tightly in the openings or was torn. There were also openings where screening or any other measure had not been put in place to prevent pest and rodents from entering the production areas. Evaluation of the facilities previously conducted by in-plant inspection personnel and supervisory officials had not identified these deficiencies.

39/51 In the deboning area, the FSIS auditor observed water dripping from the ceiling falling on top surfaces of a work station where boxes were being prepared for packaging of products. These boxes are routinely used for either vacuum packed or exposed meat products. Inspection officials had evaluated the area in question without noticing the problem.

61. NAME OF AUDITOR
Francisco Gonzalez, DVM

62. AUDITOR SIGNATURE AND DATE