



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Norman Valdivia Quijano
Chief of the Meat Inspection Service
Dirección General de Protección y Sanidad Agropecuaria
Ministry of Agriculture and Forestry
Gobierno de Nicaragua
Managua, Nicaragua

Dear Dr. Valdivia:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Nicaragua's meat inspection system July 8 through July 22, 2008. Comments from the government of Nicaragua have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at manzoor.chaudry@fsis.usda.gov.

Sincerely,

Manzoor Chaudry
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL REPORT OF AN AUDIT CARRIED OUT IN
NICARAGUA COVERING NICARAGUA'S MEAT
INSPECTION SYSTEM

JULY 8 THROUGH JULY 22, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AI	Auxiliary Inspector
CCA	Central Competent Authority
CVMI	Chief Veterinary Meat Inspector
DGPSA	<i>Direccion General de Proteccion y Sanidad Agropecuaria</i> or General Directorate for Agricultural Protection and Health
DIA	<i>Direccion de Inocuidad Agroalimentaria</i> or Division of Food Safety
<i>E. coli</i>	Generic <i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
MAG-FOR	<i>Ministerio de Agricultura y Ganaderia</i> , Ministry of Agriculture and Forestry
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/ Hazard Analysis and Critical Control Point Systems
SPS	Sanitation Performance Standards
SRM	Specified Risk Material
SSOP	Sanitation Standard Operating Procedures
<i>Salmonella</i>	<i>Salmonella</i> species
VIC	Veterinarian-In-Charge

1. INTRODUCTION

The audit took place in Nicaragua from July 8 through July 22, 2008.

An opening meeting was held on July 8, 2008 in Managua with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the details of the audit itinerary, and requested additional information needed to complete the audit of Nicaragua's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the *Direccion General de Proteccion y Sanidad Agropecuaria* (DGPSA), and when appropriate, representatives from the local inspection offices.

2. OBJECTIVE OF THE AUDIT

This was a routine audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States with special emphasis on controls for *Escherichia coli* (*E. coli*) O157:H7 in beef and humane handling and humane slaughter of livestock.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, the five establishments eligible to export to the United States (U.S.), the official government residue laboratory and the official government microbiology laboratory.

Competent Authority Visits		Comments
Competent Authority	1	Directly supervises the eligible establishments
Meat Slaughter and Processing Establishments	4	
Meat Processing and Cold Storage Establishment	1	
Residue Laboratory	1	
Microbiology Laboratory	1	

3. PROTOCOL

The official on-site audit was conducted in four parts. One part involved interviews with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in Nicaragua's inspection headquarters offices. The third part involved on-site visits to the four beef slaughter and processing establishments and one processing and cold storage establishment certified by Nicaragua as eligible to export to the U.S. The fourth part involved on-site visits to the government residue and microbiology laboratories conducting testing on product eligible for export to the U.S.

Program effectiveness determinations of Nicaragua's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS); (2) animal disease controls; (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Points (HACCP) programs and the testing program for generic *E. coli*; (4) residue controls; and (5) enforcement controls, including the testing program for *Salmonella* species (*Salmonella*). Nicaragua's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services were carried out by Nicaragua and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During the opening meeting, the auditor explained that FSIS audits a country's inspection system in accordance with two areas of focus. First, FSIS audits against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of livestock, the handling and disposal of inedible and condemned materials, species verification, and FSIS' requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Second, FSIS audits against any equivalence determinations that have been made by FSIS for Nicaragua under provisions of the Sanitary/Phytosanitary Agreement. Currently, a special equivalence determination regarding the method of analysis for Diethylstilbestrol in meat products is in effect for Nicaragua.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. laws and regulations, in particular:

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

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:

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

The last two FSIS audits of Nicaragua's inspection system were conducted in February/March 2006 and February/March 2007.

In February/March 2006, five establishments were certified by Nicaragua as eligible to export to the U.S. The following deficiencies were identified:

- In the cold-storage facility, although the establishment management reported taking product temperature and cleaning and sanitizing the thermometer and drill after each use, there were no written procedures and records to confirm this activity.
- In one establishment, plastic containers for edible product use were not properly cleaned and were reused. No clean containers were available in the edible offal area. Additionally, the area for washing dirty containers was located adjacent to the kill floor, in close proximity to passing edible product.
- No temperature-monitoring device or written records were available for one of the two refrigerators used for the storage of chemical standards.

In February/March 2007, five establishments were certified by Nicaragua as eligible to export to the U.S.; two of these five establishments were audited. The following deficiencies were identified:

- Several plastic cutting boards were observed with dark stains.
- A conveyor belt, used for transport of edible product, had two cracks and several dark stains.
- The conveyor belt that had been installed to replace the one found deficient during pre-operational sanitation inspection also had a crack and some dark stains.
- The door connecting the cooler with the deboning room was observed contacting carcasses when it was opened.
- Monitoring records for CCP 3, which had a Critical Limit (CL) of 47°F for carcass temperature in the cooler, indicated three deviations from the CL. However, no records of any corrective actions could be located.

One establishment was issued a Notice of Intent to Delist (NOID) for deficiencies in the implementation of basic requirements of the SSOP.

6. MAIN FINDINGS

6.1 Government Oversight

The office of the *Direccion General de Proteccion y Sanidad Agropecuaria (DGPSA)*, or the General Directorate for Agricultural Protection and Health, is under the umbrella of the *Ministerio de Agropecuario Forestal (MAG-FOR)*, or Ministry of Agriculture and Forestry.

The *Dirección de Inocuidad Agroalimentaria* (DIA) is responsible for providing government oversight of Nicaragua's meat inspection programs. DGPSA is Nicaragua's CCA and has direct authority over the National Laboratory of Residue and the Central Laboratory for Micro Analysis in Managua, the official government laboratories of Nicaragua. These official government laboratories perform analytical chemical and microbiological testing of meat products exported to the United States.

The Chief Veterinarian for Meat Inspection (CVMI) reports to the Director of DGPSA and supervises the five Veterinarians-in-Charge (VIC). The official guidelines and regulations are issued by the DIA headquarters in Managua. Any change in the regulations must be subjected to a rule-making process that includes analyzing and evaluating public comments. The structure and the function of the Ministry and Directorates have not changed since the last audit.

All inspection personnel assigned to the establishments certified to export meat to the United States are full-time government employees receiving no compensation from either industry or establishment personnel. Inspection personnel can hold outside employment provided it does not serve as a conflict of interest with their inspection duties.

Meat export certificates are controlled by the VIC and are signed and distributed on an as-needed basis to the official inspection personnel stationed at the certified establishments. Additionally, the VIC maintains documented control of all official government seals and stamps. The VIC in the five establishments currently certified as eligible to export to the United States maintain physical control of all assigned government seals and stamps.

Verification activities are performed through such activities as monthly supervisory reviews and inspection verification of establishment activities. Suspension and withdrawal of inspection is authorized by the Head of the Inspection Service.

6.1.1 CCA Control Systems

The DIA is headed by a CVMI who has the responsibility for oversight of Nicaragua's meat establishments. During this audit, this CVMI accompanied the FSIS auditor and served as the audit leader for the five establishment audits. He manages and communicates any new inspection guidelines, including new FSIS Directives, Notices, and regulations, to the VIC in all five U.S. eligible facilities and also provides instructions on how to implement them. The CVMI communicates with the VICs through faxes, e-mails, and hard-copy memos.

The CVMI is directly responsible for ensuring implementation of FSIS requirements by the VIC at each certified establishment. There are no regional or district offices in Nicaragua.

6.1.2 Ultimate Control And Supervision

The implementation of the inspection programs in the five eligible establishments that export meat product to the U.S. is accomplished through the VICs and their Auxiliary Inspectors (AIs). The VICs are rotated between the establishments every two years. At each certified establishment, the VIC has the authority to cease the establishment's production operations any time the wholesomeness and safety of the product is jeopardized. The VIC reports directly to the CVMI regarding enforcement activities. The CCA has direct supervision over inspection personnel at establishments certified to export to the U.S. Additionally, periodic supervisory audits are performed. Decisions to suspend the operations of an establishment for non-compliance or to delist an establishment from exporting to the U.S. are made by the Head of the Inspection Service.

The VIC has direct supervision over other inspection personnel assigned to certified establishments. In the five establishments certified to export meat to the U.S., *DIA* has the inspection personnel to carry out the FSIS requirements.

The government of Nicaragua has the organizational structure and staffing to ensure uniform implementation of U.S. import requirements.

6.1.3 Assignment of Competent, Qualified Inspectors

Inspection officials in the certified establishments are paid by the government of Nicaragua. The MAG-FOR employs a user-fees system to collect fees from the certified establishments for inspection services rendered.

All inspection personnel assigned to certified establishments undergo initial and ongoing training, as well as participate in practical on-the-job training under the combined supervision of the CVMI and the VIC.

All official veterinarians are qualified veterinarians who have obtained their college veterinary degrees from accredited veterinary colleges in Nicaragua and other countries in the region and in Europe. Each AI is required to have a high school diploma with a major in livestock or agriculture.

The government of Nicaragua has competent inspection personnel in all of the certified establishments.

6.1.4 Authority and Responsibility to Enforce the Laws

The sanitation, slaughter, and processing inspection procedures and standards, and the legal authority to enforce these requirements, are outlined and specified in two legal documents, the *Reglamento de Inspeccion Sanitaria de Carne para Establecimientos Autorizados* (Regulation of Sanitary Inspection of Meat for Authorized Establishments) and the *Ley (291) Basica de Salud Animal y Sanidad Vegetal* (Basic Law of Animal Health and Plant Health).

The official inspection personnel are authorized to enforce the government of Nicaragua's meat inspection legislation and U.S. import requirements, including animal health and welfare, control of animal disease, veterinary medicines, and the production of safe foods of animal origin. The CVMI of the *DIA* and the VIC at each certified establishment have the legal authority to suspend operations and delist certified establishments to prevent the export of unsafe meat to the U.S.

6.1.5 Adequate Administrative and Technical Support

The DGPSA has adequate administrative and technical support to operate Nicaragua's meat inspection system and to ensure its compliance with U.S. requirements. The CCA has the ability to support a third party audit.

6.2 Headquarters Audits

The auditor conducted a review of inspection system documents at the headquarters of the inspection service and in the inspection offices of the establishments. The records review focused primarily on food safety hazards and included the following:

- Methods of payment to inspection personnel.
- Proper distribution of relevant legislation to inspection personnel.
- Process of hiring, qualification, and assignment of inspection personnel to the U.S. certified establishments.
- Internal review reports.
- Other supervisory visits to establishments that were certified to export to the U.S.
- New laws and implementation documents such as regulations, notices, directives, and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter, and processing inspection procedures and standards.
- Products from livestock with conditions such as cysticercosis.
- Control of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution and seizure and control of noncompliant product.

No concerns arose as a result of the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited the four slaughter/processing establishments and one processing/cold storage establishment that have been certified by the *DIA* as eligible to export to the U.S. None was delisted and none was issued an NOID by Nicaraguan officials.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to U.S. requirements.

The residue laboratory audit focused on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, international check samples, and quality assurance programs, including standards books and corrective actions.

The following residue laboratory was reviewed:

The Lab Nacional de Residuos Quimicos y Biologicos

No concerns arose as a result of the residue laboratory audit.

The microbiology laboratory audit focused on the following parameters: the role of the laboratory relative to other laboratories involved in U.S. export testing; which U.S. export establishments and products were being tested; the U.S. export testing activities; the receipt of samples from all the establishments the laboratory says it services; the testing of samples for the relevant pathogens and at the relevant frequencies; the receipt of the correct type of sample; and the testing of the correct amount of product sample for the analysis.

The following microbiology laboratory was reviewed:

The Laboratoria Central de Diagnostico Veterinario Microbiologia de Alimento

The microbiology laboratory audit resulted in the following findings.

- The laboratory lacked the capability and a trained analyst to perform the isolation and identification of *E. coli* O157:H7 bacteria by a method equivalent to the method used by FSIS laboratories.
- The method of analysis used for isolation of *Salmonella* had not been submitted to FSIS for determination of equivalence and pre-enrichment of the sponge samples for *Salmonella* was not being performed in a manner equivalent to FSIS methods.
- The laboratory quality control procedures and records did not document significant details of culture media preparation and storage.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess Nicaragua's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments and except as noted below, Nicaragua's inspection system had controls in place for SSOP programs, good personal hygiene practices, and good product handling and storage practices.

In addition and except as noted below, Nicaragua's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

In four of the five establishments audited, deficiencies were noted in the Sanitation Controls.

These deficiencies are documented in the attached individual establishment checklists.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program.

In two of the five establishments audited, deficiencies were noted in the implementation of the pre-operational or operational SSOP.

In one of the five establishments audited, deficiencies were noted in the SSOP record-keeping.

These deficiencies are documented in the attached individual establishment checklists.

9.2 SANITATION PERFORMANCE STANDARDS

The FSIS regulations in 9 CFR 416.2 to 416.5 set forth specific sanitation performance standards that establishments must meet to prevent the creation of insanitary conditions that could cause the adulteration of meat products.

In three of the five establishments audited, deficiencies were noted in the implementation of the sanitation performance standards.

These deficiencies are documented in the attached individual establishment checklists.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Nicaragua's inspection system had adequate controls in place.

No deficiencies were reported.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem dispositions, humane handling and humane slaughter of livestock, post-mortem inspection procedures, post-mortem dispositions, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were reported.

11.2 HACCP Implementation

All of the establishments approved to export meat products to the U.S. are required to have developed and adequately implemented HACCP programs. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

In two of the five establishments audited, deficiencies were noted in the implementation of the HACCP plan in either the description of monitoring or verification of the Critical Control Points.

These deficiencies are documented in the attached individual establishment checklists.

11.3 Testing for Generic *E. coli*

Nicaragua had adopted the FSIS regulatory requirements for testing for generic *E. coli*. The four slaughter/processing establishments were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program. Testing for generic *E. coli* was properly conducted in all establishments.

11.4 Testing for *Listeria monocytogenes*

None of the establishments was producing any ready-to-eat products, either for the U.S. or for any other domestic or foreign markets, so the requirements for testing for *Listeria*

monocytogenes according to the Final Rule of June 6, 2003, did not apply to these establishments.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

No deficiencies were reported.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

13.1 Daily Inspection in Establishments

Documented daily inspection was provided in all eligible establishments for production days on which U.S. eligible product was produced.

13.2 Testing for *Salmonella* Species

Nicaragua had adopted the FSIS regulatory requirements for testing for *Salmonella* species. The four eligible slaughter/processing establishments were evaluated according to the criteria employed in the United States' domestic inspection program.

No deficiencies were reported.

The laboratory method recorded on the analytical results of the *Salmonella* testing had not been submitted to FSIS for equivalence determination.

13.3 Species Verification

At the time of this audit, Nicaragua was required to perform species verification on U.S. eligible products. Species verification was being conducted in the eligible establishments as required.

13.4 Periodic Reviews

Periodic supervisory reviews of all certified establishments were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

Furthermore, controls were in place for security items, shipment security, and products entering the establishments from outside sources.

National mandates for the implementation of the requirements for special handling of Specified Risk Materials regarding Bovine Spongiform Encephalopathy (BSE) had been implemented. Non-ambulatory cattle were condemned upon ante-mortem inspection, no beef containing SRMs was permitted in U.S. eligible product, mechanically-separated beef is ineligible for use in U.S. eligible product, and air-injection stunning was not permitted in Nicaragua.

Inspection service officials were not enforcing some of the U.S. requirements in four of the five certified establishments.

14. CLOSING MEETING

A closing meeting was held on July 22, 2008 with the CCA. At this meeting, the preliminary findings from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Timothy King, DVM
Senior Program Auditor

A handwritten signature in black ink, appearing to read 'Timothy King, DVM', with a horizontal line drawn through the signature.

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report (when available)

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Novaterra Km 42 Carretera Panamericana Norte Municipio Tipitapa 0	2. AUDIT DATE 07/15/08	3. ESTABLISHMENT NO. 2	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Timothy King, 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	O
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

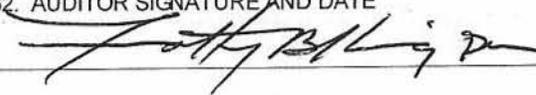
60. Observation of the Establishment

Date: 07/15/08 Est #: 2 (Matadero Novaterra [S/P/CS]) (Municipio Tipitapa, Nicaragua)

41/51. The establishment failed to maintain ventilation adequate to control condensation to the extent necessary to prevent the creation of insanitary conditions. In the box product cooler # 3, condensate was observed on the underside of the refrigeration unit drip pan. In the boxed product freezer, heavy ice buildup was observed on the walls and the supply lines to the refrigeration units. In the same freezer, the surfaces of many of the boxes were discolored and covered with frost, ice, and frozen blood. In the carcass chiller # 2, beaded condensate was observed on multiple overhead structures and condensate was dripping from a light fixture. No carcasses were present in this cooler. The inspection personnel took immediate control actions and establishment management initiated corrective actions. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 416.2(d)]

61. NAME OF AUDITOR
Timothy King, DVM

62. AUDITOR SIGNATURE AND DATE

 7/15/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Industrial Comercial San Martin Km. 67.5, Carretera Panamericana Sur P.O. Box 5 Nandaime 0	2. AUDIT DATE 07/14/2008	3. ESTABLISHMENT NO. 4	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Timothy King, 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	O
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.		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.		42. Plumbing and Sewage	
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17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/14/2008 Est #: 4 (Industrial Comercial San Martin [S/P/CS]) (Nandaime, Nicaragua)

10/51. (A) During pre-operational sanitation inspection in the deboning room, the blade guides on the band saw and the plastic guides under the bone conveyor on the center deboning table both had fat and product residue from previous production on them. In the offal preparation room of the slaughter floor, a live insect was observed under an inedible product tub. Inspection officials took control actions and establishment management initiated immediate corrective actions. (B) During operational sanitation inspection on the slaughter floor, the equipment sterilizer at the spinal cord removal station was not being maintained at the 180° Fahrenheit temperature required by the establishment's SSOP. Immediate corrective action was initiated by establishment management. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 416.13, 416.17]

39. (A) The frame on one of the tables in the deboning room was broken in two places creating an insanitary condition for the potential creation of a biofilm. (B) The gasket on the door of the # 4 carcass cooler was worn and damaged preventing effective cleaning and creation of an insanitary condition. Corrective actions were either taken or scheduled by establishment management. [9 CFR §416.2(b)]

61. NAME OF AUDITOR
Timothy King, DVM

62. AUDITOR SIGNATURE AND DATE

 7/15/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Nuevo Carnic Km. 10 1/2 Carretera Norte P.O. Box 1251 Managua 0	2. AUDIT DATE 07/9/08	3. ESTABLISHMENT NO. 5	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Timothy King, 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	O
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	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	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/9/08 Est #: 5 (Matadero Nuevo Carnic [S/P/CS]) (Managua, Nicaragua)

13/51. The Sanitation Standard Operating Procedures (SSOP) monitoring records for pre-operational sanitation inspection, on three different dates during the last two months, did not include the required entries in records for the areas and equipment inspected by the establishment monitor. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 9 CFR §416.16, 416.17]

19/51. The Hazard Analysis Critical Control Point (HACCP) written plan did not describe the Critical Control Point (CCP) ongoing verification activities in sufficient detail to determine the frequency at which the verification components would be performed. [9 CFR §327.2(a)(2)(i)(D), 9 CFR §417.2(c)(7)]

41. (A) During operational sanitation inspection, in the #5 carcass cooler water was observed dripping from overhead structures at the doorway to the cooler and from the ceiling in the cooler. (B) In the #1 carcass cooler, condensate was observed forming on the walls, doors, and many overhead structures. In both areas inspection personnel took immediate control actions and establishment management initiated corrective actions. [9 CFR §416.2(d)]

61. NAME OF AUDITOR
Tim King, DVM

62. AUDITOR SIGNATURE AND DATE

Tim King 7/15/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION IGOSA Km 107, Carretera Nandaime-Penas Blancas Rivas 0	2. AUDIT DATE 7/10/08	3. ESTABLISHMENT NO. 6	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Timothy King, 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	O
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

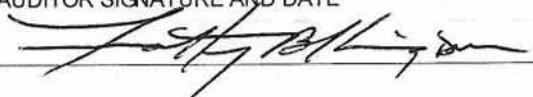
60. Observation of the Establishment

Date: 7/10/08 Est #: 6 (IGOSA [P/CS]) (Rivas, Nicaragua)

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

61. NAME OF AUDITOR
Timothy King, DVM

62. AUDITOR SIGNATURE AND DATE

 7/15/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Central S.A. (Macesa) Km. 130 1/2 Carretera a Juigalpa Juigalpa Juigalpa 0	2. AUDIT DATE 07/16/2008	3. ESTABLISHMENT NO. 8	4. NAME OF COUNTRY Nicaragua
	5. NAME OF AUDITOR(S) Timothy King, 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	O
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.		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.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/16/2008 Est #: 8 (Matadero Central S.A. (Macesa) [S/P/CS]) (Juigalpa, Nicaragua)

10/51. (A) During operational sanitation inspection, an employee in the boning room was observed handling the outer surface of product boxes and then handling edible product without first sanitizing or changing his gloves. (B) On the slaughter floor at the head inspection station, the employee trimming the heads was not adequately removing the tonsil tissue (Specified Risk Material) from the heads. The establishment management initiated immediate corrective actions in both situations. [Regulatory reference(s): 9 CFR § 310.22(a)(2), 9 CFR §327.2(a)(2)(i)(D), 9 CFR §416.13, 9 CFR §416.17]

19/51. In the written Hazard Analysis Critical Control Point (HACCP) plan, the monitoring activities described did not adequately address the control of the hazard identified at the process step. The Critical Limits (CL) that were listed were all associated with the calibration of either solutions of chemicals or equipment used in the process and did not monitor the process control point activity. [9 CFR §327.2(a)(2)(i)(D), 9 CFR §417.2(c), 9 CFR § 417.8]

61. NAME OF AUDITOR

Timothy King, DVM

62. AUDITOR SIGNATURE AND DATE

 7/16/08

UNOFFICIAL TRANSLATION

Managua, February 16, 2009

Mr.
Donald Smart
Director
International Auditing Staff
OIA-FSIS-USDA
Your hands

Dear Mr. Smart:

By this means I would like you to comment on some items that have been improved after receiving the preliminary report dated December 18, 2008, that was prepared by Dr. Timothy King:

- There is laboratory capacity for implementing the method MLG-5.04 to isolate and identify the E.Coli O157:H7 bacteria. We started implementing it on January 15 of this year.
- From November 17, 2008, the laboratory began the application of the method MLG-4.04, which is used for the isolation of salmonella, for the equivalence determination and for the pre-enrichment of the sponges' samples of salmonella. This was communicated to FSIS.
- In quality control of procedures and laboratory registries, the staff documents significant details of the preparation of the cultivation method and its storage from August 2008 on.
- All the non-compliances observed by Dr. Timothy King were corrected immediately or within ten working days after the establishments' inspection.

Without any further comments to add,

Sincerely,

Dr. Norman Valdivia Quijano
Coordinator Meat Inspection

Cc: Ms. Bernabela Orozco Membreño -Director Food Innocousness
Dr. Sonia García -Director Veterinary Diagnostics Lab.
Mr. Ervin Leiva -Embassy USDA-FSIS
File / YR