Food Safety and Inspection Service Washington, D.C. 20250

Dr. Diego Velasquez Pereira, Director Office of Agricultural Food Safety Department of HACCP Inspection and Certification Ministry of Agriculture and Forestry Gobierno de Nicaragua Managua, Nicaragua, C.A.

AUG 3 2005

Dear Dr. Velasquez Pereira:

The Food Safety Inspection Service (FSIS) completed an on-site audit of Nicaragua's meat inspection system January 25 through February 9, 2005. We received your letter dated July 18, 2005, stating that there are no comments regarding the FSIS draft final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White, Director

International Equivalence Staff Office of International Affairs

Havey White JD

Enclosure

#### Cc:

Dr. Norman Valdivia Quijano, Chief of the Meat Inspection Service, Dirección Generalde Proctección y Sanidad Agropecuaria, Ministry of Agriculture and Forestry,

Gobierno De Nicaragua, Managua, Nicaragua

Katherine Nishiura, Attaché, US Embassy, San Jose

Ervin Leiva, Agriculture Specialist, US Embassy, Managua, Nicaragua

Alcides Montiel, Minister Counselor for Trade, Embassy of Nicaragua

Robert Macke, Assistant Deputy Administrator, ITP, FAS

Jeanne Bailey, FAS Area Director

Amy Winton, State Department

Barbara Masters, Acting Administrator, FSIS

Karen Stuck, Assistant Administrator, OIA, FSIS

Bill James, Deputy Assistant Administrator, OIA, FSIS

Linda Swacina, Executive Director, Food Safety Institute of the Americas

Donald Smart, Director, Program Review, OPEER, FSIS

Sally White, Director, IES, OIA, FSIS

Clark Danford, Director, IEPS, OIA, FSIS

Mary Stanley, Director, IID, OIA, FSIS

Armia Tawadrous, Director, FSIS Codex Staff, OIA, FSIS

Gerald Zimstein, IES, OIA, FSIS

Shannon McMurtrey, IES, OIA, FSIS

Country File (Nicaragua FY 2005 Annual Audit)

### FINAL

JUL 2 6 2005

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

JANUARY 25 THROUGH FEBRUARY 9, 2005

#### TABLE OF CONTENTS

- 1. INTRODUCTION
- 2. OBJECTIVE OF THE AUDIT
- 3. PROTOCOL
- 4. LEGAL BASIS FOR THE AUDIT
- 5. SUMMARY OF PREVIOUS AUDITS
- 6. MAIN FINDINGS
  - 6.1 Government Oversight
  - 6.2 Headquarters Audit
- 7. ESTABLISHMENT AUDITS
- 8. LABORATORY AUDITS
- 9. SANITATION CONTROLS
  - 9.1 SSOP
  - 9.2 Other Sanitation Concerns
- 10. ANIMAL DISEASE CONTROLS
- 11. SLAUGHTER/PROCESSING CONTROLS
  - 11.1 Humane Handling and Slaughter
  - 11.2 HACCP Implementation
  - 11.3 Testing for Generic Escherichia coli
  - 11.4 Testing for Listeria monocytogenes
- 12. RESIDUE CONTROLS
- 13. ENFORCEMENT CONTROLS
  - 13.1 Daily Inspection
  - 13.2 Testing for Salmonella Species
  - 13.3 Species Verification
  - 13.4 Monthly Reviews
  - 13.5 Inspection System Controls
- 14. CLOSING MEETING
- 15. ATTACHMENTS TO THE AUDIT REPORT

#### ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

Al Auxiliary Inspector

CCA Central Competent Authority

CDICH Chief of the Department of Inspection and Certification/HACCP

CVMI Chief Veterinary Meat Inspector

DGPSA Dirección General de Protección y Salud Animal or the General

Directorate for Plant and Animal Health

DIA Dirección de Inocuidad Agroalimentaria or Division of Food

Safety

DISAAN Dirección de Salud Animal or Directorate of Animal Health

E. coli Escherichia coli

FSIS Food Safety and Inspection Service

MAG-FOR Ministerio Agropecuario y Forestal, or Ministry of Agriculture,

Livestock, and Forestry

PR/HACCP Pathogen Reduction/ Hazard Analysis and Critical Control Point

Systems

SSOP Sanitation Standard Operating Procedures

Salmonella Salmonella species

VMO Veterinary Medical Officer

#### 1. INTRODUCTION

The audit took place in Nicaragua from January 25 through February 9, 2005.

An opening meeting was held on January 25 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 *Ministerio Agropecuario y Forestal* (MAG-FOR), or Ministry of Agriculture, Livestock, and Forestry, and representatives from the local inspection offices.

#### 2. OBJECTIVE OF THE AUDIT

This was a routine annual 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.

In pursuit of the objective, the Senior International Audit Officer visited the following sites: the headquarters of the CCA, the two laboratories performing analytical testing on United States-destined product, and the three slaughter- and-processing establishments eligible to export to the U.S.

Competent Authority Visits		Comments	
Competent Authority	3	Managua	
Laboratories	2	Managua	
Meat Slaughter and Processing Establishments	3	Juigalpa, Nandaime, and Managua	

#### 3. PROTOCOL

The official on-site audit was conducted in four parts. One part involved visits 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 three beef slaughter and processing establishments certified by Nicaragua as eligible to export to the United States. The fourth part involved visits to two government-owned and -operated laboratories. The Laboratorio Nacional de Residuos Químicos y Biológicos, or National Laboratory for Chemical and Biological Residues, was conducting analyses of field samples for Nicaragua's national residue control program. The Laboratorio Central Diagnóstico Veterinario, or Central Veterinary Diagnostic Laboratory, was conducting analyses of field samples for the presence of Salmonella species and generic Escherichia coli (E. coli).

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); (2) animal disease controls; (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis/Critical Control Point (HACCP) programs and the testing program for generic *E. coli*; (4) residue controls; and (5) enforcement controls, including the testing program for *Salmonella* species. 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 are 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 Nicaragua's inspection system would be audited in accordance with two areas of focus. First, the auditor would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella* species.

Second, the auditor would audit against any equivalence determinations that have been made by FSIS for Nicaragua under provisions of the Sanitary/Phytosanitary Agreement. Currently, no special equivalence determinations are in effect for Nicaragua.

#### 4. LEGAL BASIS FOR THE AUDIT

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.) 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 November 2003 and October 2004. The following deficiencies were identified during the audit of November 2003:

• In one establishment, light was inadequate at a post-mortem inspection station.

- In one establishment, atlantal (lateral retro-pharyngeal) lymph nodes were not included in routine post-mortem inspection of beef heads, as required by FSIS.
- In one establishment, documentation of operational sanitation activities by the establishment was inadequate.
- In one establishment, preventive measures were not documented as part of the corrective actions taken regarding deficiencies identified by the establishment during pre-operational sanitation.
- Each of the following deficiencies regarding Sanitation Performance Standards was identified in one establishment:
  - o Inadequately-controlled condensation,
  - o Inadequate pre-operational cleaning of two band saws,
  - o Conditions likely to result in cross-contamination,
  - o Hand-operated lids on boning-room waste containers, and
  - o Inadequate maintenance of metal trays used for edible offal.
- In all three establishments, the written corrective actions to be taken in the event that critical limits are exceeded during the monitoring procedures did not include reinspection of all product produced since the last acceptable monitoring check.
- In one establishment, verification of the monitoring for one Critical Control Point was not documented by the establishment.
- In one establishment, the written descriptions of the details of the verification procedures were inadequate.
- None of the three establishments had developed statistical process control procedures to analyze the results of the testing program for generic *E. coli*; the method intended for excision sampling was being used.
- In the laboratory testing for generic *E. coli*, neither the number of Colony Forming Units inoculated into check samples nor the specific strains that were used had been determined.

During the routine audit of November 2003, two of Nicaragua's three certified establishments received Notices of Intent to Delist. As a result, FSIS took the following enforcement actions:

- 1. FSIS suspended the authority of Nicaragua to certify additional establishments for export to the U.S.
- 2. FSIS instituted 100 percent reinspection of Nicaraguan meat products at U.S. ports of entry.

3. FSIS required the government of Nicaragua to submit a comprehensive system-wide corrective action plan to FSIS within 30 days. The plan was submitted on time and addressed the system-wide problems.

The results of the October 2004 enforcement audit indicated that all deficiencies observed during the November 2003 routine annual audit had been satisfactorily addressed and corrected.

No repeat deficiencies were observed during the October 2004 enforcement audit; however, one deficiency was identified:

• In all three establishments, neither the establishments nor the inspection service were maintaining daily records to document monitoring and verification procedures to remove, segregate, and dispose of Specified Risk Materials.

#### 6. MAIN FINDINGS

#### 6.1 Government Oversight

The office of the *Dirección General de Protección y Salud Animal* (DGPSA), or the General Directorate for Plant and Animal Health, in Managua is under the umbrella of the *Ministerio Agropecuario y Forestal (MAG-FOR)*, or Ministry of Agriculture, Livestock, and Forestry. The DGPSA is Nicaragua's Central Competent Authority (CCA) and is responsible for providing government oversight of Nicaragua's meat inspection programs.

A reorganization of the structure of the meat inspection system went into effect on January 1, 2005. The main purpose of this reorganization was to facilitate the implementation of a new nationwide identification and traceability program to enable animals to be traced back to the farms/owners of origin, which is expected to occur in the second quarter of 2005. Previously, the responsibilities for both food safety and animal health were assigned to a single division under the DGPSA; under the reorganized system there are three subdivisions under the DGPSA: (1) The *Dirección de Inocuidad Agroalimentaria* (DIA), or Division of Food Safety, (2) the *Dirección de Salud Animal* (DISAAN), or Directorate of Animal Health, and (3) *Servicios Agrosanitarios*, or Food Sanitary Services, which provides oversight over the residue and microbiology laboratories.

There are three further subdivisions of the new DIA. The first is Surveillance and Traceability, which is responsible for residues and food hygiene, animal identification, and traceability, and public sanitation education. The second subdivision is Agro-Industrial Inspection, which is responsible for meat inspection activities (see below). The third subdivision is Processes and Certifications, which is responsible for the education and training of inspection and establishment personnel, for the certification of inspection and establishment personnel for competency in the requirements of HACCP and SSOP programs, and for the internal reviews of official establishments.

The division of Agro-Industrial Inspection is further divided into (A) Meat & Meat Products; (B) Dairy Products, (C) Seafood, (D) Poultry, (E) Fruits & Vegetable Inspection, (F) Coffee, and (G) Peanuts, Sorghum, and Soy.

The personnel in charge of the upper levels of the meat inspection system have not changed, although new personnel are expected to be hired in the near future.

The Chief of the Department of Inspection and Certification/HACCP (CDICH) reports to the division of Agro-Industrial Inspection and has ultimate control over all inspection activities, including the implementation of enforcement actions for noncompliance with FSIS requirements. The Chief Veterinary Meat Inspector (CVMI) reports to the CDICH and supervises the three Veterinary Medical Officers (VMOs) in charge of the three establishments certified as eligible to export to the U.S. The official list of certified establishments is maintained and controlled by the CDICH.

The Chief of the Department of Biological Residues now reports to the division of Food Sanitary Services and is responsible for the direction and management of Nicaragua's residue programs. She also provides oversight of the implementation of the residue programs, supervising seven analysts and six support staff members. She communicates via fax, hard-copy memo, e-mail, and telephone, and coordinates with the CDICH regarding residue results and any enforcement actions that may be necessary in the event that residue tolerance levels are exceeded.

New official guidelines, policies, and regulations are issued by the DGPSA headquarters in Managua. Any change in the regulations must be subjected to a rule-making process that includes analyzing and evaluating public comments.

#### 6.1.1 CCA Control Systems

The CDICH manages and communicates any new inspection guidelines, including new FSIS Directives, Notices, and regulations, to the Veterinary Medical Officers in all three of the U.S.-eligible facilities and provides instructions to on how to implement them. The CDICH communicates with the VMOs through faxes, e-mail, and hard-copy memos. The CDICH also supervises an internal HACCP team to conduct semi-annual audits of each of the three establishments' HACCP systems. This HACCP-auditing team uses an evaluation form to collect information on each regulatory aspect of the HACCP systems. The resulting information is analyzed, evaluated, and rated to determine whether certified establishments meet the basic and on-going HACCP requirements.

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

#### 6.1.2 Ultimate Control and Supervision

Direct implementation of the inspection programs in each of the three official establishments that export meat products to the U.S. is accomplished through the Front Line Supervisor (CVMI), one VMO, and six Auxiliary Inspectors (AIs). The VMOs are

rotated among the three establishments every two years. There is also a designated relief VMO ready to fill in for illness or annual leave. If an inspector is ill, the inspector from the local establishment pool with the most experience substitutes. Whenever an AI resigns, a replacement is transferred from another export establishment.

Verification of implementation of FSIS requirements is accomplished by monthly internal supervisory reviews, which are conducted by the CVMI. The central headquarters office has the legal and regulatory authority to administer the meat inspection programs.

In addition to the normal monthly reviews, the CVMI, his second-in-command, and the three VMOs in the export plants, as a team, visit one of the three export plants occasionally, to supervise and correlate activities and compliance with requirements. The last such visit was in September 2004. They are usually conducted on a monthly basis, but many audits by other countries have been conducted in the interim.

#### 6.1.3 Assignment of Competent, Qualified Inspectors

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

The CVMI is responsible for ensuring that each hired VMO and AI receives the required pre-employment training. On-the-job training of these new employees is provided by experienced VMOs in the official establishments, and lasts from three to four months. This training covers all aspects of meat inspection in export establishments. If the newly-hired VMO or AI does not demonstrate the expected competence level after the training period, the individual is not assigned to an official establishment until such time as he/she demonstrates the required competence level.

In August-September 2004, DGPSA contracted with a U.S. firm to provide training in FSIS inspection requirements. Thirty DGPSA staff members, including VMOs and AIs, participated in the training. After the training, DGPSA enhanced its inspection programs to improve the establishments' documentation of noncompliance, verification, corrective action systems, enforcement actions, and tracking and traceability of export certificates.

#### 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 la Carne para Establecimientos Autorizados* (Regulation of Sanitary Inspection of Meat for Authorized Establishments) and the *Ley Basica de Salud Animal y Sanidad Vegetal* (Basic Law of Animal Health and Plant Health). The CDICH, the CVMI, and the VMOs have the legal authority to enforce the Nicaragua's meat inspection laws, regulations, and FSIS requirements. The authority to delist is granted in Article 19 of the Regulation of Sanitary Inspection of Meat for Authorized Establishments and lies jointly with the CDICH and CVMI.

The activities and responsibilities of the official in the position of CVMI are stipulated in Articles 22 and 23 of the Regulation of Sanitary Inspection of Meat for Authorized Establishments

#### 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. MAGFOR 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 one regional office. The records review focused primarily on food safety hazards and included the following:

- 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, and
- 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 three slaughter/processing establishments that have been certified by MAG-FOR as eligible to export to the U.S. None were delisted by Nicaragua because of failure to meet basic U.S. requirements, and none received a "Notice of Intent to Delist" because of HACCP- or SSOP-implementation deficiencies.

#### 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus 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, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements. (Private laboratories are not used in Nicaragua.)

The following laboratories were audited:

- The government-owned and -operated *Laboratorio Nacional de Residuos Químicos y Biológicos*, or National Laboratory for Chemical and Biological Residues.
- The government-owned and -operated *Laboratorio Central Diagnóstico Veterinario* or Central Veterinary Diagnostic Laboratory.

The findings in these laboratories will be discussed in Section 11.3 (Testing for generic *E. coli*), 12 (RESIDUE CONTROLS), and 13.2 (Testing for *Salmonella* species) of this report.

#### 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, Nicaragua's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, 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.

#### 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. The SSOP in the three establishments were found to meet the FSIS regulatory requirements.

#### 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors 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 noted.

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 disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, 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 noted.

#### 11.2 HACCP Implementation

All establishments approved to export meat products to the United States 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.

The HACCP programs were reviewed during the on-site audits of the three establishments. All establishments had adequately implemented the PR/HACCP requirements.

#### 11.3 Testing for Generic E. coli

Nicaragua has adopted the FSIS regulatory requirements for testing for generic *E. coli*. All three 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 three establishments.

The government-owned and operated *Laboratorio Central Diagnóstico Veterinario*, or Central Veterinary Diagnostic Laboratory, in Managua, in which field samples of U.S.-eligible product are analyzed for generic *E. coli*, was audited. No deficiencies were noted.

#### 11.4 Testing for *Listeria monocytogenes*

None of the establishments audited were 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.

The government-owned and —operated *Laboratorio Nacional de Residuos Químicos y Biológicos* or National Laboratory for Chemical and Biological Residues in Managua was audited. No concerns resulted from this audit.

#### 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 three establishments for production days on which U.S.-eligible product was produced.

#### 13.2 Testing for Salmonella Species

Nicaragua has adopted the FSIS regulatory requirements for testing for *Salmonella* species. All three establishments were evaluated according to the criteria employed in the United States' domestic inspection program. No deficiencies were noted.

#### 13.3 Species Verification

At the time of this audit, Nicaragua was required to test product for species verification. Species verification was being conducted in all three establishments.

#### 13.4 Monthly Reviews

Monthly supervisory reviews of all three 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 United States 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 compliance with the requirements for special handling of Specified Risk Materials (SRMs) regarding Bovine Spongiform Encephalopathy (BSE) have been implemented. Non-ambulatory cattle are condemned upon ante-mortem inspection, no beef containing SRMs is permitted in U.S.-eligible product, mechanically-separated beef is ineligible for use in U.S.-eligible product, and air-injection stunning is not permitted in Nicaragua.

#### 14. CLOSING MEETING

A closing meeting was held on February 9 with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the lead auditor.

mangras H. Chaudry

The CCA understood and accepted the findings.

Gary D. Bolstad, DVM
International Audit Staff Officer

#### 15. ATTACHMENTS

Individual Foreign Laboratory Audit Form
Individual Foreign Establishment Audit Forms
Foreign country response to Draft Final Audit Report (no comments)

### United States Department of Agriculture Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY	
Industrial Comercial San Martin S.A.	Jan. 31, 2005	4	Nicaragua	
Nandaime	5. NAME OF AUDIT	OR(S)	6. TYPE OF AUDIT	
	Dr. Gary D. I	Bolstad	X ON-SITE AUDIT DOCUME	ENT AUDIT
Place an X in the Audit Results block to i	indicate noncomp	oliance with requiren	nents. Use O if not applicable	 ).
Part A - Sanitation Standard Operating Procedure Basic Requirements		P	art D - Continued conomic 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 (SSC Ongoing Requirements	PP)	Part E	- Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation of state of including monitoring	mentation.	36. Export		
11. Maintenance and evaluation of the effectiveness of SSOF		37. Import		. 0
<ol> <li>Corrective action when the SSOPs have failed to preven product contamination or adulteration.</li> </ol>	t direct	38. Establishment Grounds	s and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Constru	action/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	<u>-</u>	
<ol> <li>Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective</li> </ol>	actions.	42. Plumbing and Sewage	· · · · · · · · · · · · · · · · · · ·	<u> </u>
Records documenting implementation and monitoring of HACCP plan.	the	43. Water Supply		- 1
<ol> <li>The HACCP plan is signed and dated by the responsible establishment individual.</li> </ol>	-	44. Dressing Rooms/Lavat		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations		
18. Monitoring of HACCP plan.		47. Employee Hygiene		
19. Verification and validation of HACCP plan.		48. Condemned Product C	Control	<u> </u>
20. Corrective action written in HACCP plan.	:			
21. Reassessed adequacy of the HACCP plan.		Part F - I	Inspection Requirements	:
22. Records documenting: the written HACCP plan, monitorin critical control points, dates and times of specific event of	ng of the occurrences.	49. Government Staffing		
Part C - Economic / Wholesomeness		50. Daily Inspection Cover	age	
23. Labeling - Product Standards		51. Enforcement		
24. Labeling - Net Weights			<del></del>	
25. General Labeling	·	52. Humane Handling		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/	Moisture)	53. Animal Identification		
Part D - Sampling Generic <i>E. coli</i> Testing		54. Ante Mortem Inspection	n	
27. Written Procedures		55. Post Mortern Inspection	,	_
28. Sample Collection/Analysis		<u></u>	<del></del>	
29. Records		Part G - Other Regu	ulatory Oversight Requirements	•
Salmonella Performance Standards - Basic Req	uirements	56. European Community D	Prestives	0
30. Corrective Actions		57. Monthly Review		_
31. Reassessment		58.		- · · -
32. Written Assurance		59.		

#### 60. Observation of the Establishment

Est. 4: Industrial Comercial San Martin S.A., Nandaime, Nicaragua; January 31, 2005

No deficiencies were noted.

Note: All deficiencies identified during the previous two FSIS audits had been adequately addressed and corrected.

### United States Department of Agriculture Food Safety and Inspection Service

#### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUD TIDATE	3. E	STABLISHMENT NO.	4. NAME OF COUNTRY	
Nuevo Carnic S.A.	Jan 27, 2005	5		Nicaragua	
Managua, Nicaragua	5. NAME OF AUDIT	OR(S)		6. TYPE OF AUDIT	
	Dr. Gary D. I	Roleta	nd	<u> </u>	
					DOUMENT AUDIT
Place an X in the Audit Results block to ind		oliano •			cable.
Part A - Sanitation Standard Operating Procedures (S Basic Requirements	SSOP) Augit Results			art D - Continued conomic 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 implemen	ntation.	36.	Export		
11. Maintenance and evaluation of the effectiveness of SSOP's.		37.	Import		<u> </u>
<ol> <li>Corrective action when the SSOPs have failed to prevent dir product contamination or adulteration.</li> </ol>	rect	38.	Establishment Grounds	s and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39.	Establishment Constru	ction/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		l
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective act	tions.	42.	Plumbing and Sewage		
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>			Water Supply		
<ol> <li>The HACCP plan is signed and dated by the responsible establishment individual.</li> </ol>			Dressing Rooms/Lavate		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		Ī-—	Sanitary Operations		
18. Monitoring of HACCP plan.		47	Employee Hygiene		<u>-</u>
19. Verification and validation of HACCP plan.			Condemned Product Co	ontrol	
20. Corrective action written in HACCP plan.					
21. Reæsessed adequacy of the HACCP plan.			Part F - i	nspection Requirements	:
22. Records documenting: the written HACCP plan, monitoring o critical control points, dates and times of specific event occu	f the rrences.	49.	Government Staffing		
Part C - Economic / Wholesomeness		50.	Daily Inspection Covera	age	
23. Labeling - Product Standards	!	51	Enforcement		
24. Labeling - Net Weights			· · · · · - · - · - · - · - · · · · · ·		
25. General Labeling		52.	Humane Handling		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moi	sture)	53.	Animal Identification		
Part D - Sampling Generic <i>E. coli</i> Testing		54.	Ante Mortem Inspection	1	:
27. Written Procedures		55.	Post Mortem Inspection	<del></del>	
28. Sample Collection/Analysis	· -	<b>1</b>		·	
29. Records		1	Part G - Other Regu	ılatory Oversight Requirement	s
Salmonella Performance Standards - Basic Requir	ements	56.	European Community Di	rectives	0
30. Corrective Actions		57.	Manthly Review		
31. Reassessment		58.		<del></del>	
32. Written Assurance		59.			::
			·····	<del></del>	

#### 60. Observation of the Establishment

Est. 5, Nuevo Carnic S.A.; Managua, Nicaragua; January 27, 2005

No deficiencies were noted.

Note: All deficiencies identified during the previous two FSIS audits had been adequately addressed and corrected.

### United States Department of Agriculture Food Safety and Inspection Service

#### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUD!T DATE	3. ESTABLISHMENT NO. 4. NAME OF COUNTRY				
Matadero Central S.A. (MACESA)	Jan 28, 2005	8 Nicaragua				
Juigalpa, Cholales	5. NAME OF AUDIT	OR(S) 6. TYPE OF AUDIT				
Dr. Gary D. B		Bolstad X ON-SITE AUDIT DOCUME	NT AUDIT			
Place an X in the Audit Results block to in	dicate noncomp	oliance with requirements. Use O if not applicable				
Part A - Sanitation Standard Operating Procedures (SSOP)  Audit  Basic Requirements  Audit  Results		Part D - Continued Economic Sampling	Audit Results			
7. Written SSOP		33. Scheduled Sample	<u> </u>			
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 implem		36. Export				
11. Maintenance and evaluation of the effectiveness of SSOP's	<b>5</b> .	37. Import				
Corrective action when the SSOPs have failed to prevent oppoduct contamination or adulteration.	direct :	38. Establishment Grounds and Pest Control				
13. Daily records document item 10, 11 and 12 above.	į <u> </u>	39. Establishment Construction/Maintenance	<u> </u>			
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	:	40. Light				
14. Developed and implemented a written HACCP plan.		41. Ventilation	-			
<ol> <li>Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective</li> </ol>	actions.	42. Plumbing and Sewage				
<ol> <li>Records documenting implementation and monitoring of th HACCP plan.</li> </ol>	ne	43. Water Supply				
The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	ļ			
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils  46. Sanitary Operations	!			
18. Monitoring of HACCP plan.						
19. Verification and validation of HACCP plan.		47. Employee Hygiene  48. Condemned Product Control	······			
20. Corrective action written in HACCP plan.						
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements				
Records documenting: the written HACCP plan, monitoring critical control points, dates and times of specific event oc	g of the courrences.	49. Government Staffing	<u>:</u>			
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage				
Labeling - Product Standards     Labeling - Net Weights		51. Enforcement				
25. General Labeling		52. Humane Handling				
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/N	Agisture)	53. Animal Identification	<u> </u>			
Part D - Sampling		54. Ante Mortem Inspection	-			
Generic E. coli Testing			i			
27. Written Procedures		55. Post Mortem Inspection				
28. Sample Collection/Analysis  29. Records		Part G - Other Regulatory Oversight Requirements				
Salmonella Performance Standards - Basic Req	uirements	56. European Community Directives	0			
30. Corrective Actions		57. Monthly Review				
31. Reassessment		58				
32. Written Assurance		59.				

#### 60. Observation of the Establishment

Est. 8, Macesa Matadero Central S.A., Juigalpa, Nicaragua; January 28, 2005

No deficiencies were noted.

Note: All deficiencies identified during the previous two FSIS audits had been adequately addressed and corrected.

## Country Response Not Received