



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

*Leon*

**APR 26 2005**

Q.F.B. Amada Vélez Méndez  
Director General de Inocuidad Agroalimentaria,  
Acuícola y Pesquera  
Servicio Nacional de Sanidad, Inocuidad y  
Calidad Agroalimentaria (SENASICA)  
Secretaría de Agricultura, Ganadería, Desarrollo  
Rural, Pesca y Alimentación (SAGARPA)  
Municipio Libre 377  
Piso 7 Ala "B"  
Santa Cruz Atoyac  
México, D.F.  
C.P. 03310 México

Dear Ms. Vélez:

The Food Safety and Inspection Service (FSIS) conducted an enforcement audit of Mexico's meat and processed poultry inspection system November 3 through November 18, 2004. Enclosed is a copy of the final report. Included in the report as an attachment is your letter of April 7, 2005, in which you provided comments to our draft final report of the same audit. In that regard, we have revised the report to reflect your comment regarding TIF 304.

If you have any questions regarding the enclosed audit report, please contact me at telephone number (202) 720-3781, at facsimile number (202) 690-4040, or at my e-mail address (sally.white@fsis.usda.gov).

Sincerely,

Sally White  
Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

CC.

Suzanne Heinen, Minister-Counselor, American Embassy, Mexico City  
Enrique Lobo, Agricultural Minister, Embassy of Mexico, Washington, DC  
Robert Macke, Assistant Deputy Administrator, International Trade Policy, FAS  
Jeanne Bailey, FAS Area Director  
Lloyd Day, FAS  
Amy Winton, State Department  
Barbara Masters, Acting Administrator, FSIS  
Karen Stuck, Assistant Administrator, Office of International Affairs (OIA), FSIS  
Bill James, Deputy Assistant Administrator, OIA, FSIS  
Donald Smart, Director, Review Staff, FSIS  
Sally White, Director, International Equivalence Staff, OIA, FSIS  
Clark Danford, Director, IEPS, OIA, FSIS  
Mary Stanley, Director, IID, OIA, FSIS  
Armia Tawadrous, FSIS Codex Staff  
Linda Swacina, Executive Director, FSIA, OIA, FSIS  
Andreas Keller, IES, OIA, FSIS  
Steve McDermott, IES, OIA, FSIS  
Country File

FINAL

APR 18 2005

FINAL REPORT OF AN AUDIT CARRIED OUT IN MEXICO  
COVERING MEXICO'S MEAT AND PROCESSED POULTRY  
INSPECTION SYSTEM

NOVEMBER 3 THROUGH NOVEMBER 18, 2004

Food Safety and Inspection Service  
United States Department of Agriculture

## 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'/State Offices'/Local Inspection Offices' Review
7. ESTABLISHMENT AUDITS
8. LABORATORY AUDITS
9. SANITATION CONTROLS
  - 9.1 SSOP
  - 9.2 Sanitation
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*
  - 11.5 Testing for *E. coli* O157:H7
  - 11.6 Implementation of BSE Control Measures
12. RESIDUE CONTROLS
13. ENFORCEMENT CONTROLS
  - 13.1 Daily Inspection
  - 13.2 Testing for *Salmonella*
  - 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

CCA	Central Competent Authority [Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (SENASICA)]
BSE	Bovine Spongiform Encephalopathy
CFR	U.S. Code of Federal Regulations
CVO	Chief Veterinary Officer
MVZ	Medical Veterinarian of Zoonosis
NOID	Notice of Intent to Delist
SAGARPA	Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentacion
SENASICA	Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
SSOP	Sanitation Standard Operating Procedures
TIF	Tipo Inspeccion Federal
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species

## 1. INTRODUCTION

The audit took place in the Republic of Mexico from November 3 through 18, 2004.

An opening meeting was held on November 3 in Mexico City with the Central Competent Authority (CCA). At this meeting, the audit team confirmed the objective and scope of the audit and discussed the audit team's itinerary to complete the audit of Mexico's meat and processed poultry inspection system.

The audit team members were accompanied during the entire audit by representatives from the SENASICA central office and/or representatives from the SAGARPA state offices.

## 2. OBJECTIVE OF THE AUDIT

This audit was a comprehensive follow-up to the enforcement audit conducted in April-May 2004. The objective of the audit was to determine whether Mexico corrected the deviations identified during the April-May 2004, and was maintaining an equivalent inspection system.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, four SAGARPA state offices, one beef slaughter establishment, two swine slaughter establishments, nine meat and/or processed poultry processing establishments, and five microbiological laboratories.

Competent Authority Visits			Comments
Competent Authority	Central	1	SENASICA
	State	4	SAGARPA State Offices
Laboratories		5	Establishments produce beef, pork and/or poultry.
Meat Slaughter Establishments		3	
Meat/Poultry Processing Establishments		9	

## 3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with SENASICA inspection officials at the central office and SAGARPA state offices to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to 12 certified establishments and five laboratories conducting microbiological testing of samples of meat and processed poultry products. Two of these laboratories were not currently testing products being

exported to the United States. These laboratories were certified by SAGARPA to conduct official analytical testing of official government samples.

Government oversight was evaluated using the five FSIS government oversight requirements stipulated in FSIS regulations (9 CFR 327). Program effectiveness determinations of Mexico's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*.

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

At the opening meeting, the audit team explained to the CCA that their inspection system would be audited in accordance with two areas of focus. First, the auditors would audit against FSIS requirements. FSIS requirements 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 requirements for HACCP, SSOP, testing for generic *E. coli*, *Salmonella* species, *E. coli O157:H7*, and *Listeria monocytogenes*.

Second, the audit team would audit against any equivalence determinations that have been made by FSIS for Mexico under provisions of the Sanitary/Phytosanitary Agreement. Currently, Mexico has an equivalence determination regarding an exemption from performing species verification testing.

#### 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.).
- The Federal Meat Inspection Regulations (9 CFR Parts 300 to end), which include the Pathogen Reduction/HACCP regulations.

#### 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at:

[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Foreign\\_Audit\\_Reports/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp)

### FSIS audit of Mexico's inspection system conducted in May-June 2003.

- Eleven establishments and one laboratory reviewed.
- Four establishments were delisted and became ineligible to export to the United States.
- Four establishments received an NOID.
- No government inspector during third processing shift in one establishment.
- Insufficient number of government inspectors conducting post-mortem inspection in two establishments.
- Deviations identified during previous FSIS audit were not corrected in some establishments.
- Inadequate HACCP implementation in some establishments.
- Some establishments did not reassess its HACCP plan to include *E. coli* O157:H7 and/or *Listeria monocytogenes* as hazards likely to occur.
- Inadequate maintenance of facilities in some establishments.
- Inadequate government oversight.

### FSIS audit of Mexico's inspection system conducted in April-May 2004.

- 3 certified establishments were delisted.
- 1 non-certified establishment that Mexico requested for recertification was not acceptable, and would have been delisted if it had been certified.
- 3 establishments received an NOID.
- 3 establishments were cited for product contamination.
- 12 establishments were cited for inadequate HACCP implementation.
- 10 establishments were cited for inadequate SSOP implementation.
- 19 establishments were cited for inadequate government enforcement.

## 6. MAIN FINDINGS

### 6.1 Government Oversight

SENASICA has responsibility of regulating Mexico's meat and processed poultry inspection system and live animal health requirements. This responsibility includes certifying and regulating TIF establishments for the exportation of meat or processed poultry products to the United States.

The production of meat and poultry products in Mexico is either conducted in TIF establishments or municipal establishments. SENASICA has authority only over TIF establishments whereas Mexico's Department of Health has authority over municipal establishments. The majority of the meat and poultry production in Mexico is conducted in TIF establishments. Only TIF establishments have the authority to produce product for export to other countries.

### 6.1.1 CCA Control Systems

Audit of the CCA control systems included the following document reviews during on-site visits to headquarters, state offices, and local inspection offices (TIF establishments):

- Supervisory visits to establishments that were certified to export to the United States.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Label approval records.
- Sampling and analyses for residues and water supply.
- Pathogen reduction and other food safety initiatives such as SSOP and HACCP programs, generic *E. coli*, *Salmonella* species, *E. coli* O157:H7, *Listeria monocytogenes* testing, and implementation of the new BSE control measures.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and inedible and condemned materials.
- Export product inspection and control including export certificates.
- National residue control program and monitoring results.
- Enforcement records including examples of criminal prosecutions, consumer complaints, recalls, seizures and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

### 6.1.2 Ultimate Control and Supervision

Each TIF establishment is under the direct authority of a SAGARPA state office. Each state office has at least one SENASICA state supervisor who is assigned to provide government oversight of all TIF establishments within the state and to assure that inspection requirements are being enforced at the TIF establishments. Based on the size of the state and/or the number of TIF establishments, SENASICA may assign two state supervisors. In addition, SENASICA has assigned a MVZ supervisor to each TIF establishment certified to export meat or processed poultry to the United States. Additional MVZ inspection officials are assigned to certified establishments to carry out government inspection responsibilities. Since early 2004, SENASICA has hired several new MVZ inspection officials to conduct official inspection duties at TIF establishments. Daily inspection by inspection officials is being carried out in all TIF establishments certified to export to the United States.

SENASICA has adequate levels of authority (headquarters, state offices, and certified establishments) to ensure effective oversight of all U.S. import inspection requirements.

### 6.1.3 Assignment of Competent, Qualified Inspectors

Upon entering government employment as an official inspector, new employees undergo induction training as well as participate in on-the-job practical training under the supervision of experienced veterinarians. Training is supplemented by refresher courses on inspection requirements and participation in U.S. government technical assistance programs. Limited resources have restricted SENASICA's ability to conduct sufficient

training for its inspection personnel. However, since the April-May 2004 FSIS audit, Mexico has provided three training courses for its inspection personnel regarding implementation and oversight of the U.S. import inspection requirements. Additional training regarding HACCP requirements is scheduled for its inspection personnel.

#### 6.1.4 Authority and Responsibility to Enforce the Laws

SENASICA has the authority and responsibility to enforce the applicable laws relevant to establishments producing product for export to the United States. However, additional personnel at SENASICA headquarters' office would enhance Mexico's ability to ensure continued compliance of the U.S. inspection requirements.

#### 6.1.5 Adequate Administrative and Technical Support

During the audit, the audit team found that SENASICA has administrative and technical support to operate Mexico's inspection system and has the ability to support a third-party audit.

#### 6.2 Headquarters / State Offices / Local Inspection Offices Review

The audit team conducted a review of inspection documents that included the following:

- Internal review reports.
- Supervisory visits to establishments certified to export to the United States.
- Training records for inspection personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of recalls, control of noncompliance product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

### 7. ESTABLISHMENT AUDITS

The FSIS audit team reviewed the 12 TIF establishments certified to export meat and/or processed poultry products to the United States. Three were slaughter establishments and nine were processing establishments.

Specific deviations are noted on the attached individual foreign establishment audit checklists.

### 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

The FSIS auditor reviewed five laboratories conducting microbiological testing of meat and processed poultry products. No significant deviations were identified. No laboratories conducting residue testing were reviewed.

## 9. SANITATION CONTROLS

As stated earlier, the FSIS audit team focused on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas was Sanitation Controls.

Based on the on-site reviews of establishments, and except as noted below, Mexico'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 and practices, and good product handling and storage practices.

In addition, and except as noted below, Mexico'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 United States' domestic inspection program. Of the 12 establishments reviewed, there was inadequate implementation of SSOP requirements in two establishments.

SSOP implementation deviations are stated on the attached foreign establishment audit checklists.

### 9.2 Sanitation

The following deviations were identified:

- The heads of five carcasses in one establishment was contacting the floor and a non-sanitized (not identified as a product-contact surface) stepladder.
- Specs of dried white paint were on two boning tables identified as product-contact surfaces.

In both cases, immediate corrective actions occurred.

## 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS audit team 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 Mexico's inspection system had adequate controls in place with the following exception:

- An abdominal viscera, which fell on the floor and condemned, was not presented to the inspection official for examination.

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 audit team reviewed was Slaughter/Processing Controls. Controls reviewed included the following areas: ante-mortem and post-mortem inspection procedures and 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.

Review of controls also included the implementation of HACCP systems in all establishments, implementation of a testing program for generic *E. coli*, and *E. coli* O157:H7 in slaughter establishments, *Listeria monocytogenes* in processing establishments, and implementation of the BSE control measures.

Deviations identified by the FSIS audit team are addressed below, as applicable, in each category.

### 11.1 Humane Handling and Humane Slaughter

The following deviation was identified:

For two of three bovine animals observed, the stunning operator was required to apply two applications of the captive bolt stunning device to render the animals insensible. It appeared that this deviation was due to the smaller size of the two animals and the inability of the stunning operator to restrain both animals and adequately apply the stunning device to the heads.

### 11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. 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 reviews of 12 establishments. Of these establishments, there was inadequate implementation of HACCP requirements in nine establishments. The degree of non-compliance varied, but non-compliances were identified as HACCP design issues.

HACCP implementation deviations are noted on the attached foreign establishment audit checklists.

### 11.3 Testing for Generic *E. coli*

- The slaughter establishments had effectively implemented testing for generic *E. coli*.

#### 11.4 Testing for *Listeria monocytogenes*

Applicable establishments had reassessed their HACCP plans to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

#### 11.5 Testing for *E. coli* O157:H7

The applicable establishment had reassessed its HACCP plans to include *E. coli* O157:H7 as a hazard reasonably likely to occur.

#### 11.6 Implementation of BSE Control Measures

The beef slaughter establishment had effectively implemented the BSE control measures.

### 12. RESIDUE CONTROLS

The fourth of the five risk areas reviewed by FSIS is 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. During this audit, the audit team did not visit any laboratories conducting residue testing; thus the review of Mexico's national residue program was limited.

### 13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS audit team reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing programs for *Salmonella* and Species Verification.

#### 13.1 Daily Inspection

Inspection was being conducted daily in all slaughter and processing establishments.

#### 13.2 Testing for *Salmonella*

The slaughter establishments had effectively implemented the testing program for *Salmonella* species.

#### 13.3 Species Verification

FSIS had previously granted Mexico an exemption from conducting species verification testing. The FSIS audit team verified that adequate controls were in place to assure clear separation of meat products of different species.

#### 13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

#### 13.5 Inspection System Controls

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

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Furthermore, the following concerns were raised by the FSIS audit team:

- Nine of 12 establishments reviewed were cited for inadequate government enforcement. This was primarily due to deviations in the establishments' HACCP plans.

#### 14. CLOSING MEETING

A closing meeting was held on November 18, 2004 in Mexico City with the CCA. At this meeting, the primary findings from the audit were presented by the FSIS audit team.

The CCA understood and accepted the findings.

STEVEN A. MCDERMOTT  
Team Leader  
International Equivalence Staff  
Office of International Affairs



15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Checklists

Foreign Country Response to Draft Final Audit Report (when it becomes available)

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Agropecuario Sonorense, Hermosillo, Sonora Mexico	2. AUDIT DATE 11/05/04	3. ESTABLISHMENT NO. TIF 66	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Dr. Jonathan B. Coleman		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.			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.	X		49. Government Staffing	
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage	
23. Labeling - Product Standards			51. Enforcement	X
24. Labeling - Net Weights			52. Humane Handling	
25. General Labeling			53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)			54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection	X
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

November 5, 2004: Est. TIF-66, Frigorifico Agropecuario Sonorense, Hermosillo, Sonora, Mexico

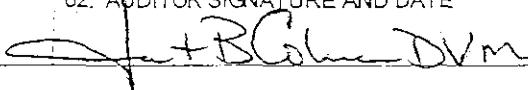
- 10/51 The heads of 5 carcasses were permitted by the establishment to contact the floor and framework of the establishment's defect trimming platform during the handling and trimming of these carcasses. Neither the floor nor the framework of the trim platform was identified as a product contact surface in the establishment's SSOP. [9 CFR 416.13]
- 15/51 Returned product was not included in the flow chart or considered in the hazard analysis. [9CFR §417.2 and 417.8]
- 22/51 The monitoring procedure for CCP 1 was being conducted in the manner and at the frequency described in the establishment's HACCP plan for slaughter; however, the results from each monitoring procedure performed was not recorded on the HACCP monitoring record. Also, each entry made on these HACCP records did not include the time at which the monitoring procedure was performed. [9 CFR 417.5(a)3 and 417.8]
- 55/51 An abdominal viscera was not presented to the SAGARPA inspector for postmortem inspection. The SAGARPA officials recommended the establishment to take appropriate corrective actions immediately. [9 CFR 310.2 (a)]

All findings were either corrected on the day of the audit or SAGARPA officials indicated they would initiate a plan of actions to ensure that the establishment complies with all appropriate USDA, FSIS regulations.

61. NAME OF AUDITOR

Dr. Jonathan B. Coleman

62. AUDITOR SIGNATURE AND DATE

 12/06/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sana Internacional, S.A. De C.V. San Luis Rio Colorado, Son., Mexico	2. AUDIT DATE 11/03/004	3. ESTABLISHMENT NO. TIF 86	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Dr. Jonathan B. Coleman		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	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 63. Observation of the Establishment

November 3, 2004 : Establishment TIF – 86, Sana Internacional, S.A. De C.V., San Luis Rio Colorado, Son., Mexico

- 22/51 The HACCP records documenting the establishment's monitoring of the critical limit for CCP2 and the results of these monitoring activities did not include quantifiable values. The HACCP plan stated CCP2 and its critical limit was designed to monitor the presence of metal in product; however, the results from the establishment's monitoring of this CCP were recorded as "Bien" (Good) on the HACCP records. The establishment corrected this noncompliance on the day of the audit. [9 CFR 417.5a3 and 9 CFR 417.8]

Following the audit, SAGARPA officials indicated they would initiate a plan of actions to ensure that the establishment complies with all parts of 9 CFR 417.

61. NAME OF AUDITOR

Dr. Jonathan B. Coleman

62. AUDITOR SIGNATURE AND DATE



12/06/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION  Sigma Alimentos Noreste, S.A. de C.V. Monterrey, Nuevo Leon	2. AUDIT DATE 11-04-2004	3. ESTABLISHMENT NO. TIF-100	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Marshall C. Tribodeaux		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	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment:

11/04/2004: Establishment TIF-100, Sigma Alimentos Noreste, S.A. de C.V., Monterrey, Nuevo Leon, Mexico  
No Findings  
Finding from previous audit corrected.

61. NAME OF AUDITOR

Marshall C. Thibodeaux

62. AUDITOR SIGNATURE AND DATE

*Marshall C. Thibodeaux* 11/04/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Ganaderia Integral Vizus SA de CV Carretera Culiacan-Vitaroto km 14.5 Culiacan, Sinoloa Mexico	2. AUDIT DATE 11/12/2004	3. ESTABLISHMENT NO. TIF-111	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Dr. Jonathan B. Coleman		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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/AQU/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 50. Observation of the Establishment

November 12, 2004: Est. TIF-111, Ganaderia Integral Vizus SA de CV, Culiacan, Sinaloa, Mexico

- 15/51 The establishment's Slaughter, Deboned products (raw not ground), and Marinated products (raw not ground) HACCP plans did not include the verification activity of direct observation of monitoring activities and corrective actions. [9 CFR 417.4(a)2 and 417.8]
- 10/51 During pre-operational sanitation inspection, many numerous specks of dried white paint were observed on the product contact surfaces of two boning tables in the viscera separation and washing area. Immediate corrective actions were taken by the establishment management. [9 CFR 416.13]
- 52/51 Two applications of the captive bolt stunning device was required to render insensible two of the three animals observed. The stunning device operator's inability to immobilize sufficiently the smaller cattle restrained in the knocking box resulted in the misplacement of the stunning device on the heads of both animals. In both cases, the operator effectively rendered insensible these animals before they were released from the stunning area. [9 CFR 313.15(a)]

All findings were either corrected on the day of the audit or SAGARPA officials indicated they would initiate a plan of actions to ensure that the establishment complies with all appropriate USDA, FSIS regulations.

61. NAME OF AUDITOR

Jonathan B. Coleman DVM

62. AUDITOR SIGNATURE AND DATE

 DVM 12/06/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Trosi de Carnes, SA de CV Apodaca (Monterrey), Nuevo Leon	2. AUDIT DATE 11/05/2004	3. ESTABLISHMENT NO. TIF-114	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Marshall C. Thibodeaux		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	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

11/05/2004 : Est. TIF-114, Trosi de Carnes, SA de CV, Apodaca (Monterrey), Nuevo Leon, Mexico  
No Findings  
Finding from previous audit corrected

61. NAME OF AUDITOR

Marshall C. Thibodeaux

62. AUDITOR SIGNATURE AND DATE

*Marshall C. Thibodeaux* 11/05/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Agropecuario Sonorense S. de R.L. de C.V. Hermosillo, Sonora, Mexico	2. AUDIT DATE 11/08/04	3. ESTABLISHMENT NO. TIF 148	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Dr. Jonathan B. Coleman		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

November 8, 2004: Est. TIF-148, Frigorifico Agropecuario Sonorense S. de R.L. de C.V.  
Hermosillo, Sonora, Mexico

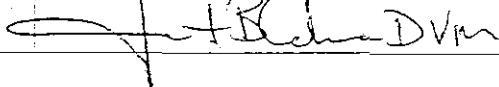
There were no significant findings observed during this audit.

Currently, the establishment chooses to control *Listeria monocytogenes* in post-lethality exposed Ready-to-eat products by meeting the regulatory requirements of 9 CFR 430.4a, 9 CFR 430.4b2 (Alternative 2), and 9 CFR 430.4c.

61. NAME OF AUDITOR

Dr. Jonathan B. Coleman

62. AUDITOR SIGNATURE AND DATE

 12/06/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Delimex de Mexico, S.A. de C.V. San Nicolás de los Garza, Nuevo León	2. AUDIT DATE 11/08/2004	3. ESTABLISHMENT NO. TIF-150	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Marshall C. Thibodeaux		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	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

11/08/2004: Est. TIF-150, Delimex de Mexico, S.A. de C.V., San Nicolás de los Garza, Nuevo León, Mexico

- 22/51 The HACCP records documenting the establishment's monitoring of the critical limit for CCP2 and the results of these monitoring activities did not include quantifiable values. The HACCP plan stated CCP2 and its critical limit was designed to monitor the presence of metal in product; however, the results from the establishment's monitoring of this CCP were recorded as a check on the HACCP records. The HACCP plan did not include a description of what the check designated. The establishment corrected this noncompliance on the day of the audit. [9 CFR 417.5a3 and 9 CFR 417.8]

61. NAME OF AUDITOR

Marshall C. Thibodeaux

62. AUDITOR SIGNATURE AND DATE

*Marshall C. Thibodeaux* 11/08/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sigma Alimentos Centro S.A. de C.V. Planta Atitalaquia Atitalaquia, Hidalgo Mexico	2. AUDIT DATE 11/15/2004	3. ESTABLISHMENT NO. TIF-158	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Marshall C. Thibodeaux		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pack Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

11/15/2004: Est. TIF-158, Sigma Alimentos Centro S.A. de C.V., Planta Atitalaquia, Atitalaquia, Hidalgo, Mexico

15/51 1) Rework product was not included in the flow chart or considered in the hazard analysis.  
[9CFR 417.2 and 417.8]

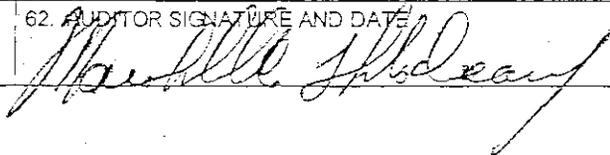
2) The written HACCP plan does address all processing steps in the flow chart, all hazards are addressed as significant; the plan does not assign these significant hazards with a critical limit or a critical control point. [9CFR 417.2(a) and 417.8]

SAGARPA officials indicated they would initiate a plan of actions to ensure that the establishment complies with all appropriate USDA, FSIS regulations.

61. NAME OF AUDITOR

Marshall C. Thibodeaux

62. AUDITOR SIGNATURE AND DATE

 11/15/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Alimentos Sigma Con Agra Foods S.A. de C.V. Linares, Nuevo Leon	2. AUDIT DATE 11/09/2004	3. ESTABLISHMENT NO. TIF-209	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Marshall C. Thibodeaux		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	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

50. Observation of the Establishment

11/09/2004: Est. TIF-209, Alimentos Sigma ConAgra Foods S.A. de C.V., Linares, Mexico

16/22/51 CCP for metal detector states a size for the critical limit, the monitoring procedure is described as continuous. No records are available for monitoring of the CCP as described in 417.5(a)(3) and agency verification 417.8.

*Marshall C. Thibodeaux* 11/09/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Productos Alimenticios Tia Lencha S.A. Cienega de Flores, Nuevo Leon	2. AUDIT DATE 11/10/2004	3. ESTABLISHMENT NO. TIF-237	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Marshall C. Thibodeaux		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	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O <sub>1</sub>		
32. Written Assurance	O		

## 60. Observation of the Establishment

11/10/2004: Est. TIF-237, Cienega de Flores, Nuevo Leon, Mexico

16/22/51 CCP for metal detector states a size for the critical limit, the monitoring procedure is described as continuous. No records are available for monitoring of the CCP as described in 417.5(a)(3), 417.2(a)(6) and 417.8

20/51 Corrective action associated with CCP1 for cooking as written in the HACCP plan do not address all four parts of 417.3(a) and 417.8

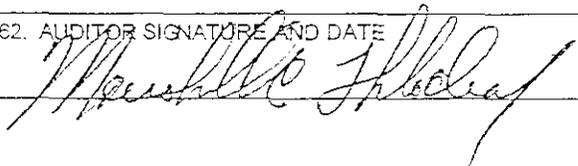
15/51 CCP2 sets a critical limit of 21% moisture in the finished product. No supporting or decision making documentation is available for this critical limit. There is no correlation between the water activity and the % moisture in product. This is a shelf stable product, dried beef with salt. This CCP is used to control pathogens that may be introduced after cooking. 417.5 and 417.8

SAGARPA officials indicated they would initiate a plan of actions to ensure that the establishment complies with all appropriate USDA, FSIS regulations.

61. NAME OF AUDITOR

Marshall C. Thibodeaux

62. AUDITOR SIGNATURE AND DATE



11/10/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Tasky De Mexico, S.A. De C.V. Ciudad Juarez, Chih., Mexico	2. AUDIT DATE 11/10/2004	3. ESTABLISHMENT NO. TIF 271	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Dr. Jonathan B. Coleman		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	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment:	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

November 10, 2004: Est. TIF-271, Tasky De Mexico, Ciudad Juarez, Chihuahua, Mexico

- 15/51 1. Returned product was not included in the flow chart or considered in the hazard analysis. [9CFR 417.2 and 417.8]
2. The HACCP plan did not include the verification activity of direct observation of monitoring activities and corrective actions. [9 CFR 417.4a2 and 417.8]
- 22/51 The HACCP records did not document the results of the verification activities performed. [9 CFR 417.5a3]

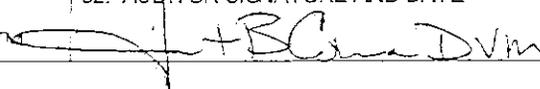
Currently, the establishment chooses to control *Listeria monocytogenes* in post-lethality exposed Ready-to-eat products by meeting the regulatory requirements of 9 CFR 430.4a, 9 CFR 430.4b2 (Alternative 2), and 9 CFR 430.4c.

All findings were either corrected on the day of the audit or SAGARPA officials indicated they would initiate a plan of actions to ensure that the establishment complies with all appropriate USDA, FSIS regulations.

61. NAME OF AUDITOR

62. AUDITOR SIGNATURE AND DATE

Jonathan Coleman DVM



12/06/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Elaboradora La Esperanza, S.A. de C.V. Sabinas Hidalgo, Nuevo Leon	2. AUDIT DATE 11/11/2004	3. ESTABLISHMENT NO. TIF-304	4. NAME OF COUNTRY Mexico
5. NAME OF AUDITOR(S) Marshall C. Thibodeaux		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	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

April 23, 2004: Est. TIF-304, Elaboradora La Esperanza, S.A. de C.V., Hidalgo, Nuevo Leon, Mexico

15/51 CCP1 sets a critical limit of 18% moisture in the finished product. No supporting or decision making documentation is available for this critical limit as described in 417.5(a)(2). There is no correlation between the water activity and the % moisture in product. This is a shelf stable product, dried beef with salt. 417.8

20/51 Corrective action as written in the HACCP plan do not address all four parts of 417.3(a) and 417.8

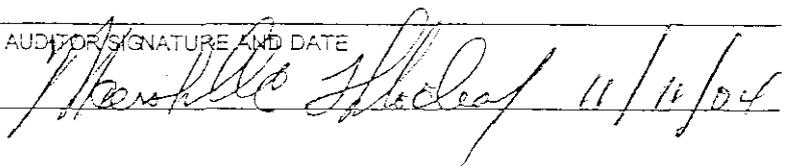
16/22/51 CCP2 for metal detector states a size for the critical limit, the monitoring procedure is described as continuous. No records are available for monitoring of the CCP as described in 417.5(a)(3) and 417.8

SAGARPA officials indicated they would initiate a plan of actions to ensure that the establishment complies with all appropriate USDA, FSIS regulations.

61. NAME OF AUDITOR

Marshall C. Thibodeaux

62. AUDITOR SIGNATURE AND DATE



11/11/04

COURTESY TRANSLATION

April 7, 2005

Officiate: BOO.04.00.01.01 1473

Ms. Karen Stuck  
Assistant Administrator  
Office of International Affairs  
Food Safety and Inspection Service

The following comments are expressed from this General Direction concerning the Final Draft Report of the audit performed on the Federal Inspection System (TIF) from November 3 to 18, 2004, by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA).

**Establishment TIF No. 66 "Frigorifico Agropecuaria Sonorense S. de R.L. de C.V."**

10/51 The heads of 5 carcasses touched the floor and the trimming structure platform. Furthermore, the floor and the structure were not identified as contact surfaces, according to the establishment's SSOP's.

The SENASICA personnel who participated in the audit did not agree with the way the auditor Jonathan B. Coleman wrote-up the observation, because he considers that he did not write what exactly was perceived, because it was not the heads that touched the floor and the plataform structure, but the ears of five heads of very large size carcasses, also the floor, and the trimming platform are only one structure and was reported as two different surfaces.

Concerning all other observations, the SENASICA personnel agrees with the auditor from FSIS-USDA.

**Establishment TIF 271 "Tasky de Mexico S.A. de C.V"**

Concerning the observations noted by the USDA-FSIS auditor, SENASICA personnel consider these to be valid, but want to make clear that the corrective actions were taken immediately.

**Establishment TIF 304 "Elaboradora La Esperanza S.A. de C.V."**

At this establishment, the state official supervisor did not agree with the observation noted by the auditor, Marshall C. Thibodeaux, who commented that the, "VALUE IS NOT QUANTIFIABLE IN THE METAL DETECTOR", since this plant doesn't consider the metal detector as a CCP in the HACCP plan, nor do they have this apparatus.

Concerning all other observations, the inspector agrees with the auditor from USDA-FSIS.

With respect to the comments concerning the other audited plants, we agree with the observations pointed out by the auditors from USDA-FSIS.

Likewise, I inform you that the observations derived from this audit performed on the visited establishments have now been corrected, the documented evidence will be sent to you following this letter.

Sincerely

Q.F.B. Amada Velez Mendez  
General Director