United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

Don

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

SEP 1 2005

Dear Ms. Vélez:

The Food Safety and Inspection Service (FSIS) recently conducted an on-site audit of Mexico's meat and processed poultry inspection system March 1 through 17, 2005. Enclosed is a copy of the FSIS final audit report. Your comments regarding the information in this report are included as an addendum to the final audit 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,

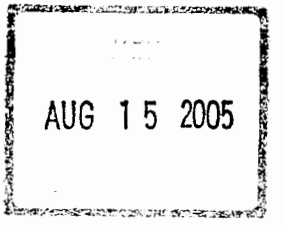
Sally White JD

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, ITP, FAS
Jeanne Bailey, FAS Area Director
Amy Winton, State Department
Barbara Masters, Administrator, FSIS
Linda Swacina, Executive Director, FSIA, OIA
Karen Stuck, Assistant Administrator, OIA, FSIS
William James, Deputy Assistant Administrator, OIA, FSIS
Donald Smart, Director, Review Staff, OPEER, FSIS
Sally White, Director, IES, OIA, FSIS
Clark Danford, Director, IEPS, OIA, FSIS
Mary Stanley, Director, IID, OIA, FSIS
Andreas Keller, IES, OIA, FSIS
Country File (Mexico)

FINAL



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

MARCH 1 THROUGH MARCH 17, 2005

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority [Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (SENASICA)
CFR	U.S. Code of Federal Regulations
CVO	Chief Veterinary Officer
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
MVZ	Medical Veterinarian and Animal Protection (Medico Veterinario Zootecnista)
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
SAGARPA	Secretary for Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentación)
Salmonella	*Salmonella* species
SENASICA	National Service for Animal Health, Food Safety, and Agricultural and Food Quality Assurance (Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria)
SSOP	Sanitation Standard Operating Procedures
TIF	Federal Inspection Type (Tipo Inspeccion Federal)

1. INTRODUCTION

The audit took place in the Republic of Mexico from March 1 through 17, 2005.

An opening meeting was held on March 1, 2005, in Mexico City with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Mexico's meat and processed poultry inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (SENASICA) and/or representatives from the SENASICA state inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit 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 and processed poultry products to the United States.

In pursuit of the objective, the following sites were visited: One SENASICA state office, six meat and/or poultry processing establishments, and one residue laboratory.

Competent Authority Visits			Comments
Competent Authority	Central	0	
	State	1	Nuveo Leon State Office
Laboratories		1	Residue Laboratory
Meat Slaughter Establishments		0	Establishments producing beef, pork and/or poultry products.
Meat/Poultry Processing Establishments		6	

3. PROTOCOL

This 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 the country's inspection headquarters or regional offices. The third part involved on-site visits to six processing establishments. The fourth part involved a visit to one government laboratory. Laboratorio Central Regional De Monterrey was conducting analyses of field samples for Mexico's national residue control program.

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*. Mexico'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 Mexico 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.

At the opening meeting, the auditor explained that Mexico's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Mexico. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those 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 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://199.140.65.44/Regulations_&_Policies/Foreign_Audit_Reports/index.asp.

During the April/May 2004 FSIS audit of Mexico's inspection system:

- 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 a Notice of Intent to Delist (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.

During the November 2004 FSIS audit of Mexico's inspection system:

- 2 establishments were cited inadequate implementation of SSOP requirements.
- 1 establishment cited for inadequate sanitation.
- 1 establishment received an NOID.
- 1 establishment was cited for animal disease control.
- 1 establishment was cited for inadequate humane slaughter.
- 9 establishments were cited for inadequate implementation of HACCP requirements.
- 9 establishments were cited for inadequate government enforcement.

6. MAIN FINDINGS

6.1 Government Oversight

SENASICA is responsible for 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

An audit of the CCA control systems included the following document reviews during on-site visits to Monterrey state office 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.
- 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, and *Listeria monocytogenes* testing.
- 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 or more 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. 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. Audit findings indicate that Mexico needs to continue training its inspection personnel to maintain competency of the FSIS inspection requirements.

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.

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 Audit

The auditor conducted a review of inspection system documents that included the following:

- Internal review reports.

- Supervisory visits to establishments that were certified to export to the United States
- Training records for inspectors and laboratory personnel.
- 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.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure 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.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of six processing establishments. None of the establishments were delisted by Mexico. Two establishments received a Notice of Intent to Delist (NOID) from Mexico's inspection officials due to inadequate implementation of *Listeria monocytogenes*, HACCP, and SSOP requirements.

This establishment may retain its certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

Specific deficiencies are noted on the attached foreign establishment audit checklists.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was 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.

The following residue laboratory was reviewed:

Laboratorio Central Regional De Monterrey which is a comité para el fomento y proteccion pecuaria del estado de Nuveo Leon, A.C.

No deficiencies were noted.

No laboratories conducting microbiological testing were reviewed.

9. SANITATION CONTROLS

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

Based on the on-site audits of establishments, and except as noted below, 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 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 six establishments audited, there was inadequate implementation of SSOP requirements in two establishments.

SSOP implementation deficiencies are noted on the attached foreign establishment audit checklists.

9.2 Sanitation

The following deficiencies were noted:

- In one establishment, maintenance and cleaning of overhead structures above exposed product/equipment (mixer, stuffer, etc.) in several production areas had been neglected to varying degrees with rust, loose and flaking paint/sealer materials, dripping condensation, and holes in walls/ceiling in evidence.

- In one establishment, SSOP records did not document all three parts of the corrective actions (especially to prevent recurrence) for Sanitation deficiencies.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, 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. 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; 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, 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 FSIS auditor are addressed below, as applicable, in each category.

11.1 Humane Handling and Slaughter

No slaughter establishments were reviewed.

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 audits of the six establishments. Of these establishments, there was inadequate implementation of HACCP requirements in five establishments.

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

11.3 Testing for Generic *E. coli*

No slaughter establishments were reviewed.

11.4 Testing for *Listeria monocytogenes*

Applicable establishments audited were producing ready-to-eat products for export to the United States. In accordance with United States requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

Deficiencies identified by FSIS auditor are noted on the attached foreign establishment audit checklists.

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 following residue laboratory was reviewed:

Laboratorio Central Regional De Monterrey which is financed by both the Mexican Government and private sector (comité para el fomento y proteccion pecuaria del estado de Nuveo Leon, A.C.)

No deficiencies were noted.

Mexico's National Residue Testing Plan for 2005 was being followed and was on schedule.

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*.

Specific deficiencies identified by FSIS auditor are noted on the attached foreign establishment audit checklists.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all processing establishments audited.

13.2 Testing for *Salmonella*

In two processing establishments, the government was not testing RTE products for *Salmonella*.

No slaughter establishments were reviewed.

13.3 Species Verification

FSIS had previously granted Mexico an exemption from conducting species verification testing. The FSIS auditor 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 SENASICA had controls in place for restricted product, inspection samples, 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 counties for further processing.

Lastly, adequate controls were found to be in place for security items, products entering the establishments from outside sources, and shipment security with the exception of the following:

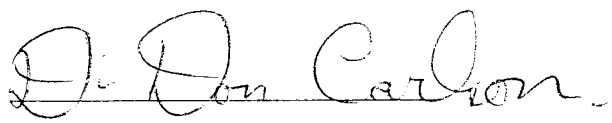
Government officials did not provide sample oversight, integrity, and security when shipping samples to the laboratory.

14. CLOSING MEETING

A closing meeting was held on March 17, 2005, in Mexico City with SENASICA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The SENASICA understood and accepted the findings.

for Dr. Nader Memarian
Senior Program Auditor



15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report *(no comments received)*

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
Elaboradora La Esperanza, S.A. Sabinas Hidalgo, Nuevo Leon	03/09/2005	TIF-304	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. *Plumbing and Sewage*	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. RTE Requirements	X
59. NOD	X
60. Sample Security and Integrity	X

60. Observation of the Establishment

Mexico - 03/09/2005 - Est. TIF-304 - Processing Establishment

15/51 The establishment did not conduct a hazard analysis to determine the food safety hazards reasonably likely to occur for each step of operation based on its flow chart {9 CFR part 417.2(a)}.

18/51 The establishment did not follow its monitoring procedures as written in its HACCP plan {9CFR part 417.2 (c)(4)}.

22/51 a) The establishment did not maintain any records of ongoing verification activities {9 CFR part 417.5(a)(3)}.
b) Monitoring records were not initialed {9CFR part 417.5(b)}.

58/51 a)The establishment selected to use Alternative 3 for *Listeria monocytogenes* but did not have a sanitation program which address {9CFR part 430.4(b)(3)}.
b)There was no monthly Ready-to-Eat product testing for *Salmonella.*

59 The Government of Mexico meat inspection official leading the audit issued a Notice of Intent to Delist (NOID) if corrective actions were not in place within 30 days of this audit for failure to comply with *Listeria monocytogenes* regulations and for HACCP plan deficiencies.

60/51 Government officials did not provide sample oversight, integrity, and security when shipping samples to the laboratory.

61. NAME OF AUDITOR
Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE
Nader Memarian DVM 03-22-05

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
Produtora De Bocados Carnicos S.A. de C.V. Apodoca, Nuevo Leon	03/07/2005	TIF-241	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, *critical control points, critical limits, procedures,* corrective actions:	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
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20. Corrective action written in HACCP plan.	
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22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
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26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
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46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Mexico - 03/07/2005 - Est. TIF-241 - Processing Establishment

15/51 The HACCP plan did not list the frequency of verification procedures {9CFR part 417.2(c)7}.

22/51 The HACCP records for Raw Not Ground did not document quantifiable values and time of the calibration of process-monitoring instruments (thermometer) {9CFR part 417.5(a) 3}.

61. NAME OF AUDITOR
Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE
Nader Memarian DVM 03-22-05

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
Productos Alimenticios Tia Lencha S.A. Cienega de Flores, Nuevo Leon	03/10/2005	TIF-237	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. RTE Requirements	X
59. Sample Security and Integrity	X

60. Observation of the Establishment

Mexico - 03/10/2005 - Est. TIF-237 - Processing Establishment

19/51 The establishment did not include the calibration of process-monitoring instruments as part of its ongoing verification activities { 9CFR part417.4(a)(2)(i)}.

20/51 The establishment did not address all four parts of the corrective action in its HACCP plan {9CFR part 417.3(a)}.

58/51 There was no monthly Ready-to-Eat product testing for *Salmonella.*

59/51 Government officials did not provide sample oversight, integrity, and security when shipping samples to the laboratory.

61. NAME OF AUDITOR
Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE
Nader Memarian 03-22-05

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
Alimentos Sigma Con Agra Foods S.A. de C.V. Linares, Nuevo Leon	03/04/2005	TIF-209	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. Sample Security and Integrity	X
59.	

60. Observation of the Establishment

Mexico - 03/04/2005 - Est. TIF-209 - Processing Establishment

13/51 Establishment SSOP records did not document all three parts of the corrective actions (especially to prevent recurrence) for Sanitation deficiencies {9CFR part 416.15}.

22/51 The HACCP verification records did not include time and the type of verification procedures (direct observation of monitor, review of the records, or calibration of process-monitoring instruments) performed by the responsible establishment employee {9 CFR part 417.5 (a) (3)} and {9CFR part 417.5(b)}.

58/51 Government officials did not provide sample oversight, integrity, and security when shipping samples to the laboratory.

61. NAME OF AUDITOR
Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE
Nader Memarian 03-22-05

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
Sigma Alimentos Centro S.A. de C.V. Planta Atitalaquia Atitalaquia, Hidalgo	03/14/2005	TIF-158	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. NOID	X
59.	

60. Observation of the Establishment

Mexico - 03/14/2005 - Est. TIF-158 - Processing Establishment

10/51 Maintenance and cleaning of overhead structures above exposed product/equipment (mixer, stuffer, etc.) in several production areas had been neglected to varying degrees with rust, loose and flaking paint/sealer, dripping condensation, and holes in walls/ceiling in evidence { 9CFR part 416.13 & 416.4}.

13/51 Establishment SSOP records did not document all three parts of the corrective actions (especially to prevent recurrence) for Sanitation deficiencies {9CFR part 416.15}.

19/51 The establishment did not follow its verification frequency as written in its HACCP plan {9CFR part 417.2 (c)(7)}.

22/51 A) The establishment verification records were not initialed
B) The establishment calibration records did not include time and initial
{9 CFR part 417.5(b)}.

58 The Government of Mexico meat inspection official leading the audit issued a Notice of Intent to Delist (NOID).

61. NAME OF AUDITOR
Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE
03-22-05

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
Delimex de Mexico, S.A. de C.V. San Nicolás de los Garza, Nuevo León	03/08/2005	TIF-150	Mexico
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Nader Memarian	[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. RTE Requirements	X
59. Sample Security and Integrity	X

60. Observation of the Establishment

Mexico - 03/08/2005 - Est. TIF-150 - Processing Establishment

58/51 Monthly Ready-to-Eat product testing for *Salmonella* and *Listeria monocytogenes* was done in a private lab which was not approved by Mexican Inspection.

59/51 Government officials did not provide sample oversight, integrity, and security when shipping samples to the laboratory.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Nader Memarian	Nader Memarian 03-22-05