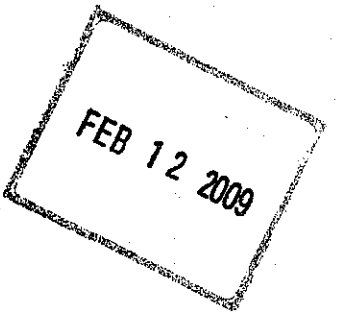
United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250



MVZ. Octavio Carranza de Mendoza
Director General
Dirección General, Inocuidad Alimentaria, Acuicola y Pesquera
Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA)
Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentación (SAGARPA)
Guillermo Perez Valenzuela 127
Colonia Coyoacan
C.P. 04000, Mexico, D.F.

Dear MVZ Carranza de Mendoza:

The Food Safety and Inspection Service (FSIS) conducted a follow-up on-site audit of Mexico's meat and poultry inspection system September 8 through September 19, 2008. No comments on the draft final report were received from the government of Mexico and a statement to that effect has been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

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

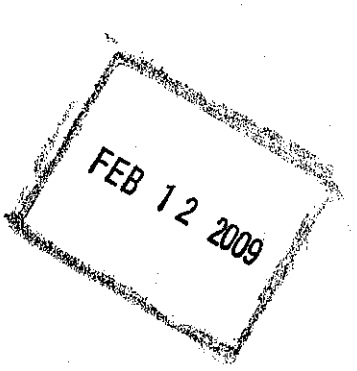
Sincerely,

for Don Carlson, acting Director

Manzoor Chaudry
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

U. S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL AUDIT STAFF
WASHINGTON, DC
202-205-3873
FAX 202-720-0676



MEMORANDUM

TO: Allan Mustard, Minister-Counselor
American Embassy, Mexico City
Paseo de la Reforma 305, Piso 2
Mexico City, D.F. 06500
Mexico

FROM: Manzoor Chaudry
Deputy Director
International Audit Staff, OIA, FSIS, USDA

SUBJECT: FSIS FINAL AUDIT REPORT FOR MEXICO (2)

Dear Mr. Mustard,

Please deliver the attached final audit report to MVZ. Octavio Carranza de Mendoza, Director General, Dirección General, Inocuidad Alimentaria, Acuicola y Pesquera, Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaia (SENASICA), Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentación (SAGARPA). Please contact me via email at manzoor.chaudry@fsis.usda.gov, if you have any further questions.

Best regards,

for Don Carlson, acting Director

Manzoor Chaudry

cc list:

Allan Mustard, Minister-Counselor, US Embassy, Mexico City
Daniel R. Williams II, Agricultural Attaché, US Embassy, Mexico City
Erich Kuss, Agricultural Attaché, US Embassy, Mexico
Carlos Vazquez, Minister Counselor for Agricultural Issues, Embassy of Mexico
OSTA/FAS
Hugh J. Maginnis, FAS Area Director
Ann Ryan, State Department
Lisa Wallenda Picard, Chief of Staff, OA
Alfred Almanza, Administrator, FSIS
Ronald K. Jones, Assistant Administrator, OIA
Philip Derfler, Assistant Administrator, OPPD, FSIS
Daniel Engeljohn, Deputy Assistant Administrator, OPPD, FSIS
Director, IAS, OIA, FSIS
Rick Harries, Acting Director, EPS, OIA
Stephen Hawkins, Acting Director, IES, OIA
Jerry Elliott, Director, IID, OIA
Barbara McNiff, Director, FSIS Codex Programs Staff, OIA
Yolande Mitchell, FCPS, OIA
David Smith, IES, OIA
Mexico Country File

FSIS:OIA:IAS:DIRECTOR:202-205-3873:Mexico
FINAL AUDIT LETTER February 12, 2009

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

SEPTEMBER 8 THROUGH SEPTEMBER 19, 2008

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

14. ENFORCEMENT CONTROLS
    14.1 Daily Inspection
    14.2 Testing for *Salmonella* Species
    14.3 Testing for *Escherichia coli* O157:H7
    14.4 Species Verification
    14.5 Periodic Reviews
    14.6 Inspection System Controls

15. CLOSING MEETING

16. ATTACHMENTS TO THE AUDIT REPORT

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)]
CENAPA	National Center for Animal Health Diagnosis (Centro Nacional de Servicios de Constatación en Salud Animal)
CFR	United States 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
RTE	Ready to Eat
SAGARPA	Secretary for Agriculture, Livestock, Rural Development, Fisheries and Food (Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca Y Alimentacion)
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 Inspección Federal)

I. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of an audit conducted in Mexico from September 8 through September 19, 2008. This was a follow-up audit with special emphasis on corrective actions instituted by SENASICA in response to the previous FSIS audit, during which systemic deficiencies were identified in three (sanitation, slaughter/ processing controls, and enforcement) of the five principle risk areas. The systemic nature of the findings resulted in the decision on the part of the Mexican government to suspend all exports to the US beginning August 29, 2008. In the absence such suspension, Mexico is eligible to export red meat, red meat products, and processed poultry products to the US[1].

From January 1 through August 28, 2008, the US received 66,773,175 lbs. of meat and poultry products from Mexico, of which 132,636 lbs. (0.2%) were rejected at US ports of entry. The principle causes for rejection included contamination, leaking containers, and missing shipping marks.

The activities of the current audit appear in the table below.

1.2 Comparison of the Current Audit and the Previous Audit

		Current Audit (2008) 9/8-9/19	Previous Audit (2008) 06/24-07/31
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	2	3
	Establishment Level	4	11
Laboratories Audited			
	Microbiology	0[5]	3
	Residue	0[5]	1
Establishments Audited			
	Slaughter/processing	2	5
	Processing	2	6
	ID Warehouses	0	0
Enforcement Actions Initiated			
	NOID	NA[2]	4
	Delistment	NA[2]	3

[1] Special restrictions under 9 CFR 94.25 exist for pork and pork products. Raw poultry from Mexico is permitted from TIF 241 if the origin of the poultry was U.S. or other END-free country eligible for export of raw poultry to U.S. Mexico is currently suspended from eligibility to export all heat treated, shelf stable, ready to eat products (HACCP process category 03F) to the United States.

[2] As Mexico was currently under voluntary suspension for exports, additional enforcement actions were not applicable within the context of this audit.

		Current Audit (2008) 9/8-9/19	Previous Audit (2008) 06/24-07/31
Establishment Findings		(4) Audited[3]	(11) Audited
	Sanitation Controls (SSOP, SPS)	3	11
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	2	11
	Residue Controls	0	0
	Microbiology Controls	1	0[4]
	Inspection/Enforcement Controls	4	11
	Humane Handling & Slaughter	1	1
Laboratory Findings		(0) Visited[5]	(4) Audited
	Microbiology Laboratories		3
	Chemical/Residue Laboratories		0

1.3 Summary Comments for the Current Audit

Insomuch as problems continued to be identified within the three risk areas of Sanitation, Slaughter/Processing, and (national) Government Oversight/Enforcement, it appears as though certain aspects of Mexico's corrective actions may have been rushed, and not given the full time necessary for adequate implementation. Current audit findings indicate that progress has been made, but the Mexican inspection personnel are still in the process of refining their understanding of FSIS requirements, along with the newly initiated procedures from Mexico's inspection Headquarters.

2. INTRODUCTION

The audit took place in Mexico from September 8 through September 19, 2008.

An opening meeting was held on September 8, 2008, in Mexico City with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and the scope of the audit, the auditors' itinerary, and requested additional information needed to complete the audit of Mexico's meat and processed poultry inspection system.

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

3. OBJECTIVE OF THE AUDIT

[3] The selection of establishments was based on a newly revised list of 14 facilities determined by the CCA as meeting FSIS requirements.
[4] At the time of this audit, Mexico had not yet fully implemented its testing program for E. coli O157:H7.
[5] Although actual laboratory visits were not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, state, and local inspection offices.

As previously indicated, this was a follow-up audit with special emphasis on corrective actions instituted by SENASICA in response to the previous audit, during which systemic deficiencies were identified. Additional points of focus included humane handling and slaughter of livestock, as well as programs associated with *Escherichia coli* O157:H7 control. The principle objective of the audit was to verify the effectiveness of corrective actions taken, so as to validate the status of Mexico's meat/poultry food-safety system as equivalent to that which exists in the US.

4. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA meat 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 and state offices. The final part involved on-site visits to four slaughter and/or processing establishments.

Program effectiveness determinations of all FSIS audits of foreign food-safety system are based on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis Critical Control Point (HACCP) programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species. In that systemic deficiencies concerning Mexico's inspection system were previously identified in the areas of sanitation; slaughter/processing controls; and enforcement, current audit methodology necessitated greater emphasis in these areas.

During all on-site establishment visits, the auditors evaluated the nature, extent, and degree to which findings impacted on food safety and public health. The auditors also assessed what improvements had been made concerning how inspection services are carried out by Mexico in order to validate that an equivalent level of 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 auditors 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 aspects, daily inspection in all certified establishments; periodic 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 and an equivalence determination allowing official testing for *Salmonella spp.* to be performed in private laboratories.

5. 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.
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.).

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the FSIS website at the following address: http:/www.fsis.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The last FSIS audit of Mexico's inspection system was conducted June 24 through July 31, 2008, during which systemic failures were identified in the following risk areas:

1) Sanitation
2) Slaughter/Processing controls
3) Enforcement

The determination that these areas were affected in a systemic manner was based on the characteristics of the findings, which included:

- A large number of establishments affected: deficiencies involving the enforcement of U.S. requirements were identified at all eleven establishments audited.
- Similar findings among establishments.
- Likelihood to affect large quantities of product, e.g., lack of hot water in key parts of the facility, product continuously contacting contaminated surfaces, dripping condensate in extensive areas of the facility.
- Deficiencies were not immediately rectifiable and deeply rooted in nature, as they related both to deficiencies within the establishment as well as awareness of inspection personnel.

Additional details concerning the three risk areas and their sub-components which contributed to the systemic nature of the findings included:

- SSOP:
    - Multiple incidences of product contamination due to cross-contamination, dripping condensate, or other foreign materials. Much of the contamination was obvious to the extent to indicate that large amounts of

product were likely to be affected during the period prior to the audit, as well as a certain tolerance for its presence by both the establishment as well as inspection personnel.
    - Failure to maintain operational records.
    - Incomplete records maintained by the establishment, as well as a discrepancy between the their content and actual conditions
- SPS:
    - Absence of hot water in key locations
    - Lack of water potability certification
    - Presence of insects in production areas
    - Inadequate handling of inedible materials
    - Presence of condensate in production areas
- HACCP programs:
    - Failure to include all processing steps and/or address all hazards in the hazard analysis
    - Incomplete corrective actions
    - Failure to follow the stated monitoring frequency
    - Unsupported choice of the alternative to control *Listeria monocytogenes* in the post-lethality environment
- Handling of Specified Risk Materials:
    - Failure to address in hazard analysis
    - Lack of written plan
    - Failure to maintain records
- Enforcement:
    - Deficiencies involving basic elements of inspection methodology:
        1) Recordkeeping:
            - At one establishment, records sufficient to document daily inspection coverage were not being maintained.
            - At one establishment, the official veterinarian was able to demonstrate only limited documentation of non-compliances identified within the establishment. Furthermore, no documentation addressing the resolution of these deficiencies was available.
            - In most establishments visited, inspection records did not accurately reflect the actual conditions observed during the FSIS audit.
        2) Post-mortem inspection
            - In one establishment, the inspection official did not observe the cranial and caudal mesenteric lymph nodes or palpate the rumino-reticular junction during post-mortem viscera inspection.
            - In one establishment, the inspector at the swine viscera station did not routinely observe both surfaces of the liver, nor perform a thorough observation and palpation of the entire mesenteric lymph node chain. In addition, the trimming of stick-wounds, which are contaminated with scald water, was not being enforced.

- In one establishment, several heads which had passed inspection and were hanging on a rack awaiting further processing were contaminated with hair. This presence of contamination was in conjunction with the observation of unsanitary head removal procedures, during which portions of the hide came in contact with the affected portions.

3) Control of inedible materials
4) Humane handling of livestock: at one of the five slaughter establishments audited, water was not available at several livestock pens in which animals were present

- Oversight-related deficiencies were identified at all three microbiology laboratories audited:
  - Sample receipt
  - Tracking
  - Reporting of sample results
  - Testing methodology for O157:H7
- Deficiencies concerning the implementation of periodic supervisory reviews:
  - No delistments/NOIDs occurred in association with reviews conducted prior the FSIS audit, yet numerous enforcement actions were taken during the audit.
  - Supervisory reviews failed to previously identify significant deficiencies encountered during the current audit, including the lack of awareness of FSIS requirements by both establishments and inspection staff.
  - At one of the three state offices audited, two consecutive supervisory reviews of a slaughter facility were conducted on days when operations were not occurring.
  - Some HACCP/SSOP-related elements included in the supervisory review reports were not being directly verified by the area supervisor.

In response to these previous audit findings, an assessment was performed by the CCA which indicated a need for further training and standardization of inspection verification practices performed at the establishment level, as well as additional supervisory controls. The determinations resulted in the submission of a corrective action plan to FSIS outlining the following steps:

1. Issue a letter to all TIF establishments eligible to export to the US, advising them that SENASICA will no longer issue export certificates as of August 29, 2008 until further audits indicate compliance with all applicable legislation.
2. Review all TIF establishments currently certified for export to the US, in a manner to identify those which were not interested or were not in compliance with US requirements. The result of this process resulted in a reduction of establishments determined to meet FSIS requirements from approximately 36 to 14.

3. Implement the BAX system at the central reference laboratory (CENAPA) to test for the presence of E. coli O157:H7 in raw beef. This is an FSIS-approved method.
4. Improve the documentation of inspection activities.
5. Issue of a letter to all establishments producing beef products, indicating a need to reassess their HACCP plan.
6. Issue a manual of standardized inspection verification procedures to be conducted on both a local and state level.

The objective of the current audit included the assessment of the implementation of these corrective actions.

7. MAIN FINDINGS

7.1 Government Oversight

SAGARPA is the Secretariat of the Mexican Government with control over livestock and animal health issues. SENASICA, a division/service of SAGARPA, is responsible for regulating Mexico's meat and processed poultry inspection system and live-animal health requirements. This responsibility includes certifying and regulating TIF (Tipo Inspección Federal) establishments for the exportation of meat or processed poultry products to the United States.

As of September 2007, the supervision of TIF establishments has undergone extensive reorganization which resulted in the creation of the following four departments, each of which is headed by its own sub-Director:

1) Approval and Certification of Establishments
2) Regulation, Inspection, Verification, and Surveillance
3) Inspection of Facilities/Product
4) National Supervision

At the time of the current audit, no changes had been made to the organizational structure within SENASICA. Interviews at the central level indicated that the intent of modifications made to its system was to enforce those activities contained within the pre-existing framework. Although no objections were raised concerning the *design* of the supervisory and communication channels supporting Mexico's inspection system, non-compliances involving the enforcement of FSIS requirements were still identified at all the establishments audited. As such, it is expected that the CCA continue to improve the *implementation* of these channels of supervision and communication.

7.1.1 CCA Control Systems

The production of meat and poultry products in Mexico is conducted either in TIF establishments or in municipal establishments. SENASICA has authority only over TIF establishments, whereas Mexico's Department of Health has authority over the municipal establishments. The majority of the meat and poultry production in Mexico is conducted

in the TIF establishments. Only TIF establishments have the authority to produce product for export to other countries.

7.1.2 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 ensure 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 one 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, depending on the size, type, and complexity of the operations, 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.

The official veterinarians in the TIF establishments, the area supervisors in the states, and all headquarters personnel in Mexico City are full time, permanent employees of the Mexican Federal Government. Salaries of the Federal Government are paid by a direct deposit/voucher system on a twice monthly basis.

During interviews conducted at the central level, representatives from SENASICA's management staff expressed an awareness of the need to improve the control which it exercises over its inspection force, and indicated that modifications to its internal audit programs were underway although not yet fully implemented. FSIS expects the CCA to keep their commitment to further develop this system in order to accurately *assess*, and ultimately *improve* performance on all levels.

7.1.3 Assignment of Competent, Qualified Inspectors

Upon entering government employment as official inspectors, 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.

During discussions held at the central level, SENASICA officials outlined the following improvements concerning the training and performance of its workforce:

- Fifteen new inspectors were in the process of being assigned to those fourteen establishments determined by the CCA as meeting US requirements.

- Procedures have been implemented to rotate inspectors between assignments with the intent to increase overall awareness and standardize performance.
- A new training coordinator was hired, and the development of a new training center in the state of Aguascalientes was underway.
- Advanced HACCP-based training of inspection personnel was scheduled for October 2008.
- An intranet system was developed and implemented to facilitate the dissemination of FSIS and other inspection-related requirements to inspection personnel.

FSIS continues the stress the importance of training, as findings identified during the current audit continue to be associated with basic principles of HACCP and SSOP. In order to ensure that an equivalent level of inspection is maintained, the CCA needs to develop the performance of its inspection personnel beyond that of basic awareness of FSIS requirements to a level where inspection methodology results in an interlocking system of controls to ensure compliance in all areas. During the current audit, aspects which of inspection methodology which could benefit from further training included:

- In one establishment, corrective actions taken in response to the contamination of bovine carcasses by condensate could not guarantee that the product was not adulterated. Inspection personnel must not only determine that corrective actions are taken by the establishment in response to SSOP and HACCP deficiencies, but must also verify that any corrective action taken is appropriate.
- In one establishment, numerous heads presenting excessive amounts of hair and knock-holes not situated in a manner to guarantee effective stunning of the animal had passed inspection personnel without further action being taken. The procedures associated with post-mortem head inspection offer information other than that related solely to pathology, and include the opportunity to verify adequate stunning and dressing procedures.
- During the interview process, the inspector at one facility was well aware of the contents of the establishment's written SRM control plan, but had difficulty in explaining how he actually went about verifying aspects of this program on a daily basis. In addition, they were not familiar with the dentition criteria used for the determination of animals 30 months or older, which is a key component for verifying a plan of this nature.

7.1.4 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, deficiencies involving the enforcement of U.S. requirements were identified at all four establishments audited:

- SSOP (three establishments)
- HACCP-Implementation (two establishments)
- Sanitation Performance Standards (two establishments)
- Humane handling & Slaughter (one establishment)

7.1.5 Adequate Administrative and Technical Support

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

While actual laboratory visits were not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, regional, and local inspection offices.

- At one establishment it was noted that inspection personnel conducting verification sampling for E. coli O157:H7 had not received test results from CENAPA.

Since the last audit, the CCA has recently developed a protocol and associated forms to further standardize and monitor activities performed by official veterinarians assigned to establishments intending to export to the US. However, at all of the establishments audited, conversations with local inspection personnel in addition to the review of completed forms indicated a need for further guidance concerning the implementation of these new protocols.

During the interviews conducted at various levels, it was noted that much of the information concerning FSIS requirements was distributed in its original format, without prior translation. Furthermore, the sentiment of persons interviewed indicated that their awareness of FSIS requirements would benefit substantially if translated versions of this information were available.

7.2 Headquarters Audit

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

- Organizational structure and chain of command within SENASICA.
- TIF system structure and responsibilities of the enforcement division in assurance of compliance with laws and regulations.
- The documents and system of communication between the headquarters, the area supervisors, and the in plant inspection personnel.
- The enforcement actions taken when non-compliance with regulatory requirements was identified.
- Qualifications and certifications required for employment in the inspection service.
- National residue and microbiological testing programs for products eligible for export to the U.S.
- Export certifications for eligible products and health certifications for animals and products received by eligible establishments.
- Documents issued by part of the CCA as part of the response to previous FSIS audit findings, which included:

- A letter to all TIF establishments eligible to export to the US, advising them that SENASICA no longer issue export certificates as of August 29, 2008 until further audits indicate compliance with all applicable legislation.
- A list of establishments which, after a review by the CCA, were determined as meeting FSIS requirements. As mentioned previously, this list had been reduced from approximately 36 to 14 establishments.
- The creation of a new "Pathogen Reduction Plan" to address *E. coli* O157:H7 sampling, as well as standardize other components of microbial testing conducted by government officials within US-legible establishments.
- An agenda for upcoming training in October, 2008.
- A new inspection manual to standardize procedures implemented on a state and local level. A review of this document was conducted by FSIS, and further collaboration concerning omissions which were identified during this process is planned.

While no direct concerns arose as a result of the examination of these documents, it should be noted that certain aspects of the program had not yet been implemented. In addition, the following information was subsequently determined during interviews carried out at the state level concerning the review of the 14 establishments conducted by the CCA:

- A review of one establishment (TIF 111) was not actually performed at the central level prior to assigning it to the list of establishments determined to meet FSIS requirements.
- The report issued by the CCA for est. TIF 300 (not audited by FSIS during the current visit, but was on the list of proposed establishments) identified numerous deficiencies within the areas of SSOP, SPS, and HACCP. In addition, comments included in the report indicated a strong sentiment of disagreement to the findings by part of the establishment. The extent of findings, coupled with the lack of cooperation from plant management calls into question the CCA's decision to include this establishment on the newly revised list.

7.3 Audit of State and Local Inspection Offices

The auditors conducted a review of inspection system documents for Sinaloa, and Nuevo Leon state offices. The records review focused primarily on food safety hazards and included the following:

- Records of supervisory visits to TIF establishments.
- Weekly reports of findings and corrective actions from the establishment MVZ supervisors.
- Records of training in HACCP design and implementation for personnel in TIF establishments.
- Copies of new regulations and requirements transmitted from the CCA.
- Documentation of investigations and enforcement actions.

At this level it was also confirmed that he state offices were in possession of the newly issued information originating from the central level. For the most part, this information had been received and under implementation. As mentioned previously, some confusion existed in the manner in which forms associated with verification of inspection activities were to be completed.

At one of the two state offices audited, the supervisor indicated that they were still not directly verifying some of the HACCP/SSOP-related elements included in the supervisory report. This is a repeat finding from the previous audit. As mentioned in the previous report, deficiencies concerning the implementation of periodic supervisory reviews are significant as they relate to the system, where these reviews serve as an additional layer of control by which the enforcement of U.S. requirements can be ensured.

8. ESTABLISHMENT AUDITS

The FSIS auditors visited a total of four establishments (two slaughter/processing establishments, and two processing-only establishments). Specific finings are included on the individual establishment checklists which are attached to this report.

9. 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.

As indicated previously, although actual laboratory visits were not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, state, and local inspection offices, during which the following deficiency was encountered.

- At one establishment, personnel conducting verification sampling for *E. coli* O157:H7 had not received test results from CENAPA, and had received a letter from the laboratory stating that samples should be accompanied by payment.

10. SANITATION CONTROLS

The FSIS auditors focused on five areas of risk to assess Mexico's meat inspection system. The first of these risk areas that the FSIS auditors 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, welfare facilities, and outside premises.

10.1 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.

In three of the four of the establishments audited, implementation of SSOP requirements was inadequate:

- Two of four establishments did not routinely document corrective actions taken in response to operational sanitation standard operating procedures (SSOP) deficiencies. This is a repeat finding from the previous audit.
- In one establishment, condensate originating from extensive areas of the overhead structures in the carcass cooler was seen dripping on numerous bovine carcasses.
    - Furthermore, the corrective actions presented by the establishment (as documented by the inspection staff) were unacceptable in that they proposed to retain the carcasses until the results of microbiological testing were received, without indication that the product would be reconditioned regardless of these results.
- In one establishment, heavily beaded condensate was observed on the horizontal housing of a meat grinder. The condensate had accumulated to the extent that contamination of the product was likely to have occurred, or was imminent.
- In the slaughter area, water was seen overflowing and dripping from the employees' work stands into a vat of product which the establishment had identified as being edible (bovine shanks/feet).

A more detailed description of these deficiencies can be found in the attached individual establishment reports.

10.2 Other Sanitation Concerns

In two of the four establishments audited, deficiencies regarding sanitation performance standards (SPS) were observed:

- In one establishment, ventilation was insufficient as it was unable to prevent the formation of condensation in several product storage and transit areas.

- In one establishment, water was seen dripping from the ceiling in extensive areas of the establishment, including rooms where product formulation, cooking, packaging, and storage occurred. The source of the water was determined to be rain which had penetrated through faulty areas of the roof. The condition of the overhead structures in some of these areas indicated a chronic nature of the event, as evidenced by the presence of rust and peeling paint. While no exposed product was observed to be affected, contamination by rainwater was observed on a large quantity of packaged product in the main storage area. In addition, the ubiquitous nature of the problem rendered it uncertain that direct contamination would not occur in those production areas which were active.

A more detailed description of these deficiencies can be found in the attached individual establishment reports.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, control over condemned and restricted products, and procedures for sanitary handling of returned and reconditioned product.

No concerns arose as a result of this review.

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

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditors reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem dispositions; 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* in slaughter establishments and for *Listeria monocytogenes* in establishments producing ready-to-eat products, and implementation of the Bovine Spongiform Encephalopathy (BSE) control measures.

12.1 Humane Handling and Slaughter

At one of the two slaughter establishments audited, the following deficiencies were identified:

- In the livestock area, the jagged stub of a metal pole was protruding from the floor of the suspect pen and was situated in a manner which could cause injury or pain to animals when present.
- In the slaughter area, it was observed that the knock-holes of numerous bovine heads were misplaced and not in a position which would guarantee proper stunning of the animal.

12.2 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 four establishments. Deficiencies concerning HACCP implementation were identified at two of the establishments audited:

- In one of four establishments, the hazard analysis was incomplete in that it did not address the following:
    - The potential germination and subsequent toxin formation of spore forming bacteria during the stabilization process.
    - The potential presence of SRMs in raw beef ingredients. However, letters of guarantee were available from suppliers indicating that only meat from cattle less than thirty months of age is utilized.
- At one establishment, the critical limit associated with the application of an antimicrobial rinse (peroxyacetic acid) on beef carcasses was incorrectly defined this value as "a maximum of 220 ppm." Discussions with plant management resulted in the determination that the intended critical limit for this CCP was actually "a minimum of 150 ppm."
- In one establishment, the HACCP plan did not include the direct observation of monitoring activities and any corrective actions taken as part of its on-going verification procedures.
- At one establishment, the following deficiencies were identified concerning SRM control:
    - The establishment had not taken the necessary steps to segregate SRMs during the head-washing process. During the review of slaughter operations, it was noted that employees occasionally wash multiple heads in one cabinet. Conducted in this manner, this practice creates a potential for cross-contamination due to leakage of brain material originating from the open knock-hole in the skull.
    - The establishment's written SRM control plan did not clearly indicate how the lingual tonsils would be separated from edible portions of the tongue.

A more detailed description of these deficiencies can be found in the attached individual establishment reports.

12.3 Testing for Generic *E. coli*

Mexico has adopted the FSIS regulatory requirements for generic *E. coli* testing.

Two of the four establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

No deficiencies were noted.

12.4 Testing for *Listeria monocytogenes*

Two of four 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 adequately reassessed to address the contamination of product by *Listeria monocytogenes* in the post-lethality environment, where applicable.

Inspection personnel assigned to those audited establishments where RTE product was being produced had implemented the necessary changes in accordance with SENASICA's new pathogen reduction program.

13. RESIDUE CONTROLS

As mentioned previously, although actual laboratory visits were not within the scope of the current audit, performance was assessed through interviews conducted at the CCA, regional, and local inspection offices. No deficiencies were identified.

14. ENFORCEMENT CONTROLS

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

- In all four establishments audited, deficiencies which should have been identified by the CCA prior to the current FSIS audit were identified.

14.1 Daily Inspection in Establishments

No deficiencies were identified. Protocols were in place to ensure for the appropriate coverage by inspection personnel during all shifts product is produced at those establishments identified as meeting FSIS requirements.

14.2 Testing for *Salmonella*

With the exception of the aforementioned equivalence determination which permits testing in private laboratories, Mexico has adopted the FSIS regulatory requirements for testing for *Salmonella.*

Two of the four establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

No deficiencies were identified

14.3 Testing for *E. coli* O157:H7

SENASICA has recently submitted a testing program for *E. coli* O157:H7 to FSIS which was subsequently determined as equivalent.

This sampling program includes the use of N60 sample collection, weekly review of establishment sampling records by the in-plant veterinarian, and monthly verification of sample results by the state supervisor. The plan also includes SSOP monitoring, as well as quality control and pathogen reduction programs

The contents of the plan also describe the measures to be taken in the event of a positive finding of *E. coli* O157:H7, including an investigation to identify the source of the contamination, and appropriate corrective actions. An intensified sampling program will be initiated, consisting of a minimum of one sample daily for eight consecutive weeks. A positive finding necessitates a reassessment of the HACCP plan by part of the establishment. Product testing positive will undergo thermal treatment, and will be barred from export to the US. Records will be maintained showing the disposition of the product and that the CCA maintained control of the product.

Mexico's program currently utilizes FSIS' MLG 5A.01 for sample analysis. This is a screening method, which will provide a presumptive positive if *E. coli* O157:H7 is present in the sample. Since Mexico is not yet able to utilize a confirmatory test method (they are attempting to adopt the FSIS MLG 5.04 method), all presumptive positives will be treated as a confirmed positive, and will be subject to the events described above.

All samples for *E. coli* O157:H7 will be analyzed in the CENAPA lab, which is the government reference lab located in Jiutepec, Morelos.

Except as noted, the current audit indicated that sample collection and testing were conducted in a manner consistent with the newly proposed sampling plan:

- At one establishment, personnel conducting verification sampling for E. coli O157:H7 had not received test results from CENAPA, and had received a letter from the laboratory stating that samples should be accompanied by payment.

14.4 Species Verification

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

14.5 Periodic Reviews

During this audit it was found that in all establishments visited, periodic supervisory reviews of certified establishments were being performed at the frequency specified by the CCA. Deficiencies concerning the manner in which these reviews were conducted have already been discussed in section 6.3 of this report.

14.6 Inspection System Controls

In most instances, the CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market. However, the following deficiencies were identified:

- At one establishment, approximately 50% of heads which had passed inspection and hanging on a rack awaiting further processing were contaminated with excessive hair.
- Interviews with in-plant personnel in conjunction with review of inspection records indicated that further guidance is needed concerning the documentation of non-compliance within establishments:
    - Not all non-compliances are documented
    - Use of multiple forms for documentation of non-compliance
    - Improper use of trend indicators
    - Inappropriate regulatory citations
    - Incomplete documents
- At one establishment, the inspector was not familiar with the dentition criteria utilized for the determination of cattle thirty months of age or older.

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, shipment security, and products entering the establishments from outside sources.

15. CLOSING MEETING

A closing meeting was held on September 19, 2008, in Mexico City with the CCA. At this meeting, the preliminary findings and conclusions from the audit were presented by the FSIS auditors.

The CCA understood and accepted the findings.

Dr. Alexander L. Lauro
Senior Program Auditor

16. ATTACHMENTS TO THE AUDIT REPORT

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

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
Ganaderia Integral Vizur, S.A. de C.V. Km. 14.5 Carretera Culiacan-Vitaruto, Edido El Pinole Navolato, Sinaloa 80300	09/12/2008	TIF 111	Mexico

5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
Dr. Alexander L. Lauro Dr. Francisco Gonzalez	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 SSOPs have failed to prevent direct product contamination or adulteration.	X
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.	
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	
28 Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment Date: 09/12/2008 Est #: TIF111 (Ganadería Integral Vizur, S.A. de C.V. [S/P/CS]) (Navolato, Mexico)

10/12/51. Condensate originating from extensive areas of the overhead structures in the carcass cooler was seen dripping on numerous bovine carcasses. Subsequent review of the inspection records which were generated as a result of this finding incorrectly identified the number of carcasses involved. Furthermore, the corrective actions presented by the establishment were unacceptable in that they proposed to retain the carcasses until the results of microbiological testing were received, without indication that the product would be reconditioned regardless of these results. The value of microbiological testing in this instance is of questionable value in that it fails to address the physical contamination of product by dust, grease, or other components found on the overhead structures from which the condensate originated. [Regulatory reference(s): 9 CFR §416.13, 416.15(b), 416.17]

10/46/51. In the slaughter area, water was seen overflowing and dripping from the employees' work stands into a vat of product which the establishment had identified as being edible (bovine shanks/feet). Discussions with the State supervisor indicated a certain level of acceptance of this condition, in that this specific type of type of product was routinely subject to intense washing during subsequent steps in the process. However, the practice of passively permitting contamination of product, regardless of subsequent reconditioning steps, is not consistent with the FSIS regulations addressing the manner in which sanitary operations are to be conducted within an establishment. [9 CFR §416.13, 416.17, 416.4(a)]

13/51. The establishment did not routinely document corrective actions taken in response to operational SSOP deficiencies. This is a repeat finding from the audit conducted on July 23, 2008. [9 CFR §416.15(b), 416.16, 416.17]

39/51. In the slaughter area, condensate was seen dripping in close proximity to the head-wash area from a broken steam pipe. [9 CFR §412.2(b)]

41/51. Ventilation in several of the production rooms and product transit hallways was inadequate, as evidenced by the presence of fog and condensate in these areas. [9 CFR §416.2(d)]

51/52. In the livestock area, the jagged stub of a metal pole was protruding from the floor of the suspect pen and was situated in a manner which could cause injury or pain to animals when they are present. [9 CFR §313.1(a)]

51/52. In the slaughter area, it was observed that the knock-holes of numerous bovine heads were misplaced and not in a position which would guarantee proper stunning of the animal. [9 CFR §313.15]

51/55. In the head storage room, approximately 50% of heads which had passed inspection and hanging on a rack awaiting further processing were contaminated with hair excessive hair. The presence of contamination was neither detected by the inspection service nor establishment personnel. [9 CFR §310.18]

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
9/12/2008

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
Ganaderia Integral S.K. S.A. de C.V. Libramiento Noreste Km. 25C. Carretera Laredo Saltillo Ciudad General Escobedo, Nuevo Leon 66050	09/17/2008	TIF 105	Mexico

5. NAME OF AUDITOR(S)
Alexander L. Lauro, DVM
Francisco Gonzalez, DVM

6. TYPE OF AUDIT

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.	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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

22/51. Review of the critical limit associated with the application of an antimicrobial rinse (peroxyacetic acid) on beef carcasses indicated that the establishment had incorrectly defined this value as "a maximum of 220 ppm." While establishing a maximum concentration is important in controlling aspects of product quality and labeling, it is the minimum concentration which is associated with food-safety. Discussions with plant management resulted in the determination that the intended critical limit for this CCP was actually "a minimum of 150 ppm." [Regulatory reference(s): 9 CFR §417.5(a)(2), 417.8]

22/51. The establishment had not taken the necessary steps to segregate SRMs during the head-washing process. During the review of slaughter operations, it was noted that employees occasionally wash multiple heads in one cabinet. Conducted in this manner, this practice creates a potential for cross-contamination due to leakage of brain material originating from the open knock-hole in the skull. As age determination is accomplished through the use of dentition at a point situated after the head-wash cabinet, the establishment is to treat all brain material as SRM during the washing stage. [9 CFR §310.22, 417.5(a)(2), 417.8]

22/51. The establishment's written SRM control plan did not clearly indicate how the lingual tonsils would be separated from edible portions of the tongue. [9 CFR §310.22, 417.5(a)(2), 417.8]

61. NAME OF AUDITOR
Alexander L. Lauro, DVM

62. AUDITOR SIGNATURE AND DATE
9/17/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION
Sigma Alimentos Noreste, S.A. de C.V.
J. Cantu Leal No. 1320 Sur, Col. Buenos Aires

Monterrey, Nuevo Leon 64800

2. AUDIT DATE: 09/15/2008

3. ESTABLISHMENT NO.: TIF 100

4. NAME OF COUNTRY: Mexico

5. NAME OF AUDITOR(S)
Alexander L. Lauro, DVM
Francisco Gonzalez DVM

6. TYPE OF AUDIT
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.	
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	X
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.	
59.	

60. Observation of the Establishment

Date: 09/15/2008 Est #: TIF 100 (Sigma Alimentos Noreste, S.A. de C.V. [PJ) (Monterrey, Mexico)

10/51. Heavily beaded condensate, situated above a vat of exposed product, was observed on the horizontal housing of a meat grinder. The condensate had accumulated to the extent that contamination of the product was likely to have occurred, or was imminent. [Regulatory reference(s): 9 CFR §416.13, 416.17]

13/51. A review of establishment records in addition to conversations with inspection personnel indicated that the establishment was not routinely documenting corrective actions taken in response to operational SSOP deficiencies. [9 CFR §416.16, 416.17]

39/51. Water was seen dripping from the ceiling in extensive areas of the establishment, including rooms where product formulation, cooking, packaging, and storage occurred. The source of the water was determined to be rain which had penetrated through faulty areas of the roof. The condition of the overhead structures in some of these areas indicated a chronic nature of the event, as evidenced by the presence of rust and peeling paint. While no contamination of exposed product was observed, as the establishment elected to suspend operations in those production areas which were most severely affected, contamination by rainwater was observed on a large quantity of packaged product in the main storage area. In addition, the ubiquitous nature of the problem rendered it uncertain that direct contamination would not occur in those production areas which were active. [9 CFR §416.2(b)]

61. NAME OF AUDITOR

Alexander L. Lauro, DVM

62. AUDITOR SIGNATURE AND DATE

Alexander L. Lauro 9/15/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION
Sana Internacional, S.A. de C.V.
Avenida Miguel de la Madrid, Parque Industrial

San Luis Rio Colorado, Sonora 83400

2. AUDIT DATE
9/10/2008

3. ESTABLISHMENT NO.
TIF 86

4. NAME OF COUNTRY
Mexico

5. NAME OF AUDITOR(S)
Dr. Alexander L. Lauro
Dr. Francisco Gonzalez

6. TYPE OF AUDIT
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	X
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.	
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.	
59.	

07/51. Although records were available which indicated that monitoring of the establishment's operational SSOP was occurring on a regular basis, a description of the monitoring procedures and the frequencies at which they are to be conducted were not included within the written plan. Without the presence of written procedures, it could not be adequately verified that monitoring of operational SSOP was occurring as intended. [Regulatory reference(s): 9 CFR §416.12(d), 416.17]

15/51. The hazard analysis addressing the production of cooked beef "cabbage rolls" did not accurately identify all the possible hazards associated with the chilling of product after cooking. This document did not address the possible germination and subsequent toxin production of spore forming organisms such as *Clostridium perfringens* during this production phase, nor did it reference any further documentation supporting this omission. As the product is subjected to a rapid freezing process during this step, it is unlikely that conditions would allow for toxins from these organisms to be produced. However, failure to address all possible hazards at this step within the content of the establishment's hazard analysis does not meet the regulatory *requirements of* 9 CFR 417.2(a)(1). [9 CFR §417.2(a)(1), 417.8]

15/51. The establishment's hazard analysis did not address the possible presence of SRMs associated with the receipt of raw beef ingredients. While letters of guarantee were available indicating that all beef components received by the establishment originated from cattle which were under thirty months of age, failure to address all potential hazards within the content of the hazard analysis does not meet the regulatory requirements of 9 CFR 417.2(a). [9 CFR §310.22(d)(1), 417.2(a)(1), 417.8]

15/51. The establishment's HACCP plan did not include the direct observation of monitoring activities and any corrective actions taken as part of its on-going verification procedures. [9 CFR §417.2(c)(7), 417.4(a)(2)(ii), 417.8]

61. NAME OF AUDITOR

Alexander Lauro, DVM

62. AUDITOR SIGNATURE AND DATE

9/10/2008

Comments to the Draft Final Report for Mexico:

No comments were received from the government of Mexico to the Draft Final Report.