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

FEB 10 2009

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 an on-site audit of Mexico's meat and poultry inspection system June 24 through July 31, 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,

by Don Carlson, acting Director

For 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
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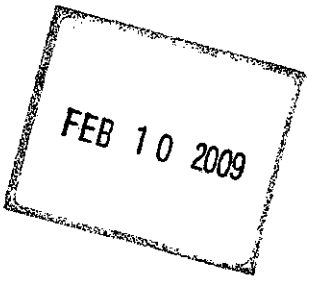

MEMORANDUM

TO: Allan Mustard, Minister-Counselor
American Embassy, Mexico City
Paseo del 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 (1)

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 (SEGARPA). Please contact me via email at manzoor.chaudry@fsis.usda.gov, if you have any further questions.

Best regards,

by Don Carlson, acting Director.

For 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
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Hugh J. Maginnis, FAS Area Director
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Daniel Engeljohn, Deputy Assistant Administrator, OPPD, FSIS
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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 9, 2009

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

JUNE 24 THROUGH JULY 31, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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[redacted]

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)

[redacted]

1. INTRODUCTION

The audit took place in Mexico from June 24 through July 31, 2008.

An opening meeting was held on June 24, 2008, in Mexico City with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and the 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 representatives from the SENASICA state inspection offices, and/or CENAPA.

2. OBJECTIVE OF THE AUDIT

This was a routine audit with special emphasis on humane handling and slaughter of livestock, as well as programs associated with *Escherichia coli* O157:H7 control. The objectives of the audit were 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 addition to controls over the microbiology and residue laboratories certified to analyze official samples collected at TIF establishments from product destined for the United States.

In pursuit of the objectives, the following sites were visited: the headquarters of the CCA, three state inspection offices, four laboratories, and eleven slaughter and/or processing establishments.

Competent Authority Visits			**Comments**
Competent Authority	Central	1	Mexico City
	State	3	Tamaulipas, Nuevo Leon, Yucatan
Laboratories		4	Three conducting microbiological testing: 1. Central Laboratory Monterrey 2. Central Laboratory Merida 3. Primus Laboratory in Culiacan One conducting chemical (residue) analysis: CENAPA reference laboratory in Jiutepac
Meat Slaughter/Processing Establishments		4	
Meat Slaughter Establishments		1	
Meat/Poultry Processing Establishments		6	

[redacted]

3. PROTOCOL

This on-site audit was conducted in four parts. One part included interviews 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 regional offices. The third part involved on-site visits to eleven slaughter and/or processing establishments. The final part included an audit of four laboratories, three conducting microbiological testing, and one analyzing samples in accordance with Mexico's national residue monitoring 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 (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 *Listeria monocytogenes* and *Salmonella* species. 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; 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 equivalence determinations in place which exempt their system from species verification testing requirements, and permits the official testing for *Salmonella spp.* to be conducted in private, rather than government laboratories.

[redacted]

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

5. 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 following establishment-related deficiencies were identified during the September 2006 audit of Mexico's inspection system:

- One establishment was issued an NOID for lack of a written plan for the testing of carcasses for generic *E. coli,* and lack of a valid statistical process control chart for recording of test results.
- Two of eight establishments were not adequately implementing SSOP requirements.
- Four of eight establishments failed to comply with SPS requirements.
- One establishment had inadequate implementation of HACCP requirements.
- In one establishment, inspection personnel were not incising all four sets of lymph nodes associated with the proper inspection of bovine heads.
- In one establishment, there was insufficient documentation within inspection records to verify the presence of inspection during all days when U.S. eligible product was produced.

In addition, the 2006 audit presented a special emphasis on microbiological testing, during which deficiencies were identified in the following areas:

- Technical support and oversight:
    - Production lots were allowed to be retested if initial test results were positive.
    - Records failed to clearly identify official government samples taken from products destined for the U.S. market.
    - Procedures for reporting official results to government inspection personnel were not documented.
    - Sample submission forms were not standardized concerning format or content.
    - Laboratory audits by SAGARPA officials had not been performed at the required frequency.

[redacted]

- Unapproved modifications to the agreed FSIS methods were being utilized.

- Laboratory quality assurance:
  - Deficiencies in the performance of instrument calibration and in the recording of calibration data.
  - Lack of positive and negative controls at all times when sample analyses were performed.
  - Improper preparation of culture media.
  - Lack of instrumentation required to perform phase contrast microscopy.
  - Use of incorrect sample portions when performing analyses.

During the August 2007 audit, one of eight establishments received an NOID for the lack of a written program to control and segregate Specified Risk Materials (SRM) in product destined for the U.S. In addition, the following deficiencies were identified:

- One establishment did not have inspection presence on a shift when U.S.-eligible product was produced. Delistment did not occur because of assurances made by the CCA to FSIS Headquarters that inspection coverage on all shifts would be immediately initiated and maintained.
- In four of eight establishments, the SSOP implementation requirements were not met.
- In six of eight establishments, the sanitation performance standards were not met (condensate, accumulation of debris on the premises, flaking paint, possible entry of pests).
- In two of eight establishments, HACCP implementation requirements were not met.
- Residue testing:
  - Analyst proficiency testing was not being conducted for one of the analyses that the laboratory routinely performed.
  - Analytical results were not distributed until payment for the analysis was received by the laboratory, resulting in occasional delays in reporting results.

Many of the deficiencies encountered during the current 2008 audit were repetitive in nature, the most significant of which include: failure to correctly implement HACCP and SSOP; SPS non-compliances involving condensate, flaking paint, and general maintenance of facilities; insufficient documentation of inspection activities; interpretation of generic *E. coli* results; inadequate post-mortem inspection procedures; identity of government samples; use of approved FSIS microbial testing methods; and payment-related delay of sample results.

6. MAIN FINDINGS

6.1 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

[redacted]

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

6.1.1 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.

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 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.

[redacted]

6.1.3 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.

- However, as many of the findings identified during the current audit were associated with basic principles of HACCP, SSOP, and generic *E. coli* testing, this may indicate a lack of proper training in these areas. Furthermore, most of the training programs presented focused on general slaughterhouse practices rather than FSIS requirements.

FSIS regulations are transposed into Mexican Federal Norms or Standards ("Officio") and sent out to inspection personnel electronically via an e-mail system and in hard copy through the area supervisors in information packets delivered to the TIF offices in the establishment. Other information concerning U.S. regulatory requirements is published in Circulars that are also sent via e-mail to the eligible establishments.

6.1.4 Authority and Responsibility to Enforce the Laws

SENASICA has the authority and responsibility to enforce the applicable laws relevant to establishments producing product for export to the United States.

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

- SSOP (eleven establishments)
- HACCP-Implementation (eleven establishments)
- Sanitation Performance Standards (eight establishments)

6.1.5 Adequate Administrative and Technical Support

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

Deficiencies were identified at all three microbiology laboratories audited involving one or more of the following elements:

- Sample receipt (one laboratory)
- Tracking (three laboratories)
- Reporting of sample results (two laboratories)
- Testing methodology (two laboratories)

A more detailed explanation of these findings can be found under section 8 (Residue and Microbiology Laboratory Audits) of this report.

[redacted]

6.2 Headquarters Audit

The auditor 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.

While no direct concerns arose as a result of the examination of these documents, the following significant points should be mentioned:

- An equivalent testing program for *E. coli* O157:H7 in manufacturing beef had not yet been instituted. The CCA is currently working with the FSIS International Equivalence Staff (IES) regarding the development of given program.
- Conversations regarding the CCA's current microbial testing policies indicated that product not meeting FSIS requirements would be directly barred from export; however, establishments do not routinely institute hold-and-test procedures. Presented as such, it was unclear how non-conforming product would actually be prevented from entering the U.S.

6.3 Audit of State and Local Inspection Offices

The auditor conducted a review of inspection system documents for the Tamaulipas, Nuevo Leon, and Yucatan 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.
- Laboratory analyses and copies of reports sent to establishments/producers.
- Documentation of investigations and enforcement actions.

[redacted]

The following deficiencies were identified:

- 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. This particular establishment was delisted during the current audit due to numerous deficiencies encountered.
- Some HACCP/SSOP-related elements included in the supervisory review reports were not being directly verified by the state supervisor.
- At one office, SSOP-related verification activities were not being assigned by the state supervisor to inspection personnel.

The deficiencies concerning the implementation of periodic supervisory reviews are significant as they related to the system, where these reviews serve as an additional layer of control by which the enforcement of U.S. requirements can be ensured.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of eleven establishments (one slaughter establishment, four slaughter/processing establishments, and six processing establishments).

During the audit, three establishments were delisted for failure to meet U.S. requirements. In addition, the CCA issued four other establishments a Notice of Intent to Delist (NOID) due to inadequate implementation of SSOP and HACCP in these establishments.

Specific deficiencies are noted on the attached individual establishment reports.

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.

During the current audit, the residue-related functions of the CENAPA government reference laboratory in Jiutepac were reviewed. No concerns arose as a result of this audit.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. *If private laboratories are used to test United States samples, the*

[redacted]

auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following microbiology laboratories were reviewed:

- Primus Laboratory in Culiacan (private).
- Central Regional Laboratory of Monterrey (private).
- Central Regional Laboratory of Merida (private).

Deficiencies were identified at all three microbiology laboratories audited involving one or more of the following elements:

- *Sample receipt*: at one laboratory, while written criteria were available concerning the discarding of unsuitable samples, the employee in charge of sample receipt was not familiar with these criteria during the audit interview.
- *Tracking* (three laboratories): although the documentation accompanying government samples sufficiently identifies them as such upon receipt, the identity of these samples was not clearly maintained upon entry into the laboratory's electronic logging system. Furthermore, during the audit of one establishment, discussions with the official veterinarian revealed that the results of government samples were sometimes sent to the establishment's QA manager, rather than to inspection personnel.
- *Reporting of sample results*: in most cases, establishments are directly responsible for the payment of samples analyzed, including government samples. Delinquent accounts can affect the analysis of these samples. In addition, during the audit of one establishment, discussions with the official veterinarian indicated that the government sample taken for the month of June had not yet been reported because, as they were not currently exporting to the U.S., the establishment refused to pay for the sample.
- *Testing methodology*: two laboratories approved for microbiological testing of *E. coli* O157:H7 were using the Neogen Reveal method, which differs from that currently utilized by FSIS. Mexico does not have an equivalence determination in place which would permit the use of this alternative method.

9. SANITATION CONTROLS

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

Review of this risk area included an assessment of 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, good product handling and storage practices, water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

[redacted]

Numerous deficiencies were identified within this risk area, and are described in the following sections.

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.

In all eleven of the establishments audited, implementation of SSOP requirements was inadequate:

- In three of eleven establishments, there was neither a procedure for the reconditioning of product in the written SSOP (i.e., 'dropped meat procedure'), nor were there documented specific occurrences of product reconditioning/disposal in the SSOP records.
- Three of eleven establishments did not routinely document corrective actions taken in response to pre-operational and/or operational sanitation standard operating procedures (SSOP) deficiencies. This finding not only identifies noncompliance with the recordkeeping components of 9 CFR 416.16 but, in the absence of given records, also indicates an inability to effectively meet those requirements associated with maintenance of the SSOP. Regulation 9 CFR 416.14, requires that an establishment routinely evaluate the effectiveness of the SSOP and the procedures therein, and revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.
- In seven of eleven establishments, records documenting pre-operational SSOP monitoring were incomplete in that measures to prevent recurrence were not always recorded.
- In three of eleven establishments, portions of carcasses were observed touching the unclean floor of a work platform.
- In one establishment, a severely scored cutting board was being used for edible product. This board was damaged to an extent to inhibit its thorough cleaning, and could result in product adulteration.
- In one establishment:
    - The inside rim of several barrels containing edible product were severely scored and soiled.
    - A plant employee was observed resting the carcass splitting-saw with its blade contacting the floor of his work platform and the front portion touching a barrel for inedible material.
    - A plant employee was observed contaminating his knife with fecal material while trimming a carcass without subsequently sanitizing his knife before the next cut.
- In one establishment, beef carcasses were observed rubbing against visibly soiled handles of pull-chains (wires) utilized for selecting overhead rails.

[redacted]

- In one establishment, an employee was observed handling crates which were in contact with the floor, and then directly touching edible product without first washing his hands.
- In one establishment:
    - Water used for sanitizing equipment was not maintained at the temperature described in the establishment's written plan (82° C/180° F).
    - Numerous carcasses throughout the establishment were contaminated with watery rail grease, flakes of paint, or other unidentified foreign material.
- In one establishment:
    - The liners of stacked boxes were observed touching the soiled floor of an employee's work platform.
    - Condensate was dripping directly onto product in two carcass coolers.
    - Exposed and contaminated product was observed in the shipping freezer.

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

9.2 Other Sanitation Concerns

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

- In one establishment, overhead pipes of the spray-chilling system were covered with a dark, tarry residue which could result in product adulteration during use.
- In three of eleven establishments, ventilation was insufficient as it was unable to prevent the formation of condensate in product storage areas.
- In one establishment, water-pipes situated in close proximity to beef carcasses were covered with insulation which was frayed and torn to the extent that product adulteration could occur.
- In one establishment, boxes and equipment were stored in a manner which precluded inspection to the extent that sanitary conditions could not be assessed.
- In four of eleven establishments, problems were identified with the hot water supply in employee restrooms and/or processing areas.
- Three of eleven establishments were unable to provide clear certification that potability requirements were being met.
- In one establishment, a conveyor belt used for the transport of vacuum-sealed product was soiled with packaging ink to such extent that its sanitary condition could not be assessed.
- In one establishment, control over green receptacles observed storing inedible materials was insufficient. These containers were identified for use with both *inedible materials and "by-products."*
- In two of eleven establishments, containers designated for edible product were used for collecting inedible materials.
- In one establishment, numerous insects were seen floating in chilling tanks containing cans which had just undergone the retort process.
- In one establishment, numerous flies were present in the slaughter area.

[redacted]

- In one establishment, the rear of the establishment was not maintained in a manner sufficient to prevent the harborage and breeding of pests in that high grass, weeds, and used equipment were present.
- In one establishment, several containers used for storing edible product had a visibly unclean exterior surface with a dark, sticky residue.
- In one establishment, the ceiling, door, and window were not constructed and maintained in a manner sufficient to prevent the entrance of vermin, such as flies, rats, and mice.
- In one establishment:
    - Pull-ropes used for the opening and closing of bay doors were extremely soiled and in contact with the floor.
    - A hand-wash sink was situated in such a manner that hog carcasses would routinely congregate directly above it, and contamination of product could occur during hand-washing procedures.

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

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 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.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem dispositions; 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.

[redacted]

11.1 Humane Handling and Slaughter

At one of the five slaughter establishments audited, water was not available at several livestock pens in which animals were present.

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 eleven establishments. Deficiencies concerning HACCP implementation were identified at all the establishments audited:

- In five of eleven establishments, the hazard analysis was incomplete in that it did not address one or more of the following:
    - Reworked product (two establishments)
    - Returned product (three establishments)
    - SRMs (three establishments)
    - Rendering of lard used in product formulation (one establishment)
    - Germination of spore forming bacteria and subsequent toxin formation during the stabilization process (one establishment)
- In one establishment, steps identified in the flow chart differed from those which were contained in the hazard analysis
- In two establishments, HACCP monitoring records did not include a time for each entry.
- In one establishment, the pre-shipment review only addressed the "raw not ground" plan, and did not include a documented review of the records associated with the slaughter process.
- In two establishments, monitoring procedures were not conducted with the frequency prescribed in the establishment's written HACCP plan.
- In three establishments, corrective actions associated with a deviation from the critical limit did not clearly indicate that no product injurious to health or otherwise adulterated as a result of the deviation entered commerce.
- In one establishment, corrective actions did not clearly indicate that the CCP would be under control after a deviation from the critical limit occurred.
- In three establishments, on-going verification procedures were incomplete in that they did not include:
    - *Records review (two establishments)*
    - Direct observation of monitoring activities/corrective actions taken (two establishments)
- One establishment had chosen "Alternative 1" as the means to control *Listeria monocytogenes* in the post-lethality environment, but could not support this decision:

[redacted]

1. Product was not subject to a post-lethality treatment which would reduce the number of microorganisms
2. No supporting documentation indicating that a two-log suppression of microbial growth exists throughout the shelf-life of the (frozen) product was available for review

- In two establishments slaughtering/processing beef, a written program for the removal, segregation, and disposition of SRMs was not in place.
- In two establishments, the SRM control plan was incomplete in that it did not address the removal, segregation, and disposition of:
  - Lingual tonsils (one establishment)
  - Brain material from knock-holes (two establishments)
- One establishment was not maintaining daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of specified risk materials (SRM), and any corrective actions taken.

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

11.3 Testing for Generic *E. coli*

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

Five of the eleven 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.

- Three establishments were sponging carcasses for generic *E. coli*, but were not using statistical process control techniques to evaluate test results. Two of these establishments were interpreting results using m/M criteria. These values are specific to the *excision* method for sampling, and not applicable to *sponging*.

11.4 Testing for *Listeria monocytogenes*

Two of eleven 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 these products by *Listeria monocytogenes* in the post-lethality environment.

No deficiencies were noted.

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.

[redacted]

During the current audit, the residue related functions of the CENAPA reference laboratory in Jiutepac (government) were reviewed. No concerns arose as a result of this audit.

13. ENFORCEMENT CONTROLS

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

U.S. inspection requirements were not being adequately enforced at all eleven establishments audited. Certain findings were on-going and broad in nature, in that they were most likely to affect large quantities of product through time. These included:

- Direct product contamination associated with noncompliant slaughter practices or facility design (e.g., heads/carcasses rubbing against employee platforms, carcasses rubbing against dirty pull-handles, employee placing the split-saw on floor of platform between carcasses)
- Establishment's failure to document corrective action records for SSOP failures and related inability for inspection to verify both corrective actions as well as the overall maintenance of SSOPs.
- Absence of hot water at key locations throughout the facility while production was occurring.

In addition, many findings were repetitive, both from a historical perspective, as well as from within the context of the current audit. As stated previously, the recurring nature of findings associated with basic principles of HACCP, SSOP, and generic *E. coli* testing, may indicate a general lack of proper training in these areas.

13.1 Daily Inspection in Establishments

While it appeared that inspection was being conducted daily in all slaughter and processing establishments, the following deficiencies were identified:

- At one establishment, records sufficient to document daily inspection coverage were not being maintained. In addition, SSOP verification procedures were not included as part of the weekly inspection assignments.
- 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.

[redacted]

13.2 Testing for *Salmonella*

Mexico has adopted the FSIS regulatory requirements for testing for *Salmonella.*

Five of the eleven 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

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 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.

13.5 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:

- Inadequate post-mortem inspection procedures were identified at three of the five slaughter establishments audited:
    - 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.

[redacted]

- In one establishment, denaturing of inedible materials was not routinely occurring prior to disposal.
- While conducting an external tour of one establishment, a pile of meat\bones was observed at the rear of the facility. These items were neither denatured, nor under any other evident form of secured control.

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.

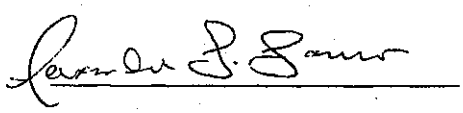
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on July 31, 2008, in Mexico City with the CCA. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

The CCA understood and accepted the findings.

Dr. Alexander L. Lauro
Senior Program Auditor



[redacted]

15. ATTACHMENTS TO THE AUDIT REPORT

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

[redacted]

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 Chata, S.A. De C.V. Camino Real No. 5 Col Bachigualato Culiacan, Sinaloa 80140	07/22/2008	TIF 89	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, DVM		[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.	
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.	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.	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	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
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	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.	

[redacted]

60. Observation of the Establishment Date: 07/22/2008 Est #: TIF 89 (Productos Chata, S.A. De C.V. [P]) (Culiacan, Mexico)

10. In the product cooler, an employee was observed handling crates which were in contact with the floor, and then directly touching edible product without first washing his hands. Inspection officials called for immediate corrective actions concerning the involved product. [Regulatory reference(s): 9 CFR §416.13, 416.5(a)]

13/51. The establishment did not routinely document corrective actions taken in response to operational SSOP deficiencies. In addition, records documenting the implementation of pre-operational sanitation standard operating procedures (SSOP) were incomplete in that measures to prevent recurrence were not always recorded. [9 CFR §416.15(b), 416.16, 416.17]

15/51. The following deficiencies were identified concerning the establishment's hazard analysis [9 CFR §417.2, 417.8]:

A) Returned product was not addressed.
B) Some steps identified in the flow chart differed from those which were contained in the hazard analysis.
C) The processing steps associated with the rendering of lard used in product formulation were not included.

22/51. The following HACCP recordkeeping non-compliances were observed:

A) The 'direct observation of monitoring' component of on-going verification procedures was not documented. [9 CFR §417.2, 417.8]
B) The documentation associated with the component of 'records review' did not include the time at which the event occurred. [9 CFR §417.4(a)(2), 417.5(b)]
C) The records documenting corrective actions taken in response to a deviation from the critical limit for thermal processing were incomplete in that they did not indicate that the cause of the deviation was eliminated. [9 CFR §417.3(a), 417.5(3), 417.8]

38/46. Numerous insects were seen floating in chilling tanks containing cans which had just undergone the retort process. The presence of insects was related to employee error and involved a cover for the outside water tower which had not been replaced. Inspection personnel instructed the establishment to take corrective actions concerning both the origin of the insects and all product involved. [9 CFR §416.2(b)(3), 416.4(a)]

38/51. Grounds at the rear of the establishment were not maintained in a manner sufficient to prevent the harborage and breeding of pests in that high grass, weeds, and used equipment were present. [9 CFR §416.2(a), 416.17]

45/51. In the processing area, several containers designated for edible product were used for collecting inedible materials. [9 CFR §416.17, 416.3(c)]

46/51. In the product cooler, several containers used for storing edible product presented a visibly unclean exterior surface with a dark, sticky residue. [9 CFR §416.17, 416.4(a)]

58. Inspection officials of Mexico issued to establishment management a Notice of Intent to Delist (NOID) if the deficiencies identified during this audit are not corrected within 30 days from the time of issuance.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, DVM	7/22/08

[redacted]

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 Et Pinole Navolato, Sinaloa 80300	07/23/2008	TIF 111	Mexico
	5. NAME OF AUDITOR(S) Dr. Alexander L. Lauro		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 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.	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.	
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.	

[redacted]

60. Observation of the Establishment — Date: 07/23/2008 Est #: TIF111 (Ganaderia Integral Vizur, S.A. de C.V. [S/P/CS]) (Navolato, Mexico)

10/51. At various locations throughout the establishment, beef carcasses were observed rubbing against visibly soiled handles of pull-chains (wires) utilized for selecting overhead rails. Inspection officials immediately called for appropriate corrective actions. [Regulatory reference(s): 9 CFR §416.13, 416.17]

12/51. A review of establishment records documenting the implementation of pre-operational sanitation standard operating procedures (SSOP) indicated that corrective actions taken in response to contamination of product-contact surfaces were incomplete in that adequate measures to prevent recurrence were not always established. In most instances, the establishment documented rewashing of equipment as a preventive measure. While rewashing of equipment may be sufficient to meet the "restoration of sanitary conditions" component of corrective actions under SSOP, it does not prevent recurrence of the problem. [9 CFR §416.15 (b), 416.17]

13/51. The establishment did not routinely document corrective actions taken in response to SSOP deficiencies. [9 CFR §416.15(b), 416.16, 416.17]

18/51. Monitoring procedures for the CCP addressing visible feces/ingesta/milk on carcasses (zero tolerance) were not always conducted at the frequency prescribed in the establishment's written HACCP plan. [9 CFR §417.2(c)(4), 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L Lauro 7/23/08

[redacted]

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 Avenida Adolfo Lopez Mateos No. 4118 San Nicolas de Los Garza, Nuevo Leon 66400	07/14/2008	TIF 150	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, DVM		[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.	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.	

FSIS- 5000-6 (04/04/2002)

[redacted]

60. Observation of the Establishment — Date: 07/14/2008 Est #: TIF 150 (Delimex de Mexico [P/CS]) (San Nicolas de Los Garza, Mexico)

13/51. The establishment neither included a procedure for the reconditioning of product during operations in their written SSOP (i.e., 'dropped meat procedure'), nor documented specific occurrences of product reconditioning/disposal in their SSOP records. [Regulatory reference(s): 9 CFR §416.16, 416.17]

15/51. The following deficiencies were identified concerning the contents of the establishment's HACCP plan(s):

A. The ongoing verification procedures did not include the element of records review. [9 CFR §417.2(c)(7), 417.4(a)(2)(iii), 417.8]

B. Returned product was not included in the flow chart or considered in the hazard analysis. [9 CFR §417.2, 417.8]

C. The hazard analysis addressing the production of cooked beef 'taquitos' 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 blast-freezing 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 does not meet relevant portions of 9 CFR 417. [9 CFR §417.2(a)(1), 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, DVM	Alexander L. Lauro 7/14/08

[redacted]

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
Empacadora Ganadera de Tamaulipas, S.A. de C.V. Carretera Estacion Manuel - Soto La Marina, Km. 144.5 Soto La Marina, Tamaulipas 87670	07/04/2008	TIF 151	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, DVM		[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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	X
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Delistment	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

FSIS- 5000-6 (04/04/2002)

[redacted]

60. Observation of the Establishment Date: 07/04/2008 Est #: TIF151 (Empacadora Ganadera de Tamaulipas, S.A. de C.V. [S]) (Soto La Marina, Mexico)

10/51. The following SSOP deficiencies were observed in the cattle slaughter area [Regulatory reference(s): 9 CFR §416.13, 416.17]:

A) The inside rim of several barrels containing edible product were severely scored and soiled.
B) A plant employee was observed resting the carcass splitting-saw with its blade contacting the floor of his work platform and the front portion touching a barrel for inedible material.
C) Kick-plates were missing from several work platforms, and carcasses were observed touching the floor of these structures or employees' boots.
D) A plant employee was observed contaminating his knife with fecal material while trimming a carcass without subsequently sanitizing his knife before the next cut.

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

20/51. The corrective actions associated with a deviation from the establishment's critical limit for the room temperature CCP did not clearly address that no product injurious to health or otherwise adulterated as a result of the deviation entered commerce. [9 CFR §417.3(a), 417.8]

22/51. Records documenting 100%-monitoring of the CCP addressing contamination of carcasses by visible feces, ingesta, and milk (i.e., zero tolerance) did not include the time whenever a deviation from the critical limit occurred. [9 CFR §417.5(b), 417.8]

22/51. The establishment did not institute measures to prevent leakage of brain tissue from the knock-hole of animals thirty months of age and older during head washing. [9 CFR §310.22, 417.5(a)(2), 417.8]

39/51. In the cattle slaughter area, water-pipes situated in close proximity to beef carcasses were covered with insulation which was frayed and torn to the extent that product adulteration could occur. [9 CFR §416.17, 416.2(b)]

39/51. In the carcass cooler, overhead pipes of the spray-chilling system were covered with a dark, tarry residue which could result in product adulteration during use. [9 CFR §416.17, 416.2(b)]

41/51. Ventilation in the viscera storage room was insufficient as it was unable to prevent the formation of fog and condensate in this area. [9 CFR §416.17, 416.2(d)]

55. The inspection official did not observe the cranial and caudal mesenteric lymph nodes or palpate the rumino-reticular junction during post-mortem viscera inspection. [9 CFR §310.1(a)]

58. Inspection officials of Mexico voluntarily removed this establishment from the list of establishments certified as eligible to export to the United States, effective 07/04/08. The FSIS auditor was in agreement with this decision.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, DVM	Alexander L. Lauro 7/4/08

[redacted]

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
Grupo Porcicola Mexicano Km. 3.5 Carretera Uman-Poxilla Uman, Yucatan 97390	07/28/2008	TIF 152	Mexico
	5. NAME OF AUDITOR(S) Alexander L. Lauro, 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 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.	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	
28. Sample Collection/Analysis	X
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	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	X
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	X
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	X
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. Delistment	X
59.	

[redacted]

60. Observation of the Establishment Date: 07/28/2008 Est #: TIF 152 (Grupo Porcicola Mexicano [S/P/CS]) (Uman, Mexico)

10/51. During the operational tour of the establishment, the following sanitation standard operating procedure (SSOP) deficiencies were identified [Regulatory reference(s): 9 CFR §416.13, 416.17]:

A) In the processing area, water used for sanitizing equipment was not maintained at the temperature described in the establishment's written plan (82° C/180 ° F).
B) Numerous carcasses throughout the establishment were contaminated with watery rail grease, flakes of paint, or other unidentified foreign material.
C) The liners of stacked boxes were observed touching the soiled floor of an employee's work platform.
D) Condensate was dripping directly onto product in two carcass coolers.
E) Boxes of exposed and contaminated product were observed in the shipping freezer.
F) In the slaughter area, hanging carcass heads were seen rubbing against the soiled floor of an employee's work platform as they moved down the line.

12/51. A review of establishment records documenting the implementation of pre-operational SSOP indicated that corrective actions taken in response to contamination of product-contact surfaces were incomplete in that adequate measures to prevent recurrence were not always established. [9 CFR §416.15(b), 416.17]

13/51. The establishment did not routinely document corrective actions taken in response to operational SSOP deficiencies. [9 CFR §416.16, 416.17]

20/51. The corrective actions associated with a deviation from the establishment's critical limit for the carcass cooling critical control point (CCP) did not clearly demonstrate that no product injurious to health or otherwise adulterated as a result of the deviation entered commerce. [9 CFR §417.3(a), 417.8]

28/51. The establishment is utilizing the "sponging" method for generic *E. coli* sampling, which requires that results be evaluated using statistical process control techniques. However, the establishment is using m/M criteria as their lower/upper control limits. As m/M values are associated with the "excision" sampling method, they are not applicable to the establishment's current sampling procedure. The correct implementation of process control techniques includes upper and lower control limits which are establishment specific. [9 CFR §310.25(a)(5)(ii)]

38. Numerous flies were seen in the slaughter area. [9 CFR §416.2(a)]

39/51. In the stunning area, the ceiling, door, and window were not constructed and maintained in a manner sufficient to prevent the entrance of vermin, such as flies, rats, and mice. [9 CFR §416.17, 416.2(b)(2)]

41/51. Overhead and dripping condensation, which could result in product adulteration, was observed in the shipping dock and carcass transit areas. [9 CFR §416.17, 416.2(d)]

44/51. No hot water was present at hand-washing sinks located in employee lavatories, the entrance to the processing area, and other rooms in which production was occurring. A supply of hot water was restored to only some of these areas upon notification of the problem to plant management. [9 CFR §416.17, 416.2(h)(2)]

45/51. In one of the processing areas, a container designated for edible product was being utilized for collecting inedible product. [9 CFR §416.17, 416.3(c)]

46/51. The following deficiencies were identified concerning operations-related portions of the sanitary performance standards (SPS)[9 CFR §416.17, 416.4(a), 416.4(b)]:

A) In the shipping dock, pull-ropes used for the opening and closing of bay doors were extremely soiled and in contact with the floor.
B) In the main processing area, a hand-wash sink was situated in such a manner that hog carcasses would routinely congregate directly above it, and contamination of product could occur during hand-washing procedures.

48/51. While conducting an external tour of the establishment, a pile of meat\bones was observed at the rear of the facility. These items were neither denatured, nor under any other evident form of secured control. [9 CFR 314]

50/51. Records sufficient to document daily inspection coverage were not being maintained. In addition, SSOP verification procedures were not included as part of the inspection assignments. [9 CFR §327.2, 416.17]

51/52. Water was not available at several livestock pens in which animals (market hogs) were present. [9 CFR §313.2(e)]

51/55. 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 were contaminated with scald water, was not being enforced. [9 CFR §310.1(a), 310.18]

58. Inspection officials of Mexico voluntarily removed this establishment from the list of establishments certified as eligible to export to the United States, effective 07/28/08. The FSIS auditor was in agreement with this decision.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, DVM	Alexander L. Lauro 7/28/08

[redacted]

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
Jose Cardenes Guzman Hacienda Las Canas En La Barraca Congregacion Calles Montemorelos, Nuevo Leon	07/10/2008	TIF 196	Mexico
	5. NAME OF AUDITOR(S) Alexander L. Lauro, 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.	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.	X
19. Verification and validation of HACCP plan.	
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.	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	X
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	X
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. NOID	X
59.	

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[redacted]

60. Observation of the Establishment Date: 07/10/2008 Est #: TIF 196 (Jose Cardenes Guzman [S/P/CS]) (Montemorelos, Mexico)

13/51. The establishment neither included a procedure for the reconditioning of product during operations in their written SSOP (i.e., 'dropped meat procedure'), nor documented specific occurrences of product reconditioning/disposal in their SSOP records. [Regulatory reference(s): 9 CFR §416.16, 416.17]

18/51. Monitoring procedures for CCP 1 (zero tolerance for feces, ingesta, and milk) were not conducted with the frequency prescribed in the establishment's written HACCP plan. [9 CFR §417.2(c)(4), 417.8]

20/51. The corrective actions associated with a deviation from the establishment's critical limit for CCP1 (zero tolerance for feces, ingesta, and milk) did not clearly indicate that no product injurious to health or otherwise adulterated as a result of the deviation entered commerce. [9 CFR §417.3(a)(b)(c), 417.8]

22/51. The establishment's SRM control plan was incomplete in that it neither addressed the removal, segregation, and disposition of all SRMs identified in 9 CFR 310.22(a), nor included specific measures to indicate that these products would be precluded for export to the US. Specific omissions included failure to address the leakage of brain material during the stunning process, as well as procedures for the removal of lingual tonsils. [9 CFR §310.22, 417.5(a)(2), 417.8]

22/51. This establishment has elected to address the slaughter process and "raw not ground" operations under separate HACCP plans. However, the pre-shipment review only addressed the "raw not ground" plan, and did not include a documented review of the records associated with the slaughter process. [9 CFR §417.5(c), 417.8]

29/51. The establishment was sponging beef carcasses for generic *Escherichia coli*, but was not using statistical process control techniques to evaluate test results. [9 CFR §310.25(a)(5)(ii)]

43/51. While the establishment is conducting frequent chemical/physical/microbiological testing of its water supply, it was unable to provide clear certification that potability requirements were being met. [9 CFR § 416.2(g)], 416.17]

43/51. The sinks in several of the employee restrooms did not have a supply of hot water. While sinks at the entry to work areas did have a proper supply, failure to provide hot water near toilet and urinal rooms does not meet the regulatory requirements of 9 CFR 416.2(g)(2). [9 CFR §416.17, 416.2(g)(2)]

51/55. In the slaughter area, several heads which had passed inspection and were hanging on a rack awaiting further processing were contaminated with hair. The presence of contamination was neither detected by the inspection service nor establishment personnel, and is in conjunction with the observation of unsanitary head removal procedures, during which portions of the hide would come in contact with the affected portions. [9 CFR §310.18]

58. Inspection officials of Mexico issued to establishment management a Notice of Intent to Delist (NOID) if the deficiencies identified during this audit are not corrected within 30 days from the time of issuance.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, DVM	Alexander L. Lauro 7/10/08

[redacted]

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
Meat Land S.A. de C.V. Carretera Cd. Juarz Durango No. 40 km 8 Lerdo, Durango	07/17/2008	TIF 328	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander Lauro, DVM		[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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. NOID	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

FSIS- 5000-6 (04/04/2002)

[redacted]

60. Observation of the Establishment Date: 07/17/2008 Est #: TIF328 (Meat Land S.A. de C.V. [P/CS]) (Lerdo, Mexico)

10/51. In the processing room, a severely scored cutting board was being used for edible product. This board was damaged to the extent to inhibit its thorough cleaning, which could result in product adulteration. [Regulatory reference(s): 9 CFR §416.3(a), 416.13, 416.17]

12/51. Conversations with plant personnel concerning the implementation of pre-operational and operational sanitation standard operating procedures (SSOP) indicated that corrective actions taken in response to contamination of product and/or product contact surfaces were incomplete in that adequate measures to prevent recurrence were not always established. [9 CFR §416.15 (b), 416.17]

13/51. The establishment did not routinely document corrective actions taken in response to both pre-operational and operational SSOP deficiencies. [9 CFR §416.16, 416.17]

15/22/51. This establishment is receiving beef carcasses, yet the presence of SRMs was not addressed in the hazard analysis and a written program for the removal, segregation, and disposition of SRMs was not in place. [9 CFR §310.22(d)(1), 417.2(a)(1)]

15/51. The ongoing verification procedures did not include the element of records review. [9 CFR §417.2(c)(7), 417.4(a)(2)(iii), 417.8]

15/51. Rework and returned product were neither included in the flow chart nor considered in the hazard analysis. [9 CFR §417.2, 417.8]

45/51. Establishment postings addressing the use of proper product storage containers associated green containers with both inedible products and 'by-products'. Further discussions with both establishment and inspection personnel indicated that some by-products were edible in nature. Inedible containers are to be used exclusively for that purpose, and clearly identified as such. [9 CFR §416.3(c), 416.17]

46. Exposed product which, according to establishment protocol, should have been wrapped in cellophane at this stage was identified in the storage cooler. Inspection personnel called for immediate corrective actions. [9 CFR §416.4(d)]

46/51. During the establishment tour, it was noted that there was no hot water present in the establishment. Although the supply of hot water was restored immediately upon communication of the problem by the auditor, the absence of hot water in the facility does not meet the regulatory requirements of 9 CFR 416. [9 CFR §416.2(h)(2), 416.4(b), 416.17]

51. The official veterinarian was able to demonstrate only limited documentation of non-compliances identified within establishment. Furthermore, no documentation addressing the resolution of these deficiencies was available. [9 CFR §416.2]

58. Inspection officials of Mexico issued to establishment management a Notice of Intent to Delist (NOID) if the deficiencies identified during this audit are not corrected within 30 days from the time of issuance.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander Lauro, DVM	7/17/08

[redacted]

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
Consorcio Dipcen, S.A. de C.V. Calle 16 De Septiembre MZ B Lote 8 No. 5 Pueblo Los Reyes Iztacala Tlalnepantla , Estado De Mexico 54090	06/26/2008	TIF 329	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander Lauro, DVM		[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.	X
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.	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	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	
43. Water Supply	X
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
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.	

FSIS- 5000-6 (04/04/2002)

[redacted]

60. Observation of the Establishment Date: 06/26/2008 Est #: TIF 329 (Consorcio Dipcen, S.A. de C.V. [P/CS]) (Tlalnepantla , Mexico)

12/51. A review of establishment records documenting the implementation of preoperational SSOP indicated that corrective actions taken in response to contamination of product-contact surfaces were incomplete in that adequate measures to prevent recurrence were not always established. In most instances, the establishment documented rewashing of equipment as a preventive measure. While rewashing of equipment may be sufficient to meet the "restoration of sanitary conditions" component of corrective actions under SSOP, it does not prevent recurrence of the problem. [Regulatory reference(s): 9 CFR §416.15(b), 416.17]

20/51. The corrective actions outlined in the HACCP plan did not clearly indicate that the CCP would be under control after a deviation from the critical limit occurred. [9 CFR §417.3(a)(1)(2), 417.8]

43/51. While this establishment is on a municipal water supply and conducts frequent chemical/physical/microbiological testing, it was unable to provide clear certification that potability requirements were being met. This applied only to water utilized for activities such as the washing of hands or equipment as only bottled water, accompanied by appropriate letters of guarantee, is routinely utilized for the formulation of product. [9 CFR § 416.2(g)], 416.17

45/51. In the processing room, a conveyor belt used for the transport of vacuum-sealed product was soiled with packaging ink to such extent that its sanitary condition could not be assessed. [9 CFR § 416.3(b), 416.17]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander Lauro, DVM	Alexander B. Lauro 6/26/08

[redacted]

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
Empacadora Gumen, S.A. de C.V. Carretera Tamuin-San Vicente Km. 11 Zona Rural Tamuin, San Luis Potosi 79200	07/01/2008	TIF 388	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander Lauro, DVM		[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.	X
16. Records documenting implementation and monitoring of the HACCP plan.	X
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.	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	X
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. Delistment	X
59.	

FSIS- 5000-6 (04/04/2002)

[redacted]

60. Observation of the Establishment

Date: 07/01/2008 Est #: TIF388 (Empacadora Gumen, S.A. de C.V. [P/CS]) (Tamuin, Mexico)

10. In the processing area, the anterior portion of a bovine carcass was observed touching the unclean floor of a work platform. [Regulatory reference(s): 9 CFR §416.13]

12/51. A review of establishment records documenting the implementation of preoperational SSOP indicated that corrective actions taken in response to contamination of product-contact surfaces were incomplete in that adequate measures to prevent recurrence were not always established. In most instances, the establishment documented rewashing of equipment as a preventive measure. While rewashing of equipment may be sufficient to meet the "restoration of sanitary conditions" component of corrective actions under SSOP, it does not prevent recurrence of the problem. [9 CFR §416.15 (b), 416.17]

13/51. The establishment neither included a procedure for the reconditioning of product during operations in their written SSOP (i.e., 'dropped meat procedure'), nor documented specific occurrences of product reconditioning/disposal in their SSOP records. [9 CFR §416.16, 416.17]

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

16/51. The establishment was not maintaining daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition of specified risk materials (SRM), and any corrective actions taken. [9 CFR §310.22(d)(4), 417.5(a)(2), 417.8]

20/51. The corrective actions associated with a deviation from the establishment's critical limit for the room temperature CCP did not clearly indicate that no product injurious to health or otherwise adulterated as a result of the deviation entered commerce. Furthermore, corrective actions for this CCP were general in nature, and not specifically adapted to the particular event. [9 CFR §417.3(a)(b)(c), 417.8]

43/51. While the establishment is conducting frequent chemical/physical/microbiological testing of its water supply, it was unable to provide clear certification that potability requirements were being met. [9 CFR §416.17, 416.2(g)]

58. Inspection officials of Mexico voluntarily removed this establishment from the list of establishments certified as eligible to export to the United States, effective 07/01/08. This event is in conjunction with a Notice of Intent to Delist (NOID) issued at this establishment the year prior.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander Lauro, DVM	Alexander S. Lauro 7/1/08

[redacted]

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
Albo Alimentos, S.A. de C.V. Calle Platon Sanchez No. 2020 Norte Colonia Terminal Monterrey, Nuevo Leon 64580	07/15/2008	TIF 391	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, DVM		[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.	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.	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	X
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	X
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	X
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.	

[redacted]

60. Observation of the Establishment | Date: 07/15/2008 Est #: TIF391 (Albo Alimentos, S.A. de C.V. [P/CS]) (Monterrey, Mexico)

13/51. The establishment neither included a procedure for the reconditioning of product during operations in their written SSOP, nor documented specific occurrences of contaminated product reconditioning/disposal in their SSOP records. [Regulatory reference(s): 9 CFR §416.16, 416.17]

15/51. This establishment occasionally utilizes beef neck bones in the formulation of product ("beef barbacoa'"), yet the presence of SRMs was not addressed in the hazard analysis and a written program for the removal, segregation, and disposition of these materials was not in place. [9 CFR §310.22(d)(1), 417.2(a)(1)]

22/51. The establishment is producing a ready-to-eat (RTE) product which is exposed to the post-lethality environment and has chosen "Alternative 1" as the means to control contamination of product by *Listeria monocytogenes* prior to packaging. However, the establishment could not support this decision as there was no evidence that product was subject to a post-lethality treatment which would reduce the number of microorganisms at this stage. Furthermore, although the product is frozen, the establishment did not provide supporting documentation to indicate that a two-log suppression of microbial growth exists throughout the shelf-life of the product. [9 CFR §417.5(a)(2), 417.8, 430.4]

39/51. In various areas of the establishment, boxes and equipment were stored in a manner which precluded inspection to the extent that sanitary conditions could not be assessed. [9 CFR §416.2, 416.17]

41/51. In the meat storage cooler, beaded condensate was present on numerous plastic bins and boxes containing edible product. [9 CFR §416.17, 416.2(d)]

43/51. During the establishment tour, several of the sinks in processing areas and employee restrooms did not have hot water. Further discussions with Inspection officials indicated that while the possibility to have hot water in these areas existed, the actual frequency at which this occurred was sporadic in nature. The absence of hot water at these locations during all production phases does not meet the regulatory requirements of 9 CFR 416. [9 CFR §416.2(h)(2), 416.4(b), 416.17]

43/51. While this establishment is on a municipal supply and conducts frequent chemical/physical/microbiological testing of water, it was unable to provide clear certification that potability requirements were being met. [9 CFR §416.17, 416.2(g)]

48/51. During the filling process, overspill of product is collected in plastic bags which, while presenting the appearance of edible product, are held in buckets labeled for inedible use. Discussions with inspection personnel indicated that denaturing of these materials was not occurring prior to disposal of the plastic bags into garbage bins outside the establishment. [9 CFR §325.11]

58. Inspection officials of Mexico issued to establishment management a Notice of Intent to Delist (NOID) if the deficiencies identified during this audit are not corrected within 30 days from the time of issuance.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, DVM	Alexander L. Lauro 7/15/08

[redacted]

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
Praderas Huastecas S.P.R. de R.L. Pedro A. des los Santos Degollado Col. Victor Manuel Santos Tamuin, San Luis Potosi 79200	07/02/2008	TIF 407	Mexico
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander Lauro, DVM		[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	
28. Sample Collection/Analysis	X
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.	

FSIS- 5000-6 (04/04/2002)

[redacted]

60. Observation of the Establishment Date: 07/02/2008 Est #: TIF407 (Praderas Huastecas S.P.R. de R.L. [S/P/CS]) (Tamuin, Mexico)

13/51. Establishment records documenting the implementation of pre-operational sanitation standard operating procedures (SSOP) were incomplete in that measures to prevent recurrence were not always recorded. [Regulatory reference(s): 9 CFR §416.15 (b), 416.17]

22/51. The establishment's HACCP monitoring records did not include a time for each entry. [9 CFR §417.5(b), 417.8]

28/51. The establishment is utilizing the "sponging" method for generic *E. coli* sampling, which requires that results be evaluated using statistical process control techniques. However, the establishment is using m/M criteria as their lower/upper control limits. As m/M values are associated with the "excision" sampling method, they are not applicable to the establishment's current sampling procedure. The correct implementation of process control techniques includes upper and lower control limits which are establishment specific. [9 CFR §310.25(a)(5)(ii)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander Lauro, DVM	Alexander P Lauro 7/2/08

[redacted]

Comments to the Draft Final Report for MEXICO:

No comments were received from the government of Mexico on the Draft Final Report for the first audit of FY 2008..