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

FEB 12 2009

Dr. Claudio Ternicier González
Chief, Departmento Proteccion Pecuaria
Servicio Agricola y Ganadero
Ministry of Agriculture
Avda. Bulnes 140
Piso 7
Santiago
Republic of Chile

Dear Dr. Ternicier:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Chile's meat and poultry inspection system July 8 through August 8, 2008. Comments from the government of Chile have 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,

Don Carlson, acting Director

Manzoor Chaudry
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

U. S. DEPARTMENT OF AGRICULTURE
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FEB 12 2009

MEMORANDUM

TO: Joseph Lopez, Agricultural Attaché
US Embassy, Santiago
Avda. Andrés Bello 2800
Las Condes
Santiago
Republic of Chile

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

SUBJECT: FSIS FINAL AUDIT REPORT FOR CHILE

Dear Mr. Lopez,

Please deliver the attached final audit report to Dr. Claudio Ternicier, Chief, Departmento Proteccion Pecuaria, Servicio Agricola y Ganadero, Ministry of Agriculture. 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

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Chile Country File

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

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

JULY 8 THROUGH AUGUST 8, 2008

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. SUMMARY
   1.1 Description/Eligibility
   1.2 Comparison of Current Audit and Previous Audit
   1.3 Summary Comments for the Current Audit

2. INTRODUCTION

3. OBJECTIVE OF THE AUDIT

4. PROTOCOL

5. LEGAL BASIS FOR THE AUDIT

6. SUMMARY OF PREVIOUS AUDITS

7. MAIN FINDINGS
   7.1 Government Oversight
   7.2 Headquarters Audit
   7.3 Audit of Regional and Local Inspection Sites

8. ESTABLISHMENT AUDITS

9. LABORATORY AUDITS

10. SANITATION CONTROLS
    10.1 Sanitation Standard Operating Procedures
    10.2 Sanitation Performance Standards

11. ANIMAL DISEASE CONTROLS

12. SLAUGHTER/PROCESSING CONTROLS
    12.1 Humane Handling and Humane Slaughter
    12.2 HACCP Implementation
    12.3 Testing for generic *Escherichia coli*
    12.4 Testing for *Listeria monocytogenes*

13. RESIDUE CONTROLS

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

15. CLOSING MEETING

16. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority, the Agriculture and Livestock Service (Servicio Agricola y Ganadero)
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RIS	Regional Inspection Supervisor
SAG	Servicio Agricola y Ganadero
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
VIC	Veterinarian-in-Charge

SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Chile from July 8 through August 8, 2008. This was a routine audit. Chile is eligible to export meat and poultry products to the United States. Between January 1, 2007 and June 30, 2008, Chile exported more than 9.78 million pounds of meat and poultry products to the United States, of which 3.8 million pounds were reinspected at US ports of entry (POE). A total of 65 thousand pounds were rejected at POE, of which no rejections were for food-safety concerns. The activities of the current audit appear in the table below.

1.2 Comparison of the Current Audit and the Previous Audit

		07/08-08/08, 2008	03/15-04/03, 2007
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	2	1
	Establishment Level	10	3
Laboratories Audited			
	Microbiology	2	1
	Residue	2	0
Establishments Audited			
	Slaughter/processing	10	3
	Processing	0	0
	ID Warehouses	0	0
Enforcement Actions Initiated			
	NOID	1	0
	Delistment	0	0
Risk Area Findings		(10 Ests. audited)	(3 Ests. audited)
	Sanitation Controls (SSOP, SPS)	9	3
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	8	3
	Residue Controls	2	0
	Microbiology Controls	1	0
	Inspection/Enforcement Controls	9	3
	E. coli O157:H7	4	0
	Generic *E. coli* testing	6	1

1.3 Summary Comments for the Current Audit

The results of this audit reflected that in 9 establishments, some of the FSIS requirements were not fully enforced by Chilean inspection system. In addition, one establishment was issued an NOID.

2. INTRODUCTION

The audit took place in Chile from July 8 through August 8, 2008.

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

The auditor was accompanied during the entire audit by representatives from the CCA, the Agriculture and Livestock Service (Servicio Agricola y Ganadero, SAG), and/or representatives from the regional and local inspection offices.

3. OBJECTIVE OF THE AUDIT

This was a routine audit with special emphases on *Escherichia coli* O157:H7 (*E. coli* O157:H7) controls, humane handling and slaughter of livestock, and good commercial practices for poultry. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat and poultry products to the United States.

4. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters, regional, and inspection offices located within individual establishments. The third part involved on-site visits to ten establishments: six meat slaughter/processing establishments and 4 poultry slaughter/processing establishments. The fourth part involved visits to one private microbiology laboratory, one government microbiology laboratory, one private residue laboratory, and one government residue laboratory. All were conducting tests on product destined for export to the United States.

Program effectiveness determinations of Chile'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 *Salmonella* species. Chile'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 Chile 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 Chile's meat and poultry inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Chile. FSIS requirements include, among other things, daily inspection in all certified establishments, periodic supervisory reviews of 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, Sanitation Performance Standards (SPS), and testing for generic *E. coli, E. coli* O157:H7, and *Salmonella.*

Equivalence determinations are those that have been made by FSIS for Chile under provisions of the Sanitary/Phytosanitary Agreement. Following are the equivalence determinations that have been requested by Chile and determined equivalent by FSIS.

A. Generic *E. coli* Testing

Chile has an equivalence determination to collect generic *E. coli* samples at an additional site in addition to the three set forth in the FSIS requirements. In Chile, the fourth generic *E. coli* sampling site is from the neck for cattle and from the back for swine.

B. *Salmonella* Testing

Salmonella Sample Collection -- Frequency

- In the Chilean *Salmonella* testing program for meat, five samples are collected each week by the veterinarian-in-charge. These five samples are all collected on the same day of the week. The day of the week is rotated each week of the month for such collection, which means that in a 4-week month there would be a total of 20 samples collected.

Salmonella Testing Program -- Location of Samples

- *Salmonella s*amples are to be collected from the head (jowls), abdomen (belly), back and leg (ham) for swine; hip (rump), lap (belly), chest (brisket), and neck for bovines.

Salmonella Testing Program -- Size of Samples

- The Chileans collect *Salmonella* samples, for swine and bovine using the sponge (swab) method in an area 100 cm2 (each site measuring 10 x 10 cm) for a total area of 400 cm2.

Salmonella Testing Program -- Enforcement

- When a positive sample arises for the first time, the establishment must present a contingency plan of corrective actions within 48 hours. The veterinarian in charge then takes four samples (two samples per week for 2-weeks) to verify the effectiveness of the corrective actions. If there is no positive sample result, then the establishment returns to a normal sampling regime.

Salmonella Testing Program -- Enforcement

- Upon a second sample set failure, the establishment must re-assess its HACCP plan. Intensified, targeted sampling is also instituted by the veterinarian in charge. This means that 20 samples are collected in a 2-week timeframe with five samples collected for two different days each of the 2-weeks. If all the samples are negative, the establishment returns to a normal sampling regime.

Salmonella Testing Program -- Enforcement

- If not, and a third sample set failure occurs, the establishment's export certification is suspended. The establishment must initiate a complete evaluation of their systems and is only able to return to normal operation once SAG has verified that all the requirements are being met and everything is in order to alleviate the reasons for the *Salmonella* sample set failures.

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. 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 (PR)/HACCP regulations
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
- The Poultry Products Inspection Regulations (9 CFR Part 381)

6. SUMMARY OF PREVIOUS AUDITS

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

The following deficiencies were identified during the routine audit of Chile's meat inspection system in March/April 2006:

Sanitation Controls

- Sanitation Standard Operating Procedures (SSOP)

- In one establishment, preventive measures were not included in corrective actions in pre-operational sanitation records.

- Sanitation Performance Standards (SPS)

- In many areas throughout one establishment, there were small holes in the walls that had not been sealed.
- In one establishment, there was standing water from a plugged drain along the wall in the cutting room. The drain did not appear to be adequate to the water flow in the area. The establishment was aware of the problem and stated that they were investigating a long-term solution. The area was immediately cleaned up.
- In one establishment, liquid was present on the ceiling and under surfaces of many pieces of equipment in both the combo pack and cutting room. Since it was early in operations, it was not possible to tell if this liquid was condensation or left over sanitizer. No actions were taken until the auditor pointed out the liquid. Corrective actions were immediately and effectively taken by the establishment following and under SAG supervision.

Slaughter/Processing Controls

- Hazard Analysis and Critical Control Point (HACCP)
  - In one establishment, HACCP descriptions of CCPs did not include adequate descriptions of verification activities. Not all required verification activities were included.
  - In one establishment, the records for CCP2, zero tolerance, had incomplete descriptions for corrective actions and preventive measures. The records also did not have monitor's initials for individual monitoring events.
  - The hazard analysis did not reflect the consideration of BSE as a hazard. Both the establishment and SAG stated that the risk had been considered, however because of the BSE-free status of Chile, it was not considered necessary to show that in the hazard analysis. However, all the required SRM controls for carcasses under 30 months are in place. Appropriate separation of over 30 month carcasses so that they are not in export lots is also in place.
  - CCP records did not have times or initials of the monitor for individual monitoring events. Preventive measures also were not included as a part of the corrective actions recorded for the CCP for zero tolerance.

Pathogen Reduction - *Escherichia coli (E. coli)*

- In one establishment, generic *E. coli* samples were not collected in a random manner, but every 300th carcass. This was done at the direction of the SAG IIC. This was shown to be a local misunderstanding. However, the establishment was taking daily samples which were random and keeping complete records that reflected the FSIS charting procedures.

Residue Controls

- Check samples were not provided neither to the analyst(s) at the residue laboratory audited nor to those at supervised laboratories during inter-lab rounds for the analysis of mycotoxins, including aflatoxin.

The following deficiencies were identified during the routine audit of Chile's meat inspection system in March/April 2007:

Sanitation Controls

- SSOP
  - In one establishment, condensate from cooling units was observed dripping onto exposed meat products in the carcass coolers.
  - In two establishments, documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation did not include preventive measures.

- SPS
  - In one establishment, loose and flaking joint sealant and a number of holes in the ceiling were observed above product and food contact surfaces in the cutting room.

- In another establishment, production line employees did not remove or change their working clothing before or after going to an open area, which was outside of the production departments, and then returning to production areas inside the establishment.
- In the third establishment: a) A gap approximately two centimeters wide was observed under the loading dock door leading to the outside of the establishment. This gap could allow the entrance of pests into the establishment. b) The quality and intensity of the lighting in the carcass coolers was insufficient to allow inspection personnel to perform their duties.

Slaughter/Processing Controls

- HACCP

- In one establishment, monitoring records for CCP1 contained check marks instead of quantifiable values.
- In one establishment, monitoring records for CCP1 and CCP2 did not follow the frequency prescribed in the written HACCP plan.
- In one establishment, the written HACCP plan did not contain a description of the verification procedures (calibration of process-monitoring instruments and direct observation of monitoring activities) and the frequency with which those procedures were to be performed.
- In two establishments, verification records did not include direct observation of monitoring activities.
- In three establishments, verification records did not document the type of verification procedures performed and the results of the verification.
- In three establishments, verification records did not document the times when the specific events occurred.
- In three establishments, documentation of corrective actions for CCPs did not address all four parts of corrective actions.
- In one establishment, no calibration records were available for any of the thermometers being used in the establishment.

Pathogen Reduction - *Escherichia coli (E. coli)*

- Generic *E. coli* samples were collected from bovine carcasses after the final wash and before entering the chillers instead of chilled bovine carcasses as required by FSIS.

7. MAIN FINDINGS

7.1 Government Oversight

The Chilean meat and poultry inspection system is centralized in the national government. The Central Competent Authority (CCA) is the Agriculture and Livestock Service, (Servicio Agricola y Ganadero, SAG), which is part of the Ministry of Agriculture. SAG has the responsibility for carrying out Chile's inspection program including oversight and enforcement of the FSIS regulatory requirements in establishments certified to export to the United States.

SAG regulatory oversight of its meat inspection and certification system control consists of four levels: central, regional, local, and establishment.

The central level is divided into five coordinations: a) National Coordination of Farms under Official Certification; b) National Inspection Coordination; c) National Certification Coordination; d) National Pathogen Reduction Coordination; and e) National Residue Control Coordination.

The regional level inspection responsibilities are managed from 13 regional offices. Each regional office has a Livestock Regional Officer-in-Charge and a Regional Inspection Supervisor (RIS). The RIS is in charge of periodic supervisory visits to the U.S. certified establishments.

The local level consists of 62 local offices throughout Chile. Within each local office was the local Veterinary Officer who served as a field supervisor over the official veterinarians located at the establishment level.

At the establishment level, the Veterinarian-in-Charge (VIC) is responsible for overall inspection activities at that establishment. Under the VIC are additional veterinary and non-veterinary meat inspectors.

7.1.1 CCA Control Systems

Implementation of inspection activities is accomplished by the Veterinarian-in-Charge of each official establishment, with oversight from the regional offices and headquarters. Verification of implementation is accomplished by periodic (monthly in Chile) supervisory reviews conducted by the Regional Inspection Supervisor.

7.1.2 Ultimate Control and Supervision

The SAG has the legal authority to supervise and enforce Chile's meat and poultry inspection activities through its linear government oversight.

The in-plant inspection personnel are supervised by the Veterinarian-in-Charge who has the authority to suspend the establishment's production operation any time the wholesomeness and safety of the product are jeopardized. The VIC reports directly to the Local Veterinary Officer and Regional Inspection Supervisor. The RIS is responsible for performing comprehensive periodic internal reviews of the establishments certified as eligible to produce products for export to the United States.

All inspection personnel assigned to establishments certified to export meat to the United States were full time and government employees receiving no remunerations from either industry groups or establishment personnel.

7.1.3 Assignment of Competent, Qualified Inspectors

Each Regional Director is responsible for the initial hiring, training and payment of veterinarians and non-veterinary meat inspectors. All official veterinarians and meat

inspectors employed by Chile's meat and poultry inspection program possessed the required educational degree necessary to meet minimum qualifications. These inspection personnel went through introductory training as well as participation in on-the-job training under the supervision of experience veterinarians. Continual training was provided for all inspection personnel as needed. The regional offices maintained individual training records of inspection personnel.

7.1.4 Authority and Responsibility to Enforce the Laws

SAG has the legal authority and the responsibility to enforce U.S. requirements. Chile's meat and poultry inspection sanitation procedures and standards are regulated by the following laws:

- SAG's Organic Law No. 18.755 (amended by Law No.19.238)
- Meat Law No. 19.162
- Health Ministry and SAG Agreement Delegation
- Decree No. 977 for Food Sanitary Regulations
- Resolution No. 2592 for SAG National Direction
- Technical Standard No. 62

7.1.5 Adequate Administrative and Technical Support

SAG had administrative and technical support to operate its meat inspection program and had the resources to support a third party audit.

7.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters of the inspection service. The records review focused primarily on food safety hazards and included the following:

- Periodic internal review reports.
- Supervisory visits to establishments certified to export to the United States.
- Training records for inspection personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses protocols for residues.
- Sampling and laboratory analyses protocols for generic *E. coli* and *Salmonella*.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of consumer complaints.

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

7.3 Audit of Regional and Local Inspection Sites

The Regional Offices in Quillota and Rancagua were visited and interviews were conducted with the Regional Director, the Livestock Regional Officer-in-Charge, and the Regional Inspection Supervisor.

The local offices of the Veterinarian-in-Charge (VIC) in each of the ten establishments were audited.

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 10 establishments: Two swine slaughter and processing establishments, four bovine slaughter and processing establishments, and four poultry slaughter and processing establishments. No establishments were delisted by the SAG. One establishment received a Notice of Intent to Delist (NOID) by SAG officials during this audit.

Specific deficiencies are noted in the attached individual establishment reports.

9. LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to U.S. 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.

Two residue laboratories were audited:

1) The Analab, located in Santiago, is a private laboratory which conducts analyses of field samples for Chile's national residue program. This laboratory has received ISO Standard 17025 accreditation.

The following findings were noted:

- Official standards book for preparation of stock solution did not contain the signature or date of verification by the responsible supervisor.
- Cross outs and overwrites were not dated.
- Handwritten information on a printout did not have the signature of the person entering the information or the date.

2) The Central Lo Aguirre, located in Lo Aguirre, is a government laboratory with two divisions. The residue division conducts analyses of field samples for Chile's national residue program. The microbiology division conducts analyses of field samples for the presence of *E. coli* O157:H7 and species verification. This laboratory has received ISO Standard 17025 accreditation.

The following findings were noted:

- Official standards book for preparation of stock solution did not contain the signature or date of verification by the responsible supervisor.
- The standard solution's label did not have the name of the preparer.

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 U.S. samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

Two microbiology laboratories were audited:

1) The Regional SAG Laboratory, located in Osorno, is a government laboratory certified to perform microbiological analyses for SAG monitoring programs.

No concerns arose as a result of this audit.

2) The Laboratorio Servicio Mantencion Ltda (SEMA), located in Melipilla, is a private laboratory which conducts analyses of field samples for the presence of *Salmonella* species and generic *E. coli*. This laboratory has received ISO Standard 17025 accreditation.

The following finding was noted:

- Some of the samples were not identified with a unique identification number through out the analytical process. They were identified with the establishment's name and/or two different samples were sharing the same internal laboratory identification number.

10. SANITATION CONTROLS

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

Based on the on-site audits of establishments, and except as noted below, Chile's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, and except as noted below, Chile's inspection system had SPS controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, workspace, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

10.1 Santiation Standard Operating Pocedures

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. The SSOPs in all 10 establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies noted in regard to implementation requirements:

- In three establishments, documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation did not include all three parts of the corrective actions.
- In six establishments, condensate originating from overhead structures was observed dripping onto exposed products.
- In one establishment, a torn conveyor belt used for transporting edible product was observed in the processing room. This belt was damaged to an extent which would inhibit its thorough cleaning and could result in product adulteration during operations.
- In one establishment, several white plastic tubs used to transport meat products contained product residues from the previous day's production. These tubs had already undergone establishment inspection and were released for use.
- In one establishment, split beef carcasses were observed contacting non-food contact surfaces such as door frames, poles, water pipes, employees' platform, and a stationary ladder in a room between one of the carcass coolers and the cutting room.

10.2 Sanitation Performance Standards

The following deficiencies were noted:

- In two establishments, the quality and intensity of the lighting was insufficient to conduct a proper inspection.
- In three establishments, maintenance of overhead structures above exposed products or equipment had been neglected.
- In one establishment: a) Production line employees were not able to remove or change their work clothes before or after restroom use due to improper design of the area. b) Rough, interrupted, and uneven welds were observed on the food contact surfaces of several stainless steel containers which could prevent the adequate removal of product residue and become a source of product contamination.

11. 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, control over condemned and restricted product, procedures for sanitary handling of returned and reconditioned product, and the implementation of the requirements for control of Bovine Spongiform Encephalopathy (BSE). The auditor determined that Chile's inspection system had adequate controls in place. No deficiencies were noted.

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

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments.

12.1 Humane Handling and Slaughter

No deficiencies were noted.

12.2 HACCP Implementation.

All establishments approved to export meat and poultry 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 U S. domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the 10 establishments. All establishments had implemented the HACCP requirements. However, inadequate HACCP implementation in regard to monitoring, verification, and corrective actions were identified as follows:

- Two establishments did not follow their verification frequencies in accordance with their HACCP plans.
- One establishment could not provide supporting documentation associated with the selection of its verification procedures or the frequency of those procedures.
- In three establishments, returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis.
- In six establishments, some of the verification records did not document the type of verification procedures performed, the times, or the results of the ongoing verification activities.
- In two establishments, documentation of corrective actions taken in response to a deviation from a critical limit did not include all four parts of corrective actions.
- In one establishment, monitoring records for CCP2 contained checkmarks instead of actual quantifiable values.
- In one establishment, monitoring records did not include the initials of the responsible establishment employee(s) making the entries.

12.3 Testing for Generic *E. coli*

Chile has an equivalence determination to collect an additional generic *E. coli* sample from the three set forth in the FSIS requirements.

Testing for generic *E. coli* was properly conducted in all meat slaughter establishments, except as noted below:

- In six establishments, generic *E. coli* samples were collected from livestock carcasses after the final wash and before entering the chillers instead of chilled carcasses as required by FSIS.

12.4 Testing for *Listeria monocytogenes*

Chile has not submitted the required documents for FSIS to complete an equivalence determination regarding RTE products. Therefore, Chile is not eligible to export ready-to-eat (RTE) products to the United States.

13. RESIDUE CONTROLS

Chile's National Residue Testing Plan for 2008 was being followed and was on schedule.

14. 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*.

14.1 Daily Inspection in Establishments

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

14.2 Testing for *Salmonella*

Testing for *Salmonella* was being conducted as required.

14.3 Testing for *E. coli* O157:H7

Chile's official program for *E. coli* O157:H7 requires government microbiological sampling of beef trimmings in establishments authorized to export to the United States.

The following deficiency was reported:

- There has not been any official sampling/testing for *E. coli* O157:H7 of beef trimmings exported to the United States in 2008.

14.4 Species Verification

Species verification was being conducted as required.

14.5 Periodic Supervisory Reviews

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

14.6 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection (except as noted below) 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. Chile has not imported any livestock from other countries.

- In two swine slaughter establishments, the submaxillary lymph nodes were not incised/examined by the responsible official inspector.

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

15. CLOSING MEETING

A closing meeting was held on August 8, 2008, in Santiago with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

for.
Dr. Nader Memarian
Senior Program Auditor

by Don Carlos DVM

16. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report

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
Sopraval S.A. Panamericana Norte Km 12 La Calera	07/11/2008	509	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. *Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.*	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
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.	

60. Observation of the Establishment

Date: 07/11/2008 Est #: 509 (Sopraval S.A. [S/P/CS]) (La Calera, Chile)

10/51 A conveyor belt used for transporting edible product was observed in the processing room. This belt was damaged to an extent which would inhibit its thorough cleaning, and could result in product adulteration during operations. [Regulatory references: 9 CFR 416.3(a), 9CFR 416.13, and 9CFR 416.17]

15/51 Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis. [9CFR 417.2 and 9CFR 417.8]

19/51 The establishment did not follow its verification frequency in accordance to its HACCP plan. [9CFR part 417.4 and 9CFR 417.8]

22/51 The establishment verification records did not document the results of the verification activities. [9CFR 417.5 (a)(3) and 9CFR 417.8]

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader Memarian 7-11-08

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
Faenadora Lo Miranda Carretera H-30 N. 3814 Rancagua	08/01/2008	602 (POULTRY)	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
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.	

60. Observation of the Establishment

Date: 08/01/2008 Est #: 602 (POULTRY) (Faenadora Lo Miranda [S/P/CS]) (Rancagua, Chile)

10 Condensate from over head structures was observed dripping onto exposed poultry carcasses in the poultry chiller tank. [Regulatory reference: 9CFR 416.13 and 9CFR 416.2(d)]
Immediate corrective action was ordered by inspection officials.

15/51 Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis. [Regulatory references: 9CFR 417.2 and 9CFR 417.8]

22/51 A) Verification records did not document the type of the verification procedures and the results of the verification. [9CFR 417.5(a)(3) and 9CFR 417.8]
B) Monitoring records did not include the initials by the responsible establishment employee(s) making the entries. {9CFR part 417.5(b) and 417.8}

40 The quality and intensity of the lighting was insufficient to conduct a proper verification inspection in the pre-chill inspection station. [9CFR 416.2 (c)]

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	8-1-08

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
Faenadora Lo Miranda Carretera H-30 N. 3814 Rancagua	08/01/2008	602 (PORK)	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 08/01/2008 Est #: 602 (PORK) (Faenadora Lo Miranda [S/P/CS]) (Rancagua, Chile)

13/51 Documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation did not address all three parts of the corrective actions. [Regulatory references: 9CFR 416.15(b), 9CFR 416.16(a), and 9CFR 416.17]

22/51 A) Documentation of corrective actions did not address all four parts of corrective actions. [9CFR 417.5(a)(3) and 9CFR 417.8]
B) Monitoring records for CCP2 (zero tolerance) contained check marks instead of quantifiable values. [9CFR 417.5(a)(3) and 9CFR 417.8]

28/51 Generic *Escherichia coli* samples were collected from swine carcasses after the final wash and before entering the chillers instead of chilled swine carcasses as required by FSIS. [9CFR 310.25 (a)(2)(ii)]

55/51 The submaxillary lymph nodes were not incised/examined by the responsible official inspector. Immediate corrective action was ordered by inspection officials.

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader M 8-1-08 DVM

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
Faenadora Rosario Ltda. *Ruta H-50 Km. 04* Rosario	07/22/2008	606	Chile
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 07/22/2008 Est #: 606 (Faenadora Rosario Ltda. [S/P/CS]) (Rosario, Chile)

10 Condensate from cooling units was observed dripping onto exposed meat products in the cutting room. [Regulatory reference: 9CFR 416.13 and 9CFR 416.2(d)]
Immediate corrective action was ordered by inspection officials.

22/51 Some of the verification records did not document the times when the specific events occurred or the results of the verification. [9CFR 417.5(a)(3) and 9CFR 417.8]

28/51 Generic *Escherichia coli* samples were collected from swine carcasses after the final wash and before entering the chillers instead of chilled swine carcasses as required by FSIS. [9CFR 310.25 (a)(2)(ii)]

55/51 The submaxillary lymph nodes were not incised/examined by the responsible official inspector.
Immediate corrective action was ordered by inspection officials.

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader Me 7-22-08

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
Faenadora San Vicente Carretera H-66 G San Vicente T.T.	07/23/2008	608	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. *General Labeling*	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
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	
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.	

60. Observation of the Establishment

Date: 07/23/2008 Est #: 608 (Faenadora San Vicente [S/P/CS]) (San Vicente T.T., Chile)

There were no significant findings to report after consideration of the nature, degree and extent of all observations.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	7-23-08

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
Agroindustrias Lomos Colorados Camino Coronel N. 6670 Concepcion	07/25/08	809	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	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	
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.	

60. Observation of the Establishment

Date: 07/25/08 Est #: 809 (Agroindustrias Lomos Colorados [S/P/CS]) (Concepcion, Chile)

13/51 Documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation did not include all three parts of the corrective actions. [Regulatory references: 9CFR 416.15(b), 9CFR 416.16(a), and 9CFR 416.17]

15/51 Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis. [9CFR 417.2 and 9CFR 417.8]

22/51 The establishment verification records did not document the results of the verification activities. [9CFR 417.5 (a)(3) and 9CFR 417.8]

28/51 Generic *Escherichia coli* samples were collected from bovine carcasses after the final wash and before entering the chillers instead of chilled bovine carcasses as required by FSIS. [9CFR 310.25 (a)(2)(ii)]

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	7-25-08

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
Frigrifico Temuco Temuco	07/17/2008	912	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	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	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	
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.	

60. Observation of the Establishment

Date: 07/17/2008 Est #: 912 (Frigrifico Temuco [S/P/CS]) (Temuco, Chile)

10 A. Several white color plastic tubs used to transport meat products were identified with product residues from the previous day's production. These empty tubs were being stored in the clean container storage area. They had passed establishment sanitary inspection and were ready to use. [Regulatory reference: 9CFR 416.13(c)]
B. Condensate from cooling units was observed dripping onto exposed meat products in the carcass coolers. [9CFR 416.13 and 9CFR 416.2(d)]]
Immediate corrective actions were ordered by inspection officials.

28/51 Generic *Escherichia coli* samples were collected from bovine carcasses after the final wash and before entering the chillers instead of chilled bovine carcasses as required by FSIS. [9CFR 310.25 (a)(2)(ii)]

46/51 Maintenance of the over head structures in two of the carcass coolers had been neglected with loose and flaking paint and numerous holes in ceiling in evidence. [9CFR 416.4 and 416.17]

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader Memarian DVM 7-17-08

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
Frigorifico de Osorno S.A. Francisco del Campo 200, Osorno	07/14/2008	1026	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
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	X
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	X
45. Equipment and Utensils	X
46. Sanitary Operations	
47. Employee Hygiene	X
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. NOID	X
59.	

60. Observation of the Establishment

Date: 07/14/2008 Est #: 1026 (Frigorifico de Osorno S.A. [S/P/CS]) (Osorno, Chile)

10 Heavily beaded condensate from the over head structures was observed dripping onto exposed bovine carcasses in seven of the carcass coolers. [Regulatory reference: 9CFR 416.13 and 9CFR 416.2(d)]]
Immediate corrective action was ordered by inspection officials.

11/51 Split beef carcasses were observed contacting non-food contact surfaces of door frames, poles, water pipes, employee's platform, and a stationary ladder in a room between one of the carcass coolers and the cutting room. [9 CFR 416.14 and 9CFR 416.17]
Immediate corrective action was ordered by inspection officials.

19/51 The establishment did not follow its verification frequency for direct observation of monitoring procedures in accordance to its HACCP plan. [9CFR 417.2 (c)7, 9CFR 417.4, and 9CFR 417.8]

22/51 The establishment did not maintain supporting documents associated with the selection of the verification procedures and the frequency of those procedures. [9CFR 417.5 and 9CFR 417.8]

28/51 Generic *Escherichia coli* samples were collected from bovine carcasses after the final wash and before entering the chillers instead of chilled bovine carcasses as required by FSIS. [9CFR 310.25 (a)(2)(ii)]

39/51 Maintenance of overhead structures, above exposed product and equipment, had been neglected with build up of rust on the carcass cooler's rails and numerous holes in the cutting room ceiling. [9CFR 416.2 and 9CFR 416.17]

40 The quality and intensity of the lighting was insufficient to conduct a proper post-mortem inspection in the final inspection station. [9CFR 416.2 (c)]

44/47 Production line employees were not able to remove or change their working clothing before or after using restrooms due to improper design of the area. [9CFR 416.2 (h) and 9CFR 416.5]

45 Rough, interrupted, and uneven welds were observed on the food contact surfaces of several stainless steel containers which may prevent the adequate removal of product residue and could become a source of product contamination. [9CFR 416.3]

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader Memarian 7-14-08

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
Frigorifico O Higgins S.A. Camino a Melipilla 8139 Santiago	07/29/2007	1303	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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.	

60. Observation of the Establishment

Date: 07/29/2007 Est #: 1303 (Frigorifico O Higgins S.A. [S/P/CS]) (Santiago, Chile)

10 Condensate from over head structures was observed dripping onto exposed bovine carcasses in three of the carcass coolers. [Regulatory reference: 9CFR 416.13 and 9CFR 416.2(d)]
Immediate corrective action was ordered by inspection officials.

22/51 Some of the verification records did not document the times when the specific events occurred or the results of the verification. [9CFR 417.5(a)(3) and 9CFR 417.8]

28/51 Generic *Escherichia coli* samples were collected from bovine carcasses after the final wash and before entering the chillers instead of chilled bovine carcasses as required by FSIS. [9CFR 310.25 (a)(2)(ii)]

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader Memarian 7-29-08

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
Agroindustrial El Pacio LTD Los Libertadores 1714 El Paico	08/04/2008	1307	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, 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 SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
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.	

60. Observation of the Establishment

Date: 08/04/2008 Est #: 1307 (Agroindustrial El Pacio LTD [S/P/CS]) (El Paico, Chile)

10 Condensate originating from overhead structures was observed dripping directly into the poultry chilling tank containing carcasses. [Regulatory reference: 9CFR 416.13 and 9CFR 416.2(d)]
Immediate corrective action was ordered by inspection officials.

13/51 Documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation did not include all three parts of the corrective actions. [9CFR 416.15(b), 9CFR 416.16(a), and 9CFR 416.17]

22/51 A) Documentation of corrective actions taken in response to a deviation from a critical limit did not include all four parts of the corrective actions. [9CFR 417.5(a)(3) and 9CFR 417.8]
B) Some of the verification records did not document the times when the specific events occurred or the results of the ongoing verification activities. [9CFR 417.5(a)(3) and 9CFR 417.8]

39/46 Maintenance of overhead structures above exposed product and equipment had been neglected as evidenced by numerous holes in the cutting room ceiling. [9CFR 416.2 and 9CFR 416.4]

The auditor was assured by the inspection officials and/or establishment personnel that all deficiencies found in this audit would be scheduled for correction.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader Memarian DVM 8-4-08

GOBIERNO DE CHILE
MINISTERIO DE AGRICULTURA
SAG

División Protección Pecuaria

RESPONSE TO DRAFT REPORT OF THE AUDIT OF FSIS 8 JULY TO 8 AUGUST OF 2008.

With reference to:

7 MAIN FINDINGS:
• 7.1-Government Oversight:
No deficiencies were reported

Item 8 ESTABLISHMENTS AUDITS
Reports to the observations are specified in the annex relating to each of the establishments.

9. LABORATORY AUDITS.
Referring to the findings in the laboratories visited, the Service will strengthen and will emphasize those aspects seen in the upcoming supervisions and especially in the annual audit performed in all laboratories in the network. Besides these include controls on their own records.

With regard to the audit to the SEMA Lab:
Response to Comments in the Annex.

Item 10. SANITATION CONTROLS .
• 10.1 Sanitation Standard Operating Procedures
Health Operations (SSOP)
Reports to the observations are specified in the annex relating to each of the establishments.

• 10.2 Sanitation Performance Standards
Reports to the observations are specified in the annex relating to each of the establishments.

11 ANIMAL DISEASE CONTROL.
No deficiencies were reported.
Item

12. SLAUGHTER/PROCESSING CONTROLS

• 12.1 Humane Handling and Slaughter.
No deficiencies were reported.

• 12.2 HACCP Implementation: Reports to the observations are specified in the annex *relating to each of the establishments.*

•12.3 Testing for Generic E. coli:
In the officer sampling E. coli generic as in the daily sampling of E. coli of the establishment, the samples are obtained from the carcass, prior to entering the chilling in previous to the sanitization if it happens.

This is a requirement to comply with the system for microbiological control official who is harmonized and recognized by the European Union.

• 12.4 Testing for Listeria monocytogenes

We will be send within the first half of December 2008, the proposal of the Agricultural and Livestock Service for equivalency with the FSIS, System Verification Officer for meat products ready for consumption export to the United States (International Affairs Division SAG) .

13. RESIDUE CONTROLS
No deficiencies were reported

Point 14. ENFORCEMENT CONTROL.
14.1 Daily Inspection in the establishments.

14.2 Testing for Salmonella.

14.3 Testing for *E. Coli 0157: H7*

The Chief of the Animal Protection Division instructed the regional SAG through Circular No. 790 dated November 5, 2008, taking samples for testing officer E. coli O157: H7 in ground beef and trimming cattle for export to the United States, to take place during the months of November and December 2008. That Verification Officer will continue with a monthly frequency from the year 2009.

14.4 Species Verification.
No deficiencies were reported

14.5 Periodic Supervisory Reviews:
Revision period of supervision: No deficiencies were reported

14.6 Inspection System Controls
Reports to the findings are specified in the annex relating to each of the establishments.

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO

Auditor: Dr. Nader Memarian

OFFICIAL US AUDIT

SOPRAVAL

OBSERVATION	CORRECTIVE ACTION	PREVENTIVE MEASURE
A conveyor belt used for transporting edible products was observed in the processing room. This belt was damaged to an exent which would inhibit its thorough cleaning, and could result in product adulteration during the operations.	A purchase order for this belt is issued on the same date of the audit.	reinforcement of the preventive maintenance programme for equipments
Returned products were not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis.	The Quality Assurance Programme team will meet once a week to analyse a new concept according to a work plan: compilation and evaluation of hazards and the conditions that cause them in order to decide which are the significant hazards that affect safety, specifying risk and seriousness and thus to include them in the HACCP Plan (Gantt chart is enclosed).	N/A
The establishment does not follow its verification frequency in accordance to its HACCP plan.	All quality inspectors are trained in order to enforce this frequency.	N/A
The establishment verification records do not document the results of the verification activities	All quality inspectors are trained with regard to this new concept.	N/A

EXECUTION DATE	SAG VERIFICATION
July 18, 2008	July 18, 2008
First meeting of Quality Assurance Programme on July 28, 2008, analysis finished on November 19, 2008	November 21, 2008
July 18, 2008	July 21, 2008
July 18, 2008	July 21, 2008

GOBIERNO DE CHILE

Auditor: Dr. Nader Memarian

OFFICIAL US AUDIT

SOPRAVAL

OBSERVATION	CORRECTIVE ACTION	PREVENTIVE MEASURE	EXECUTION DATE	SAG VERIFICATION
A conveyor belt used for transporting edible products was observed in the processing room. This belt was damaged to an exent which would inhibit its thorough cleaning, and could result in product adulteration during the operations.	A purchase order for this belt is issued on the same date of the audit.	reinforcement of the preventive maintenance programme for equipments	July 18, 2008	July 18, 2008
Returned products were not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis.	The Quality Assurance Programme team will meet once a week to analyse a new concept according to a work plan: compilation and evaluation of hazards and the conditions that cause them in order to decide which are the significant hazards that affect safety, specifying risk and seriousness and thus to include them in the HACCP Plan (Gantt chart is enclosed).	N/A	First meeting of Quality Assurance Programme on July 28, 2008, analysis finished on November 19, 2008	November 21, 2008
The establishment does not follow its verification frequency in accordance to its HACCP plan.	All quality inspectors are trained in order to enforce this frequency.	N/A	July 18, 2008	July 21, 2008
The establishment verification records do not document the results of the verification activities	All quality inspectors are trained with regard to this new concept.	N/A	July 18, 2008	July 21, 2008

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

REPORT ON OBSERVATIONS OF FSIS AUDIT MADE ON AUGUST 01 TO LO MIRANDA POULTRY PLANT REGISTER 06-02

Observation	Corrective Action	Preventive action	Committed Date	Responsible Company	SAG Verifier Result/Name/Signature
1. Condensate from overhead structures was observed dripping into poultry carcasses in the chiller tank. 9 CFR 416.13 and 9 CFR 416.2 (d)	1. Packing is changed in flanges and weather strips in lock gate, reinforcing with pre-operational and operational condensation sanitation. 2. Revision and general intervention to IKL machine to repair leaks. 3. An operation procedure of ice machines will be incorporated, which implies stopping the machines in 80% of the current operation time. This will be validated once 100% of the cold capacity of the poultry plant is operating.	Capture of IKL cone condensation dripping	(1) August 25, 2008 (2) September 09, 2008 (3) March 2009	(1), (2) Joaquin Baeza Maintenance Vice-Manager (3) Rodrigo Abarzua Poultry Plant Vice-Manager	Corrective Action No. 1, Solved. Corrective Action No. 2, Solved. Corrective Action No. 3, Pending. Mariela Valdes Toro OVS Head of Team

2. The quality and intensity of light were insufficient to conduct a proper verification inspection in the pre-chill inspection station. 9 CFR 416.2 (c)	(1) Halogen lighting was installed in both plants according to the lux required by the United States. (2) Verification platform of plant 2 will be extended.	Permanent inspection platform is used for verifications of CCP1 that have the lux required by the US.	September 22, 2008	Patricia Landaida Head of Quality Assurance	Corrective Actions 1 and 2, Solved. Mariela Valdes Toro OVS Head of Team
3. (A) Verification records did not document the type of the verification procedure and the results of the verification. 9 CFR 417.5(a) (3) and 9 CFR 417.8. (B) Monitoring records did not include the initials by the responsible establishment employee(s) making the entries. 9 CFR 417.5 (b) and 417.8	(A) The verification records are modified, adding the type and result of the procedure. (B) The records are modified, including the name and signature of the employee responsible of making the verifications.		(A) August 18, 2008 (B) August 18, 2008	Patricia Landaida Head of Quality Assurance	Corrective Actions A and B, solved Mariela Valdes Toro OVS Head of Team

4. Returned products were not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis. 9 CFR 417.2 and 9 CFR 417.8	The operational step returns is added in the hazard analysis and HACCP.		September 01, 2008	Patricia Landaida Head of Quality Assurance	Solved Mariela Valdes Toro OVS Head of Team

GOBIERNO DE CHILE
MINISTERIO DE AGRICULTURA

OFFICIAL REPORT ON OFFICIAL FSIS AUDIT JULY 2008
FAENADORA LO MIRANDA 06-02
PORK PLANT

N°	OBSERVATION DETECTED	CORRECTIVE ACTION(S)	PREVENTIVE ACTION(S)	RESPONSIBLE	SAG VERIFICATION (Result/name/date)
1	Documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation does not include the 3 parts of the corrective actions according to 9 CFR 416.15 (b), 416.16 (a) and 416.17	Modifications in the pre-operational and operational SSOP records of the pork plant are made, expanding the records of area which were not included in them. In addition, SAG inspectors include the observations of their verification in the company's register in order to adopt the necessary corrective and preventive measures.	The company carries out weekly meetings with the contracting company in charge of the SSOP in order to prevent the repetition of failures in the execution of SSOPs. Training to monitors responsible of the checking of SSOPs is made with the aim of improving their work.	Patricia Landaida R. Head of Quality Assurance of the plant	The verification is made in the days after the FSIS visit on a daily basis, evaluating the execution of Corrective and Preventive Actions, with these being found in CONFORMITY Responsible OVS:Ana Roa Troncoso / Mario Pérez Poblete Date: As of August 11, 2008
2	Documentation of corrective actions does not include all 4 parts of corrective actions according to 9 CFR 417.5 (a)(3) and 417.8	Modifications in the records of CCPs are made, in which a field where the name and signature of the person responsible of verification and that of monitoring is incorporated, as well as the time when the verification and monitoring actions according to the frequency established in the procedures. The records also include a field aimed at the monitoring of corrective actions adopted in case of an inadequate CCP. SAG inspectors carry out direct verification of every CCP on a daily basis; likewise, in case of inadequate CCPs, they verify the identification of the affected lot and the monitoring of the corrective actions adopted by the company in a direct manner and with documents, registering the verification of this operation with their signature in the company's monitoring record.	The format of records and procedures are modified in order to comply with the provisions of 9 CFR 417.5 (a) (3). The whole SAG team was brought together to receive instructions on the CPP verification, non-compliance of these, and the record and monitoring of corrective and preventive actions adopted by the company.	Patricia Landaida R. Head of Quality Assurance of the plant Ana Roa Troncoso / Mario Pérez Poblete OVS Heads of SAG Team plant 06-02	Verification of the actions taken by the plant as of August 11, 2008, with the last monitoring being executed on November 21, being found in CONFORMITY Meeting with SAG team made on August 04, 2008 Responsible OVS: Ana Roa Troncoso / Mario Pérez Poblete
3	Monitoring records for CCP 2 (zero tolerance) contained check marks instead of quantifiable values (9 CFR 417.5 (a) (3) and 417.8	Monitoring records of CCPs are changed, considering quantitative values, with a 0 being determined if no faults are detected and 1 in case of a fault or non-conformity in the monitoring.	The change of records applies to PCC 1 and PCC 2	Patricia Landaida R. Head of Quality Assurance of the plant	In CONFORMITY, November 21, 2008. OVS Responsible of verification: Ana Roa Troncoso / Mario Pérez Poblete
4	Generic E.Coli samples are taken from carcasses after the final wash and before entering the chillers, instead of already chilled carcasses as required by FSIS (9 CFR 310.25 (a) 2 (ii)	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	THE SAMPLING IS MADE ACCORDING TO THE STIPULATIONS IN PROCEDURE HANDBOOK PRP/MP1 AND PRP/MP 2 FROM THE AGRICULTURE AND LIVESTOCK SERVICE
5	The submaxillary lymph nodes are not incised/examined by the responsible official inspector.		A meeting will be made with the whole team of inspectors (Veterinarians and Auxiliary technicians) to indicate the observations by the FSIS Inspector during the visit in order to correct those relevant to the Official Inspection of the system; additionally, instructions for self-training is being prepared for the whole team of Official Inspectors.	Ana Roa Troncoso / Mario Pérez Poblete OVS Heads of SAG Team plant 06-02	In CONFORMITY, August 04, 2008. OVS Responsible of verification: Ana Roa Troncoso / Mario Pérez Poblete

MARIO D. PÉREZ POBLETE
OVS HEAD OFFICIAL SAG TEAM
FAENADORA LO MIRANDA LTDA - PORKS
06-02

ANA E. ROA TRONCOSO
OVS HEAD OFFICIAL SAG TEAM
FAENADORA LO MIRANDA LTDA - PORKS
06-02

SAG VERIFICATION AFTER FSIS REPORT FOR *FDRA. ROSARIO LTDA.*

No.	Observation detected	Corrective Action(s)	Preventive Action(s)	Responsible	SAG Verification (Result/ name/ date)
1	Condensate from refrigeration units was observed dripping onto meat products in the cutting room. [Regulatory References 9 CFR 416.13 and 9 CFR 416.2 (d)]	At the moment of detecting the event, SAG personnel provides instructions and the permanent drying of the condensation by the company in charge of cleaning is established as corrective measure in order to prevent its dripping onto the products.	The company checks the refrigeration units, its cleaning and the records of weekly cleaning work, verifying its compliance. The register RO-RG-ACL-203 Operational Condensation (Annexe 1) is created, through which the appearance of condensation is verified 4 times per shift; in addition, staff of the cleaning company for every shift is in charge of monitoring and controlling during the whole shift the specific appearance of condensation.	Head of Quality Assurance Department *Faenadora Rosario Ltda*	FULFILLED Pablo Ramírez September 15, 08
2	Some of the verification records of the establishment did not document the time when specific cases occurred or the results from the verification activities. [9 CFR 417.5(a) (3) and 9 CFR 417.8]	In the verification registers a column is added in order to register the verification result of records and the time when it was made, an example of record and what was added is enclosed (Annexe 2).	N/A	Head of Quality Assurance Department *Faenadora Rosario Ltda*	FULFILLED Pablo Ramírez August 18, 2008
No.	Observation detected	Corrective Action(s)	Preventive Action(s)	Responsible	SAG Verification

					(Result/ name/ date)
3	Generic E.Coli samples were taken from swine carcasses after the final wash and before entering the chillers, instead of chilled carcasses as required by FSIS [9 CFR 310.25 (a) 2 (ii)]	N/A	N/A	Observation: Sampling is made according to Procedure PRP/MP1, which in point 7.11 indicates that sampling must be carried out prior to chilling of carcasses.	Pablo Ramírez October 17, 2008
4	No incisions/analyses were made to submaxillary lymph nodes by the official inspector in charge.	At the same time the event is detected, an Official Veterinarian/Inspector corrects the work of the OIT in charge of the inspection of heads.	The staff in charge of the official inspection of heads is instructed on the correct procedure of incision and inspection of nodes.	Pablo Ramírez Head of SAG team	July 25, 2008

SAG VERIFICATION AFTER FSIS REPORT FOR *FDRA. ROSARIO LTDA.*

No.	Observation detected	Corrective Action(s)	Preventive Action(s)	Responsible	SAG Verification (Result/ name/ date)
1	Condensate from refrigeration units was observed dripping onto meat products in the cutting room. [Regulatory References 9 CFR 416.13 and 9 CFR 416.2 (d)]	At the moment of detecting the event, SAG personnel provides instructions and the permanent drying of the condensation by the company in charge of cleaning is established as corrective measure in order to prevent its dripping onto the products.	The company checks the refrigeration units, its cleaning and the records of weekly cleaning work, verifying its compliance. The register RO-RG-ACL-203 Operational Condensation (Annexe 1) is created, through which the appearance of condensation is verified 4 times per shift; in addition, staff of the cleaning company for every shift is in charge of monitoring and controlling during the whole shift the specific appearance of condensation.	Head of Quality Assurance Department *Faenadora Rosario Ltda*	FULFILLED Pablo Ramírez September 15, 08
2	Some of the verification *records of the establishment* did not document the time when specific cases occurred or the results from the verification activities. [9 CFR 417.5(a) (3) and 9 CFR 417.8]	In the verification registers a column is added in order to register the verification result of records and the time when it was made, an example of record and what was added is enclosed (Annexe 2).	N/A	Head of Quality Assurance Department *Faenadora Rosario Ltda*	FULFILLED Pablo Ramírez August 18, 2008
No.	Observation detected	Corrective Action(s)	Preventive Action(s)	Responsible	SAG Verification

					(Result/ name/ date)
3	Generic E.Coli samples were taken from swine carcasses after the final wash and before entering the chillers, instead of chilled carcasses as required by FSIS [9 CFR 310.25 (a) 2 (ii)]	N/A	N/A	Observation: Sampling is made according to Procedure PRP/MP1, which in point 7.11 indicates that sampling must be carried out prior to chilling of carcasses.	Pablo Ramírez October 17, 2008
4	No incisions/analyses were made to submaxillary lymph nodes by the official inspector in charge.	At the same time the event is detected, an Official Veterinarian/Inspector corrects the work of the OIT in charge of the inspection of heads.	The staff in charge of the official inspection of heads is instructed on the correct procedure of incision and inspection of nodes.	Pablo Ramírez Head of SAG team	July 25, 2008

REPORT ON FSIS AUDIT MONITORING

Establishment: **AGROINDUSTRIAS LOMAS COLORADAS LTDA.**
Region: ***BíoBío***
Verification date: **November 24, 2008**
Name of Verifier: **ROBERTO OYARZO O.**

OBSERVATION	CORRECTIVE ACTION	PREVENTIVE MEASURE IMPLEMENTED	OFFICIAL VERIFICATION DATE	NAME AND SIGNATURE OF VERIFIER
13/51				
Documentation of corrective action taken in response to deficiencies identified during pre-operational and operational sanitation did not include all three parts of the corrective actions.	A description of the three parts of the corrective actions according to 9CFR 416 is defined in the SSOP form: 1.- Ensure the proper disposition of the contaminated product, purifying and sanitizing the surface of the product. 2.- Clean and sanitize the surface of direct contact with the product. 3. Prevent the recurrence of contamination, instructing that responsible of cleaning and disinfecting the place affected and re-evaluating the SSOP Programmed if the presence of contamination is recurrent.	The cleaning and disinfecting procedures from the SSOP programme are checked, regarding: 1.- The concentration and application chemicals used. 2.- The correct application frequency. 3.- Monitors are trained in their position according to 9CFR 416.	November 24, 2008	Roberto Oyarzo O.

15/51				
Returned product was not included in the flow chart as a processing step and food safety hazards for this processing step were not identified in the hazard analysis.	The return of products is added to the flow chart of the slaughter (final product pole meat) and butchering (refrigerated and chilled product in boxes) processes. The return of products is added to hazard analysis, including as CCP the return of refrigerated product in box, incorporating to the CCP B1 D1 form, temperature control of the returned product.	The HACCP plan is revised and validated for the inclusion and analysis of hazards from the stage of product return.	November 24, 2008	Roberto Oyarzo O
22/51				
The establishment verification records did not document the results of the verification activities.	A manual for the verification of monitoring and control records is prepared, aimed at verifiers from the HACCP plan, where they are instructed to include the verification result according to 9CFR, 417.	Training of record verifiers.	November 24, 2008	Roberto Oyarzo O
28/51				
Generic *Escherichia coli* samples were collected from bovine carcasses after the final wash and before entering the chillers insted of chilled bovine carcasses as required by FSIS.	Not Fulfilled: An E. Coli sampling is being made, according to the provisions in SAG's procedure manual, which establishes that "The sample must be collected before subjecting the carcass to cold," page 31, point 3 from PRP/PM1.	Not applicable	November 24, 2008	Roberto Oyarzo O

OFFICIAL REPORT				
Observation	**Corrective action implemented**	**Preventive Measure implemented**	**Official Verification**	**Name and signature of official verifier**
A. Several plastic white tubs used to transport meat products were identified with product residues from the previous day's production. These empty tubs were being stored in the clean container storage area. They had passed establishment sanitary inspection and were ready to use. [Regulatory reference: 9 CFR 416.13 (c)]	1. - Dirty tubs were returned to the washing area, meat residues were removed and then washed and sanitised for their use in the butchering; the clean tubs were immediately covered with a plastic film.	1.- The cleaning of tubs is checked on a daily basis before starting the butchering through the pre-operational checking of the corresponding area, which is recorded by the quality monitor in the form "cleaning control of the butchering line" (SSOP1-R7): **Operative.** 2.- Cleaning staff will be reinstructed regarding the cleaning of tubs as well as the quality monitors about the pre-operational checking. 3.-. A new checking of the SOP for the butchering process will be generated, establishing the obligation of keeping every tub with product covered with a plastic film. This will be instructed and informed to the area supervisor for its fulfilment and a change in SSOP form will be made verifying the cleaning on a daily basis.	CORRECTIVE July 17, 2008 PREVENTIVE 1.- September 01, 2008 2.-	Sergio Sayago
B. Condensate from refrigeration units was observed dripping onto meat products in the carcass coolers. [9CFR 416.13 and 9 CFR 416.2 (d)]	1.-The operator of the cold room is instructed and informed of this situation, who immediately took away the carcasses under the refrigeration unit through a transfer to the parallel line; in that place an inspection of the carcass is made by	1.- In order to avoid the dripping of the affected room, trays will be installed under cold units, ensuring that the water dripping falls into them, as well as the use of an insulating material in cold unit pipes that take water to prevent filtration and subsequent leak through them.	Corrective: 1, 2 July 17, 2008 3.- August 15, 2008	

Observation	Corrective action implemented	Preventive Measure implemented	Official Verification	Name and signature of official verifier
	a quality monitor. In the cases where the contamination of the carcass was detected, purification was carried out in the affected area and sanitation was made to carcasses, destining them to the domestic market. 2. - In addition, the operator of the cold room dried the affected area of the room with a dry mop. This procedure will be executed as necessary while the preventive action is carried out. 3.-In the analysis made to this noncompliance, it was determined that part of the dripping was due to the infiltrated water coming from the roof of the plant (leaks). Therefore, oil separators from the area of water leak were sealed.	2.- The refrigeration room SOP will be analysed and a monitoring register for condensation will be established which will be performed 24 and 48 hrs. after the carcasses are entered in the coolers. 3.- A change of refrigeration room ceiling will be made to prevent new water filtration onto carcasses. **Room 2→ Operative Implementation date for solution, Rooms 1, 3, 4, 5 and 6→ December 22, 08**	Preventive: 3.-November 17, 2008 for room 2.	
Generic Escherichia Coli samples were collected from bovine carcasses after the final wash and before entering the chillers, instead of chilled bovine carcasses as required by FSIS. [9 CFR 310.25 (a) (2) (ii)]	Central level			

Observation	Corrective action implemented	Preventive Measure implemented	Official Verification	Name and signature of official verifier
Maintenance of over head structures in two of the carcass coolers had been neglected with loose and flaking paint and numerous holes in ceiling in evidence. [9 CFR 416.4 and 416.17]	1.-Purification of contaminating elements and sanitation of affected area of carcasses with peracetic acid at 200 ppm. 2.-Incorporation of a carcass re-inspection form (SOP13-R1) through a sampling plan Chilean regulation 44 2007, and at the same time, the operator makes a visual inspection at the entry of the butchering room to 100% of the carcasses.	1. - The refrigeration room staff will be instructed to avoid putting the carcasses under places affected in the room. 2.- Ceilings will be changed in cold storage rooms No. 1, 2, 3, 4. Pre-painted thermal panels will be installed in order to avoid using paints in ceilings which could flake, and thus there will be no holes given the smooth surface of the panel, facilitating the cleaning and sanitation of room ceilings. **Room 2→ Operative Rooms 1, 3, 4, 5 and 6 → Implementation date for solution: December 22, 2008**	Corrective: 1.- July 17, 2008 2.- July 21, 2008 Preventive: 1.- July 21, 2008 2.-November 17, 2008 for room 2.	

OFFICIAL REPORT

Observation	Corrective action implemented	Preventive Measure implemented	Official Verification	Name and signature of official verifier
A. Several plastic white tubs used to transport meat products were identified with product residues from the previous day's production. These empty tubs were being stored in the clean container storage area. They had passed establishment sanitary inspection and were ready to use. [Regulatory reference: 9 CFR 416.13 (c)]	1. - Dirty tubs were returned to the washing area, meat residues were removed and then washed and sanitised for their use in the butchering; the clean tubs were immediately covered with a plastic film.	1.- The cleaning of tubs is checked on a daily basis before starting the butchering through the pre-operational checking of the corresponding area, which is recorded by the quality monitor in the form "cleaning control of the butchering line" (SSOP1-R7): **Operative.** 2.- Cleaning staff will be reinstructed regarding the cleaning of tubs as well as the quality monitors about the pre-operational checking. 3.-. A new checking of the SOP for the butchering process will be generated, establishing the obligation of keeping every tub with product covered with a plastic film. This will be instructed and informed to the area supervisor for its fulfilment and a change in SSOP form will be made verifying the cleaning on a daily basis.	CORRECTIVE July 17, 2008 PREVENTIVE 1.- September 01, 2008 2.-	Sergio Sayago
B. Condensate from refrigeration units was observed dripping onto meat products in the carcass coolers. [9CFR 416.13 and 9 CFR 416.2 (d)]	1.-The operator of the cold room is instructed and informed of this situation, who immediately took away the carcasses under the refrigeration unit through a transfer to the parallel line; in that place an inspection of the carcass is made by	1.- In order to avoid the dripping of the affected room, trays will be installed under cold units, ensuring that the water dripping falls into them, as well as the use of an insulating material in cold unit pipes that take water to prevent filtration and subsequent leak through them.	Corrective: 1, 2 July 17, 2008 3.- August 15, 2008	

Observation	Corrective action implemented	Preventive Measure implemented	Official Verification	Name and signature of official verifier
	a quality monitor. In the cases where the contamination of the carcass was detected, purification was carried out in the affected area and sanitation was made to carcasses, destining them to the domestic market. 2. - In addition, the operator of the cold room dried the affected area of the room with a dry mop. This procedure will be executed as necessary while the preventive action is carried out. 3.-In the analysis made to this noncompliance, it was determined that part of the dripping was due to the infiltrated water coming from the roof of the plant (leaks). Therefore, oil separators from the area of water leak were sealed.	2.- The refrigeration room SOP will be analysed and a monitoring register for condensation will be established which will be performed 24 and 48 hrs. after the carcasses are entered in the coolers. 3.- A change of refrigeration room ceiling will be made to prevent new water filtration onto carcasses. **Room 2→ Operative Implementation date for solution, Rooms 1, 3, 4, 5 and 6→ December 22, 08**	Preventive: 3.-November 17, 2008 for room 2.	
Generic Escherichia Coli samples were collected from bovine carcasses after the final wash and before entering the chillers, instead of chilled bovine carcasses as required by FSIS. [9 CFR 310.25 (a) (2) (ii)]	Central level			

Observation	Corrective action implemented	Preventive Measure implemented	Official Verification	Name and signature of official verifier
Maintenance of over head structures in two of the carcass coolers had been neglected with loose and flaking paint and numerous holes in ceiling in evidence. [9 CFR 416.4 and 416.17]	1.-Purification of contaminating elements and sanitation of affected area of carcasses with peracetic acid at 200 ppm. 2.-Incorporation of a carcass re-inspection form (SOP13-R1) through a sampling plan Chilean regulation 44 2007, and at the same time, the operator makes a visual inspection at the entry of the butchering room to 100% of the carcasses.	1. - The refrigeration room staff will be instructed to avoid putting the carcasses under places affected in the room. 2.- Ceilings will be changed in cold storage rooms No. 1, 2, 3, 4. Pre-painted thermal panels will be installed in order to avoid using paints in ceilings which could flake, and thus there will be no holes given the smooth surface of the panel, facilitating the cleaning and sanitation of room ceilings. **Room 2→ Operative Rooms 1, 3, 4, 5 and 6 → Implementation date for solution: December 22, 2008**	Corrective: 1.- July 17, 2008 2.- July 21, 2008 Preventive: 1.- July 21, 2008 2.-November 17, 2008 for room 2.	

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

VERIFICATION REPORT REGARDING FSIS AUDIT OBSERVATIONS

- **Establishment:** *Frigorífico de Osorno S.A.*
- **Date:** November 21, 2008
- **SAG Verification team:** - Dr. Elizabeth Ojeda G. Head of SAG Inspection Team

OBSERVATION	CORRECTIVE ACTION IMPLEMENTED	PREVENTIVE MEASURE	OFFICIAL VERIFICATION DATE	NAME AND SIGNATURE OF VERIFICADOR
10. Heavily beaded condensate from the over head structures was observed dripping onto exposed bovine carcasses in seven of the carcass coolers.	The ventilation systems with inadequate operation were improved. The operative management of the mentioned areas is improved. Responsible staff per area and responsible production line of the operational management is established in case of condensation. The Standard Operating Procedure of the Condensation Management is instructed and spread among cleaning staff and processing operators.	Preventive maintenance of ventilation systems. Permanent training on measures regarding door use and other predisposing conditions in rooms. Improvement of time and managements executed in cleaning procedures of processing sectors, reinforcing the drying time after sanitation process, among others. The company established in its procedures a SOP for the management of product that has been adulterated by any type of contamination and lost its safety; for this, the product is kept identified and segregated in a specific area until the corrective actions and microbiological analyses described in the procedure are carried out and its condition as fit for human consumption is regained, or else its removal as	August 18, 2008 September 25, 2008 October 13, 2008 November 21, 2008	

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

OBSERVATION	CORRECTIVE ACTION IMPLEMENTED	PREVENTIVE MEASURE	OFFICIAL VERIFICATION DATE	NAME AND SIGNATURE OF VERIFICADOR
		product unfit for human consumption is determined.		
11/51 Split beef carcasses were observed contacting non-food contact surfaces of door frames, poles, water pipes, employee's plaform, and a stationary ladder in a room between one of the carcass coolers and the cutting room. (9CFR 416.14 and 9 CFR 416.17) Immediate corrective action was ordered by inspection officials.	Removal and redistribution of areas inserted in the transit of meats in pole apt to be relocated or redirected (platforms, guard rails, etc.) Operation reinstruction to the staff in charge of pushing and handling carcasses in non-automatic segments is made, reinforcing the concept of free transit and the health implications for operators. For this, stainless steel hooks must be used to avoid the contact with surfaces which are not to be touched, which was added in the corresponding SOP. The number of activities performed was reduced in the weighing sector of quarter carcass, increasing the used area and avoiding the possibility of contact with secondary surfaces. The distance between the platforms and the circulation line of poles was adjusted, which was added to the corresponding SOP, ensuring the absence of contact with not suitable	Establishment and reinforcement of permanent programme for management, pushing and handling of meats in pole in the annual training programmes with emphasis on safeguards, storage conditions, handlings reducing the possibility of contact with surfaces during the handling of products. Strengthening of the training of maintenance personnel to define new structures, establishment of machineries and movements that protect the free transit of meat pole, complying with the distances that ensure the free transit stipulated by regulation. Improvement in the coordination of delivery, receipt and processing of quarter carcass in the quartering area, avoiding to saturate the capacity of the sector, improving the quick management that prevents the possibility of contact with secondary surfaces.	August 18, 2008 September 25, 2008 October 13, 2008 November 21, 2008	

OBSERVATION	CORRECTIVE ACTION IMPLEMENTED	PREVENTIVE MEASURE	OFFICIAL VERIFICATION DATE	NAME AND SIGNATURE OF VERIFICADOR
	surfaces.			
19/51 The establishment did not follow its verification frequency for direct observation to the monitoring procedures in accordance with its HACCP plan (9 CFR 417.2 (c) 7,9 CFR 417.4 and 9 CFR 417.8)	The establishment expanded the verification responsibility of the system to part of the team from the Quality Assurance Department in order to support the work of the person responsible of the establishment's quality system and entrust the number of activities included in this concept.	The establishment set a timetable and an annual verification programme, executing a cadastre of 100% of the items in the Quality Assurance System (GMP – HACCP) in order to organise and improve the coordination of the verifications and thus avoiding the absence of these on any items.	August 18, 2008 September 25, 2008 October 13, 2008 November 21, 2008	
22/51 The establishment did not maintain supporting documents associated with the selection of the verification procedures and the frequency of those procedures. (9 CFR 417.5 and 9 CFR 417.8)	A statistical review of the past behaviour of the CCP, monitoring and verifications available per production line, including 2007 and the first half of 2008, was conducted. A background statistical review of client complaints during the first half of 2008 was executed with the object of correlating the behaviour of in-line CCP. A background microbiological review of meat products under HACCP during the	Strengthening, establishment and analysis of statistical control files which allow to permanently support the verification frequencies in place or their necessary adjustment.	August 18, 2008 September 25, 2008 October 13, 2008 November 21, 2008	

	aforementioned periods was carried out. A study programme and monitoring of daily verifications was made for a period of 4 weeks in order to correlate with the background observed the historical background for the periods analysed.			
28/51 Generic Escherichia Coli samples were collected from bovine carcasses after the final wash and before entering the chillers, instead of chilled bovine carcasses as required by FSIS. (9 CFR 310.25 (a) (2) (ii)	***THIS NONCONFORMITY MUST BE ANALYSED AND ANSWERED BY THE LIVESTOCK PROTECTION DIVISION, SINCE THE SAMPLING IS PEFORMED ACCORDING TO THE STIPULATIONS OF PM1 AND PM2 OF THE PATHOGEN REDUCTION PROGRAMME.***			
39/51 Maintenance of overhead structures, above exposed products and equipments, had been neglected with build up of rust on the carcass cooler's rails and numerous holes in the cutting room ceiling. (9 CFR 416.2 and 9 CFR 416.17)	The establishment conducts a cadastre of all the rusty structures and that required maintenance and executed the corrective maintenance. Maintenance teams were reinforced with external maintenance staff especially assigned to complete the internal maintenance personnel. Maintenance segmented per item or concept to be established was incorporated (work group assigned to rust-removal work, repairing of surfaces, overhead structures, etc.).	The cleaning procedure for rails, lubrication of trolleys and draining periods in order to prevent filtrations onto products, are re-evaluated. All the overhead structures were included in cadastres of equipments and/or tools for the preventive maintenance, increasing the frequency; the authorisation of equipments and/or areas is granted by the Quality Assurance staff.	August 18, 2008 September 25, 2008 October 13, 2008 November 21, 2008	

40 The quality and intensity of Lightning were insufficient to conduct a proper post-mortem inspection in the final inspection station (9 CFR 416.2 (c)	White halogen light were installed along the final-inspection section, increasing the lux levels in legs and shoulders with the aim of improving the conditions to detect the unwanted elements and those inspection conditions for the whole carcass.	A lux evaluation programme managed by the Risk Prevention Department is established with at least one half-yearly evaluation of all the process points in order to keep an objective evaluation of the establishment's lightning levels.	August 18, 2008 September 25, 2008 October 13, 2008 November 21, 2008	
44/47 Production line employees were not able to remove or change their working clothing before or after using restrooms due to improper design of the area (9 CFR 416.2 (h) and 9 CFR 416.5)	Working clothing was changed for *Frigosorno* handling staff, which included a two-piece uniform to make the access to restrooms easier prior to removing the uniform when entering these sectors. Reinstruction of the staff of the area was executed regarding GMP, emphasising health safeguard, access management and conditions of the staff from processing areas. On-site training was performed with production and quality supervisors to increment staff visualisation and reinstruction.	A specific manual was prepared, handing it out to every food handler; and it was enclosed to the background records of the staff as an evidence of permanent instruction and training on the conditions of staff access to the establishment's restrooms. The possibility of keeping the permanent reinforcement in the internal training is considered. In the butchering and hamburger areas, new changing rooms and restrooms are being built, where the transit flow of the staff is organised in such a way that they must remove their working clothing to access the restrooms.	August 18, 2008 September 25, 2008 October 13, 2008 November 21, 2008	
45 Rough, interrupted and uneven welds were observed on the food contact surfaces of several stainless steel containers, which may prevent the adequate	The company carried out a cadastre of all machineries, equipments and/or tools that showed problems, making a timetable to perform repairs and/or replacements, first-contact equipments and structures first.	Frigosorno S.A.'s preventive maintenance programme is strengthened. A production evaluation protocol for equipments, tools or machineries, prior to installation in production line is established,	August 18, 2008 September 25, 2008 October 13, 2008 November 21, 2008	

removal of product residue and could become a source of product contamination.		reducing the entry of equipments, structures and surfaces incompatible with the industry, lowering the possibility of questionable structures in the line. A programme or internal course is established on technical aspects of the food industry in order to establish a rotating plan within the plant's annual training programme.		

FRIGORIFICO DE O"HIGGINS

FINDINGS	CORRECTIVE ACTION	PREVENTIVE MEASURES	OFITIAL VERICATION DATE	NAME OF THE OFITIAL VERIFICATION
Condensate from over head structures was observed dripping onto exposed bovine carcasses in three of the carcass cooler .	A new registry was create to verify the presence or absence of condensation in the coolers, so as to take corrective action if is necessary. This is set in the register Monitoring The Presence of condensation CM-CAL-OPV-R-13.		30-07-2008	Andrea Rivera MVO
Some of the verification records did not document the times when the specific events occurred or the results of the verification.	It is incorporated in the HACCP document CM-CAL-HV-D-13, that all the checks carried out in the PCC records should be include the date, time and outcome of the investigation. On the other hand, are trained to all staff responsible.		02-12-2008	Andrea Rivera MVO

AGROINDUSTRIAL EL PAICO

FINDINGS	CORRECTIVE ACTION	PREVENTIVE MEASURES	OFITIAL VERICATION DATE	NAME OF THE OFITIAL VERIFICATION
Condensate originating from overhead structures was observed dripping directly into the poultry chilling tank containing carcasses.	The procedure is performed with hair dryer telescopic; each time it is presented condensation	We carried out structural change in the location of the hatch discharge of ice. Was hired an engineering study for a global solution across the floor.	11.08.08	Gladys Ríos
Documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation did not include all three parts of the corrective actions	Are incorporated into the documents and records: the reestablish of sanitary conditions, and the eventual disposal of products and reinforcement to avoid the recurrence.	Review of compliance with the US requirements, through the detailed study of the requirements contained in Chapter III 9CFR; considered to the activities of the Plant.	30.12.08	Gladys Ríos
A) Documentation of corrective action taken in response to a deviation from a critical limit did not include all four parts of the corrective actions.	It describes the four parts of the corrective actions at the HACCP Plan, which is associated with the tables and records management.	Review of compliance with the US requirements, through the detailed study of the requirements contained in Chapter III 9CFR; considered to the activities of the Plant.	30.12.08	Gladys Ríos

B) Some of the verification records did not document the times when the specific events occurred or the results of the ongoing verification activities.	We carried out the modification of the Daily Record Checks (RVD)	Review of compliance with the US requirements, through the detailed study of the requirements contained in Chapter III 9CFR; considered to the activities of the Plant.	30.09.08	Gladys Ríos
Maintenance of overhead structures above exposed product and equipment had been neglected as evidenced by numerous holes in the cutting room ceiling	Until the final preventive acction we will take place sanitation procedures on ceiling each weekend.	Repair is performed on ceiling to plug all the holes that are discovered and implemented manteinance estructure procedures	03.11.08	Gladys Ríos

GOBIERNO DE CHILE
MINISTERIO DE AGRICULTURA
SAG

00158

División de Protección Pecuaria

13662

SANTIAGO,

- 9 DIC 2008

Sr
Donald Smart
Director
International Audit Staff
Office Of International affairs
FSIS-USDA

Estimado Señor:

De acuerdo a lo solicitado, adjunto envío a Ud. respuesta a las observaciones del informe borrador final de la auditoría llevada a cabo in Chile, y que cubre el sistema de inspección de productos de carne y aves, realizada desde Julio 8 á Agosto 8 del 2008

Saluda atentamente a Ud.,

SERVICIO AGRICOLA Y GANADERO
DIVISION PROTECCION PECUARIA

CLAUDIO TERNICIER GONZALEZ
JEFE
MEDICO VETERINARIO
JEFE DIVISION DE PROTECCION PECUARIA

CVP/FAM/sjf
04-12-08

División de Protección Pecuaria. SAG / Avenida Bulnes 140, 7° Piso. Santiago
Fono: 3451400; Fax: 3451403; E-mail: propec@sag.gob.cl

GOBIERNO DE CHILE
MINISTERIO DE AGRICULTURA
SAG

División Protección Pecuaria

RESPUESTA AL BORRADOR DE INFORME DE AUDITORIA DE FSIS DEL 8 DE JULIO AL 8 DE AGOSTO DEL 2008.

Con referencia al:

Punto 7 PRINCIPALES HALLAZGOS:

- 7.1-Supervisión Gubernamental:

No se reportaron deficiencias

Punto 8 AUDITORIA A LOS ESTABLECIMIENTOS

Los informes a las observaciones se encuentran especificados en los anexos correspondientes a cada uno de los establecimientos.

Punto 9. AUDITORIA DE LOS LABORATORIOS.

En relación a los hallazgos encontrados en los laboratorios visitados, El Servicio fortalecerá y pondrá énfasis en los aspectos observados en las próximas supervisiones y especialmente en la auditoria anual que realice en todos los laboratorios de la red. Además incluirá estos controles en sus propios registros.

Con relación a la Auditoría al Lab SEMA:
Respuesta a las Observaciones en el Anexo .....

Punto 10. CONTROL DE SANITIZACION.

- 10.1 Procedimientos estandarizados de Operaciones Sanitarias(SSOP)

Los informes a las observaciones se encuentran especificados en los anexos correspondientes a cada uno de los establecimientos.

- 10.2 SPS Estándares de Desempeño Sanitarios:

Los informes a las observaciones se encuentran especificados en los anexos correspondientes a cada uno de los establecimientos.

Punto 11 CONTROL DE ENFERMEDADES EN ANIMALES.

No presentaba Deficiencias.

Punto 12. CONTROL DE FAENAMIENTO Y PROCESO.

- 12.1 Manejo y faenamiento humanitario:

No presentaba Deficiencias.

- 12.2 Implementación de HACCP:

Los informes a las observaciones se encuentran especificados en los anexos correspondientes a cada uno de los establecimientos.

- 12.3 Monitoreo de *E. Coli* Genérica:

  En el muestreo oficial de *E. coli* genérica al igual que en el muestreo diario de *E. coli* del establecimiento, las muestras se obtienen desde las canales/carcasas, previo a que ingresen a la sala de frío (cámara de oreo) en carnes rojas a la sanitización si la hubiese.

Lo anterior, es un requisito para dar cumplimiento al sistema de control microbiológico oficial que se encuentra armonizado y reconocido por la Unión Europea.

- 12.4 Muestreo para *Listeria monocytogenes*

Se enviará dentro de la primera quincena del mes de diciembre de 2008, la propuesta del Servicio Agrícola y Ganadero para equivalencia con el FSIS, del Sistema de Verificación Oficial para productos cárnicos listos para consumo de exportación a los Estados Unidos (División Asuntos Internacionales SAG).

Punto 13. CONTROL DE RESIDUOS

No se detectaron deficiencias

Punto 14.CONTROL DE APLICACIÓN DE NORMATIVAS. ENFORCEMENT.

14.1 Inspección Diaria en el establecimiento.

14.2 Monitoreo de Salmonella.

14.3 Monitoreo de E.Coli 0157:H7

La Jefatutra de la División Protección Pecuaria instruyó a las Direcciones Regionales SAG mediante Circular N° 790 de fecha 5 de noviembre de 2008, la toma de muestras para la verificación oficial de *E. coli O157:H7* en carne molida y trimming bovina de exportación a los Estados Unidos, a efectuarse durante los meses de noviembre y diciembre de 2008. Dicha Verificación Oficial continuará con una frecuencia mensual a contar del año 2009.

14.4 Verificación de Especies.

No se detectaron deficiencias

14.5 Revision periodica de Supervisión:

No se detectaron deficiencias

14.6 Sistema de Control de Inspección

Los informes a las observaciones se encuentran especificados en los anexos correspondientes a cada uno de los establecimientos.

Laboratorio SEMA Ltda

RG-089	Registros Generales

Sección : no corresponde		Página 1 de 2
Título: Registro de seguimiento de acciones Correctivas o Preventivas		Elaborado por. J. Raviola
Edición : 06	Fecha : 11/05	Aprobado por : M Valenzuela

Registro de seguimiento de acciones Correctivas o Preventivas

A. Inicio de la Acción Correctiva CODIGO REGISTRO: AE-008 (ver *)

No Conformidad N°: 08 Detectada en: Auditoría Externa 1/SAG/ Microbiología Fecha: 13-08-2008
Algunas de la Muestras no estaban identificadas con un numero único de identificación a través del proceso analítico. Estas fueron identificadas con el nombre del establecimiento y/o 2 diferentes muestras compartían el mismo numero de identificación interna del laboratorio.
¿Se aplica acción correctiva? SI X NO ____

FIRMA AUDITOR ENCARGADO

M Valenzuela
Marcela Valenzuela Vargas
Jefe Laboratorio

B. Involucrados en la solución:

Nombre	Cargo
1. Marcela Valenzuela.	1. Jefe Laboratorio.
2. Gemma Vera.	2. Encargado área Microbiología.
3. Lorena Cruz	3. Microbiólogo.
4. Cecilia Jeria	4. Microbiólogo.
5. Patricio Vielma.	5. Microbiólogo.
6: Cristian Varas	6. Microbiólogo.
7. Marlene Encina	7. Microbiólogo

C. Análisis (Anexo 1) y solución del problema

Solución propuesta:
Como acción inmediata y Correctiva: Se solicita a los clientes que envían muestras dentro del alcance del Programa de Reducción de Patógenos y que digitan directamente sus muestras las Sistema Sislab del Laboratorio, consideren un ingreso por cada tipo de análisis independiente de la identificación original de la muestra.
Se incluya en procedimiento interno el control en la recepción administrativa de las muestras de manera de verificar que la identificación sea única, es decir asociada a un solo análisis.
Se modifica documentación interna de seguimiento de muestras durante el proceso de análisis de manera que no indique la planta de procedencia de la muestra (Registro de Trazabilidad de Muestras SAG E.coli, RM-002; Registro de Trazabilidad de Muestras SAG RAM, RM-003 y Registro de Trazabilidad de Muestras SAG Salmonella RM-004).

Fecha de Implementación:30/10/2008
Responsable y fecha de la verificación de la implementación Jorge Raviola 03/11/2008

M Valenzuela
Marcela Valenzuela Vargas
Jefe Laboratorio

Fecha del Acuerdo: 23/09/2008

D. Seguimiento de acciones Correctivas

Responsable de la verificación: Jorge Raviola
Fecha en que se realiza la verificación: 30/12/2008
¿La solución implementada es satisfactoria? SI ____ NO ____
OBSERVACIONES:

CIERRE DE NO CONFORMIDADES CON SOLUCION SATISFACTORIA

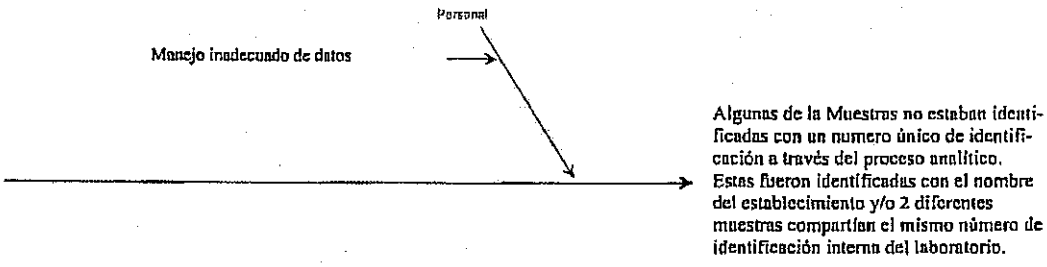
Fecha: FIRMA Y CARGO RESPONSABLE

* = Ver Procedimiento General PG-080 implementación y seguimiento acciones correctivas

Anexo 1

NO CONFORMIDAD Nº 08

Diagrama de Ishikawa



NO CONFORMIDAD Nº 08 Estudio de causal

El sistema de ingreso con el que cuenta el laboratorio Sema, es un software que se instala en los Pc de los clientes, ellos ingresan sus muestras registrando los datos necesarios que permitan identificarla y los análisis que requiere, el sistema en forma automática le asigna clave por muestra (compuesto por fecha y un correlativo diario dentro del total de muestras recibidas), es por ello que una misma muestra independiente del número de análisis solicitados conserva la misma clave para cada uno de ellos, no se consideraba la posibilidad de error ya que se aplican distintas metodologías de análisis.

M Valenzuela
Marcela Valenzuela Vargas
Jefe Laboratorio

* = Ver Procedimiento General PG-080 implementación y seguimiento acciones correctivas

GOBIERNO DE CHILE

AUDITORÍA OFICIAL EEUU

Establecimiento SOPRAVAL

fecha: 11/07/2008
Auditor: Dr. Nader Memarian

OBSERVACION	A.CORRECTIVA.	M.PREVENTIVA	FECHA IMPLEM	VERIFICACI ON SAG
Una cinta transportadora, usada para producto comestible fue observada en la sala de procesos. Esta cinta presentaba gran parte dañada, lo que impide su completa limpieza y podría provocar adulteración del producto durante las operaciones	se emite orden de compra para esta cinta el mismo día de la auditoría	reforzamiento del programa de mantención preventiva de equipos	18-07-2008	18-07-2008
El producto devuelto no está incorporado en el diagrama de flujo como un paso en el proceso ni como peligro para la seguridad del alimento y no fueron identificados en el análisis de peligro.	El equipo PAC se reunirá una vez por semana para analizar un nuevo concepto de acuerdo a un plan de trabajo: recopilación y evaluación de peligros y las condiciones que los originan para decidir cuales son los peligros significativos que afectan la inocuidad, especificando riesgo y severidad y así incluirlas en el Plan HACCP (se adjunta carta Gantt)	N/A	primera reunión PAC el 28/07/2008 término de análisis 19/11/2008	21-11-2008
El establecimiento no realiza la verificación de acuerdo a la frecuencia establecida en su plan HACCP	se capacita a todos los inspectores de calidad para que hagan cumplir esta frecuencia	N/A	18-07-2008	21-07-2008
En los registros de verificación del establecimiento no está documentado los resultados de las activi-dades de verificación.	se capacita a todos los inspectores de calidad respecto de este nuevo concepto	N/A	18-07-2008	21-07-2008

SGF.

GOBIERNO DE CHILE
MINISTERIO DE AGRICULTURA
SAG

Sección Protección Pecuaria SAG Región O'Higgins / Cuevas 480, Rancagua
Fono: 221955 - 226996; Fax: 223803; E-mail: alvaro.alegria@sag.gob.cl

Fax N°: 54	Fecha: 25 NOV 2008
N° de páginas incluyendo cubierta: 1	
Señor: JEFE DIVISION PROTECCION PECUARIA	
Teléfono:	Fax:
c.c.: SUBDPTO. INDUSTRIA Y TECNOLOGIA PECUARIA	
Asunto: Respuesta informe FSIS	
Enviado por: SR. ALVARO ALEGRIA MATUS DIRECTOR REGIONAL SAG REGION DE O'HIGGINS	

[X] Urgente [X] Conocimiento [ ] Responder

En Respuesta a un e'mail enviado por la Srta. Sandra Jerez de fecha 17 de noviembre de 2008, en que pide responder el Informe borrador de FSIS a más tardar con fecha de hoy, le informo que todas las empresas auditadas implementaron acciones que fueron verificadas por inspectores SAG en cada una de ellas.

El resultado de estas verificaciones se adjuntan a este FAX separadas por planta:

1. Faenadora Lo Miranda Ltda., planta aves, 4 hojas.
2. Faenadora Lo Miranda Ltda., planta cerdos, 1 hoja.
3. Faenadora Rosario Ltda., 2 hojas.

Sin otro particular, saluda atentamente,

SERVICIO AGRICOLA Y GANADERO - VI REGION - DIRECTOR

ALVARO ALEGRIA MATUS
INGENIERO AGRONOMO
DIRECTOR SAG REGION O'HIGGINS

Servicio Agrícola y Ganadero - Encargado Protección Pecuaria - Regional

Fdo. Cvpa.
N° 1012708

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DIVISIÓN PROTECCIÓN PECUARIA
Fecha Ingreso: 25 NOV. 2008 N°
Unidad Ind y Tecnol.

Conocimiento		Conversar	
S. Opinión		Urgente	
Respuesta		Archivar	

Observaciones

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

INFORME OBSERVACIONES AUDITORIA FSIS REALIZADA 01 AGOSTO PLANTA LO MIRANDA AVES.

REGISTRO 06-02

Observación	Acción Correctiva	Acción Preventiva	Fecha Compromiso	Responsable empresa	Verificador SAG Resultado/Nombre / Firma
1- Se observó condensado que salía de estructuras en altura goteaba sobre canales de aves de corral mencionadas en el 1 estanque de enfriamiento. 9 CFR 416.13 y 9 CFR 416. 2 (d)	1-Se cambia empaquetadura en flanges y burletes en compuerta y se refuerza con aseo de condensación preoperacional y operacional. 2-Revisión e intervención general máquina IKL para corregir filtraciones. 3-Se implementará procedimiento de operación de máquinas generadoras de hielo, el cual implica detener las máquinas en un 80% del tiempo funcionamiento actual, lo cual será validado una vez teniendo operativos el 100% de la capacidad de frío de la planta aves	Captura goteo condensación cono IKL	(1) 25-08-2008 (2) 22-09-2008 (3) Marzo 2009	(1), (2)Joaquín Baeza Subgerente mantención (3) Rodrigo Abarzua Sugerente Planta Aves	Acción correctiva Nº 1, Solucionado. Acción correctiva Nº 2, Solucionado Acción correctiva Nº 3 Pendiente. Mariela Valdés Toro MVO Jefe Equipo

SERVICIO AGRICOLA Y GANADERO OFICINA RANCAGUA INSPECCION VI REGION

2- La calidad e intensidad de la iluminación eran insuficientes para realizar una inspección de verificación adecuada en la estación de inspección de preenfriado. 9 CFR 416.2 (c)	(1)Se instala en ambas plantas iluminación halógena de acuerdo a los lux que pide EE.UU. (2)Se agrandará plataforma verificación planta 2.	Se utiliza plataforma inspección permanente para las verificaciones PCC 1 que presenta los lux exigidos por EE.UU.	22-09-2008	Patricia Landaida Jefa Aseguramiento Calidad	Acciones Correctivas 1 y 2, Solucionadas Mariela Valdés Toro MVO Jefe Equipo
3 -(A) Los registros de verificación no documentan el tipo de procedimiento de verificación y los resultados de la verificación. 9 CFR 417.5 (a) (3) y 9 CFR 417.8 (B) Los registros de monitoreo no incluían las iniciales del o los empleados del establecimiento responsables de realizar las anotaciones 9 CFR 417.5 (b) y 417.8	(A)Se modifican los registros de verificación agregando el tipo y resultado del procedimiento. (B) Los registros son modificados incluyendo el nombre y firma del empleado responsable de realizar las verificaciones.		(A)18-08-2008 (B) 18-08-2008	Patricia Landaida Jefa Aseguramiento Calidad	Acciones Correctivas A y B, Solucionadas Mariela Valdés Toro MVO Jefe Equipo

4- Los productos retornados no se incluían en el diagrama de flujo como paso del procesamiento, y los peligros de inocuidad de los alimentos para este paso del procesamiento no se identifican en el análisis de peligros. 9 CFR 417.2 y 9 CFR 417.8	Se Agregan en análisis de peligros y HACCP el paso operacional devoluciones		01-09-2008	Patricia Landaida Jefa Aseguramiento Calidad	Solucionado Mariela Valdés Toro MVO Jefe Equipo

GOBIERNO DE CHILE

INFORME OFICIAL AUDITORIA OFICIAL FSIS JULIO 2008
FAENADORA LO MIRANDA 06-02
PLANTA CERDOS

Nº	OBSERVACIÓN DETECTADA	ACCIÓN (ES) CORRECTIVA (S)	ACCIÓN (ES) PREVENTIVA (S)	RESPONSABLE	VERIFICACIÓN SAG (Resultado/nombre/fecha)
1	Documentación de las acciones correctivas tomadas en respuesta a deficiencias identificadas durante la sanitización preoperacional y operacional no señala las tres partes de las acciones correctivas según 9 CFR 416.15 (a), 416.16 (a) y 416.17	Se realizan modificaciones en los registros SSOP preoperacionales y operacionales de la planta de cerdos, ampliando el registro de superficies que no se encontraban incluidas en ellos, además, los Inspectores SAG incluyen las observaciones de su verificación en el registro de la empresa para que se tomen las medidas correctivas y preventivas necesarias	La empresa realiza reuniones semanales en conjunto con la empresa contratista a cargo de los SSOP con el fin de prevenir la repetitividad de las fallas en la implementación de los SSOP. Se realizan capacitaciones de los Monitores a cargo de la revisión de los SSOP para mejorar su gestión.	Patricia Landaida R. Jefe de Aseguramiento de Calidad de la planta	Se realiza la verificación en los días posteriores a la visita del FSIS en forma diaria, evaluando la ejecución de las Acciones Correctivas y Preventivas, encontrándose CONFORME M.V.O. Responsables: Ana Roa Troncoso / Mario Pérez Poblete Fecha : A contar del 11 de Agosto de 2008
2	La documentación de las acciones correctivas no señalan las 4 partes de las acciones correctivas según 9 CFR 417.5 (a)(3) y 417.8	Se realizan cambios en los registros de los PCOs, en los cuales se incorpora un campo donde se incluye el Nombre y firma del responsable de la verificación y del monitoreador, además se incorpora la hora en la cual realizan las acciones de verificación y monitoreo según la frecuencia establecida en los procedimientos. Los registros además incluyen un campo orientado hacia el seguimiento de las acciones correctivas tomadas ante un desvío del PCC. Los Inspectores SAG realizan la verificación directa de cada PCOs en forma diaria; además, ante la ocurrencia de desvíos de un PCC, verifican la identificación del lote afectado y el seguimiento de las acciones correctivas tomadas por la empresa en forma directa y documental, registrando la verificación de esta operación con su firma en el registro de seguimiento de la empresa	Se cambian los formatos de los registros y procedimientos para dar cumplimiento a lo establecido en el 9 CFR 417.5 (a) (3). Se reúne a todo el Equipo SAG de la planta para dar las instrucciones sobre la verificación de los PCC, desvíos de estos y el registro y seguimiento de las acciones correctivas, preventivas tomadas por la empresa.	Patricia Landaida R. Jefe de Aseguramiento de Calidad de la planta Ana Roa troncoso / Mario Pérez Poblete M.V.O. Jefes de Equipo SAG planta 06-02	Verificación de las acciones tomadas por la planta a contar del 11 de agosto de 2008, realizándose el último seguimiento en fecha 21 de noviembre, encontrándose CONFORME Reunión con equipo SAG de la planta realizada el 04 de agosto de 2008 MVO Responsables: Ana Roa Troncoso / Mario Pérez Poblete
3	Registros de monitoreo para el PCC 2 (cero tolerancia) contiene marcas de chequeo en vez de valores cuantificables (9 CFR 417.5 (a) (3) y 417.8	Se realiza el cambio de los registros de monitoreo de PCCs, considerando valores cuantitativos, determinándose un 0 si no se detectan defectos y 1 en caso de presentar defecto o no conformidad en el monitoreo	El cambio de registro aplica para el PCC 1 y PCC 2	Patricia Landaida R. Jefe de Aseguramiento de Calidad de la planta	CONFORME, 21 de noviembre de 2008. MVO Responsable verificación: Ana Roa Troncoso / Mario Pérez Poblete
4	Muestras de E.Coli genérica son tomadas en canales después de la ducha final y antes del enfriado, en vez de hacerlo sobre canales ya enfriadas, como lo requiere el FSIS (9 CFR 310.25 (a) 2 (i)	NO APLICA	NO APLICA	NO APLICA	EL MUESTREO SE REALIZA SEGÚN LO ESTIPULADO EN EL MANUAL DE PROCEDIMIENTOS PRP/MP1 Y PRP/MP 2 DEL SERVICIO AGRÍCOLA Y GANADERO
5	Los Intermediatos subcontratistas no son incluidos/examinados por el Inspector Oficial	Se realiza la corrección inmediata al inspector al cual se le detectó la falta de inspección	Se realiza reunión con todo el equipo de Inspectores (Médicos Veterinarios y Técnicos Auxiliares) para indicar las observaciones realizadas por el Inspector del FSIS durante su visita, con el fin de corregir aquellas que competen a la Inspección Oficial del sistema; además se prepara charla instructiva de auto capacitación para todo el equipo de Inspectores Oficiales	Ana Roa troncoso / Mario Pérez Poblete M.V.O. Jefes de Equipo SAG planta 06-02	CONFORME, 04 de Agosto de 2008. MVO Responsable verificación: Ana Roa Troncoso / Mario Pérez Poblete

VERIFICACION SAG INFORME FSIS PARA FDRA. ROSARIO LTDA.

Nº	Observación detectada	Acción(es) Correctiva(s)	Acción(es) Preventiva(s)	Responsable	Verificación SAG (Resultado/nombre/fecha)
1	Se observó que condensado que salía de unidades de refrigeración goteaba sobre productos cárnicos en la sala de cortes. [Referencias normativas: 9 CFR 416.13 y 9 CFR 416.2 (d)]	En el momento de detectarse el hecho personal SAG instruye en ese momento y se instaura como medida correctiva el secado permanente de la condensación por parte de la empresa encargada del aseo para evitar su goteo sobre los productos.	Empresa revisa unidades de refrigeración, su limpieza y registros de trabajo de limpieza semanal verificando su cumplimiento. Se crea el registro RO-RG-ACL-203 con fecha de 3 /09 /08 Operacional condensación (Anexo 1)con el cual se verifica 4 veces por turno la aparición de condensación, además se deja por cada turno operacionales de la empresa de aseo, encargados de monitorear y controlar durante todo el turno la aparición puntual de condensación.	Jefe del Depto. de Aseguramiento de Calidad Faenadora Rosario Ltda	Cumple Pablo Ramírez 15/09/08
2	Algunos de los registros de verificación del establecimiento no documentaban la hora en que ocurrían casos específicos o los resultados de las actividades de verificación [9 CFR 417.5(a) (3) y 9 CFR 417.8]	Se incorpora en los registros de verificación una columna para anotar el resultado de la verificación de registros y la hora en que se realizó, se adjunta (anexo 2) ejemplo de registro y lo que se incorporó.	N/A	Jefe del Depto. de Aseguramiento de Calidad Faenadora Rosario Ltda	Cumple Pablo Ramírez 18/08/08

Nº	Observación detectada	Acción(es) Correctiva(s)	Acción(es) Preventiva(s)	Responsable	Verificación SAG (Resultado/nombre/fecha)
3	Se recogieron muestras de *Escherichia coli* genérica desde canales de cerdo, luego del lavado final y antes de ingresarlas a las neveras, en lugar de canales de cerdo congeladas según lo exige el FSIS. [9 CFR 310.25 (a) (2) (ii)]	N/A	N/A	Observación: Muestreo se realiza según Procedimiento PRP/MP1, que en el punto 7.11 indica que muestreodebe ser previo al enfriado e las canales.	Pablo Ramírez 17/10/08
4	No se hicieron incisiones/exámenes a los ganglios linfáticos submaxilares por parte del inspector oficial a cargo	En el mismo momento de detectarse el hecho un MVIO corrige el accionar del TIO a cargo de la inspección de cabezas	Se induce al personal encargado de la inspección oficial de cabezas sobre la correcta manera de incidir e inspeccionar los ganglios de esta.	Pablo Ramírez Jefe de Equipo SAG	25/07/08

GOBIERNO DE CHILE
MINISTERIO DE AGRICULTURA
SAG

S/K

DIVISIÓN PROTECCIÓN PECUARIA
Fecha Ingreso 02 DIC. 2008 Nº
Unidad
Conocimiento
S. Opinión
Respuesta
Conversar
Urgente
Archivar
Observaciones

SECCION PROTECCION PECUARIA

ORD. : Nº 3779 /

ANT. : H.E./2008, SAG CONCEPCION.

MAT.: ENVIA INFORME.

CONCEPCION, 01 DIC 2008

DE : DIRECTOR REGIONAL (S) SAG REGION DEL BIOBIO.

A : JEFE DIVISION PROTECCION PECUARIA, SAG SANTIAGO.

1. Adjunto envío a usted informe de seguimiento de acciones correctivas de Agroindustrias Lomas Coloradas Ltda.., correspondiente a medidas implementadas luego de la auditoría del FSIS de Estados Unidos.

Saluda atentamente a usted,

Servicio Agrícola y Ganadero
DIRECTOR REGIONAL
VIII REGION

CESAR ESCOBAR CANDIA
MEDICO VETERINARIO
DIRECTOR REGIONAL (S) SAG
REGION DEL BIOBIO

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OF. DE PARTES CENTRAL
FOLIO SCAN 20563
2 DIC 2008
PASE A
CON ANT. SAG SIN ANT.

Dirección Regional S.A.G.
Serrano Nº 529, 2º Piso, Concepción.
Teléfonos: 2620280, 2620281. 2620282, 2620283, 2620284; Fax: 2620285
FONO DIRECTOR REGIONAL 620286.

GOBIERNO DE CHILE
MINISTERIO DE AGRICULTURA
S A G

OFICINA DE PARTES

FECHA: 26 NOV. 2008
BANDEJA..... TARJETA..... LINEA.....
PASE A: PG FECHA:

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO

H.E. Nº: 66

Concepción, 26/11/2008.

DE: JEFE EQUIPO INSPECCION SAG AGROLOMAS.

A: JEFA DE OFICINA SAG CONCEPCION

Junto con saludarle, adjunto envío informe de seguimiento de acciones correctivas de Agroindustrias Lomas Coloradas Ltda., en respuesta a observaciones de auditoria del FSIS. Este informe debe ser enviado al nivel central dirigido a la Dra. Sandra Jerez.

Sin otro particular,

Roberto Oyarzo O.
Médico Veterinario
Jefe Equipo SAG Agrolomas

INFORME DE SEGUIMIENTO AUDITORIA FSIS

Establecimiento: **AGROINDUSTRIAS LOMAS COLORADAS LTDA.**
Region: **BioBío**
Fecha de la Verificación: **24 de Noviembre 2008**
Nombre del Verificador. **ROBERTO OYARZO O.**

Observación	Accion Correctiva	Medida preventiva Implementada	Fecha de Verificacion Oficial	Nombre y Firma del Verificador Oficial
13/51				
A) La Documentacion de acciones correctivas obtenida en respuesta las deficiencias identificadas en los procedimientos preoperacionales y operacionales no icluyen los tres componentes de las acciones correctivas. (referencia regulatoria 9CFR 416.15 (b), 9CFR 416.16(a), y 9CFR 416.17)	Se definen en la planilla SSOP una descripcion de los tres componentes de las acciones correctivas segun 9CFR 416: 1.- Asergurar la apropiada disposición del producto contaminado, expurgando y sanitizando la superficie del producto. 2.- Limpiar y sanitizar la superficie de contacto directo con el producto. 3.- Prevenir la recurrencia de la contaminacion instruyendo al responsable de la limpieza y desinfeccion del lugar afectado y reevaluando el Programa SSOP si la presencia de contaminacion es recurrente.	Se revisan los procedimientos de limpieza y desinfeccion del programa SSOP, en realcion a : 1,- La concentracion y aplicación de los productos quimicos utilizados 2.- La correcta frecuencia de aplicación 3.- Se capacita a los monitores en su funcion de acuerdo al 9CFR 416.	24-11-2008	Roberto Oyarzo O.
15/51				

B) Los productos de devolución no estan incluidos en el flujograma del proceso, y los peligros de seguridad alimentaria para esta etapa del proceso no fueron identificados en el analisis de riesgo. 9CFR 417.2 (a)(3) y 417.8)	La devolución de productos se incorpora al flujograma del proceso de faena (producto final carne en vara) y desposte (producto refrigerado y congelado en cajas). Se incorpora la etapa de devolución de productos al analisis de peligro, incluyendo como PCC la devolución de producto refrigerado en caja, incorporandolo a la planilla de PCC B1.D1, control de T° del producto de devolución.	Se revisa y valida el Plan HACCP para la inclusión y analisis de peligro de la etapa de devolución de productos.	24-11-2008	Roberto Oyarzo O.
22/51				
Los registros de verificación del establecimiento no incluyen documentos de los resultados de las actividades de verificacion. 9CFR 417.5 (a)(3) and 9CFR 417.8).	Se crea e implementa instructivo para la verificación de monitoreos y registros de control, dirigido a los verificadores del plan HACCP, donde se instruye a incluir el resultado de la verificacion según 9CFR, 417.	Capacitación de los verificadores de los registros.	24-11-2008	Roberto Oyarzo O.
28/51				
Las muestras de E. coli genérico son obtenidas desde canales después del lavado final y antes de entrar en la camara de refrigeración , y no en canales bovinas refrigeradas como es requerido por el FSIS. 9CFR 310.25 (a)(2)(ii)	No cumple: Se esta realizando muestreo de E. Coli, según lo indicado en el manual de procedimientos del SAG. La cual dice que:"La muestra debe ser tomada antes de someter la canal a frio", página 31, punto número 3. del PRP/MP1	No aplica	24-11-2008	Roberto Oyarzo O.

Frigorífico Temuco

INFORME OFICIAL

Observación	Acción Correctiva implementada	Medida Preventiva implementada	Fecha de Verificación Oficial	Nombre y Firma del Verificador Oficia
A. Se detectó que varias cubetas plásticas de color blanco, utilizadas para transportar productos cárnicos, contenían residuos de productos de la producción del día anterior. Estas cubetas vacías estaban siendo guardadas en el área limpia de almacenamiento de envases. Éstas ya habían pasado por una inspección sanitaria del establecimiento y estaban listas para utilizarse. [Referencias normativas: 9 CFR 416.13 (c)]	1.- Se devolvieron las bandejas sucias al área de lavado, se retiraron los restos de carne y posteriormente se lavaron y sanitizaron para su uso en el desposte; las bandejas limpias se cubrieron inmediatamente con film plástico.	1.-Se verifica diariamente la limpieza de las bandejas antes de comenzar el desposte a través de la revisión preoperacional del área correspondiente lo cual queda registrado por el monitor de calidad en planilla de "control de limpieza línea de desposte" (SSOP1-R7): **Operativo.** 2.-Se realizará una reinstrucción al personal de aseo en lo referente a la limpieza de bandejas y a la vez a los monitores de calidad con respecto a la revisión preoperacional 3.-. Se generará una nueva revisión del SOP del proceso de desposte donde se estipulará la obligación de mantener cada bandeja con producto tapada con film plástico, lo cual se informará e instruirá al supervisor de área para su cumplimiento y se hará un cambio de planilla de SSOP donde se verificara diariamente la limpieza	CORRECTIVA 17-07-2008 PREVENTIVA 1.- 01-09-2008 2.-	Sergio Sayago
B. Se observó que condensado que salía de unidades de refrigeración goteaba sobre los productos cárnicos mencionados en las neveras para canales.	1.-Se informa e instruye al operario de cámara de esta situación quien procede al retiro inmediato de las canales que se encuentran bajo el equipo de frío a través del traspaso a la línea paralela, en ese lugar se realiza revisión de la canal por un	1.-Para evitar el goteo de la cámara afectada realizará la instalación de bandejas bajo los equipos de frío que aseguren la caída de agua dentro de ellas y el uso de un material aislante en las cañerías de los equipos de frío que llevan el agua para evitar la filtración y posterior	Correctivas: 1, 2 17-07-2008 3.- 15-08-2008	

Frigorífico Temuco

Observación	Acción Correctiva implementada	Medida Preventiva implementada	Fecha de Verificación Oficial	Nombre y Firma del Verificador Oficia
[9CFR 416.13 y 9 CFR 416.2 (d)]	monitor de calidad, en los casos donde se encontró contaminación de la canal se realizó expurgo de la zona afectada y posterior sanitización de estas, destinándose al mercado nacional. 2.-El operario de cámara a su vez secó el área afectada de la cámara con una mopa seca; este procedimiento se realizara mientras y las veces que sea necesario se implemente la acción preventiva. 3.-En el análisis realizado a esta no conformidad se determinó que el parte del goteo era resultado de una infiltración de agua proveniente del techo de la planta (goteras). Por lo tanto, se sellaron los separadores de aceites, correspondientes al sector del goteo de agua	goteo a través de estas. 2.-Se analizara el SOP de cámara y se establecerá un registro de monitoreo de condensación el que se realizara a las 24 y 48 hrs. después de ingresadas las canales a cámaras. 3.-Se realizará también un cambio de cielo en las cámaras para evitar nuevas filtraciones de agua sobre las canales. **Cámara 2→ Operativa** **Fecha puesta en marcha solución, Cámaras 1, 3, 4, 5 y 6→ 22-12-08**	Preventivas: 3.-17-11-2008 para la cámara 2	
Se recogieron muestras de Escherichia coli genérica desde canales de bovinos, luego del lavado final y antes de ingresarlas a las neveras, en lugar de canales de bovinos congelados según lo exige el FSIS. [9 CFR 310.25 (a) (2) (ii)]	Nivel central			

Frigorífico Temuco

Observación	Acción Correctiva implementada	Medida Preventiva implementada	Fecha de Verificación Oficial	Nombre y Firma del Verificador Oficia
La mantención de estructuras elevadas en dos de las cámaras para canales era deficiente con pintura suelta y descascarándose, y una serie de agujeros en el techo (cielo) a la vista. [9 CFR 416.4 y 416.17]	1.-Expurgo de elementos contaminantes y sanitización del área afectada de las canales con acido peracético a 200 ppm. 2.-Implementación de planilla de reinspección de la canal (SOP13-R1) por plan de muestreo norma chilena 44 2007 y a la vez el operario hace una inspección visual al ingreso de sala de desposte al 100% de las canales.	1.-Se instruirá al personal de cámara no colocar las canales bajo los lugares afectados de la cámara. 2.-Se realizarán cambios en los cielos de las cámaras de almacenamiento refrigerado de varas nº 1, 2, 3, 4. se instalarán termopaneles pre pintados y de esta forma se evitará el uso de pintura en los cielos que podría descascararse y además no habrán orificios debido a la superficie lisa que presenta la instalación facilitando así la limpieza e higienización del cielo de las cámaras. **Cámara 2: Operativa** **Cámaras 1, 3, 4, 5 y 6 → Fecha puesta en marcha de la solución: 22-12-08**	Correctivas: 1.-17-07-2008. 2.-21-07-2008. Preventivas: 1.-21-07-2008 2.- 17-11-2008	

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GOBIERNO DE CHILE
MINISTERIO DE AGRICULTURA
SAG

División de Protección Pecuaria

SANTIAGO, 11021

25 SEP 2008

Dr. Donald Smart, Director

USDA, FSIS, OIA, IAS

Rm. 3805-S - 1400 Independence Ave., SW

Washington, DC 20250

De mi consideración:

Adjunto envió a Ud informe elaborado por la Región de los Lagos, sobre el establecimiento FRIGOSOR, relacionado con la verificación del cumplimiento de los hallazgos detectados en la Auditoría del 14 de Julio del 2008, que dieron origen a una Notificación de Intención de Deslistamiento (NOID).
Informo a Usted que la auditoría de Verificación fue realizada 18 de Agosto del 2008.

Atentamente

CLAUDIO TERNICIER GONZALEZ
JEFE DE DIVISION DE PROTECCIÓN PECUARIA
SERVICIO AGRICOLA Y GANADERO

OVP/FAM/sjl
Distribución:
- Sr. Joseph López, Agregado Agrícola de los Estados Unidos en Chile.
- Sr. Eduardo Santos, Agregado Agrícola en Estados Unidos.
- Jefe División de Asuntos Internacionales.
- Jefe División de Protección Pecuaria.
- Oficina de Partes.
- Archivo.-

División de Protección Pecuaria. SAG / Avenida Bulnes 140, 7º Piso. Santiago
Fono: 3451400; Fax: 3451403; E-mail: propec@sag.gob.cl

190408

Courtesy translation

SANTIAGO,

Dr. Donald Smart, Director

USDA, FSIS, OIA, IAS

Rm. 3805-S - 1400 Independence Ave., SW

Washington, DC 20250

Dear Dr. Smart,

Please find attached a report prepared by Los Lagos region about establishment FRIGOSOR, related to the verification of the compliance of the findings detected on the July 14, 2008 audit, which originated a Delisting Intention Notification.

We also inform you that the verification audit was performed on August 18, 2008.
Sincerely

CLAUDIO TERNICIER GONZALEZ
JEFE DE DIVISION DE PROTECCIÓN PECUARIA
SERVICIO AGRICOLA Y GANADERO

División de Protección Pecuaria. SAG / Avenida Bulnes 140, 7° Piso. Santiago
Fono: 3451400; Fax: 3451403; E-mail: propec@sag.gob.cl

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

5JF.

Protección Pecuaria SAG Región de los Lagos

ORD N° : 2970
ANT : No Hay.
MAT : Envío Informe Oficial Respuesta de Informe FSIS.-

Puerto Montt, 26 NOV. 2008

DE: DIRECTOR REGIONAL SAG REGION DE LOS LAGOS.

A: JEFE DE DIVISION DE PROTECCION PECUARIA.

1. Junto con saludarlo, adjunto Informe Oficial de Respuesta a las No Conformidades del Establecimiento Frigorífico de Osorno N°10-26, descritas en Informe Oficial del FSIS-USA.

2.Sin otro particular, se despide Atte., de Ud.,

DIVISIÓN PROTECCIÓN PECUARIA
Ingreso: 27 NOV. 2008 N°
Conversar
Urgente
Archivar

SERVICIO AGRICOLA Y GANADERO DIRECTOR REGIONAL

WASHINGTON GUERRERO CARRILLO
MEDICO VETERINARIO
DIRECTOR REGIONAL SAG REGION DE LOS LAGOS.

SERVICIO AGRICOLA Y GANADERO JEFE SECCION PROTECCION PECUARIA

OF. DE PARTES CENTRAL
FOLIO SCAN 20452
27 NOV 2008
PASE A
CON ANT. SAG SIN ANT.

EBG/CGM/cgm
24/11/2008
Distribución:
- JEFE DE DIVISION DE PROTECCION PECUARIA.
- Enc. Regional Pecuario SAG Región de los Lagos.
- Jefa de Oficina Osorno.
- Jefe Equipo Inspección Frigosor.
- Supervisor Regional Inspección y Certificación.
- Partes (2).

Protección Pecuaria SAG Región de los Lagos / Tucapel 140, Puerto Montt
Fonos: 65-258639 / 262420 / 274208 / 274209; Fax: 252439 / 483934; E-mail: pecuaria.ptomontt@sag.gob.cl

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

INFORME VERIFICACION OBSERVACIONES AUDITORIA FSIS

- **Establecimiento:** Frigorífico de Osorno S.A.
- **Fecha :** 21 de Noviembre de 2008
- **Equipo Verificación SAG:** - Dra. Elizabeth Ojeda G. Jefa Equipo Inspección SAG

OBSERVACION	ACCION CORRECTIVA IMPLEMENTADA	MEDIDA PREVENTIVA	FECHA VERIFICACION OFICIAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICIAL
10. Se observó que bastante condensado que salía de unidades de refrigeración goteaba sobre productos bovinos en siete de las neveras para canales. (Referencia Normativa: 9 CFR 416.13 y 9 CFR 416.2 (d) Los funcionarios de inspección ordenaron una acción correctiva inmediata.	Se mejoran los sistemas de ventilación que presentaban funcionamiento inadecuado. Se mejora el manejo operativo de las áreas señaladas. Se estipula personal responsable por área y línea productiva responsable del manejo operacional en caso de existir condensación. Se instruye y difunde el Procedimiento Operacional Estándar del Manejo de Condensación a nivel de funcionarios de aseo y operadores de proceso.	Mantenimiento preventivo de sistemas de ventilación. Capacitación permanente de medidas de manejos de puertas y otras condiciones predisponentes en cámaras. Mejora en los tiempos y manejos ejecutados en los procedimientos de limpieza de sectores de procesamiento, reforzando dinámicas de secado post procesos de higienización entre otros. La empresa estableció en sus procedimientos un SOP para el manejo de producto que ha sido adulterado por algún tipo de contaminación y ha perdido su inocuidad, para lo cual queda identificado y	18.08.08 25.09.08 13.10.08 21.11.08	ELIZABETH OJEDA GODOY JEFE EQUIPO INSPECCION SANITARIA SERVICIO AGRICOLA Y GANADERO

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

OBSERVACION	ACCION CORRECTIVA IMPLEMENTADA	MEDIDA PREVENTIVA	FECHA VERIFICACION OFICIAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICIAL
		segregado en un área específica hasta que se realicen las acciones correctivas y análisis microbiológicos descritos en el Procedimiento y determinen que recuperó su condición de aptitud de consumo o de lo contrario se disponga su eliminación como producto no apto para consumo humano.		
11/51 Se detectaron canales de vacuno partidas en contacto con superficies como marcos de puerta, varas, tuberías de agua, plataformas de empleados y una escalera fija en una sala entre una de las neveras de canales y la sala de corte (9CFR 416.14 y 9 CFR 416.17) Los funcionarios de inspección ordenaron una acción correctiva inmediata.	Retiro y redistribución de superficies interpuestas en el tránsito de carnes en vara factibles de ser reubicadas o redireccionadas (plataformas, barandas de sujeción, etc.) Reinstrucción operativa al personal de empuje y maniobras de canales en tramos no automáticos, reforzando el concepto de libre tránsito y las implicancias sanitarias a nivel de operadores, para lo cual deben utilizar ganchos de acero inoxidable y direccionar las varas para evitar que tomen contacto con superficies no destinadas para ello, lo cual	Establecimiento y reforzamiento del programa permanente de manejo, empuje y manipulación de carnes en vara en los programas anuales de capacitación con énfasis a los resguardos, condiciones de almacenaje, maniobras que minimicen la posibilidad de contactos con superficies durante los manejos de productos. Reforzamiento en la capacitación del personal de mantenimiento para concretar nuevas estructuras, establecimiento de maquinarias, y dinámicas, que	18.08.08 25.09.08 13.10.08 21.11.08	[illegible]ZABETH OJEDA GODOY [illegible] INSPECCION SANITARIA [illegible] Y GANADERO

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

OBSERVACION	ACCION CORRECTIVA IMPLEMENTADA	MEDIDA PREVENTIVA	FECHA VERIFICACION OFICIAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICIAL
	fue incorporado en el SOP respectivo. Se minimizó el número de actividades ejecutadas en el sector pesaje de cuartos de canal, ampliando la superficie utilizable , evitando la posibilidad de contacto Con superficies secundarias. Se ajustó la distancia entre las plataformas y la línea de circulación de las varas, lo cual fue incorporado al SOP respectivo, garantizando la ausencia de contacto con superficies no aptas.	salvaguarden el libre tránsito de las carnes en vara, respetando los márgenes o distancias, que den garantía del libre tránsito estipulados por normativa. Mejoramiento en la coordinación de entrega, recepción y procesamiento de cuartos de canal en el área de cuarteo, evitando sobresaturar la capacidad del sector potenciando el manejo expedito que evite la predisposición de contacto con superficies secundarias.		
19/51 El establecimiento no cumplía con su frecuencia de observación directa a los procedimientos de monitoreo en conformidad con su plan de HACCP (9 CFR 417.2 (c) 7,9 CFR 417.4 y 9 CFR 417.8)	El establecimiento amplió la responsabilidad de verificación del sistema a parte del Equipo del Departamento de Aseguramiento de Calidad, para así apoyar las labores del responsable del sistema de calidad del establecimiento y poder delegar el número de actividades contempladas bajo este concepto.	El establecimiento estableció calendarización y programa anual de verificaciones, para lo cual ejecutó catastro del 100% de los diferentes ítems del Sistema de Aseguramiento de Calidad (GMP – HACCP) de forma de ordenar y mejorar la coordinación de las mismas para evitar la ausencia de verificaciones sobre algún ítem del sistema, mejorando la gestión y coordinación de dichas actividades, y evitando	18.08.08 25.09.08 13.10.08 21.11.08	ELIZABETH OJEDA GODOY JEFE EQUIPO INSPECCION SANITARIA SERVICIO AGRICOLA Y GANADERO

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

OBSERVACION	ACCION CORRECTIVA IMPLEMENTADA	MEDIDA PREVENTIVA	FECHA VERIFICACION OFICIAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICIAL
		ausencias de verificaciones.		
22/51 El establecimiento no mantenía documentos de respaldo asociados con la selección de los procedimientos de verificación y la frecuencia de dichos procedimientos. (9 CFR 417.5 y 9 CFR 417.8)	Se realizó revisión estadística *histórica del comportamiento* de los PCC, monitoreos y verificaciones existentes por línea productiva incluyendo períodos 2007 y primer semestre del 2008. Se ejecutó revisión estadística histórica de quejas del cliente durante el primer semestre del 2008 para correlacionar el comportamiento del PCC en línea. Se ejecutó revisión histórica microbiológica de productos cárnicos bajo HACCP, en iguales períodos que los anteriormente señalados. Se ejecutó programa de estudio y seguimiento de verificaciones diarias, por un período de cuatro semanas para correlacionar con los antecedentes observados en *los antecedentes* observados en los antecedentes históricos para los períodos analizados.	Reforzamiento, *establecimiento y análisis de* archivos de control estadístico que permitan apoyar permanentemente las frecuencias de verificación en uso, o sus necesidades de ajuste.	18.08.08 25.09.08 13.10.08 21.11.08	ELIZABETH OJEDA GODOY JEFE GRUPO INSPECCION SANITARIA SERVICIO AGRICOLA Y GANADERO

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

OBSERVACION	ACCION CORRECTIVA IMPLEMENTADA	MEDIDA PREVENTIVA	FECHA VERIFICACION OFICIAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICIAL
28/51 Se recogieron muestras de *Escherichia coli* genérica desde canales de bovinos, luego del lavado final y antes de ingresarlas a las neveras, en lugar de canales bovinas congeladas como lo exige el FSIS (9 CFR 310.25 (a) (2) (ii)	***ESTA NO CONFORMIDAD DEBE SER ANALIZADA Y RESPONDIDA POR DIVISION DE PROTECCION PECUARIA, YA QUE MUESTREO SE REALIZA DE ACUERDO A LO ESTABLECIDO POR MP1 Y MP2 DEL PROGRAMA DE REDUCCION DE PATOGENOS.***			
39/51 La mantención de estructuras elevadas sobre productos antes mencionados o equipos era deficiente, con acumulación de óxido en los rieles de las neveras para canales y varios agujeros en el cielo de la sala de cortes (9 CFR 416.2 y 9 CFR 416.17)	El establecimiento realiza catastro de todas las estructuras oxidadas y que requerían mantención y ejecutó la mantención correctiva. Se estableció reforzamiento de equipos de trabajo de mantenimiento con personal externo especialmente destinado a complementar el equipo de mantenimiento interno. Se estableció mantenimiento sectorizado por ítem o concepto a levantar (grupo de trabajo destinado a trabajos de eliminación de oxido, Reparación de superficies, estructuras de altura, etc.)	Se reevalúa procedimiento de limpieza de rieles, lubricación de trollers y tiempos de escurrimiento de manera de evitar el escurrimiento sobre el producto. Todas las estructuras de altura se incluyeron en catastros de equipos y/o implementos para la mantención preventiva, en la cual se aumentó la frecuencia y la autorización de los equipos y/o áreas es realizada por Personal de Aseguramiento de Calidad.	18.08.08 25.09.08 13.10.08 21.11.08	ELIZABETH OJEDA GODOY ENCARGADA INSPECCION SANITARIA SERVICIO AGRICOLA Y GANADERO

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
SAG

OBSERVACION	ACCION CORRECTIVA IMPLEMENTADA	MEDIDA PREVENTIVA	FECHA VERIFICACION OFICIAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICIAL
40 La calidad e intensidad de la iluminación eran insuficientes para realizar una inspección postmortem adecuada en la última estación de inspección (9 CFR 416.2 (c)	Se establecieron halógenos de luz blanca en todo el tramo de *inspecciones finales*, incrementando los niveles lux a nivel de piernas y paletas potenciando las condiciones para poder detectar elementos no deseados y potenciar las condiciones de inspección a nivel de la totalidad de la canal.	Se establece programa De evaluación de lux a cargo del *Departamento* de Prevención de riesgos con a lo menos una evaluación semestral de todos los puntos de proceso, de forma de mantener una evaluación objetiva de los niveles de iluminación del Establecimiento.	18.08.08 25.09.08 13.10.08 21.11.08	ELIZABETH OJEDA GODOY JEFE EQUIPO INSPECCION SANITARIA SERVICIO AGRICOLA Y GANADERO
44/47 Los empleados de la línea de producción no podían sacar o cambiarse la indumentaria de trabajo antes o después de utilizar el baño, debido al inadecuado diseño del área (9 CFR 416.2 (h) y 9 CFR 416.5)	Se ejecutó cambio de indumentaria al personal manipulador de Frigosorno que implicó uniforme de dos piezas para facilitar las maniobras de acceso a baños previo retiro del uniforme al acceder a estos sectores. Se ejecutó reinstrucción del personal del área en términos de GMP con énfasis en resguardo sanitario, manejo y condiciones de acceso del personal de áreas de proceso. Se realizaron capacitaciones en terreno con supervisores productivos y de calidad para intensificar visualización y reinstrucción al personal.	Se creó instructivo específico que fue entregado a cada manipulador de alimentos y adjuntando en la hoja de antecedentes del personal como constancia de instrucción y capacitación permanente de las condiciones de acceso del personal a baños del establecimiento. Se contempla en las capacitaciones internas del establecimiento mantener el reforzamiento permanente. En las áreas de desposte y hamburguesas se construye una nueva área de camarines y baños en el cual el flujo de	18.08.08 25.09.08 13.10.08 21.11.08	ELIZABETH OJEDA GODOY JEFE EQUIPO INSPECCION SANITARIA SERVICIO AGRICOLA Y GANADERO

GOBIERNO DE CHILE
SERVICIO AGRICOLA Y GANADERO
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OBSERVACION	ACCION CORRECTIVA IMPLEMENTADA	MEDIDA PREVENTIVA	FECHA VERIFICACION OFICIAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICIAL
		tránsito de personal queda dispuesto de manera tal que para acceder a los baños deben quitarse la ropa de trabajo.		
45 Se observaron soldaduras irregulares, interrumpidas y desiguales en las superficies de contacto con alimentos de varios contenedores de acero inoxidable, lo que podría impedir la extracción adecuada de residuos del producto y convertirse en una fuente de contaminación para éste.	La empresa realizó catastro de maquinarias, equipos y/o implementos que presentaban problemas con lo cual ejecutó una calendarización para realizar los arreglos y/o reemplazos, comenzando con los equipos y estructuras de primer contacto.	Se refuerza programa de mantenimiento preventivo de Frigosorno S.A. Se establece protocolo de evaluación productiva de equipos, implementos o maquinarias, previa instalación en líneas productivas minimizando el ingreso de equipos, estructuras y superficies no compatibles con la industria, minimizando la predisposición a estructuras cuestionables al interior de la línea. Se establece programa o curso interno de aspectos técnicos de industria de alimentos para establecer plan rotativo dentro del programa anual de capacitaciones de planta.	18.08.08 25.09.08 13.10.08 21.11.08	ELIZABETH OJEDA GODOY EFECTIVO INSPECCION SANITARIA SERVICIO AGRICOLA Y GANADERO

FRIGORIFICO DE O"HIGGINS

OBSERVACION	ACCION CORRECTIVA	MEDIDA	FECHA DE VERIFICACION OFICIAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICAL
Se observa condensación desde las estructuras superiores goteando sobre las carcasas de bovino expuestas en tres de las camaras de refrigeración de carcasas.	La empresa implementó un nuevo registro que permite verificar la presencia o ausencia de condensación en las cámaras, de tal forma de tomar las acciones correctivas que sean necesarias. Lo anterior, queda establecido en el registro de Monitoreo de La Presencia de Condensación CM-CAL-OPV-R-13.		30-07-2008	Andrea Rivera MVO
Algunas de los registros de verificacion no registran la hora en que ocurren los eventos especificos o los resultados de la verificación.	Se incorporó en el Documento HACCP Vacuno CM-CAL-HV-D-13, que todas las verificaciones realizadas en los registros de PCC deben incluir la fecha, hora y resultado de la verificación. Por otra parte, se capacitó a todo el personal responsable.		02-12-2008	Andrea Rivera MVO
La muestras de *Escherichia coli* fueron tomadas de carcasas de bovino despues del lavado final y antes de entrar a las camaras de enfriado en vez de las carcasas enfriadas como es requerido por el FSIS.	Este monitoreo esta siendo llevado según el procedimiento del programa de reducción de patógenos MP1 and MP2.			

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OBSERVACION	ACCION CORRECTIVA	MEDIDA PREVENTIVA	FECHA DE VERIFICACIÓN OFICAL	NOMBRE Y FIRMA DEL VERIFICADOR OFICAL
Se observa condensación originada de las estructuras superiores fue observada goteando directamente dentro de los tankes de chiller de pollo que contenian carcasas.	El procedimiento es desarrollado con barredor telescopico; cada vez que se presenta condensación.	Se realiza modificación estructural en la ubicación de la escotilla de descarga de hielo. Se contrató un Estudio de Ingeniería para la solución global en toda la Planta	11.08.08	Gladys Rios
La documentación de las acciones correctivas tomadas en respuesta a las deficiencias identificadas durante la sanitización preoperacional y operacional no incluye todas las tres partes de las acciones correctivas	Se incorporan en los documentos y registros: el restablecimiento de las condiciones sanitarias; la disposición eventual de productos y el reforzamiento que evite la recurrencia de desviaciones	Revisión de cumplimiento normativo con las exigencias de USA, a través del estudio detallado de los requerimientos contenidos en el 9CFR cap.III; que son atingentes a las actividades de la Planta	30.12.08	Gladys Rios
A) La documentación de las acciones correctivas tomadas en respuesta a las desviaciones de los limites criticos no incluyen las cuatro partes de las acciones correctivas.	Se describen los 4 tipos en el punto de Acciones Correctivas de cada Plan HACCP; lo que se asocia con los cuadros de gestión y los registros	Revisión de cumplimiento normativo con las exigencias de USA, a través del estudio detallado de los requerimientos contenidos en el 9CFR cap.III; que son atingentes a las actividades de la Planta	30.12.08	Gladys Rios
B) Algunos de los registros de verificación no documentan los tiempos cuando los eventos especificos ocurren o el resultado de las actividades de verificación.	Se realiza la modificación del Registro de Verificaciones Diarias (RVD)	Revisión de cumplimiento normativo con las exigencias de USA, a través del estudio detallado de los requerimientos contenidos en el 9CFR cap.III; que son atingentes a las actividades de la Planta	30.09.08	Gladys Rios
La mantención de las estructuras sobre el producto expuesto y los equipos estan descuidados, lo que se evidencia por lo numerosos agujeros el el cielo raso de la sala de corte.	Hasta la solución definitiva se realizará aseo por parte de SSGG en los techos los fines de semana.	Se realiza reparación de cielos para tapar todos los agujeros que estén descubiertos y aplicar Procedimiento de Mantención de Infraestructura	03.11.08	Gladys Rios