



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

Dr. Claudio Ternicier González  
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Departamento Proteccion Pecuaría  
Servicio Agrícola y Ganadero  
Ministry of Agriculture  
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Santiago, Chile

NOV 29 2007

Dear Dr. Ternicier:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Chile's meat inspection system March 15 through April 3, 2007. Comments received from the government of Chile have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at [donald.smart@fsis.usda.gov](mailto:donald.smart@fsis.usda.gov).

Sincerely,

Donald Smart  
Director  
International Audit Staff  
Office of International Affairs

Enclosure

**FINAL**

NOV 21 2007

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

**MARCH 15 THROUGH APRIL 3, 2007**

Food Safety and Inspection Service  
United States Department of Agriculture

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

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

## 1. INTRODUCTION

The audit took place in Chile from March 15 through April 3, 2007.

An opening meeting was held on March 15, 2007, 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 inspection system.

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

## 2. OBJECTIVE OF THE AUDIT

This was a routine audit of Chile's meat inspection system. 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 products to the United States

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one regional inspection office, one private microbiological laboratory, one beef slaughter and processing establishment, and two lamb slaughter and processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Santiago
	Regional	1	Chillan
	Local	3	Establishment level
Laboratories		1	
Meat Slaughter & Processing Establishments		3	

## 3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters, regional, and local offices. The third part involved on-site visits to three slaughter and processing establishments. The fourth part involved a visit to one private microbiological laboratory. LABSER was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella* in meat.

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*. 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 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 to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, Sanitation Performance Standards (SPS), and testing for generic *E. coli* 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, with the day of the week such collection is made rotated each week of the month, which means that in a four week month there would be a total of 20 samples collected.

##### *Salmonella* Testing Program -- Location of Samples

- *Salmonella* samples 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 bovines using the sponge (swab) method in an area 100 cm<sup>2</sup> (each site measuring 10 x 10 cm) for a total area of 400 cm<sup>2</sup>.

#### 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 two 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 two week timeframe with five samples collected for two different days each of the two 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.

#### 4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction (PR)/HACCP regulations.

#### 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:  
[http://www.fsis.usda.gov/Regulations\\_&\\_Policies/Foreign\\_Audit\\_Reports/index.asp](http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp).

The following deficiencies were identified during the follow-up initial audit of Chile's meat inspection system in July 2004:

#### Sanitation Controls

##### - SSOP

- In one establishment, the descriptions of sanitation non-compliances were incomplete.
- In one establishment, corrective actions for the disposition of possible contaminated product were incomplete.
- In one establishment, during pre-operational sanitation inspection, there was deterioration on the interior seal of the intestine spinner.

- In one establishment, during pre-operational sanitation inspection, there was grease and deterioration on the paddles of the ice chiller in the offal room.
- In one establishment, parts of several overhead cooling units in the cold storage and freezer rooms were covered with ice creating potential product contamination. However, at that time, no product was stored under the affected units.

#### Slaughter/Processing Controls

##### - HACCP Implementation

- In one establishment, there was some confusion in the understanding of the critical control point (CCP) for Zero Tolerance. However, the end result was that no carcasses were observed past the inspection point or in coolers that exhibited contamination with fecal material, ingesta or milk.

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

- In one establishment, the statistical process control for evaluating generic *Escherichia coli* (*E. coli*) had not been conducted, even though data was charted.

#### Species Verification Testing

- Species verification was not being conducted at either establishment.

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

#### Sanitation Controls

##### - 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

### - HACCP Implementation

- 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 CCP 2, 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 but because of the BSE-free status of Chile, it was not considered necessary to show that analysis 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.

## 6. MAIN FINDINGS

### 6.1 Government Oversight

The Chilean meat inspection system is centralized in the national government. The Central Competent Authority (CCA) is the Agriculture and Livestock Service, (Servicio Agrícola y Ganadero, SAG), which is part of the Ministry of Agriculture. SAG has the responsibility for carrying out Chile's meat 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 visit 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.

#### 6.1.1 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.

#### 6.1.2 Ultimate Control and Supervision

The SAG has the legal authority to supervise and enforce Chile's meat 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.

#### 6.1.3 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 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.

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

SAG has the legal authority and the responsibility to enforce U.S. requirements. Chile's meat 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

#### 6.1.5 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.

#### 6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at headquarters, one regional office, and at all three of the establishments audited. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments certified to export to the United States.
- Training records for inspectors 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.

#### 6.3.1 Audit of Regional and Local Inspection Sites

The Region VIII office in Concepción was 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 three establishments were audited.

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of three establishments; all were slaughter and processing establishments. None of these establishments were delisted or given a Notice of Intent to Delist (NOID) by SAG officials during this audit. However, the Chilean meat inspection officials had issued a suspension certificate for one of these establishments on March 16, 2007, for repeated noncompliances.

Specific deficiencies are noted in the attached individual establishment audit forms.

## 8. LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States requirements.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

The following laboratory was audited:

The LABSER Laboratory, located in Rancagua, is a private laboratory certified to perform microbiological analyses for SAG certified export establishments. Discussions about the operations of the laboratory and specific analyses were held with the laboratory director, laboratory personnel, and microbiological laboratory programs personnel from SAG. Although no procedural deficiencies were noted, there were no records available to reflect that an equivalence determination has been made by FSIS for the use of this private laboratory.

## 9. SANITATION CONTROLS

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

Based on the on-site audits of establishments, and except as noted below, 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, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

## 9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOPs in all three establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies noted in regard to implementation requirements:

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

## 9.2 SPS

The following deficiencies were noted:

- In one 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 another establishment:
  - 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.
  - The quality and intensity of the lighting in the carcass coolers was insufficient to allow inspection personnel to perform their duties.
- In the third 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.

## 10. ANIMAL DISEASE CONTROLS

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

## 11. SLAUGHTER/PROCESSING CONTROLS

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

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

### 11.1 Humane Handling and Slaughter

No deficiencies were noted.

### 11.2 HACCP Implementation.

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

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

- Monitoring:
  - In one establishment, monitoring records for CCP1 (zero tolerance) contained check marks instead of quantifiable values.
  - In another establishment, monitoring records for CCP1 and CCP2 did not follow the frequency prescribed in the written HACCP plan.
- Verification:
  - In all three establishments, verification records did not document the times when the specific events occurred.
  - In all three establishments, verification records did not document the type of the verification procedures performed and the results of the verification.
  - In two establishments, verification records did not include direct observation of monitoring activities.
  - 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.

- Corrective Actions:
  - In all three establishments, documentation of corrective actions for CCPs did not address all four parts of corrective actions.
- Instrument Calibration:
  - In one establishment, no calibration records were available for any of the thermometers being used in the establishment.

### 11.3 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 of the three slaughter establishments, except as noted below:

- In one establishment, 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.

### 11.4 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.

## 12. RESIDUE CONTROLS

During the current March/April audit of 2007, no residue laboratories were audited. Chile's National Residue Testing Plan for 2007 was being followed and was on schedule.

## 13. ENFORCEMENT CONTROLS

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

### 13.1 Daily Inspection in Establishments

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

### 13.2 Testing for *Salmonella*

*Salmonella* testing was not being properly conducted. No equivalence determination has been made to use private laboratories for *Salmonella* testing.

### 13.3 Species Verification

Species verification was being conducted as required.

### 13.4 Periodic Supervisory Reviews

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

### 13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market. Chile has not imported any livestock from other countries.

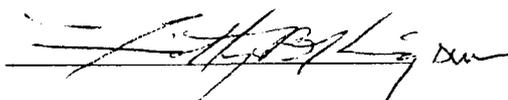
In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

## 14. CLOSING MEETING

A closing meeting was held on April 03, 2007, 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.

 Dr. Nader Memarian  
Senior Program Auditor



## 15. 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 Carnes Nuble S.A. Panamericana Norte Km. 3,  Chillan	2. AUDIT DATE 03/27/07	3. ESTABLISHMENT NO. 08-04	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

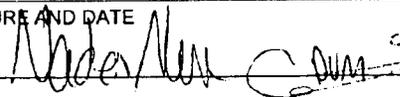
Date: 03/27/07 Est #: 08-04 (Carnes Nuble S.A. [S/P/CS]) (Chillan, Chile)

- 22/51 A) Monitoring records for CCP1 (zero tolerance for feces, ingesta, and milk) contained check marks instead of quantifiable values. [Regulatory references: 9CFR 417.5(a)(3) and 417.8]
- B) Verification records for CCP1 did not document the type of the verification procedures performed and the results of the verification. [9CFR 417.5(a)(3) and 417.8]
- C) Verification records for CCP2 (product temperature) did not include direct observation of monitoring activities. [9CFR 417.4(a)(2) and 417.8]
- D) Verification records for calibration of process-monitoring instruments did not document the times when the specific events occurred. [9CFR 417.5(a)(3) and 417.8]
- E) Documentation of corrective actions for CCP1 did not address all four parts of corrective actions. [9CFR 417.5(a)(3) and 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 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. [9CFR 416.2(b)]  
Immediate corrective actions for this deficiency were ordered by inspection service personnel.
- 40/51 The quality and intensity of the lighting in the carcass coolers was insufficient to allow inspection personnel to perform their duties. [9CFR 307.2(m)(2) and part 416.2(c)]  
Immediate corrective actions for this deficiency were ordered by inspection service personnel.

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  
Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE

 03-27-07

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Simunovic S.A. Km. 13,7 Norte  Punta Arenas	2. AUDIT DATE 03/20/07	3. ESTABLISHMENT NO. 12-01	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

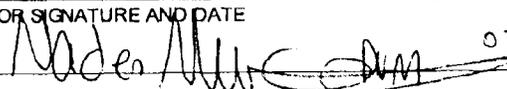
Date: 03/20/07 Est #: 12-01 (Frigorifico Simunovic S.A. [S/P/CS]) (Punta Arenas, Chile)

- 10 Condensate from cooling units was observed dripping onto exposed meat products in the carcass coolers. [Regulatory reference: 9CFR 416.13]  
Immediate corrective actions for this deficiency were ordered by inspection service personnel.
- 13/51 Documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation did not include preventive measures. [9CFR 416.15(b), 416.16(a), and 416.17]
- 22/51 A) Verification records for CCP1 (zero tolerance for feces, ingesta, and milk) did not document the type of the verification procedures and the results of the verification. [9CFR 417.5 (a)(3) and 417.8]
- B) Verification records for CCP1 did not include direct observation of monitoring activities. [9CFR 417.4(a)(2) and 417.8]
- C) Verification records for CCP1 did not document the times when the specific events occurred. [9CFR 417.5(a)(3) and 417.8]
- D) Documentation of corrective actions for CCP1 did not address all four parts of corrective actions. [9CFR 417.5(a)(3) and 417.8]
- 39/51 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. [9CFR 416.4]  
Immediate corrective actions for this deficiency were ordered by inspection service personnel.

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  
Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE

  
03-20-07

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Patagonia SA John Williams No. 1  Porvenir	2. AUDIT DATE 03/22/07	3. ESTABLISHMENT NO. 12-10	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

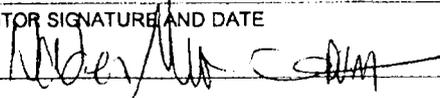
Date: 03/22/07 Est #: 12-10 (Frigorifico Patagonia SA [S/P/CS]) (Porvenir, Chile)

- 13/51 Documentation of corrective actions taken in response to deficiencies identified during pre-operational and operational sanitation did not include preventive measures. [Regulatory references: 9CFR 416.15(b), 416.16(a), and 416.17]
- 15/51 The establishment's 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. [9CFR 417.2(c)(7), 417.4(a)(2), and 417.8]
- 22/51 A) Monitoring records for CCP1 (no visible contamination on lamb carcasses in the slaughter room) and CCP2 (no visible contamination on lamb cuts in the cutting room) did not follow the frequency prescribed in the written HACCP plan. [9CFR 417.5 (a)(3) and 417.8]
- B) Verification records for CCP1 and CCP2 did not document the type of the verification procedures and the results of the verification. [9CFR 417.5(a)(3) and 417.8]
- C) Verification records for CCP1 and CCP2 did not document the times when the specific events occurred. [9CFR 417.5(a)(3) and 417.8]
- D) Documentation of corrective actions for CCP1 and CCP2 did not address all four parts of corrective actions. [9CFR 417.5(a)(3) and 417.8]
- E) No calibration records were available for any of the thermometers being used in the establishment. [9CFR 417.5(a)(3) and 417.8]
- 47 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. [9CFR 416.5(b)]
- 58 The Chilean meat inspection officials had issued a suspension certificate to this establishment on March 16, 2007, for repeated noncompliances.

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  
Nader Memarian, DVM

62. AUDITOR SIGNATURE AND DATE

 03-22-07



GOBIERNO DE CHILE  
MINISTERIO DE AGRICULTURA  
SAG

División de Protección Pecuaria

Courtesy translation

SANTIAGO,

10406

**Dr. Donald Smart**

Director

International Audit Staff.

Office of International Affairs

Food Safety and Inspection Service

Rm.2137-S

1400 Independence Ave., SW

Washington, DC 20250

- 9 OCT 2007

Dear Dr. Smart

In relation to the results of the audits done by the FSIS Auditor Dr Nader Memarian, on march 2007, I'm please to enclose the report with our analysis and commentaries, including the measures adopted to solve the finding detected.

Sincerely,



**GUILLERMO QUINTEROS CORNEJO**  
MEDICO VETERINARIO  
JEFE (S) DIVISION DE PROTECCION PECUARIA

LMB/FAM/sjf

5-10-07

DISTRIBUCION:

- Agregado Agrícola de Estados Unidos en Chile.
- Sr Eduardo Santos, Agregado Agrícola de Chile en Estados Unidos.
- Jefe de División de Asuntos Internacionales.
- Jefe División de Protección Pecuaria
- Jefe Subdepto. Industria y Tecnología Pecuaria
- Oficina de Partes
- Archivos.-



GOBIERNO DE CHILE  
MINISTERIO DE AGRICULTURA  
SAG

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Livestock Protection Division

**REPLY TO THE DRAFT OF THE FSIS AUDIT REPORT AS FROM MARCH 15th TO  
APRIL 3th, 2007.**

The reply to the report draft will address the audit carried out in March, 2007 referred to as:

Number 6 MAIN FINDINGS:

- 6.1- Supervision by the Government:

There were no deficiencies reported.

- 6.2 Central Level Audit: Headquarters audit..

There were no deficiencies reported.

- 6.3.1 Audit to Local and Region Inspection Sites.

There were no deficiencies reported.

Number 7. AUDIT TO ESTABLISHMENTS.

In connection with specific deficiencies in audited establishments, they are corrected and reported with the corresponding fulfillment report from the establishments, Annexe 1 XII Región and Annexe 2, VIII Región.

Number 8. AUDIT TO RESIDUE AND MICROBIOLOGY LABS.

About Residues, no deficiencies on procedures were noted.

With relation to Microbiology the information attaches in the Annexe 3.

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Number 9. SANITATION CONTROL.

- 9.1 SSOP

On the detected deficiency:

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

The correction with the corresponding fulfillment report is reported in Annexes 1 and 2.

- 9.2 SPS In relation to the following detected deficiencies:

- "In one 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 department, and then returning to production areas inside the establishment."
- In another establishment:
  - 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.
  - The quality and intensity of the lightning in the carcass coolers was insufficient to allow inspection personnel to perform their duties.
- In the third establishment, loose and flaking joint sealant and a number of holes in the ceiling were observed above product and food contact surface in the cutting room.

The correction and its corresponding fulfillment report is shown in Annexes 1 and 2

Number 10 ANIMAL DISEASE CONTROL.

Any deficiency was shown.



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## Number 11. SLAUGHTERING AND PROCESS CONTROL

- 11.1 Humanitarian Handling and Slaughtering:

Any deficiency was shown.

- 11.2 HACCP Implementation:

About deficiencies as detected:

- Monitoring:
  - In one establishment, monitoring records for the CCP1 (zero tolerance) contained check marks instead of quantifiable values.
  - In another establishment, monitoring records for CCP1 and CCP2 did not follow the frequency prescribed in the written HACCP plan.

The correction and its corresponding fulfillment report is shown in Annexes 1 and 2

- Verification:
  - In all three establishments, verification records did not document the times when the specific events.
  - In all three establishments, verification records did not document the type of the verification procedures performed, and the results of the verification.
  - In two establishments, verification records did not include direct observation of monitoring activities.
  - At one establishment, the written HACCP plan do not include a description of verification procedures, (calibration of process-monitoring instruments and direct observation of monitoring activities) and the frequency with which those procedures were to be performed.

The correction and its corresponding fulfillment report is shown in Annexes 1 and 2

- Corrective actions
  - In all three establishments, documentation of corrective actions for CCPs did not address all four parts of corrective actions.



GOBIERNO DE CHILE  
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Livestock Protection Division

The correction and its corresponding fulfillment report is shown in Annexes 1 and 2

- Instrument calibration:
  - In one establishment, no calibration records were available for any of the thermometers used in the establishment.

The correction and its corresponding fulfillment report is shown in Annexes 1 and 2

#### 11.3 Sampling for generic E. Coli .

- In one establishment, generic *Escherichia .coli* samples were collected from bovine carcasses after the final wash and before entering chillers, instead of chilled bovine carcasses as required by FSIS.

The correction is reported in Annexe 3

#### 11.4 Testing for *Listeria monocitogenes*

The information is reported in Annexe 3

### Number 12. RESIDUE CONTROL

There were no deficiencies reported

### Number 13. CONTROL OF DIRECTIVE APPLICATION. ENFORCEMENT.

#### 13.1 Daily inspections in establishments.

There were no deficiencies reported

#### 13.2 Salmonella sampling.

- Salmonella testing was not being properly conducted. No equivalence determination has been made to use private laboratories for *Salmonella* testing.

The correction is reported in Annexe 3

#### 13.3 Species verification.

There were no deficiencies reported

#### 13.4 Periodic Supervisory Reviews

#### 13.5 Control of inspection system

There were no deficiencies reported