



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

Dr. Hernan Rojas  
Jefe Departamento Proteccion Pecuaria  
Servicio Agricola y Ganadero  
Ministry of Agriculture  
Avda. Bulnes 140  
Piso 7  
Santiago, Chile

JUL 23 2004

Dear Dr. Rojas:

The Food Safety and Inspection Service (FSIS) completed an on-site audit of Chile's meat inspection system. The audit was conducted from December 3 through 12, 2003. The comments from Chile have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at [sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov).

Sincerely,

*for*  
Sally White, Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

cc:

Christine Sloop, Agriculture Attaché, US Embassy, Santiago

Eduardo Santos, Counselor for Agriculture, Embassy of Chile

Linda Swacina, Deputy Administrator, FSIS

Jeanne Bailey, Area Officer, FAS

Amy Winton, State Department

Karen Stuck, Assistant Administrator, OIA

Bill James, Deputy Assistant Administrator, OIA, FSIS

Donald Smart, Director, Review Staff, OPEER, FSIS

Clark Danford, Director, IEPS, OIA, FSIS

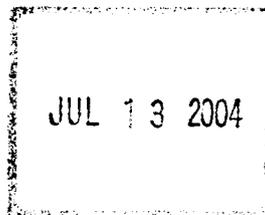
Sally White, Director, IES, OIA, FSIS

Mary Stanley, Director, IID, OIA, FSIS

Shannon McMurtrey, IES, OIA, FSIS

Country File

# FINAL



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

DECEMBER 3 through 12, 2003

Food Safety and Inspection Service  
United States Department of Agriculture

## TABLE OF CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE AUDIT
3. PROTOCOL
4. LEGAL BASIS FOR THE AUDIT
5. SUMMARY OF PREVIOUS AUDITS
6. MAIN FINDINGS
  - 6.1 Government Oversight
  - 6.2 Headquarters Audit
7. ESTABLISHMENT AUDITS
8. LABORATORY AUDITS
9. SANITATION CONTROLS
  - 9.1 SSOP
  - 9.2 Sanitation
10. ANIMAL DISEASE CONTROLS
11. SLAUGHTER/PROCESSING CONTROLS
  - 11.1 Humane Handling and Slaughter
  - 11.2 HACCP Implementation
  - 11.3 Testing for Generic *Escherichia coli*
  - 11.4 Testing for *Listeria Monocytogenes*
12. RESIDUE CONTROLS
13. ENFORCEMENT CONTROLS
  - 13.1 Daily Inspection
  - 13.2 Testing for *Salmonella*
  - 13.3 Species Verification
  - 13.4 Monthly Reviews
  - 13.5 Inspection System Controls
14. CLOSING MEETING
15. ATTACHMENTS TO THE AUDIT REPORT

## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority – Servicio Agrícola y Ganadero (SAG)
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species

## 1. INTRODUCTION

The audit took place in Chile from December 3 through 12, 2003.

An opening meeting was held on December 3, 2003, 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, Servicio Agrícola y Ganadero (SAG), and/or representatives from the regional and local inspection offices.

## 2. OBJECTIVE OF THE AUDIT

This audit was an initial audit follow-up. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter establishments certified by the CCA as meeting the requirements to export meat products to the United States.

In pursuit of the objective, the following sites were visited: one beef and one swine slaughter/processing establishment.

## 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 on-site visits to two slaughter/processing establishments.

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, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. 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, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing,

species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those that have been made by FSIS for Chile under provisions of the Sanitary/Phytosanitary Agreement. There has not been any equivalence determinations granted for Chile.

#### 4. LEGAL BASIS FOR THE AUDIT

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

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

#### 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:  
[http://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 initial audit of Chile's meat inspection system in June 2002:

##### SANITATION CONTROLS (June 2002)

- Condensation was dripping onto uncovered product in all but one of the slaughter establishments.
- The level of light intensity at inspection sites was inadequate in all slaughter establishments.
- Fecal material and/or grease were observed on carcasses, cuts of meat and conveyor belts in several establishments resulting in contamination of product.
- Excessive hair and bile contamination was observed in several swine slaughter establishments.
- SSOPs were not fully implemented in establishments.
- Pre-operational sanitation was inadequate in the one establishment where it was observed.
- Operational sanitation was not addressed in at least one establishment.

Most of the sanitation concerns found during the on-site visits to the establishments were not addressed by inspection personnel and were not corrected by the establishments.

##### SLAUGHTER/PROCESSING CONTROLS (June 2002)

The team verified that slaughter/processing controls were effectively implemented, except for the following deficiencies:

- The HACCP plans in slaughter establishments did not incorporate adequate corrective action and verification requirements.
- Bovine slaughter establishments had not implemented HACCP programs.
- Deviations of critical limits were observed in records and a corrective action was only taken on the sampled product and not for all product represented by the sample.
- The procedures were not clearly defined for control of the disposition of product that does not meet export requirements.
- There was no testing for generic *E. coli* in slaughter establishments.
- Microbial testing results were not used as an effective sanitation indicator.
- There were no guidelines for corrective action when meat products were not in compliance with microbial standards.
- There was no statistical analysis of results of microbial testing.
- There was no national program to control the use of food additives.
- There was no process for analyzing the purity of food additives.
- The requirements for control of non-food compounds (cleaning/sanitizing compounds and pesticides) in slaughter and processing establishments were not clearly defined.
- The microbial sampling plans for each type of product being produced were not identified.

Most of the slaughter/processing concerns found during the on-site visits to the establishments were not addressed by inspection personnel and were not corrected by the establishments.

#### ANIMAL DISEASE CONTROLS (June 2002)

The team verified the implementation of equivalent animal disease controls. No animals from outside of Chile will be slaughtered for use in products to be exported to the United States. Prior to shipment, fresh, frozen, raw, and cooked products will comply with USDA's Animal and Plant Health Inspection Service's (APHIS) restrictions and requirements.

#### RESIDUE CONTROLS (June 2002)

The team verified the implementation of equivalent residue controls. Chile's residue sampling plan for meat had been implemented. Residue violations were adequately addressed and farm operations function properly. Overall, Chile's national residue control program was effectively implemented, except for the following:

- The analytical methodology used for prohibited compounds was inadequate.
- The limit of detection levels for prohibited compounds were higher than the limit of detection levels U.S. laboratories are able to reach.
- There appeared to be very little testing of suspect animals.
- The objectives of the residue sampling plan were not clearly defined.
- Criteria for adding to or removing compounds from the residue testing program were not clearly defined.

- The process for re-assessing the residue plan was not defined.
- The “one-month” time frame allotted for completing analysis of samples often was not met.
- Organizational charts were not available for many of the laboratories.
- Some instruments used for conducting residue analyses had not been operational for several months. As a result, required analyses were not performed.
- The laboratories did not always use the official analytical analyses methods.
- Regulatory follow-up on violative findings was inconsistent.

### ENFORCEMENT CONTROLS (June 2002)

The team verified that the enforcement controls were effectively implemented, except for the following deficiencies:

- *Salmonella* and *E. coli* performance standards were not the same as U.S. requirements and did not target the same pathogens.
- There was no adequate control of fecal contamination on carcasses.
- There was no system in place to denature inedible product that was being transported to a rendering plant (rendering facility not on same premises as slaughter establishment).
- In one beef slaughter and two pork slaughter establishments there was no system to clearly differentiate edible product from inedible product.
- There was no clearly defined enforcement program for preventing product contamination from grease, hair, bile or fecal material in all slaughter establishments visited.
- No enforcement action was taken when serious fecal contamination of carcasses was observed in one slaughter establishment.
- The procedures for controlling the disposition of product that does not meet export requirements were not clearly defined.
- The enforcement program was not effectively implemented to correct process deviations and ensure food safety at the slaughter establishment level.

## 6. MAIN FINDINGS

### 6.1 Government Oversight

The control of Chile’s meat inspection service is under the jurisdiction of the Agriculture and Livestock Service, which specifically supervises the slaughter and inspection of meat products. The Agriculture and Livestock Service grants sanitary certificates that certify the animals, animal-origin products and by-products exports. Regional offices provide oversight of inspection in the regions with supervisors providing guidance for inspection activities.

#### 6.1.1 CCA Control Systems

The organizational structure and the staffing in both establishments appeared to be adequate.

### 6.1.2 Ultimate Control and Supervision

The Ministry of Agriculture did not have a full legal control and supervision in one of the two establishments visited.

### 6.1.3 Assignment of Competent, Qualified Inspectors

At the establishment level, the official veterinarians and the auxiliary inspectors appeared to be adequately trained, except in the pork slaughter establishment in Rosario, where the Ministry of Health delegated establishment employees for post-mortem inspection activity.

### 6.1.4 Authority and Responsibility to Enforce the Laws

In one establishment, the light at the inspection areas was not sufficient. This was a repeat finding. FSIS requires 50 foot-candles of shadow-free light at inspection surfaces. The SAG officials ordered light meters to enforce this requirement.

### 6.1.5 Adequate Administrative and Technical Support

The Ministry of Agriculture has the ability to support a third-party audit.

## 6.2 Headquarters Audit

The auditor did not conduct a review of inspection system documents at SAG headquarters or regional offices. The records review was performed in the inspection offices at the audited establishments. It focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that ask for certification to export to the United States.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.

### 6.3.1 Audit of Regional and Local Inspection Sites

Inspection offices in the pork and beef slaughter establishments were visited. The *Salmonella* testing results were evaluated according to the Chilean requirements.

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two slaughter establishments. Chile has not been approved for the export of meat products to the U.S. Therefore, neither of the establishments could have been delisted.

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

## 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

There was no visit to the residue or microbiology laboratories during this audit.

## 9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused 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 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 the two establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies noted in regard to implementation requirements:

- In one establishment, pre-operational sanitation inspection was not properly performed in the de-boning room. Grease, fat, and pieces of meat were observed on product-contact areas (conveyor belts, boning tables). The inspection service had not finished its review when the establishment started its operation (9 CFR 416.13 (a)).
- In one establishment, it was observed during pre-operational sanitation inspection that the cleaning crew was setting their buckets with cleaning liquid chemicals on the floor and then, without sanitizing, putting them on the product-contact areas (9 CFR 416.15).

- Horn removing equipment was not properly sanitized (only once, at the end of the shift) in one establishment (9 CFR 416.13).
- In one establishment, the bung operating employee contaminated the rectal cavity with a knife that was not properly sanitized (9 CFR 416.13).

## 9.2 Sanitation

The following deficiencies were noted:

- In one establishment, an open door was observed in the box storage room (9 CFR 416.2 (b)).
- In one establishment, there was insufficient light intensity at the establishment's re-inspection tables (9 CFR 416.2 (c)).
- In one establishment, inadequate drainage was observed in the suspect pen at the ante-mortem inspection area (9 CFR 416.2 (e)(f)).
- In one establishment, several deep cuts were observed on the product-contact surface of the conveyor belt, and establishment employees did not properly clean their aprons in the de-boning room (9 CFR 416.3).

## 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that 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 in June 2002.

## 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 two slaughter establishments. One establishment had adequately implemented the HACCP requirements.

- In one establishment, the HACCP program did not include all requirements for corrective action for deviations of critical limits (9 CFR 417.3 (a)(b)(c)).
- No verification (direct observation) of the monitoring of critical limits was performed in the company's HACCP program. Additionally, critical limits were not checked before the product was shipped (pre-shipment review, 9 CFR 417.4).

## 11.3 Testing for Generic *E. coli*

Chile has adopted the European Union (EU) regulatory requirements for generic *E. coli* testing, which was found to be equivalent by the FSIS. Chile was basing the number of micro HACCP tests on time (five samples every fifth day).

Testing for generic *E. coli* was properly conducted in both slaughter establishments using EU criteria (sampling locations on carcasses were in four sites, not three like the FSIS method).

## 11.4 Testing for *Listeria monocytogenes*

Establishments audited were not producing ready-to-eat products for export to the United States; therefore, no testing for *Listeria* was performed.

## 12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was residue controls. These controls were audited at the establishment level and no deficiencies were noted.

Chile's National Residue Testing Plan for 2003 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 slaughter/processing establishments.

### 13.2 Testing for *Salmonella*

Chile has adopted the EU requirements for testing for *Salmonella*, which were found to be equivalent by FSIS.

Testing for *Salmonella* was properly conducted in both slaughter establishments.

### 13.3 Species Verification

Species verification was not being conducted in these slaughter establishments.

### 13.4 Monthly Reviews

In all establishments visited, monthly supervisory reviews were being performed and documented as required.

### 13.5 Inspection System Controls

The CCA did not have controls in place for ante-mortem and post-mortem inspection procedures and dispositions in one establishment.

- In one establishment, inedible product was not properly denatured (9 CFR 325).
- In one establishment, plastic containers used for edible and inedible product were mixed together in the de-boning room (9 CFR 416.3(c)).
- In one establishment, the edible and inedible plastic containers were not properly identified and used in the slaughter room and the offal processing room (9 CFR 416.4(c)).
- In one establishment, the suspect pen in the ante-mortem inspection area had no provision for drinking water and insufficient lighting (9 CFR 313.2 (e); 307.2 (b)).
- In one establishment, ante-mortem inspection of moving animals was performed only from one side.
- In one establishment, after the bleeding operation, the knife was not sanitized between carcasses by the establishment employee (9 CFR 416.4 (a)).
- Establishment employees were designated by veterinarians from the Ministry of Health to perform head inspection. This post-mortem inspection procedure was not performed properly.

Chile will only export product from animals raised in their own country.

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

#### 14. CLOSING MEETING

A closing meeting was held on December 11, 2003, in Santiago, Chile, 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.

Oto Urban  
International Audit Staff Officer

*Mr. Mangar H. Chaudry*

## 15. ATTACHMENTS

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

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Feanadora Rosario LTDA, Rosario	2. AUDIT DATE 12-04-03	3. ESTABLISHMENT NO. 06-06	4. NAME OF COUNTRY Chile
5. NAME OF AUDITOR(S) Dr. Oto Urban		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	O
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.	X	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<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	X
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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	X
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.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	X
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	X
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	X
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:

Chile Est. 05-06 12-04-03

10. Preoperational sanitation was not properly performed in the de-boning room. Grease, fat, and pieces of meat were observed on the product contact areas (conveyor belts, boning tables). Inspection service had not finished its checking, while in the mean time establishment started its operation. These deficient procedures were discussed with the establishment officials and the inspection service. Both promised to correct these deficiencies.

12. It was observed during the preoperational sanitation that the cleaning crew was setting their buckets with cleaning liquid chemicals on the floor and then without sanitizing them on the product contact area. This deficiency was corrected for the moment by the establishment but it was observed again during the following break.

19/51. No verification (direct observation) of the monitoring of critical limits was performed in the company's HACCP program. Additionally, critical limits were not checked before the product was shipped (pre-shipment review). The establishment promised to correct these deficiencies.

20/51. The establishment's HACCP program did not include all requirements for corrective action for CCPs. This deficiency was discussed with the establishment management that promised to correct it.

38. Door was observed to be open to the box storage room. This deficiency was immediately corrected by the establishment management.

40/51. There was no sufficient illumination at the establishment's re-inspection tables. This deficiency was scheduled for correction by the establishment officials.

42/51. No proper drainage was observed in the suspect pen at the ante-mortem inspection. This deficiency was scheduled for the corrective action by the establishment officials.

45. Several deep cuts were observed on the conveyor belt and the establishment employees did not properly cleaned their aprons in the de-boning room area.

48. Inedible product was not properly denatured in the outside premises.

48/51. Plastic containers used for edible and inedible product were mixed together in the de-boning room. This deficiency was corrected by the establishment officials.

54/51. Ante-mortem inspection of moving animals was performed only from the one side.

55. After bleeding operation, the knife was not sanitized between carcasses by the establishment employee. The operator changed his procedure after instructed by the IIC.

55. Establishment employees were designated by Veterinarians from Ministry of Health to perform head inspection. This post-mortem inspection procedure was not performed properly.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

 2/10/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Carnes Nuble S.A. Panamericana Norte km 3 Chillan – VIII Region, Chile	2. AUDIT DATE 12-09-03	3. ESTABLISHMENT NO. 08-04	4. NAME OF COUNTRY Chile
5. NAME OF AUDITOR(S) Dr. Oto Urban		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	O
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 SSOPs 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	
<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	X
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.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	X
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	X
<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			

80. Observation of the Establishment:

Chile Est. 08-04 12-09-03

10/51 Horn removing equipment was not properly sanitized (only once, at the end of the shift). This deficiency was scheduled for corrective action by the inspection service.

10/51 Bung operating employee contaminated the rectal cavity with knife which was not properly sanitized.

48/51 Edible and inedible plastic containers were not properly identified and used in some cases in the slaughter room and the offal processing room. The establishment employee promised to correct this deficiency.

54/51 Suspect pen at the ante-mortem inspection, did not have proper installation of drinking water and sufficient light. This deficiency was scheduled for correction by the establishment maintenance supervisor,

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

*Dr. Mangoo H. Chaudry* 2/15/04

Official Translations

GOVERNMENT OF CHILE  
Agriculture Service

Santiago, April 26, 2004 \* 3986

Doctor Karen Stuck  
Acting Deputy Assistant Administrator  
Office of International Affairs  
Food Safety and Inspection Service  
U.S. Department of Agriculture  
1400 Independence Ave.  
Washington, D.C., 20250

Dear Doctor Stuck:

In reference to the results of the audit conducted by Dr. Urban in December of 2003, I am pleased to attach the analysis and comments of the said report, along with the measures adopted in order to solve the problems found in the audit. This way, we will be prepared for the next visit scheduled for your summer season (June or July 2004).

In addition, for your convenience, these documents are being translated and will be sent to you soon.

Sincerely,

HERNAN ROJAS OLAVARRIA  
Veterinarian (Signed)  
Chief of the Department of Animal Protection

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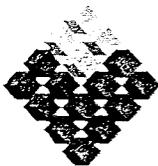
c/c

- Mrs. Christine Sloop  
- Mr. Eduardo Santos

OYP/CPA/CTG/MAM (four initials)  
26042004

Handwritten: IES 348  
BW 5/25/04

01801AAA  
5-25-04  
emc



GOBIERNO DE CHILE  
SERVICIO AGRÍCOLA Y GANADERO

Courtesy Translation

Santiago,

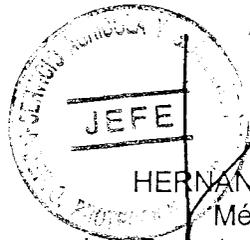
Dr. Karen Stuck  
Acting Deputy Assistant Administrator  
Office of International Affairs  
Food Safety and Inspection Service  
U.S. Department of Agriculture  
1400 Independence Ave.  
Washington, D.C., 20250

Dear Dr Stuck:

In relation to the results of the audit made by Dr. Urban on December 2003, I'm glad to enclose you the analysis and comments about the report, with the measures we have taken to correct all the deficiencies found by the audit. With them we will be prepared for the next visit that it will be in your next summer (June or July, 2004).

I also inform you that these documents we are sending you, they are now being translated and they will be sent in the next days, for a better comprehension

Sincerely yours



  
HERNÁN ROJAS OLAVARRÍA  
Médico Veterinario  
Jefe Departamento Protección Pecuaria

ANSWER TO THE FINAL DRAFT OF THE AUDIT ON THE RED  
MEATS INSPECTION SYSTEM OF CHILE,  
CONDUCTED IN DECEMBER OF 2003

Agriculture Service  
Ministry of Agriculture of Chile.

## **Answers to the observations found:**

### 6.1.2. Control and supervision.

On December 15, 2003 it was implemented in the Sixth Region the Veterinarian inspection delegation at the export facilities from the Ministry of Health to the Ministry of Agriculture; therefore, beginning on that date, the supervision and control in all export facilities are the responsibility of the SAG (Servicio Agrícola y Ganadero). (Annex N° 1)

### 6.1.3. Assignment of qualified and competent inspectors.

Once the SAG took control of the inspection at the export facilities, the SAG decided to hire the professional and technical personnel, duly trained and experienced, to perform the inspection tasks. These functionaries are hired under contract and paid by the Official Service.

### 6.1.4 Authority and responsibility for the verification of the regulations.

The SAG provided the equipment to control and verify the light intensity in the inspection areas. (Annex N° 2)

## 9.1 SSOP.

Once the delegation of the inspection from the Ministry of Health to the SAG is implemented, the official teams at the facilities shall follow the "Manual for Inspection and Certification of Meats for Export Procedures" in which it is explicitly indicated the procedure for the pre-operational cleanliness and the utilization of a written authorization for the beginning of the processes of sacrifice and cutting up,

The application of the formats of said manual was reiterated through the Circular N° 219 of April 23, 2004. In that Circular it is pointed out that the inspection teams shall instruct the facility personnel to improve and go deeper in their own controls of the procedures and the results of the pre-operational cleanliness. (Annex 3)

Through faxes N° 419 and 420 of March 16, 2004, the inspection teams were notified that the observation of the application of incorrect practices in the processes of evisceration and dehorning, ought to be notified to the companies as a non-conformity and the inspection teams ought to verify the application of corrective measures and report the closing of these non-conformities. (Annex 4)

## 9.2 Sanitization.

Through the faxes N° 419 and 420 above mentioned, the Regional Administrations were notified about the specific observations on the facilities audited, and they were requested to inform of the corrections made on the observations pointed during the visit and in the report. We attach a copy of the report of the correction of non-conformities detected.

## 11.2 Implementation of the HACCP

Through Circular N° 219, the SAG instructed the official inspection teams at each facility and the regional supervisors that, in the documentation of the critical points of contact, when reporting the corrective measures, the following points must to be included:

- a.- The identification of the cause of deviation.
- b.- The correction action implemented in order to control the critical point of control.
- c.- The measures established to prevent the deviation from occurring again.
- d.- The measures taken in order to prevent that an altered product or one that is hazardous to the health, caused by the deviation from the critical point, be commercialized.

In addition, the official inspection team was instructed to verify the compliance with these four principles by the products before their delivery.

Notwithstanding that the permanent supervision of the teams of Assurance of the company quality and the verification of the monitoring of the critical points of control, is considered among the activities of the SAG, the official inspection teams were instructed to establish a stamp and signature on the data sheets of the company for their monitoring.

Through Circular N° 219, the official inspection teams were instructed to inform the companies that for each delivery of products they must present a checking list with the results of the monitoring of the critical points of control for the purpose of verifying that the products to be shipped have been manufactured in controlled conditions of innocuousness. (Annex 3)

## 13.5 Inspection Procedures.

Once the inspection teams at the VI Region have been implemented, the Department of Animal Production of the SAG has developed audits in the facilities for the purpose of determining the correct application of Ante-mortem and Post-mortem procedures and methodologies, which are only performed by official personnel.

At the export facilities of the Sixth Region, the inspection and certification is currently under the responsibility of the SAG. (Documents and a report on the VI Region are attached). (Annex 1)

Through the Circular N° 219 it was reiterated to the Regional Administrations that the verification of the correct procedures of ante-mortem and post-mortem inspection must be included within the supervision duties. (Annex 3)

Through the Fax N° 638 of April 23, 1004, it was requested to the Regional Administrations to evaluate the light intensity on the inspection sites in compliance with the FSIS (50 Foot-Candles) requirements. (Annex 2)

Equipment to measure the light intensity has been made available to the Regional Supervisors for them to include the verification of the light intensity on the inspection sites within their monthly supervision routine.

Santiago, Chile, April 26, 2004

# ANNEX 1

Seal stamped reading: "National Administration -2 (illegible) 2004 - Reg. N° 36987"

Government of Chile  
Agriculture Service  
Sixth Region

Letter: 2083  
ANT.: None  
Subject: Report on implementation as indicated.

Rancagua, December 29, 2003

From: MR. PATRICIO E. ESTRADA URIBE  
REGIONAL DIRECTOR S.A.G. VI REGION

To: MR. HERNAN ROJAS O.  
CHIEF OF THE DEPARTMENT OF ANIMAL PROTECTION

Please find attached the Report N° 2071, that notifies of the implementation of the conventions of delegation and technical-administrative structure for the animal exportation.

It shows the current staff at each plant, the distribution of the Slaughterhouses with their Administrative offices by sector and the professional in support of the Regional supervision team.

Sincerely,

PATRICIO E. ESTRADA URIBE  
Agricultural Engineer (Signed)  
Director S.A.G. VI Region

Seal stamped reading: (illegible)

PEEU/kza.  
Sent to:  
General Secretary S.A.G.  
Environmental Health Director, Rancagua  
Mr. Seremi of Agriculture  
Referred.  
Off. Of Pailes

Seal stamped reading: (illegible)

Government of Chile  
Agriculture Service  
SAG

Regional Administration, SAG VI Region/ Cuevas 480, Rancagua  
Telephone: 221109; Fax: 223803; E-mail: patricio.estrada@sag.gob.cl

ORD.: 2071  
ANT.: None  
Subject: Report on the implementation of conventions  
of delegation and the technical-administrative  
structure for the exportation of animals.  
Rancagua, December 24, 2003

From: Mr. PATRICIO ESTRADA URIBE  
DIRECTOR S.A.G. VI REGION

To: THE CHIEFS OF THE S.A.G. OFFICES VI REGION  
S.A.G. REGIONAL AGENTS VI REGION

In reference to the inspection and certification of meat products for export originated in the processing plants in the VI region, currently subject to the Convention of Delegation of the Veterinary Inspection with the O'Higgins Health Service, I hereby notify you that:

1. The following is the current roster by plant:

PROCESSING PLANT: LO MIRANDA LTDA. (06-02)

PORK MEAT

Last name	Mother's Maiden Name	Name	Position
CABELLOS	REYES	Alejandra	Technician
ESPINOZA	LUCERO	Christian	Technician
LOPEZ	SALAZAR	Marlene	Technician
MELLADO	BARRA	Victor	Veterinarian
MERINO	GUTIERREZ	Glenda	Veterinarian
OLGUIN	CARRASCO	Luis	Veterinarian
OSORIO	REBOLLEDO	Manuel	Technician
PEREZ	JRIBARREN	Macarena	Technician
PEREZ	PINAR	Igor	Veterinarian
PEREZ	POBLETE	Mario	Veterinarian
QUINTEROS	GONZALEZ	Emilio	Technician
VASQUEZ	PACHECO	Rolando	Technician
VILLAVICENCIO	GAETE	Hugo	Technician
ZUNIGA	LIZAMA	Enrique	Veterinarian

PROCESSING PLANT: ROSARIO LTDA. (06-08)

PORK MEAT

Last name	Mother's Maiden Name	Name	Position
ACEVEDO	CHAMORRÓ	Patricia	Veterinarian
BAEZ	ESPINOZA	Cristian	Technician
CANDIA	SAN JUAN	Rodrigo	Technician
DIAZ	PICHUANTE	Maria	Technician
ECHEGARAY	CHAVEZ	Miriam	Technician
FLORES	JABRE	Ricardo	Technician
LEIVA	TORRES	Mario	Veterinarian
MANCILLA	GUERRERO	Eugenio	Technician
MANRIQUEZ	ZUNIGA	Marisol	Veterinarian
ORTEGA	ROJAS	Jaime	Veterinarian
PINA	CORNEJO	Waldo	Veterinarian
RIQUELME	GONZALEZ	Cristian	Technician
ROJAS	CORNEJO	Soledad	Veterinarian
SOTO	VALENZUELA	Enzo	Technician

PROCESSING PLANT: EL MILAGRO S.A. (06-03)

PORK MEATS

Last name	Mother's Maiden Name	Name	Position
FIELDHOUSE	ALARCON	Guillermo	Veterinarian
GONZALEZ	VILLAR	Roberto	Technician
LEYTON	LABARCA	Gustavo	Veterinarian
TORRES	MIRANDA	Humberto	Technician

PROCESSING PLANT: SAN VICENTE LTDA. (06-08)

CHICKEN MEATS

Last name	Mother's Maiden Name	Name	Position
BUSTOS	SALAZAR	Paulo	Veterinarian
CARIS	FUENTES	Leonardo	Technician
CORNEJO	DONOSO	Juan	Technician
GONZALEZ	ESCOBAR	Ivan	Technician
GORRINO	UGALDE	Guillermo	Veterinarian
RODRIGUEZ	FUENTES	Marcelo	Veterinarian
SAAVEDRA	MORALES	Jose	Technician

Note: The persons whose names are inside a frame are Team Chiefs.

2. Due to their geographic location, the Processing Plants: Lo Miranda Ltda., Rosario Ltda. and El Milagro S.A. are to report administratively to the Rancagua SAG sector, and the San Vicente Ltda. Processing Plant to the San Vicente sector.

3. The regional supervision team counts with the support of Mr. Diego RAMIREZ, a supervisor veterinarian, who can be momentarily located at the San Vicente SAG office at: calle Walter Martínez 149, 2° piso, San Vicente T.T., telephone: 5711530, mobile: 0-97423478

Sincerely,

Seal stamped reading: "Agriculture Service - SAG - Director"

PATRICIO ESTRADA URIBE (Signed)  
AGRICULTURAL ENGINEER  
REGIONAL DIRECTOR, SAG VI REGION

MRT

SENT TO:

- The indicated one
- Chiefs of Plant Inspection Teams
- Chief of the Department of Animal Protection

United States Department of Agriculture  
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Peanadora Rosario LTDA, Rosario	2. AUDIT DATE 12-04-03	3. ESTABLISHMENT NO. 06-06	4. NAME OF COUNTRY Chile
5. NAME OF AUDITOR(S) Dr. Oto Urban		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	O
9. Signed and dated SSOP, by on-site or overseas authority.			35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			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	X
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils	X
18. Monitoring of HACCP plan.			46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X		47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X		48. Condemned Product Control	X
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements	
22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing	
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage	
23. Labeling - Product Standards	O		51. Enforcement	X
24. Labeling - Net Weights	O		52. Humane Handling	
25. General Labeling	O		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQU/Pork Skins/Moisture)	O		54. Ante Mortem Inspection	X
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection	X
27. Written Procedures			Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis			56. European Community Directives	O
29. Records			57. Monthly Review	
Salmonella Performance Standards - Basic Requirements			58.	
30. Corrective Actions			59.	
31. Reassessment				
32. Written Assurance				

60. Observation of the Establishment

Chile Est. 06-06 12-04-03

10. Preoperational sanitation was not properly performed in the de-boning room. Grease, fat, and pieces of meat were observed on the product contact areas (conveyor belts, boning tables). Inspection service had not finished its checking, while in the mean time establishment started its operation. These deficient procedures were discussed with the establishment officials and the inspection service. Both promised to correct these deficiencies.

12. It was observed during the preoperational sanitation that the cleaning crew was setting their buckets with cleaning liquid chemicals on the floor and then without sanitizing them on the product contact area. This deficiency was corrected for the moment by the establishment but it was observed again during the following break.

19/51. No verification (direct observation) of the monitoring of critical limits was performed in the company's HACCP program. Additionally, critical limits were not checked before the product was shipped (pre-shipment review). The establishment promised to correct these deficiencies.

20/51. The establishment's HACCP program did not include all requirements for corrective action for CCPs. This deficiency was discussed with the establishment management that promised to correct it.

38. Door was observed to be open to the box storage room. This deficiency was immediately corrected by the establishment management.

40/51. There was no sufficient illumination at the establishment's re-inspection tables. This deficiency was scheduled for correction by the establishment officials.

42/51. No proper drainage was observed in the suspect pen at the ante-mortem inspection. This deficiency was scheduled for the corrective action by the establishment officials.

45. Several deep cuts were observed on the conveyor belt and the establishment employees did not properly cleaned their aprons in the de-boning room area.

48. Inedible product was not properly denatured in the outside premises.

48/51. Plastic containers used for edible and inedible product were mixed together in the de-boning room. This deficiency was corrected by the establishment officials.

54/51. Ante-mortem inspection of moving animals was performed only from the one side.

55. After bleeding operation, the knife was not sanitized between carcasses by the establishment employee. The operator changed his procedure after instructed by the IIC.

55. Establishment employees were designated by Veterinarians from Ministry of Health to perform head inspection. This post-mortem inspection procedure was not performed properly.

61. NAME OF AUDITOR  
Dr. Otto Urban

62. AUDITOR SIGNATURE AND DATE

*Dr. Manjiv H. Chaudry* 2/12/04

SOLUTION PROPOSALS TO THE OBSERVATIONS DETECTED DURING  
THE FSIS AUDIT ON THE ROSARIO LTDA. PROCESSING PLANT  
(Reg SAG No: 06-06).

**Point 10. Implementation of SSOP, including monitoring and inspection.**

**Observation:** The sanitization process was not correctly performed since the inspection and corrections were not completed at the beginning of the cutting up.

**Explanation:** The quality of the cleanliness at the minute of the inspection was adequate; some deficiencies were found, which were corrected; regarding the start of operations, it is reported that there were several rods (sic) not equalized awaiting authorization.

**Solution:** The equalizing chamber is currently closed and will so remain until further authorization from SAG, accompanied by a registry of cutting up authorization; in addition, a cleaning team from a company was permanently incorporated as per the revision of SAG, to take the corrective actions as needed; and the night shift pre-operational cleaning roster was increased by 30%.

**Point 12. Corrective actions when the SOOP have failed to prevent the direct contamination or adulteration of the product.**

**Observation:** During the pre-operational process of sanitization it was observed that the cleaning team placed on the floor the pails containing chemicals, and afterwards, without sanitizing them, the pails were placed on contact areas; this deficiency was corrected at that moment, but it was again observed on the next stop.

**Explanation:** the wooden rollers where the pails were placed were afterwards sanitized.

**Solution:** In order to reduce the contamination, bags are placed between the wooden rollers and the pails.

**Point 19/51. Verification and validation of the HACCP plan.**

**Observation:** Non-verification (direct observation) of the monitoring of the critical limits of the company's HACCP program. In addition, the critical limits were not checked before the shipment of the product (pre-shipment control).

**Explanation:** Due to the lack of understanding of what the auditor requested, at that moment the MVO did not show the auditors the daily verification sheets of PCCs, which has always been used and kept with the registries updated. In addition, the SAG did not make available the verification registry showing that the products being shipped had passed within the critical limits.

**Solution:** The daily control sheets of PCCs continues to be used and, in addition, a new sheet: *monthly summary registry of SAG official verifications* is in use, to be considered in the approval of the products to be shipped.

**Point 20/51. Corrective actions written in HACCP plan.**

**Observation:** the HACCP program at the plant does not include all the requirements for the corrective actions of the PCCs.

**Explanation:** This issue remains to be confirmed since all the HACCP updating was done following the FSIS requirements. This subject was checked by the Dr. Blair, consultant, and found to be satisfactory.

**Solution:** The company is committed to re-evaluating its documentary HACCP system.

**Point 38. Plague control.**

**Observation:** Open boxes were observed at the door of the storage building.

**Explanation:** At the moment of the inspection, boxes were being received and shipped at the same time.

**Solution:** The procedure of closing this door immediately after the reception of materials was established; likewise, weather stripping is placed on the doors to keep them sealed.

**Point 40/51. Lights.**

**Observation:** Insufficient light on re-inspection tables.

**Explanation:** The table was installed for SAG work and utilized for the inspection of boxes to be shipped; due to its position inside the room, the amount of Lux received was insufficient for the inspection.

**Solution:** Lights were installed at the inspection table.

In addition, the lighting in all points of inspection is being checked to determine its compliance with the standards required by FSIS (500 lux). The company is committed to increasing the light intensity on those places that are not in compliance with the standards.

**Point 42/51. Plumbing**

**Observation:** Lack an adequate drainage in the corrals with animals found to be suspects during the ante-mortem inspection.

**Explanation:** This matter had not been considered; according to FSIS, the water runs toward the hallway where the veterinarians walk during the inspection; therefore, they may spread the contamination to the rest of the corrals.

**Solution:** The company plans the construction of drainage in the corrals. Estimated completion time: the month of April, 2004.

**Point 45. Equipment and utensils.**

**Observation:** Several deep cuts were observed on the cutting up conveyor belt; therefore, the sanitary conditions of them are inappropriate.

**Explanation:** This observation was made on the cutting up main conveyor belt where the saws are located, which are causing the damage.

**Solution:** New belts will be installed. In addition, the belts shall be replaced every three months or as established by the company's inspection in agreement with the SAG.

**Point 48. Control of the unqualified product.**

**Observation:** The product that has been determined to be unqualified is not denaturalized.

**Explanation:** The control of seized products was the responsibility of the Health Service. They were in control of the containers, seals, dead animals, etc., with no procedure for the marking or denaturalization of the product.

**Solution:** Currently, the matter is being controlled by the SAG and the procedure to denaturalize the unqualified product with methylene blue before being taken to the seizure container, is being implemented.

**Point 48/51. Control of the unqualified product.**

**Observation:** Plastic containers used for qualified and unqualified products are mixed at the cutting up stage.

**Explanation:** The auditor might have misunderstood the concept that the plant has regarding the qualified, unsatisfactory and unqualified products, since there is a separation of these products. There are shelves where trays containing unqualified products are stored (yellow trays), separated from the unsatisfactory products which are located at the end of the lines (white trays). In addition, there is a registry per shift where a record of unsatisfactory products is kept.

**Solution:** The company will train the personnel in charge regarding the unqualified and non-satisfactory products.

**Point 54/51. Ante-mortem inspection.**

**Observation:** The ante-mortem inspection of animals in movement is performed on one side only.

**Explanation:** This task was performed by the Health Service personnel without considering foreign standards regulating the inspection.

**Solution:** This task is currently performed by the SAG which will take the precaution of conducting a thorough inspection at the unloading stage. In addition, to be in compliance with this requirement, a mirror shall be installed at the site in order to examine the pig on both sides.

**Point 55. Post mortem inspection.**

**Observation:** The knife utilized for the bleeding operation is not sanitized between each rod by the plant employees.

**Explanation:** At the moment of the inspection, the Rota steck system, which ensures the sterilization of each knife, was not working. The bleeding was performed by a manual knife that was sanitized once every three pigs.

**Solution:** The following procedure is implemented: Each time a manual knife needs to be used, it shall be sterilized after each pig. The company is training the employees for that purpose.

**Point 55. Post mortem inspection.**

**Observation:** Certain employees at the facilities, as designated by the veterinarians from the Ministry of Health conduct the inspection of heads. This post-mortem inspection procedure was found inappropriate.

**Explanation:** To the date of the inspection, the post-mortem inspection was being performed by the Health Service that, in the inspection, did not consider the personnel for the inspection of heads. As a "temporary solution", it was decided to place the company's personnel under the supervision of the Health Service, in such a manner that, if something abnormal were found, they would immediately notify the veterinarian on duty.

**Solution:** The inspection system is currently under the control of the SAG and personal from SAG (one technician) for the inspection of heads, has been made permanently available to them.

Henry Gonzalez J. (Signed)  
Animal Regional Agent  
SAG VI Region.

Diego Ramirez A. (Signed)  
Animal Export Supervisor  
SAG. VI Region.

Rancagua, March 17, 2004.

## ANNEX 2

GOVERNMENT OF CHILE  
Agriculture Services  
SAG

Department of Animal Protection, SAG / Avenida Bulnes 140, 7° piso, Santiago  
Telephone: 696 7311; Fax: 671 6184; E-mail: propec@sag.gob.cl

Fax N°: 638		/ Date: April 23, 2004	
N° of pages including cover sheet:			
To: The VI, VIII and RM Regional Directors			
Telephone:		/ Fax:	
Attn.: Animal Regional Agents			
Subject: Light Intensity Information Request			
Sent by: Chief of the Department of Animal Protection			
Urgent XXX	Information	Answer XXX	

By the present letter I request you to inform this Department regarding the light intensity at the points of inspection, expressed in Foot Candle units, at the processing plants in your region.

The measurements at the Red Meats (Bovine and Swine) and White Meats (Chicken and Turkey) Processing Plants, are to be made at each point of inspection at the level of the object being inspected (organ or carcass).

This information is essential to answer the report on the Audit to the FSIS inspection system conducted in December 2003.

Sincerely,

MARIA LUZ DENTONE SILVA (Signed)  
VETERINARIAN  
CHIEF (S) OF THE DEPARTMENT OF ANIMAL PROTECTION

Seal stamped reading: (Illegible)

P/SJF (Initials)

# ANNEX 3

GOVERNMENT OF CHILE  
Agriculture Service

Circ. : N° 219  
ANT. : None  
SUB. : NEW INSTRUCTIONS AS  
INDICATED

SANTIAGO April 23, 2004

From: CHIEF OF THE DEPARTMENT OF ANIMAL PROTECTION

To: SAG REGIONAL DIRECTORS OF THE I TO THE XII AND RM.

As a conclusion to the analysis of the observations made in the FSIS audit of December 2003, the Animal Protection Department of the SAG has established the following instruction to be implemented by the facilities participating in the procedures of the U.S.A. red meat inspection system, of the SAG.

**1. Regarding the controls of cleanliness and disinfection, the SAG inspection teams:**

- 1.1 Shall verify the correct working conditions of the SSOP controls as implemented by the company.
- 1.2 Shall require that in the company's training program, the employee training on cleanliness and disinfection procedures be included, in order to ensure the correct application of them.
- 1.3 Shall inform and notify to the company that the SSOP ought to specifically consider, in addition, the activities of pre-operational and operational controls, which shall be verified by the designated SAG inspection team.
- 1.4 Shall apply the instructions indicated in the "Manual of Inspection and Certification of Red Meats for Export Procedures", regarding the: "Daily pre-operational report on plant hygiene", "authorization to begin sacrifice" and "authorization to begin cutting up".
- 1.5 Shall inform the company that the corrective actions of the SSOP Program shall include preventive measures in order to prevent the repetition of the non-satisfactory procedures detected.
- 1.6 Shall notify the company of the renovation of any decayed material that hinders an adequate cleaning and disinfection of it.

**2. Regarding the implementation of the HACCP system, the SAG permanent inspection teams:**

- 2.1 Shall inform the company that the corrective actions implemented, before the deviations of the PCC, shall include the following four criteria to make the follow-up and correct the non-satisfactory procedures.
  - a. Identification and elimination of the cause of deviation.

- b. Verification of the return of the PCC control, after the application of the corrective action.
- c. To establish preventive actions aimed at preventing a new occurrence of the deviation.
- d. To establish the procedures of control and verification to ensure that the products unqualified for the human consumption, manufactured during the deviation of the PCC, are not shipped to the market.

2.2 Shall verify that the company implements the procedure indicated at 2.1.

2.3 Shall registry their activities of verification of the HACCP plan, implemented by the company, through the seal and initials of the inspector on the company's monitoring registries.

2.4 Shall require the company to present, for each shipment of products, a registry of the monitoring of the PCC, which shall be verified by the official team.

### **3. Regarding the Inspection Procedures:**

3.1 The regional supervisor of the inspection teams shall supervise and evaluate the correct application of the inspection procedures as established in the "Manual of Inspection and Certification of Red Meats for Export Procedures".

3.2 The regional supervisor of the inspection teams shall supervise and evaluate the correct application of the procedure instructions established by the Service, through manuals and circulars.

Sincerely,

MARIA LUZ DENTONE SILVA (Signed)  
VETERINARIAN  
CHIEF(S) OF THE DEPARTMENT OF ANIMAL PROTECTION

Seal stamped reading: "Agriculture Service - Department of Animal Protection - Deputy Chief"

OVP/DGM/SJF (Initials)

Sent to:

- SAG Regional Director of the I to the XII and RM.
- Animal Regional Agent of the I to the XII and RM.
- Department of Animal Protection
- File

# ANNEX 4

GOVERNMENT OF CHILE  
Agriculture Services  
SAG

Department of Animal Protection, SAG / Avenida Bulnes 140, 7° piso, Santiago  
Telephone: 696 7311; Fax: 671 6184; E-mail: propec@sag.gob.cl

Fax N°: 420		/ Date: March 16, 1004	
N° of pages including cover sheet: 3			
To: THE SAG REGIONAL DIRECTOR, VIII REGION			
Telephone:		/ Fax:	
Attn.: Animal Regional Agent			
Subject: Send FSIS Audit Report			
Sent by: Chief of the Department of Animal Protection			
Urgent		Information X	Answer

Please find enclosed the audit report to the red meats inspection system, conducted at the Carnes Nuble processing plant by personal of the FSIS in December of 2003.

I will appreciate your information regarding the progress made towards the correction of the points observed.

Sincerely,

HERNAN ROJAS OLAVARRIA (Signed)  
VETERINARIAN  
CHIEF OF THE DEPARTMENT OF ANIMAL PROTECTION

Seal stamped reading: "Agriculture Service - Department of Animal Protection - Chief"

OVP/CPA/CTG/MAM/ (Initials)

GOVERNMENT OF CHILE  
Agriculture Services  
SAG

Department of Animal Protection, SAG / Avenida Bulnes 140, 7° piso, Santiago  
Telephone: 696 7311; Fax: 671 6184; E-mail: propec@sag.gob.cl

Fax N°: 419		/ Date: March 16, 1004	
N° of pages including cover sheet: 3			
To: THE SAG REGIONAL DIRECTOR, VI REGION			
Telephone:		/ Fax:	
Attn.: Animal Regional Agent			
Subject: Send FSIS Audit Report			
Sent by: Chief of the Department of Animal Protection			
Urgent		Information X	Answer

Please find enclosed the audit report on the red meats inspection system, conducted at the ROSARIO processing plant by personal of the FSIS in December of 2003.

I will appreciate your information regarding the progress made towards the correction of the points observed.

Sincerely,

HERNAN ROJAS OLAVARRIA (Signed)  
VETERINARIAN  
CHIEF OF THE DEPARTMENT OF ANIMAL PROTECTION

Seal stamped reading: "Agriculture Service - Department of Animal Protection - Chief"

OVP/CPA/CTG/MAM/ (Initials)

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 - VIII Region, Chile	2. AUDIT DATE 12-09-03	3. ESTABLISHMENT NO. 08-04	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) Dr. Oto Urban		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	O
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.		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.		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/Restrooms	
<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	X
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.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Enforcement	X
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQU/Perk Skins/Moisture)	O	54. Ante Mortem Inspection	X
<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		60.	
32. Written Assurance		61.	

## 60. Observation of the Establishment

Chile Est. 08-04 12-09-03

10/51 Horn removing equipment was not properly sanitized (only once, at the end of the shift). This deficiency was scheduled for corrective action by the inspection service.

10/51 Bung operating employee contaminated the rectal cavity with knife which was not properly sanitized.

48/51 Edible and inedible plastic containers were not properly identified and used in some cases in the slaughter room and the offal processing room. The establishment employee promised to correct this deficiency.

54/51 Suspect pen at the ante-mortem inspection, did not have proper installation of drinking water and sufficient light. This deficiency was scheduled for correction by the establishment maintenance supervisor,

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

for Mangos A. Chaudry 2/10/04

GOVERNMENT OF CHILE  
Agriculture Services  
SAG

SAG Office Carnes Nubla Processing Plant / Panamericana Norte Km. 3, Chillan  
Telephone: 42-207218; Fax42-271957; E-mail: sag@carnes.cl

Fax N°: 06	/ Date: April 23, 2004
N° of pages including cover sheet: 3	
To: OSCAR VIDELA P., SAG Metropolitan Region	
Fax: 2-6716184	
Attention: Office of the Under Secretary of Industry and Technology. DPP - SAG	
Sent by: Liliana Perez Cardenas, SAG Official Supervisor, Carnes Nuble S.A. Processing Plant	
Subject: FSIS Audit Follow-up	

URGENT

Information

Answer

PLEASE FIND ATTACHED TO FAX 006 FROM THE SAG OFFICE AT CARNES NUBLE S.A. PROCESSING PLANT, THE FOLLOW-UP REPORT CHRONOGRAM OF COMPLIANCE WITH FSIS AUDIT, CARNES NUBLE PROCESSING PLANT COMPLIANCE REPORT.

SINCERELY,

Liliana Perez Cardenas  
Supervisor, SAG, Chillan

Copy to: Ramon Vera  
Eduardo Fuhrer

GOVERNMENT OF CHILE  
Agriculture Service  
SAG

REPORT ON AUDIT FOLLOW-UP

Chillan, April 24, 2004

To: Mr. Oscar Videla P.  
Chief of the Office of the  
Under Secretary of Industry and Technology  
Santiago

Please be advised of the follow-up performed by the personnel of the official inspection Team at the Carnes Nuble S.A. processing plant, on the non-conformities to the FSIS, Dr. Oto Urban, conducted on December 3, 2004.

Non Conformity	Chronogram Plant Compliance to 03-31-04	Follow-up EIO SAG in Plant 04-22-04
Lack of dehorning sterilization device	04-30-2004	Do follow-up 04-30-2004
Lack of sterilization of knife used in rimming operation	Solved	Satisfactory
Lack of identification of plastic trays used for non-edible products	Solved	Satisfactory
The isolation corral for ante-mortem inspection does not have water available for the animals to drink.	05-15-2004	Satisfactory
Insufficient light at the isolation corral for ante-mortem inspection	Solved	Satisfactory

Note: The Carnes Nuble S.A. Processing Plant sent the answer to the audit department on the 31st day of March of 2004

Liliana Perez C. (Signed)  
SAC Regional Supervisor  
SAG-Chillan