



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

IES Chen

MAY - 4 2005

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

Dear Dr. Rojas:

The Food Safety and Inspection Service conducted an initial on-site audit of Chile's poultry inspection system December 7 through December 17, 2004. Comments from Chile on the draft final report have been included as an attachment to 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.

Sincerely,

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

Enclosure

FINAL

APR 26 2005

**FINAL REPORT OF AN INITIAL ON-SITE AUDIT
COVERING CHILE'S POULTRY INSPECTION SYSTEM**

DECEMBER 7 THROUGH DECEMBER 17, 2004

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

APHIS	Animal and Plant Health Inspection Service
CCA	Central Competent Authority
CVO	Chief Veterinary Officer
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
SAG	Agricultural and Livestock Service (Servicio Agrícola y Ganadero)
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures

1. INTRODUCTION

The audit took place in Chile from December 7 to December 17, 2004.

An opening meeting was held on December 7, 2004, in Santiago, Chile with the Central Competent Authority (CCA), which is the Agricultural and Livestock Service [Servicio Agrícola y Ganadero (SAG)], Department of Livestock Protection (Departamento de Protección Pecuaria). Personnel from the regional and local levels of the SAG Department of Livestock Protection were also present. At this meeting, the Food Safety and Inspection Service (FSIS) audit team leader confirmed the objective and scope of the audit, the audit itinerary, and requested additional information needed to complete the initial on-site audit of Chile's poultry inspection system.

The audit team members were accompanied during the entire audit by a representative from the SAG Department of Livestock Protection and, when appropriate, representatives from the regional, local, and establishment inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was an initial on-site audit of the Chilean poultry inspection system. The objective of the audit was to determine whether Chile's poultry inspection system meets the United States' import inspection requirements.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, two regional offices, one local office, two slaughter establishments, five residue laboratories and three microbiological laboratories.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	2	
	Local	1	
	Establishment	2	
Laboratories	Microbiological	3	
	Residue	5	
Poultry Slaughter Establishments		2	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials in Santiago 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 two slaughter establishments. The fourth part involved visits to three microbiological laboratories and five residue laboratories. The microbiological laboratories were conducting analysis of field samples for the presence of

generic *Escherichia coli* (*E. coli*), and *Salmonella*. The residue laboratories conducted analysis of field samples for Chile's national residue control program.

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 and Critical Control Point (HACCP) programs and testing programs for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Chile's poultry inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the audit team members evaluated the nature, extent, and degree to which findings impacted on food safety and public health. The audit team also assessed how poultry inspection services are carried out by the government of Chile and determined if establishment and inspection system controls were in place to ensure that the poultry products that Chile seeks to export to the United States would be safe, unadulterated, and properly labeled.

At the opening meeting, the audit team leader explained to the SAG officials that the Chilean inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Chile. FSIS requirements include daily inspection in all 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, species verification testing, requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*, and government oversight/enforcement activities.

Currently, Chile has no equivalence determinations for poultry products.

4. LEGAL BASIS FOR THE AUDIT

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

- The Poultry Products Inspection Act (21 U.S. Code 451 et seq.).
- The Poultry Products Inspection Regulations (9 CFR Part 381), which include the United States import requirements and the Pathogen Reduction (PR)/HACCP and SSOP regulations.

5. SUMMARY OF PREVIOUS AUDITS

No previous audits of Chile's poultry inspection system have been conducted by FSIS.

6. MAIN FINDINGS

6.1 Government Oversight

Meat inspection activities are centrally located in Santiago and are administered by the SAG Department of Livestock Protection. The Chief of the Department of Livestock Protection Department has direct authority over all poultry establishments, including those seeking to be

certified to export poultry products to the United States. The Chief of the Department of Livestock Protection serves as the Chief Veterinary Officer for Chile's poultry inspection system. The central headquarters office has the legal and regulatory authority to administer the poultry inspection program. The official list of establishments is maintained and controlled by the Chief of the SAG Department of Livestock Protection. New official guidelines and regulations are also issued and disseminated to the lower level inspection offices by CCA headquarters in Santiago.

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 monthly supervisory reviews conducted by the Regional Supervisory Inspector.

SAG's Department of Livestock Protection has mechanisms in place to control products from livestock suspected of animal and/or public health risks. In addition, controls are in place and carried out to prevent fraud or misuse of export certificates, as well as ensure the integrity of export product inspection process.

6.1.1 CCA Control Systems

The SAG Department of Livestock Protection has the organizational structure and staffing to ensure uniform implementation of United States' requirements.

6.1.2 Ultimate Control And Supervision

The SAG Department of Livestock Protection has ultimate control of inspection activities. The supervision of non-veterinary inspectors at the establishment level is the responsibility of the Veterinarian-in-Charge. The Veterinarians-in-Charge are supervised by the Regional Directors and the Regional Supervisory Inspectors. Staffing appeared adequate in individual establishments.

6.1.3 Assignment of Competent, Qualified Inspectors

The central headquarters is responsible for ensuring adequate training of veterinarians and inspectors before assignment to an official establishment. Training is overseen by SAG and administered in partnership with local universities. The program includes 292+ hours of training for basic certification before on the job training is carried out by the Veterinarian-in-Charge in each establishment. Additional training is generally coordinated and provided by the CCA, although as the need arises other training may be coordinated at the regional or establishment level. Chile has also had numerous participants in the FSIS sponsored Meat and Poultry Inspection Seminar in recent years, as well as contracted with consultants for additional training in United States' import inspection requirements.

6.1.4 Authority and Responsibility to Enforce the Laws

The CCA and the official inspection personnel have the authority and responsibility to enforce United States' requirements. The Chief of the SAG Department of Livestock Protection, the Regional Directors, and Supervisors, as well as the Veterinarians-in-Charge at each establishment are all authorized to enforce the government of Chile's poultry inspection

requirements and the United States' import requirements, including animal health and welfare, control of animal disease, veterinary medicines, and the production of safe foods of animal origin. The Veterinarians-in-Charge at each establishment, as well as the Regional Supervisors and Directors, and designated headquarters personnel all have the legal authority to suspend operations and delist certified establishments to prevent the export of unsafe poultry products to the United States.

6.1.5 Administrative and Technical Support

The SAG Department of Livestock Protection appears to have adequate technical support.

6.2 Headquarters Audit

The audit team met with the Chief of the SAG Department of Livestock Protection and other government officials at the CCA headquarters to obtain a better understanding of the oversight and enforcement responsibilities of the government of Chile. Official pay records, training records, and other enforcement and oversight documentation were reviewed at the headquarters and regional levels, which have direct oversight of the establishment level inspection functions.

6.2.1 Audit of Regional and Local Inspection Sites

Two Department of Livestock Protection regional offices located in Rancagua (Region VI) and Quillota (Region V) respectively were audited. In addition, one local inspection office, also located in Quillota, was audited. The two establishment inspection offices were audited.

The regional and local level office audits revealed that all relevant regulations, notices, and other inspection documents and records were effectively disseminated from headquarters through the regional offices to the local and establishment level offices. This activity was accomplished by hard copy and e-mail.

The local level offices do not perform inspection oversight and enforcement functions. Rather, these offices are primarily responsible for administrative support to the establishments and the regional office. Functions include inspector payment record keeping, assignment of personnel, and other administrative and human resource activities. While there is a veterinarian assigned to each local office, these individuals do not have responsibility for the oversight of establishment level inspection functions and implementation of United States' import inspection requirements.

No deficiencies were observed except the following:

- In one Regional Office, the verification documentation was not included in the record for corrective actions taken as a result of observations made during a monthly supervisory visit. The SAG Department of Livestock Protection officials understood the issue and committed to providing this documentation in the future.

7. ESTABLISHMENT AUDITS

Two poultry slaughter establishments that are seeking certification to export poultry products to the United States were presented for review to FSIS as fully meeting the United States' import

inspection requirements. One establishment was a chicken slaughter establishment and the other one a turkey slaughter establishment.

Chile is not yet approved to export poultry products to the United States and because this was an initial on-site audit, no delistments or notices of intent to delist (NOID) were issued. However, in the case of one establishment, if it had been certified it would have received an NOID. SAG officials issued the equivalent of a 30-day letter for observed deficiencies.

Specific deficiencies are noted on the attached Foreign Establishment Audit Checklists.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

Residue laboratory audits focused on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

The following residue laboratories were reviewed. The first two laboratories work jointly to carry out reference laboratory functions.

- Department of Laboratory and Quarantine Service (Departamento de Laboratorio y Estacion Cuarentenaria Pecuaria in Santiago
- Nuclear Applications Department, Chilean Nuclear Energy Commission in Santiago
- ANALAB Chile, S.A. in Santiago
- Corthorn Quality (Chile), S.A. in Santiago
- Laboratory of Veterinary Pharmacology in Santiago

The microbiology laboratory audits that were conducted focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. The following microbiology laboratories were audited. The first laboratory serves as the reference laboratory for microbiology analysis.

- Agriculture and Livestock Service (Servicio Agrícola y Ganadero, SAG) Laboratory in Santiago
- LABSER in Rancagua
- University of Chile, Faculty of Science for Chemistry and Pharmaceuticals in Santiago

The FSIS requirements were being followed as required in the microbiology and residue laboratories and no deficiencies were observed. Residue testing is being accomplished as required by the national plan.

9. SANITATION CONTROLS

As previously stated, FSIS focuses on five areas of risk to assess an exporting country's poultry inspection system. The first of these risk areas that the audit team reviewed was Sanitation Controls.

Chile's poultry 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 and 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 SSOP in both establishments audited were found to meet the basic FSIS regulatory requirements with the following deficiencies noted in regard to implementation requirements:

- In one establishment, product contact surfaces on some belts were frayed. Product contact surfaces on some metal cups (and other welds all around the establishment) in the offal room had breaks and unsmooth welds, which could allow for the buildup of biofilm (product residue).
- In one establishment, the descriptions of deficiencies on pre-operational sanitation records were inadequate to identify the findings. Although provisions for preventive measures were present in the SSOP plans, the SSOP records did not record preventive measures for the deficiencies.

9.2 Sanitation

The following Sanitation Performance Standard (SPS) deficiencies were observed:

- In one establishment, there was insufficient light at the reprocessing stations in processing.
- In another establishment, there was insufficient light (multiple readings below 200 foot candles) at one end of the inspection table at critical control point (CCP) #1.
- In one establishment, the overhead wheels at the turns of the chain in slaughter and processing had frayed edges. These wheels were directly over product.
- In another establishment, there was condensation on the guidelines, bars and support structures above the product conveyor belt for the removal of breast meat.
- In one establishment, the hand washing sinks were either not working or inaccessible/inconvenient for employees in the processing and packaging areas.
- In one establishment, containers for condemned materials were allowed to come into contact with containers for edible materials. No actual cross contamination was observed. The containers were also not easily accessible to the employees in the area.
- In one establishment, containers for inedible materials were interchangeable with those for edible materials. In the plastic containers, a red plastic bag was inserted and marked as condemned. In metal bins, only a sign marking it as condemned was hung on the container.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS audit team reviewed was Animal Disease. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The audit team determined that the inspection system of Chile had adequate controls in place. No deficiencies were noted.

There have been no outbreaks of animal diseases with public health significance since 2002. The Animal and Plant Health Inspection Service (APHIS) does not currently have any import restrictions on poultry products from Chile.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS audit team reviewed was Slaughter/Processing Controls. These include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records.

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

In both establishments, slaughter and processing deficiencies were observed. The FSIS auditor observed deficiencies in HACCP implementation and *E. coli* testing.

11.1 Humane Handling and Humane Slaughter

Controls for the humane handling and humane slaughter of poultry were in place and being followed as required.

11.2 HACCP Implementation

All establishments that will be certified to export poultry products to the United States, with the exception of facilities dedicated to cold storage, are required to have adequately developed and implemented HACCP programs. The HACCP programs were evaluated according to the criteria employed in the United States' domestic inspection program.

During this audit, both establishments audited were required to meet the HACCP requirements. Chile had adequately implemented the HACCP requirements except for the following deficiency:

- In one establishment, verification for the CCPs in the HACCP plan did not include direct observation of the monitor, records review, or calibration of monitoring equipment in the listed activities of verification. However, both records review and calibration of monitoring instruments were being conducted and adequately documented.

11.3 Testing for Generic *E. coli*

Chile has adopted the FSIS regulatory requirements for generic *E. coli* testing, except for the following deficiency:

- In both slaughter establishments, the *E. coli* sampling is done by SAG. At the direction of SAG, the number of samples is five per week, which does not meet the requirements of 9 CFR, Part 381.94 for frequency.
 - SAG officials are adopting the FSIS requirements in full until such time as their base line risk assessment is complete and they can submit and receive approval of an equivalence determination request for an alternate testing schedule.

11.4 Testing for *Listeria monocytogenes*

Neither of the two establishments audited was producing ready-to-eat poultry products. As a result, the FSIS requirements for *Listeria monocytogenes* testing do not apply.

12. RESIDUE CONTROLS

The fourth of the five risk areas the FSIS audit team reviewed was Residue Controls. These include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

Five residue laboratories were reviewed during this audit, two of which are carrying out reference laboratory functions. Residue testing is being accomplished as required by the national plan with the following exception:

- The records revealed there is a significant time gap between when the results are received at SAG Headquarters and when they are received at the establishment. This gap extended up to eleven months in some cases. Documents show that the turnaround time at the lab for analysis was within expectations (30 days).
 - SAG officials have committed to developing guidelines and protocols for the timely transmission of the results to the establishment inspection team within specified time frames.

No deficiencies in testing methodology were observed in the residue laboratories.

13. ENFORCEMENT CONTROLS

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

13.1 Daily Inspection in Establishments

Daily inspection was being conducted as required in the both establishments audited.

13.2 Testing for *Salmonella*

Chile has adopted the FSIS regulatory requirements for testing for *Salmonella* species.

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

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

13.3 Species Verification

In both establishments, species verification testing was not being conducted as required.

13.4 Monthly Reviews

In both establishments, monthly supervisory reviews were being performed 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.

Controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing. Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Inspection system controls were being met, except for the following deficiency:

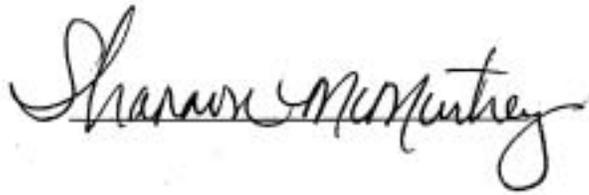
- In one Regional office, the verification documentation was not included in the record for corrective actions taken as a result of observations made during a monthly supervisory visit. The Regional office understood the issue and provided documentation for this record and committed ensuring this documentation was included with the record in the future.

14. CLOSING MEETING

A closing meeting was held on December 17, 2004, in Santiago with the CCA. At this meeting, the preliminary findings from the audit were presented by the audit team leader.

The CCA understood and accepted the findings.

Shannon McMurtrey
Lead Auditor

A handwritten signature in black ink that reads "Shannon McMurtrey". The signature is written in a cursive style with a horizontal line drawn through the middle of the letters.

15. ATTACHMENTS TO THE AUDIT REPORT

Foreign Laboratory Audit Forms

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 Faenadora San Vicente Carretera H-66 - G, Km 19.2 San Vicente de Tagua Tagua Chile	2. AUDIT DATE 09 Dec. 2004	3. ESTABLISHMENT NO. 06-08	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) Roel K. Craver, 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 0 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	X
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
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	
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.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	0	51. Enforcement	X
24. Labeling - Net Weights	0	52. Humane Handling	
25. General Labeling	0	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	56. European Community Directives	0
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. 06-08

09 December 2004

Note - Labeling has not yet been requested for US export products.

10/51 - Product contact surfaces on some belts were frayed. Product contact surfaces on some metal cups (and other welds all around the establishment) in the offal room had breaks and unsmooth welds which could allow for biofilm formation. CFR 9 § 416.13 & 416.17

28/51 - Generic *Escherichia coli* (*E. coli*) sampling is done by SAG. The number of samples is 5 per/week which does not meet the requirements of 9 CFR § 381.94 for frequency. This is more like a verification sampling than the required establishment sampling. This method of sampling is at the direction of SAG.

34/51 - No species testing was being done.

40/51 - There was insufficient illumination at the reprocessing stations in processing. 9 CFR § 416.2c & 416.6

45/51 - The overhead wheels at the turns of the chain in slaughter and processing had frayed edges. These wheels were directly over product. 9 CFR § 416.3 & 416.6

61. NAME OF AUDITOR

Aurora K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Aurora K. Craver, DVM 10/9/04

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sopraval S.A. Panamericana Norte Km. 112 Casilla 41 La Calera, Chile	2. AUDIT DATE 14 Dec. 2004	3. ESTABLISHMENT NO. 05-09	4. NAME OF COUNTRY Chile
	5. NAME OF AUDITOR(S) Rori K. Craver, 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. Specs Testing	X
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		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	
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	X
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	X
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.		48. Condensed 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		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	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. 05-09
14 December 2004

Note – Labeling has not yet been requested for US export products.

13 – The descriptions of deficiencies on pre-operational sanitation records were inadequate to identify the findings. Although provisions for preventive measures were present in the SSOP plans, the SSOP records did not record preventive measures for the deficiencies. 9 CFR § 416.15

19/51 – Verification for the CCPs in the HACCP plan did not include direct observation of the monitor, records review or calibration of monitoring equipment in the listed activities of verification. However, both records review and calibration of monitoring instruments were being conducted and adequately documented. 9 CFR § 417.4 (a) (2) & 417.8

28/51 - Generic *Escherichia coli* (*E. coli*) sampling is done by SAG. The number of samples is 5 per/week which does not meet the requirements of 9 CFR § 381.94 for frequency. This is more like a verification sampling than the required establishment sampling. This method of sampling is at the direction of SAG.

34/51 – No species testing was being done.

40/51 – There was insufficient illumination (multiple readings below 200 footcandles) at one end of the inspection table at CCP1. 9 CFR § 416.2c & 416.6

41 – There was condensation on the guidelines, bars and support structures above the product conveyor belt for the removal of breast meat. 9 CFR § 416.2d

44/51 - Hand washing sinks were either not working or inaccessible/inconvenient for employees in the processing and packaging areas. 9 CFR § 416.2 (b) (2) & 416.6

45/51 – Containers for inedible materials were interchangeable with those for edible materials. In the plastic containers, a red plastic bag was inserted and marked as condemned. In metal bins, only a sign marking it as condemned was hung on the container. 9 CFR § 416.3c & 416.6

48 – Containers for condemned materials were allowed to come into contact with containers for edible materials. No actual cross contamination was observed. The containers also were not easily accessible to the employees in the area. 9 CFR § 416.4d

NOTE: Since this was an initial audit, the establishment was not certified. However, had this been a certified establishment, it would have received an NOID.

61. NAME OF AUDITOR

Aurora K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Aurora K. Craver DVM, 12/14/04

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
 12/14/04

NAME OF FOREIGN LABORATORY
 Corthron Wuality (Chile), S.A

FOREIGN GOV'T AGENCY
 SAG, Government of Chile

CITY & COUNTRY
 Santiago, Chile

ADDRESS OF LABORATORY
 Palacio Riesco, Huechuraba, Santiago

NAME OF REVIEWER
 Dr. B. P. Dey

NAME OF FOREIGN OFFICIAL
 Raul A. Corthron, Director

Residue Code/Name			500	500												
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE													
	Sample Handling	01		A	A											
	Sample Frequency	02		A	A											
	Timely Analysis	03		A	A											
	Compositing Procedure	04		N	N											
	Interpret Comp Data	05		A	A											
	Data Reporting	06	A	A												
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A												
	Correct Tissue(s)	08	A	A												
	Equipment Operation	09	A	A												
	Instrument Printouts	10	A	A												
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A												
	Recovery Frequency	12	A	A												
	Percent Recovery	13	A	A												
	Check Sample Frequency	14	A	A												
	All Analyst W/Check Samples	15	A	A												
	Corrective Actions	16	A	A												
	International Check Samples	17	A	A												
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE													
OTHER REVIEW		19	EVAL. CODE													
		20														

Signature of reviewer

B.P. Dey

Date

12/14/04

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 12/14/04	NAME OF FOREIGN LABORATORY Corthron Quality (Chile)S.A.
FOREIGN GOV'T AGENCY SAG, Government of Chile	CITY & COUNTRY Santiago, Chile		ADDRESS OF LABORATORY Palacio Riesco, Huechuraba
NAME OF REVIEWER , SantiagoDr. B. P. Dey		NAME OF FOREIGN OFFICIAL Raul A Corthron, Director	

RESIDUE	ITEM NO.	COMMENTS
		A = Acceptable; N = Not Applicable; O= Not Observed; U = Unacceptable Please see attached page
500	GC/MS	
500*	ELISA	

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
 12/9/04

NAME OF FOREIGN LABORATORY
 Nuclear application Department
 Chilean Nuclear Energy Commission

FOREIGN GOV'T AGENCY
 Government of Chile

CITY & COUNTRY
 Santiago, Chile

ADDRESS OF LABORATORY
 Ave Nueva Bilbao 12.501,
 Las Codes, P.O.0500687, Santiago, Chile

NAME OF REVIEWER
 Dr. B. P. Dey

NAME OF FOREIGN OFFICIAL
 Dr. Nuri Gras
 Head, Metrology In Chemistry section, Nuclear Application Department

Residue Code/Name

501

SAMPLING PROCEDURES

REVIEW ITEMS	ITEM #
Sample Handling	01
Sample Frequency	02
Timely Analysis	03
Compositing Procedure	04
Interpret Comp Data	05
Data Reporting	06

EVALUATION CODE

O
 A
 A
 A
 A
 A

ANALYTICAL PROCEDURES

Acceptable Method	07
Correct Tissue(s)	08
Equipment Operation	09
Instrument Printouts	10

EVALUATION CODE

A
 A
 A
 A

QUALITY ASSURANCE PROCEDURES

Minimum Detection Levels	11
Recovery Frequency	12
Percent Recovery	13
Check Sample Frequency	14
All Analyst W/Check Samples	15
Corrective Actions	16
International Check Samples	17

EVALUATION CODE

A
 A
 A
 N
 A
 N
 A

REVIEW

Corrected Prior Deficiencies 18

EVAL. CODE

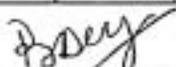
N

OTHER REVIEW

19
 20

EVAL. CODE

Signature of reviewer



Date 12/14/04

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 12/9/04	NAME OF FOREIGN LABORATORY Nuclear Applications Department Chilean Nuclear Energy Commission
FOREIGN GOV'T AGENCY Government of Chile	CITY & COUNTRY Santiago, Chile		ADDRESS OF LABORATORY Ave Nueva Bilbao 12.501, Las Codos, P.O 0600687, Santiago, Chile
NAME OF REVIEWER Dr. B. P. Dey	NAME OF FOREIGN OFFICIAL Dr. Nuri Gras, Head, Metrology In Chemistry section, Nuclear Application Department		

RESIDUE	ITEM NO.	COMMENTS
501		<p>A = Acceptable; N = Not Applicable; O= Not Observed; U = Unacceptable</p> <p>Diethylstilbestrol</p>

REVIEW DATE
 12.8.04

NAME OF FOREIGN LABORATORY
 ANALAB Chile, S.A.I

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 SAG, Government of Chile

CITY & COUNTRY
 Santiago, Chile

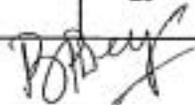
ADDRESS OF LABORATORY
 Exequiel Fernandez 3682
 Macu, Santiago

NAME OF REVIEWER
 Dr. B. P. Dey

NAME OF FOREIGN OFFICIAL
 Jorge Espinoza Munita

Residue Code/Name		401	100	370										
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01		A	A	A								
	Sample Frequency	02		A	A	A								
	Timely Analysis	03		A	A	A								
	Compositing Procedure	04		N	N	N								
	Interpret Comp Data	05		A	A	A								
Data Reporting	06	A	A	A										
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A									
	Correct Tissue(s)	08	A	A	A									
	Equipment Operation	09	A	A	A									
	Instrument Printouts	10	A	A	A									
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A									
	Recovery Frequency	12	A	A	A									
	Percent Recovery	13	A	A	A									
	Check Sample Frequency	14	A	A	A									
	All Analyst W/Check Samples	15	A	A	A									
	Corrective Actions	16	A	A	A									
International Check Samples	17	A	A	A										
REVIEW	Corrected Prior Deficiencies	18	EVAL CODE											
OTHER REVIEW		19	EVAL CODE											
		20	EVAL CODE											

Signature of reviewer



Date

12/14/04

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 12.8.04	NAME OF FOREIGN LABORATORY ANALAB Chile, S.A.
FOREIGN GOV'T AGENCY SAG, Government of Chile	CITY & COUNTRY Santiago, Chile		ADDRESS OF LABORATORY Esquirol Fernandez 2692 Macu, Santiago
NAME OF REVIEWER Dr. B. P. Dey	NAME OF FOREIGN OFFICIAL Jorge Espinoza Munita		

RESIDUE	ITEM NO.	COMMENTS
		A = Acceptable; N = Not Applicable; O= Not Observed; U = Unacceptable
100		Halocarbons
370		Organic Phosphorous Compound
401		Arsenic

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
 12/9/04

NAME OF FOREIGN LABORATORY
 Departamento de Laboratorio y Estacion Cuarentenaria Pecuaria

FOREIGN GOVT AGENCY
 Government of Chile

CITY & COUNTRY
 Santiago, Chile

ADDRESS OF LABORATORY
 Av Bulnes 140

NAME OF REVIEWER
 Dr. B. P. Dey

NAME OF FOREIGN OFFICIAL
 Pedro Enrique Alfaro, Bioquimico, Jeff Seccion Quimica, Ambiental y Alimentaria

Residue Code/Name			800													
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE													
	Sample Handling	01		A												
	Sample Frequency	02		N												
	Timely Analysis	03		N												
	Compositing Procedure	04		N												
	Interpret Comp Data	05		A												
Data Reporting	06	N														
ANALYTICAL PROCEDURES	Acceptable Method	07	A													
	Correct Tissue(s)	08	A													
	Equipment Operation	09	A													
	Instrument Printouts	10	A													
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A													
	Recovery Frequency	12	A													
	Percent Recovery	13	A													
	Check Sample Frequency	14	N													
	All Analyst W/Check Samples	15	N													
	Corrective Actions	16	N													
International Check Samples	17	A														
REVIEW	Corrected Prior Deficiencias	18	EVAL. CODE	N												
OTHER REVIEW		19	EVAL. CODE													
		20														

Signature of reviewer

B. P. Dey

Date 12/14/04

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 12/9/04	NAME OF FOREIGN LABORATORY Departamento de Laboratorio y Estacion Cuarentenaria Pecuaria
FOREIGN GOV'T AGENCY Government of Chile	CITY & COUNTRY Santiago, Chile	ADDRESS OF LABORATORY Av. Bulnes 140	
NAME OF REVIEWER Dr. B. P. Dey	NAME OF FOREIGN OFFICIAL Pedro Enrique Alfaro, Bioquimico, Jefe Seccion Quimica, Ambiental y Alimentaria		

RESIDUE	ITEM NO.	COMMENTS
800		<p>A = Acceptable; N = Not Applicable; O = Not Observed; U = Unacceptable</p> <p>Sulfonamides</p>

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
 12/13/04

NAME OF FOREIGN LABORATORY
 Laboratory Veterinary Pharmacology,
 University of Chile

FOREIGN GOV'T AGENCY
 SAG, Government of Chile

CITY & COUNTRY
 Santiago, Chile

ADDRESS OF LABORATORY
 Santa Rosa 11735
 La Pinata, Santiago, Chile

NAME OF REVIEWER
 Dr. B. P. Dey

NAME OF FOREIGN OFFICIAL
 Dr. Betty San Martin, Director

Residue Code/Name

200 800

SAMPLING PROCEDURES

REVIEW ITEMS	ITEM #
Sample Handling	01
Sample Frequency	02
Timely Analysis	03
Compositing Procedure	04
Interpret Comp Data	05
Data Reporting	06

EVLUATION CODE

A	A
A	A
A	N
N	A
A	A
A	A

ANALYTICAL PROCEDURES

Acceptable Method	07
Correct Tissue(s)	08
Equipment Operation	09
Instrument Printouts	10

EVLUATION CODE

A	A
A	A
A	A
A	A

QUALITY ASSURANCE PROCEDURES

Minimum Detection Levels	11
Recovery Frequency	12
Percent Recovery	13
Check Sample Frequency	14
All Analyst W/Check Samples	15
Corrective Actions	16
International Check Samples	17

EVLUATION CODE

A	A
A	A
A	A
A	A
A	A
A	A
A	A

REVIEW

Corrected Prior Deficiencies 18

EVAL. CODE

OTHER REVIEW

19
20

EVAL. CODE

Signature of reviewer

B. P. Dey

Date

12/14/04

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE 12.13.04	NAME OF FOREIGN LABORATORY Laboratory Veterinary Pharmacology, University of Chile
FOREIGN GOV'T AGENCY SAG, Government of Chile	CITY & COUNTRY Santiago, Chile	ADDRESS OF LABORATORY Santa Poes 11735 La Pirata, Santiago, Chile	
NAME OF REVIEWER		NAME OF FOREIGN OFFICIAL Dr. Betty San Martin, Director	

RESIDUE	ITEM NO.	COMMENTS
		A = Acceptable; N = Not Applicable; O= Not Observed; U = Unacceptable
200		Antibiotics
800		Sulfonamides

[Logo]
GOVERNMENT OF CHILE
DEPARTMENT OF AGRICULTURE
SAG

Livestock Protection Division

Santiago, March 31st 2005

02948

Sally White
Director
International Equivalence Staff
Office of International Affairs
Food Safety and Inspection Service
Room 2137-S
1400 Independence Avenue, SW
Washington, DC 20250

Dear Sally:

In relation to the results of the poultry audit done by an FSIS team during December 2004, I'm pleased to enclose the report with our analysis and comments, including the measures adopted to solve the discrepancies detected.

Sincerely,

/seal/
Agriculture and Livestock Services
/illegible/

[illegible signature]
HERNAN ROJAS OLAVARRIA
Director
Livestock Protection Division

/illegible signature/
CTG/OVP/MPB

CC: Mrs. Christina Sloop; Agricultural Attaché to the United States Embassy,
Mr. Eduardo Santos; Agricultural Attaché to the Chilean Embassy in the United States,
Foreign Commerce Subdivision (U.S.A.)

IES 782
bw 4/7

RESPONSE TO THE DRAFT REPORT OF THE AUDIT PREFORMED BY FSIS FROM DECEMBER 7 THROUGH 17, 2004.

The response to the draft report will cover the audit preformed on December 2004

In reference to:

Topic 6. IMPORTANT FINDINGS:

- 6.1 – Governmental Supervision:
No observations were noted.

- 6.2 Central Level Audit:
The corrective measures adopted as result of the observations made during the monthly supervisions are included in all regional departments.

Topic 7. ESTABLISHMENT AUDIT:

With regards to the specific discrepancies found in the audited establishments, these are being thoroughly explained in the corresponding achievement report, Attachment 1.

Topic 8. WASTE AND MICROBIOLOGY LABORATORIES AUDIT:

No observations were noted.

Topic 9. SANITIZATION CONTROL:

- 9.1 Observations noted about SSOP and Sanitization were explained in the corresponding achievement report, Attachment 1.
- 9.2 Observations noted about Sanitization were explained in the corresponding achievement report, Attachment 1.

Topic 10. ANIMAL DISEASE CONTROL:

No observations were noted.

Topic 11. SLAUGHTER CONTROL AND PROCESS:

- 11.1 Human handling and humane slaughtering:
No observations were noted.

- 11.2 HACCP Implementation
Observations noted about HACCP implementation were explained in the achievement report, Attachment 1.

- 11.3 Generic E. coli Sampling
SAG has determined to adopt strong measures for 9 CFR. Starting March 2005, the required modifications will begin to be implemented.

- 11.4 Monocytogenes Listeria Sampling

It's not applicable. Ready-for-Consumption Products (RTE) are not yet being requested for Export.

Topic 12. WASTE MANAGEMENT

Attachment 2 indicates the progress of distribution times of results of waste management to SAG headquarters and to the establishments.

Topic 13. CONTROL OF REGULATIONS IMPLEMENTATION

13.3 SAG is developing the procedures and establishing the frequency for the implementation of the Species Verification Test.

VERIFICATION OF CORRECTIVE MEASURES ADOPTED BY EST. 06-08 AS A RESULT OF AN AUDIT PERFORMED TO THE POULTRY INSPECTION SYSTEM BY
 THE UNITED STATES

FINDINGS	IMMEDIATE CORRECTIVE MEASURE	PREVENTIVE CORRECTIVE MEASURE	PERSON HELD ACCOUNTABLE	VERIFICATIONS, (1) 01/17/2005 (2) 03/21/2005
Note: A request for export products to the United States has not been made yet	Make a request to APA	Make a request to APA	Pablo Valdes	None
10/51 The contact surface of some belts were worn out. The product contact surface in some metallic (illegible) (b) and in other welds in the whole establishment (c) there were (illegible) in the miscellaneous room and welds that were not polished, which could have created a (illegible) coating. CFR (416 & 416.17	a. The damaged crop belt was immediately replaced and (illegible) by the maintenance staff. b. The (illegible) of the (illegible) machine is changed. c. As a preventive measure, a calendar will be created for observation and replacement of belts on a monthly basis.	a. As a preventive measure, a calendar will be created for observation and replacement of belts on a monthly basis. b. Maintenance staff will make a registry of the plant areas where similar structures are present which could have the same defect present, designing a corrective maintenance program ending 01/16/2005 and a monthly preventive maintenance. 3. The plant is been following a welding improvement program which will end on 01/15/2004. Later the Maintenance Dept. will follow with a monthly inspection and repair welding program.	Gustavo Campos Remigio Jana	a. Carried out on (illegible) b. Carried out on (illegible) c. Carried out on (illegible)
28/51 The generic E. coli Samples were taken by SAG. The sample amount is 5 per week, which does not meet the frequency requirements set by 9 CFR 381.94. This is rather a verification sample than the samples required by the establishment. This sampling method is the one directed by SAG.	None	None	SAG	None
34/51- No species samples were made	None	None	SAG	None
40/51- The lighting system in processing and reprocessing areas was inadequate. 9 CFR 416.2c & 418.6	It is hereby requested that maintenance provide a better lighting system in all processing areas mentioned.	The lighting system maintenance will be included in the preventive maintenance program of the plant.	Gustavo Campos 12/19/2004	Carried out on 03/05/2005
45/51 - When twisting the chain in the slaughter house and during processing, the upper wheels had worn out edgings. These wheels were in direct contact with the product. 9 CFR 416.3 & 418.8	Maintenance Supervisor requests assessment of proper frequency in order to carry out a maintenance program in this respect.	Preventive maintenance program to these wheels will be coordinated through a maintenance computerized system on a monthly basis in order to prevent this damage from risking the purity of the products.	Gustavo Campos	Carried out on (illegible)

Marcelo RODRIGUEZ MV MgCs
 Veterinarian Inspector, Team Supervisor
 SAG Est. 06-08
 /illegible signature/

San Vicente. SAG VI Region / (illegible) Martínez 349, Segundo piso (2nd Floor), San Vicente de T.T.
 (illegible) Fax: (56 72) 573790 e-mail: sector.sanvicente@sag.cob.cl

OFFICIAL VERIFICATION OF CORRECTIVE MEASURES ADOPTED BY EST. 05-09 TO OBSERVATIONS NOTED IN THE FSIS 12/15/2004 AUDIT

[Logo]

GOVERNMENT OF CHILE

AGRICULTURE AND LIVESTOCK SERVICE

Nº	NON CONFORMITY OBSERVATIONS	CORRECTIVE MEASURES	PREVENTIVE MEASURES	PERSON HELD ACCOUNTABLE/ DEADLINE		
1	The description of inefficiency of preoperational records were unacceptable. For the deficiencies detected, only corrective and no preventive measures were noted.	In the existing documentation of the HACCP system, the corrective and preventive measures are recorded electronically, including analysis of the main cause and follow up. Based on observations made by the audit staff, all the PCC and SSOP record forms, corrective and preventive measure columns together with responsible persons and deadlines are included in the monitoring records. Besides, a column is added to specify the type of verification made (paper, monitoring surveillance or calibration)	Each time an HACCP and SSOP registry is made, these requirements will be analyzed and included in the forms.	HACCP	Verified and resolved	
2	The PCC verification in the HACCP plan does not include direct observation from monitor, records revision or equipment calibration on the verified activity list.	All types of verifications are included in the HACCP plan, and the direct monitor measurement is included on the official verifications.	Monthly programming to be made by the official service and the type of verification to be made, in a way that all types should be included for all types of PCC.	Company: To be included in its HACCP plan. SAG: Direct monitoring shall be included as part of verification.		Verified and resolved.
4	No species samples available.	Not applicable in the plant. This is a decision to be made by Central SAG				

OFFICIAL VERIFICATION OF CORRECTIVE MEASURES ADOPTED BY EST. 05-09 TO OBSERVATIONS NOTED IN THE FSIS 12/15/2004 AUDIT

[Logo]

GOVERNMENT OF CHILE
AGRICULTURE AND LIVESTOCK SERVICE

N°	NON CONFORMITY OBSERVATIONS	CORRECTIVE MEASURES	PREVENTIVE MEASURES	PERSON HELD ACCOUNTABLE/DEADLINE		
5	Lighting system is inadequate (under 200 footcandles) at the end of inspection area of PCC 1.	A tubing was removed in this area which was creating a shadow	Lighting system shall be supervised daily, these are included in the surveillance registries of daily control in each area (ACL-R-00-00-01), 02, 03 and 04). These controls were carried out but just one measurement was made on the table, for that reasons Inspectors received a second training to complete monitoring. This new monitoring shall be included in the Quality Plan.	Engineering Supervisor 12/17/04 Head of Quality Control/ Industrial Plants 12/15/04	Verified and resolved	
6	Cutting: Condensation was observed in the breast automated line. Preventive measures should be stronger in order to avoid condensation as well as the measures taken to prevent condensation from forming during process.	Presently, controls of preoperational cleansing monitoring are being carried out at the beginning of shift, and also during the shift in the cleansing registry (SSOP-R-00-018). Control of operational cleansing shall be reinforced and Quality Control Inspectors and Area Supervisor shall receive a second training on corrective measures to be adopted. Records of training and control formats of operational and preoperational cleansing are enclosed.	Within the "Best Slaughter Plant" project, it was concluded that the equipment had to be removed in January 2005. Therefore, the Teflon replacement shall not be included in the Preventive Measure Program.	Head of Quality Control/ Industrial Plants 12/17/04 SIG Supervisor 2005		Verified and resolved
7	Malfunctioning of washbasin was detected in some rooms and some of them were inaccessible for some workers. This was detected in the breathing room, shipping room and subsequent process.	The current amount and localization of washbasins in the plant were studied, and it was determined to add 10 new washbasins, 2 for the breathing room, 3 in the shipping area and 1 in subsequent processing area, 1 in marinating area, 3 in cutting and cleaning. These stainless steel pedal-operated washbasins will be installed in the areas previously mentioned in the attached diagram. Two washbasins will be installed on December 16 th 2004 and the remaining 8 shall be installed before December 30 th 2004, due to the fact that they are not currently available in the market. All the washbasins in the processing area will have, besides soap and sanitizer, towel paper	Every time there is a change in the Plant layout, the washbasins shall be inspected for compliance.	Head of Quality Control/ Industrial Plants		Verified and resolved

		dispenser. The holes on the wall were sealed and an overall inspection of the plan will be carried out in order to correct other possible holes detected in other areas.				
--	--	--	--	--	--	--

OFFICIAL VERIFICATION OF CORRECTIVE MEASURES ADOPTED BY EST. 05-09 TO OBSERVATIONS NOTED IN THE FSIS 12/15/2004 AUDIT

[Logo]

GOVERNMENT OF CHILE

- AGRICULTURE AND LIVESTOCK SERVICE

N°	NON CONFORMITY OBSERVATIONS	CORRECTIVE MEASURES	PREVENTIVE MEASURES	PERSON HELD ACCOUNTABLE/DEADLINE		
8	Containers intended for pertinent products are being used for non-pertinent products.	Tray and buggies flow in the shall be supervised, and it is determined that: for confiscation control, only the blue trays that are closed with red bags shall be used for that purpose or buggies (illegible) with the word "Confiscation" on the visible sides, intended for such use. With regards to the location, the areas of operational collection were pointed out in the layout, which are collected in the confiscation room. The selected areas shall be marked with posters for its location. An instructive diagram for the confiscation control was created and were incorporated to the sections that handle confiscations. A document defining the use of trays in the plant according to color was written.	Modify the issue on confiscation control in the GMP controls in agreement with the new definition. A design of (illegible) shall be developed in agreement with plant (illegible), which shall show a diagram in a definite way.	Quality Control Supervisor/ Industrial Plants 12/16/04 SIG Supervisor 12/27/04		Verified and resolved.
9	Containers intended for non-pertinent products were in direct contact with pertinent products, although no contamination was detected, the risk is still present. Besides, these should be accessible for the operators.	In the description of the title of operators handling food it is defined as competitor a course on food handling, which is included in the year training program. This course program shall be reinforced in the issues on crossed contamination in the inner training with reinforcement of related instructions through coaching. In agreement with enclosed program. The training shall be graded through a questionnaire at the end of the lecture and the learning capacity shall be evaluated through analysis of results of GMO Checklist, done every three months by Quality Control, and the results shall be compared to previous checklists to the training the ones made after this one. The inner training includes the following issues: <ol style="list-style-type: none"> 1. Concept of crossed contamination. 2. Risks of crossed contamination. 3. Preventive, corrective measures and associated records. 4. Example of malpractices. 	The modification of external course on "Health and Implementation of HACCP System" shall be included in the training program, thus reinforcing the issue on crossed contamination presented in the program, to be started on December 27 th in groups program for 2005. The purposes of this programs are: Fulfill the training requirements established by the Food Health Regulation and by SAG. Get to know the good practices for the handling of food, which are necessary to protect the customer and prevent him from getting infected with diseases through food. Implement healthy and safe procedures for storing, transportation and distribution of food products. Get to know the quality control system implemented in the plant and the role each person plays for fulfilling of the same. In the course, you will be evaluated through	SIG Supervisor 2005		Verified and resolved

Waste Management Plan

Samples taken for the Waste Management Plan meet a cycle which starts from the moment that they are taken in the plants until the results go back to the plants again, this period (Total Time for Response), according to some observations made by the FSIS auditor is too long for our program.

The commitment adopted by Service in December 2004 was to decrease the response time, and the following measures were taken for that purpose:

1. The calendar for sample taking in the plant was programmed on a weekly basis, which allows to get focused on the samples arrival at laboratories.
2. Analysis to be made in the program were divided by type of material, this allows the program of equipment use and improves its efficiency.

As a result of these measures, the total time for response has been reduced considerably.

Diagram No. 1 shows the average time laboratories take to render an analysis result, it is noted an average of less than 13 days.

Table 1:

Laboratory	Species			
	Broiler	Pigs	Turkeys	Cattle
Analab	13.6	11.4	13.4	13.8
Corthorn Quality	12.4	11.7	15.8	12.9
University of Chile	6.1	13.8	9.4	11.9
General Average	10.2	12.8	11.9	12.6

Table 2 shows the average time in days that take to receive the analysis results from the moment of sample taking until Service gets to know the results, this period includes the deadlines indicated in the previous diagram.

Laboratory	Species			
	Broiler	Pigs	Turkeys	Cattle
Analab	21.2	22.6	24.2	26.4
Corthorn Quality	18.1	18.6	24.2	21.8
University of Chile	21.0	19.9	15.1	23.7
General Average	19.7	19.7	20.1	22.9

In order to speed up the process of the waste management program, a software was developed in 2004. This information system will start to function in the first semester of this year and will expedite the transmission of information in each of the system phases.