



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

*Country
file*

JAN 13 2006

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 from August 9 through 18, 2005. 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 JD

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

DEC 23 2005

FINAL

**DRAFT FINAL REPORT OF AN INITIAL EQUIVALENCE AUDIT
CARRIED OUT IN CHILE COVERING
CHILE'S POULTRY INSPECTION SYSTEM**

AUGUST 9 THROUGH AUGUST 18, 2005

**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 August 9 to August 18, 2005.

An opening meeting was held on August 9, 2005 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 itineraries, and requested additional information needed to complete this follow-up initial equivalence 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. OBJECTIVES OF THE AUDIT

This audit was a follow-up initial equivalence audit. There were two objectives of the audit. The first objective was to determine whether appropriate corrective actions were taken or verified by SAG to correct the deficiencies found during the December 2004 audit. The second objective was to assess if Chile's application for initial equivalence for poultry is ready to move forward with the rulemaking process.

In pursuit of the objectives, the following sites were visited: the headquarters of the CCA, two regional offices, one local office, and two poultry slaughter establishments

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	2	
	Local	1	
	Establishment	2	
Laboratories	Microbiological	0	
	Residue	0	
Poultry Slaughter Establishments		2	

3. PROTOCOL

This on-site audit was conducted in three 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 poultry slaughter 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 (SSOP) and Sanitation Performance Standards (SPS), (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 both on-site establishment visits, the FSIS auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health. The auditor 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 and 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

In December 2004, FSIS conducted an initial equivalence audit of Chile's poultry inspection system. No notices of intent to delist or delistments were issued because this was an initial on-

site audit. However, in the case of one establishment, if it had been certified, it would have received a notice of intent to delist.

GOVERNMENT OVERSIGHT:

- 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.
- Inspection officials at the establishments were not fully enforcing FSIS requirements.

SANITATION CONTROLS:

- In both establishments, sanitation deficiencies were observed. In one establishment, product contact surfaces on some belts were frayed. Product contact surfaces on some metal cups in the offal room (and other welds all around the establishment) had breaks and unsmooth welds, which could allow for biofilm formation.
- There was insufficient light at the reprocessing stations in the processing area of one establishment. In the other establishment; there was insufficient light (multiple readings below 200 foot candles) at one end of the inspection table at critical control point #1.
- Condensation on the guide bars and support structures above the product conveyor belt for the removal of breast meat was observed in one establishment.
- Containers for condemned materials were allowed to come into contact with containers for edible materials. No actual cross contamination was observed. Containers for inedible materials were interchangeable with those for edible materials.

SLAUGHTER/PROCESSING CONTROLS:

- Verification for the CCPs did not include direct observation of the monitor, records review, or calibration of monitoring equipment in the listed activities of verification in one establishment. However, both records review and calibration of monitoring instruments were being conducted and adequately documented.
- In both establishments, *E. coli* sampling was done by SAG but the number of samples was five per/week, which did not meet FSIS requirements.

RESIDUE CONTROLS:

- There was a significant time delay in receiving the lab results at SAG Headquarters, at Regional Offices, and in establishment offices. This delay extended up to eleven months in some cases.

ENFORCEMENT CONTROLS:

- Enforcement of SSOP, SPS, and HACCP requirements at the establishment level was inadequate. For example, frayed product contact surfaces of some belts and rough welds on metal cups were observed in the offal room. There was insufficient light at the reprocessing stations of processing and at the inspection table at critical control point #1.

- 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.
- These establishments were allowed by the inspection officials to produce product without sufficient documented corrective/preventive actions taken by the establishment officials.

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 to ensure the integrity of the 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 the 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.

6.1.5 Administrative and Technical Support

The SAG Department of Livestock Protection appears to have adequate administrative and technical support for its poultry inspection system.

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. Also, 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.

7. ESTABLISHMENT AUDITS

Two poultry slaughter establishments were presented to FSIS as fully meeting the United States' import inspection requirements. One establishment was a chicken slaughter establishment and the other one was a turkey slaughter establishment.

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

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

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

No residue or microbiology laboratories were audited.

9. SANITATION CONTROLS

As previously stated, FSIS focuses on five areas of risk in order to assess an exporting country's poultry inspection system. The first of these risk areas that the FSIS auditor 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, written preventive measures for findings on pre-operational sanitation verification by the establishment were not specific enough to allow for evaluation of effectiveness.

All deficiencies observed in December 2004 had been corrected.

9.2 Sanitation Performance Standards

The following deficiencies were observed:

- In one establishment, two areas in the slaughter line at the sanitizer line re-hang area and at the gizzard preparation area did not have sufficient drainage causing a water back-up in the areas.
- In the same establishment, potential cross contamination of necks was observed on the crop extractor because of build-up of trachea and crops.
- In the other establishment, condemned poultry paws, placed in a combo outside for rendering pick-up, were not being denatured.

All deficiencies observed in December 2004 have been corrected.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease. These controls include ensuring adequate animal identification, control over condemned and restricted product, implementation of the Bovine Spongiform Encephalopathy requirements, 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. There are currently no import restrictions on poultry products from Chile.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor 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.

All deficiencies observed during December 2004 have been corrected.

11.1 Humane Handling and Humane Slaughter

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

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, individual entries on HACCP monitoring records did not have the initials of the monitor at the time of entry. There was only one signature for the entire day.

All deficiencies observed during December 2004 have been corrected

11.3 Testing for Generic *E. coli*

Chile has adopted the FSIS regulatory requirements for generic *E. coli* testing. Two establishments were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

No deficiencies were noted.

11.4 Testing of Ready-to-Eat Products

Neither of the two establishments audited were producing ready-to-eat poultry products. As a result, the FSIS testing requirements for ready-to-eat products do not apply. However, both are interested in exporting ready-to-eat products after Chile is granted approval for export. SAG was informed that the CCA would need to verify that FSIS requirements relating to ready-to-eat products had been implemented by the establishment prior to granting permission to the establishment for export of ready-to-eat products to the United States. The CCA would also need to verify that certified laboratories have properly trained staff and necessary equipment in place to analyze samples of ready-to-eat products for *Listeria monocytogenes* and *Salmonella*.

12. RESIDUE CONTROLS

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

Only records of residue testing were audited during this visit. The residue testing reporting deficiency noted during the previous audit had been corrected.

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 both establishments audited.

13.2 Testing for *Salmonella*

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

Both of the 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 poultry from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible poultry 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 deficiencies:

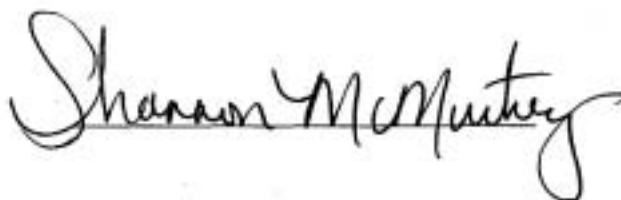
- In one establishment, one slaughter line did not have sufficient drainage.
- In the other establishment, records of preventive measures were not specific enough and individual CCP monitoring records had not been initialed.

14. CLOSING MEETING

A closing meeting was held on August 18, 2005, 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.

 Dr. M. Ghias Mughal
Lead Auditor



15. ATTACHMENTS TO THE AUDIT REPORT

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 Fagnadora San Vicente Carretera H - 66 - G, Km 19.2 San Vicente de Tagua Tagua Chile	2. AUDIT DATE 10 August 05	3. ESTABLISHMENT NO. 06-08	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 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. Specie Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		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	
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	
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.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		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
Faenadora San Vicente
San Vicente de Tagua Tagua

10 August 2005

13/51 – Written preventive measures for findings on pre-operational sanitation verification by the establishment were not specific enough to allow for evaluation of effectiveness. 9 CFR § 416.16(a) & 416.17

22/51 – Individual entries on HACCP monitoring records did not have the initials of the monitor at the time of the entry, only a signature for the entire day. 9 CFR § 417.5(b) & 417.8

48 – Condemned poultry paws which had been placed in a combo outside for rendering pick-up were not being denatured. SAG ordered immediate corrective action. Paws are normally a processed product for export. 9 CFR § 381.95

All previous findings have been corrected.

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver DVM 10 Aug 2005

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 12 Aug. 2005	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. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		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	X
13. Daily records document items 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		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.		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		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		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. 05-09
Sopraval S. A.
La Calera

12 August 2005

38 – Rodent traps placed on the outside of the building were incorrectly placed (not up against the walls of the building) and therefore would not be effective. 9 CFR § 416.2(a)

42/51 – Two areas in the slaughter line, at the sanitizer line rehang and at the gizzard preparation area did not have sufficient drainage causing a water back-up in the areas. This was a common drainage system. 9 CFR § 416.2(e)(4)

45 – Potential cross contamination of necks was observed on the crop extractor because of build-up of trachea and crops not pulled out the mechanism by the vacuum pressure. 9 CFR § 416.3(a)

All findings from last audit have been corrected.

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver DVM 12 Aug 05



Santiago,

16. NOV 2005 • 13973

Dr. Sally White
Director
International Equivalent Staff
Office of International Affairs
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue.
Washington, DC 20250

Dear Dr White,

Please find attached our official reply to the non conformities detected in the poultry audit carried out in august 2005. We understand this to be the completion of the technical stage in the process of mutual equivalence of the inspection and certification systems of our countries.

Yours sincerely,


HERNAN ROJAS OLAVARRIA
JEFE
DIVISION PROTECCION PECUARIA


JRM/MB
11/11/2005

- CC : - Sra. Christine Sloop, Agregada Agrícola de los Estado Unidos en Chile.
- Sr. Eduardo Santos, Agregado Agrícola en Estados Unidos.
- Subdepartamento de Comercio Exterior (Estados Unidos).
- Subdepartamento de Industria y Tecnología

1ES - #130
Rp 12/2/05

RESPONSE TO THE DRAFT REPORT OF THE FSIS AUDIT OF AUGUST 9-18, 2005.

The response to the draft report will cover the audit carried out in August 2005.

With reference to:

Point 6. MAIN FINDINGS:

- 6.1-Governmental Supervision:
No observations were presented.

- 6.2 Audit of Central Level:
No observations were presented.

Point 7. AUDIT OF FACILITIES.

The specific deficiencies of the two audited facilities are answered in the respective compliance report in Annex 1.

Point 8. AUDIT OF RESIDUES AND MICROBIOLOGIC LABORATORIES.

There was no audit carried out of the residues and microbiologic laboratories.

Point 9. SANITIZATION CONTROL.

9.1 The observations of the SSOPs observed are answered in the respective compliance report in Annex 1.

9.2 The observations of the SPS observed are answered in the respective compliance report in Annex 1.

Point 10. DISEASE CONTROL IN ANIMALS.

No observations were presented.

Point 11. SLAUGHTER AND PROCESS CONTROL.

- 11.1 Humane handling and slaughter:
No observations were presented.

- 11.2 HACCP implementation:
The observations on HACCP implementation are answered in the compliance report in Annex 1.

- 11.3 Sampling for generic E. coli.
No observations were presented.

- 11.4 Sampling for *Listeria monocytogens*
Not applicable since export of Ready-to-Eat products (RTE) has not been requested yet.

Point 12. RESIDUE CONTROL

No observations were presented.

Point 13. ENFORCEMENT CONTROLS

13.1 Daily inspection at facilities.

No observations were presented.

13.2 Sampling for Salmonella.

No observations were presented.

13.3 Verification of Species

The SAG is prepared to implement the verification of species Test; it only needs to purchase the corresponding Kits, which is currently being processed.

This procedure will take place in the Food Microbiologic laboratory of the Bacteriologic Unit of the Lo Aguirre official laboratory which is equipped with the appropriate infrastructure and trained personnel to carry out this type of analysis with a technique approved as USDA-FSIS protocol. This technique indicates the use of repetitions in 4 dishes (quadruplicate) for each control and each sample. This experience was implemented previously in 2002 with the purpose of monitoring the presence of animal protein in feed for ruminants.

13.4 Monthly revision.

No observations were presented.

13.5 Inspection System Controls.

The observations on Inspection System controls are answered in the compliance report in Annex 1.

ANNEX 1

COMPLIANCE REPORT FOR SAN VICENTE FACILITY 06-08

Non compliances Detected	Corrective Action	Personnel in charge / Date
<p>The written preventive measures for the pre-operational verification results of the sanitation of the facility were not specific enough to permit the evaluation of efficiency.</p>	<p>In order to achieve a better result of the preventive actions that originate from the root cause analysis of the defects found during pre-operational revisions of the SSOP carried out at the plant, by both plant and official SAG personnel, it has been decided to hold a weekly meeting with the participation of personnel of the Agricultural and Livestock Service, the Quality Assurance, Maintenance and Production Departments of the San Vicente Slaughterhouse and the outsourced company in charge of cleaning operations.</p> <p>The purpose of this meeting is to establish the corresponding preventive actions with regard to the identified root causes and to assess the effectiveness of the established measures. A follow-up of the preventive actions will be carried out once the period of time established for their implementation is fulfilled. This information is recorded in document SV-RG-GEN-026 Record Keeping of Preventive Actions.</p> <p>The Department Chief of Quality Assurance is in charge of holding this meeting and recording the decisions taken herein and, along with SAG personnel, to verify the competency and effectiveness of the measures established.</p>	<p>Pablo Valdés October 2005</p>
<p>The individual entries in the HACCP that supervised the records did not have the initials of the monitor at the time of the entry, only the signatures for the entire day.</p>	<p>Monitoring worksheets of each CCP were modified so that they now record the identification of the person who carried out the monitoring and the time this took place.</p>	<p>Pablo Valdés September 2005</p>
<p>Feet of seized domestic birds that had been placed outside in a combo for their processing in a digester were not denaturalized. The SAG requested the immediate corrective action. Feet are products normally processed for export.</p>	<p>Denaturalization of seized poultry that are produced during the slaughter process is a normal part of the SAG inspection routine. Instructions were reinforced to inform the Agricultural and Livestock Service each time a product is destined to the digester and its seizure is due to an unusual reason, so that the SAG can be informed of the occurrence and can apply the corresponding chemical product; by doing so, the product is promptly denaturalized. The document SV-RG-FAE-050 Monitoring Non-habitual Seizures will be used to carry out this communication, each time it is necessary to do so.</p>	<p>Pablo Valdés September 2005</p>

DR. GUILLERMO GORRIÑO U.
CHIEF OF OFFICIAL INSPECTION TEAM
SAN VICENTE FACILITY

COMPLIANCE REPORT OF SOPRAVAL FACILITY 05-09

N°	OBSERVATIONS OF NON COMPLIANCES	CORRECTIVE ACTIONS	PREVENTIVE ACTIONS	PERSON IN CHARGE / TERM
1	The evisceration room is not equipped with an efficient drain capable of sustaining the evacuation requirements at specific stations of the process. Accumulation of organic residues was observed at: extraction of cloaca station; gizzard cleaning station; and product sanitization carousel.	On August 15, the frequency of the operational clean-up was modified: the retrieval of solids, in order to prevent drains from clogging up, took place 4 times a day and currently takes place 6 times a day.	The pre-operational clean-up procedure of the drains was modified. Three types of clean-ups are carried out: one physical clean-up consisting of cleaning drainage walls with a scraping element once a month; a daily physical-chemical clean-up and a third one consisting of flooding the drains in the area for several hours and then flushing it with water (weekly).	Giuseppe Siverio August 30, 2005
2	The crop extracting machine has permanent accumulated residue owing to blockage in the evacuation duct. This generates eventual crossed contamination of the carcasses when they arrive to this point.	This point is cleaned of its accumulated material each one (1) hour, or every time the line stops.	The modification of the clean-up system of the machine is being studied so that it does not have to be stopped every time it requires cleaning.	Giuseppe Siverio corrective: 12/08/05 preventive: March 2006
3	Rat bait stations located in the external perimeter are not fixed nor aligned to the wall, which diminishes their effectiveness due to the rodents' habits. Rat bait stations should be placed parallel and fixed to the wall.	Rat bait stations are fixed to the wall or the floor in such a way that they are always facing the same direction and are attached to the wall.	The supplier was requested to analyze if this was the best way to respond to this observation; if not, he must submit a proposal.	Andrea Kamp corrective: 12/08/05 preventive: 30/12/05

SANDRA OLIVARES
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SOPRAVAL FACILITY