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

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Dr. Claudio TERNICIER González
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Ministry of Agriculture
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Santiago, Chile

Dear Dr. Ternicier

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Chile's meat/poultry inspection system July 15 to August 7, 2009. You were invited to provide comments regarding the information in the draft final audit report. No comments were received from the government of Chile within 60 days. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

James Adams, DVM
Director
International Audit Staff
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Enclosure

cc:

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

JULY 15 THROUGH AUGUST 7, 2009

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

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

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Chile from July 15 through August 7, 2009. This was a routine audit with a special emphasis on microbiological testing programs and corrective actions taken in response to a Notice of Intent to Delist (NOID) issued during the previous audit. Chile is eligible to export red meat, red meat products, poultry meat, and poultry meat products to the United States. Between January 1 and July 31, 2009, Chile exported 8,686,377 pounds of meat and poultry products to the United States, of which 3,670,054 pounds were reinspected at US ports of entry (POE). A total of 3,428 pounds were rejected at POE, of which no rejections were for food-safety concerns. The activities of the current audit appear in the table below.

The findings of the previous audit during July-August 2008 resulted in no restrictions of the ability of any establishment in Chile to export meat products to the US.

1.2 Comparison of the Current Audit and the Previous Audit

		07/15-08/07, 2009	07/08-08/08, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	2	2
	Local	2	0
	Establishment Level	10	10
Laboratories Audited			
	Microbiology	0	2
	Residue	0	2
Establishments Audited			
	Slaughter/processing	10	10
	Processing	0	0
	ID Warehouses	0	0
Enforcement Actions Initiated			
	NOID	0	1
	Delistment	5	0
Risk Area Findings		(10 Ests. audited)	(10 Ests. audited)
	Sanitation Controls (SSOPS, SPS)	4	9
	Animal Disease Controls	6	0
	Slaughter/Processing (PR/HACCP)	7	8
	Residue Controls	0	2
	Microbiology Controls	0	1
	Inspection/Enforcement Controls	10	3
	Special Emphasis (HH, O157:H7)	1	6
	Facilities for Inspection	4	0

1.3 Summary Comments for the Current Audit

All four poultry establishments eligible to export to the United States were delisted by FSIS during this current audit (beginning July 31, 2009) for failure to conduct adequate post-mortem inspection: Inspectors were not routinely inspecting either the insides or the full outer surfaces of the carcasses.

The establishment that received the NOID in 2008 was delisted during this current audit by Chile's Central Competent Authority (CCA) due to repeat non-compliances (maintenance of over-product equipment, lighting at an inspection station, and following the written frequency for direct observation of monitoring). The non-compliances reflected serious concerns in the risk area of enforcement of FSIS regulations.

At Chile's request the auditor was authorized to re-visit two of the delisted poultry establishments; he determined that post-mortem inspection procedures had been brought into compliance. On the basis of this and of documentation provided to FSIS by the CCA regarding corrective actions and training programs, FSIS re-listed the four poultry establishments for US export; however, poultry products produced beginning July 31 and ending August 8 remain ineligible for entry into the US.

2. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the US Department of Agriculture conducted an audit of Chile's meat and poultry inspection system on July 15 through August 7, 2009.

An opening meeting was held on July 15 in Santiago with the Central Competent Authority (CCA) – *Servicio Agricola y Ganadero* (SAG), or Agriculture and Livestock Service. In this meeting, the auditor confirmed the objective and scope of the audit and the auditor's itinerary and requested additional information needed to complete the audit of Chile's meat and poultry inspection system.

Representatives from SAG headquarters and/or representatives from its regional and local inspection offices accompanied the auditor during each audit activity.

3. OBJECTIVES OF THE AUDIT

The objectives were (1) to determine whether the concerns identified during the 2008 audit had been appropriately addressed and (2) to evaluate the performance of SAG with respect to government oversight and enforcement of the Chilean and FSIS regulatory requirements relative to maintaining an inspection system equivalent to that of the United States. This included the following areas of special emphasis:

- Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) Requirements
- Humane handling and slaughter of livestock

- Government oversight
- Controls for *E. coli* O157:H7
- Controls for Bovine Spongiform Encephalopathy (BSE)
- Daily inspection
- Payment of inspectors
- The CCA's oversight of slaughter establishments' implementation of controls to prevent contamination of carcasses with feces or ingesta
- Field inspection personnel's knowledge and application of the FSIS regulatory requirements

4. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with SAG officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records and personnel interviews in the country's inspection headquarters and in two regional and two local inspection offices. The third part involved on-site visits to 10 slaughter-and-processing establishments.

Program effectiveness determinations of Chile's inspection system focused on five areas of government controls and oversight and five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPS), (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of HACCP programs and a testing program for generic *Escherichia coli (E. coli)*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species.

During the establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection activities are carried out by SAG and determined if controls were in place to ensure that the production of meat and meat products were safe, unadulterated and properly labeled.

In the opening meeting, the auditor explained that Chile's meat inspection system would be audited against the following standards: (1) FSIS regulatory requirements, as applicable, (2) SAG requirements specific to exporting meat and meat products to the US, and (3) FSIS equivalence determinations specific to Chile. FSIS requirements include, among other things, daily inspection in all applicable certified establishments, periodic supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts thereof, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOPS, and testing programs for generic *E. coli* and *Salmonella* species.

The following FSIS equivalence determinations have been made for Chile under the provisions of the World Trade Organization Sanitary/Phytosanitary Agreement:

- An additional generic *E. coli* sample is collected, in addition to the three set forth in the FSIS requirements. Chile is collecting the fourth generic *E. coli* sample from the neck for cattle and in the case of swine, collecting an additional sample from the back.

- Chile has implemented a zero tolerance for *Salmonella spp.* on raw products produced in official establishments.

- Chile uses private laboratories to test product for the presence of *Salmonella* in meat and poultry products produced by U.S. certified plants.

- In the Chilean *Salmonella* testing program for meat, 5 samples are collected each week by the veterinarian-in-charge. These 5 samples are all collected on the same day of the week, with the day of the week such collection is made rotated each week of the month, so in a four-week month a total of 20 samples are collected.

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

- *Salmonella* samples for swine and bovines are collected using the sponge (swab) method in each of 4 100-cm2 areas for a total area of 400 cm2.

- When a positive *Salmonella* sample occurs for the first time, the Official Veterinary Inspector issues a Non Conformity Notification within 24 hours of obtaining the results from the laboratory. The establishment must present a contingency plan of corrective actions within 48 hours. The Veterinarian-In-Charge then takes 28 samples, 48 hours after implementation of the corrective actions. If all samples are negative, then the establishment returns to a normal sampling regime. If one or more are positive then this process is repeated. If, during the second round of follow up testing, there is a positive, then the Official Veterinary Inspector notifies the SAG Regional Director, and the export certification is suspended.

- In bovine, porcine, ovine, and caprine carcasses, samples for *Salmonella* testing are collected from the carcasses at the end of the slaughter process, prior to further processing or packaging.

- There are two verifications for generic *E. coli*: the establishment carries out a daily sampling following FSIS frequencies which is verified by the Official Veterinary Inspector, and the Official Veterinary Inspector takes official verification samples weekly (5 samples for each species).

- If there are more than 3 out of a series of 13 samples which have generic *E. coli* results between "m" and "M," then the establishment must identify the cause, implement corrective actions, and analyze/modify the SSOPs as necessary. If one or more of the results are above "M," then the establishment must do the same as described above as well as analyzing the HACCP plan or the GMP and modify as necessary. Each time that "M" is exceeded the Official Veterinary Inspector issues a Non-Compliance Report to the establishment. The inspection officials verify corrective actions any time they are put in place.

- The daily samples for generic *E. coli* that are collected by the establishment are analyzed by a private laboratory which is accredited by SAG. The weekly verification samples that are collected by the Official Veterinary Inspector can be sent either to a government laboratory or to a private laboratory accredited by SAG.

- For bovine, ovine, and caprine carcasses, sampling sites for generic *E. coli* include the neck; for swine, the loin is included.

- The results of the analyses are sent to the Official Veterinarian inspector who sent the sample within a period of no longer than 24 hours after the sample is taken.

- Official verification samples for generic *E. coli* are collected weekly (5 samples per species), and the establishment performs daily sampling, which is verified by the Official Veterinary Inspector, according to FSIS frequency.

- For sample analysis, Chile has submitted AOAC Method 991.14, and AOAC Method 998.08. These AOAC methods were determined equivalent by IES on March 9, 2006. Also submitted by Chile was AOAC method 966.24. IES and OPHS determined that this method was equivalent on May 20, 2009. Chile has verified that these lab methods are implemented as described in the AOAC procedures.

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).

- The Federal Meat Inspection Regulations (9 CFR, Parts 301 to end), which include the PR/HACCP regulations.

- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) and the Poultry Products Inspection Regulations (9 CFR, Part 381)

6. SUMMARY OF THE PREVIOUS TWO FSIS AUDITS

Final audit reports are available on FSIS' website at:
http://www.fsis.usda.gov/regulations/Foreign_Audit_Reports/index.asp.

July-August 2008

Ten of the 13 certified establishments, two regional offices, two microbiology laboratories, and two residue laboratories, were audited. The following non-compliances were reported:

- Non-compliances regarding enforcement of some aspects of FSIS regulatory requirements that should have been identified in advance by SAG were reported in nine of the ten establishments audited.
- One establishment received a NOID by the CCA due to non-compliances that included product contamination through condensation, common contact, HACCP-implementation non-compliances, neglected maintenance & cleaning of overhead structures, and inadequate lighting at the final inspection station
- No establishments were delisted.
- Sanitation non-compliances were reported in 9 establishments.
- Non-compliances regarding HACCP programs were reported in 8 establishments.
- Non-compliances regarding testing for generic *E. coli* were reported in 6 establishments.
- Non-compliances regarding testing for E. coli O157:H7 were reported in four establishments.
- In the residue laboratories, some signatures were missing from stock solution preparation documentation, from a printout, and on the label of a standard solution. Also, some corrections in documents were not dated.
- In one microbiology laboratory, some samples were not identified with a unique identification number throughout the analytical process.

March-April 2007

All three of the certified establishments, one regional office, and one microbiology laboratory were audited; there were no delistments and no NOIDs. The following non-compliances were reported:

- Non-compliances regarding enforcement of some aspects of FSIS regulatory requirements that should have been identified in advance by SAG were reported in nine of the ten establishments.
- Sanitation non-compliances were reported in all three establishments.
- Non-compliances regarding HACCP programs were reported in all three establishments.
- A non-compliance regarding testing for generic *E. coli* was reported in one establishment.

7. MAIN FINDINGS

7.1 Government Oversight

The organizational structure of Chile's meat and poultry inspection system has not changed since the last FSIS audit. The Central Competent Authority (CCA) for the Chilean meat and poultry inspection system is the *Servicio Agricola y Ganadero* (SAG), or the Agriculture and Livestock Service, which is part of the *Ministerio de Agricultura*, the Ministry of Agriculture. SAG has the responsibility for carrying out Chile's inspection program, including oversight and enforcement of the FSIS regulatory requirements in meat and poultry establishments certified by SAG as eligible to export to the United States, and also in residue and microbiology laboratories in which US-eligible product is analyzed. SAG's regulatory oversight of its meat inspection and certification system control consists of four levels: Central, regional, local, and establishment.

The Ministry's Sub-Department for Industry and Technology is divided into five units: the National Unit of Farms under Official Certification, the National Inspection Unit, the National Certification Unit, the National Pathogen Reduction Unit, and the National Residue Control Unit.

The inspection responsibilities are managed from 15 regional offices (6 regions contain US-eligible establishments). Each regional office has a Livestock Regional Officer-in-Charge and a Regional Inspection Supervisor (RIS). The RIS is in charge of the required periodic supervisory visits to the establishments certified as eligible to export to the United States. The activities of the Regional Office include:

- Surveillance
- Prevention of the introduction of exotic diseases
- Epidemiological surveillance
- Eradication of TB and Brucellosis
- Livestock movement traceability
- Industry and technology
- Integrated Official Inspection System (*Planteles Animales Bajo Certificación Oficiál*=PABCO, or Animal Farms Under Official Control)
- Quality Assurance systems
- Inspection in slaughter and processing facilities
- Export certification
- Residue control program
- Pathogen reduction program (The results are sent by e-mail and with hard copy to the VIC with copies to the Regional Supervisor.)
- Registration and control of veterinary drugs and control of feed ingredients
- Defense – control of imports
- Livestock Computer System (*Sistema Información Pecuaria*=SIPEC) – a data base for the registration of the activities of all livestock establishments.

There are also 62 local offices. In each local office there is a Local Veterinary Officer (LVO), who serves as a field supervisor over the official veterinarians assigned in the establishments. The local offices handle the administrative oversight of the inspection teams in the establishments; technical oversight is provided by the regional offices. The Head of the Local Office provides administrative support, equipment & work clothing, salaries, shift logistics, vacations, medical leaves, etc. to the inspection teams in the establishments.

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

7.1.1 CCA Control Systems

Implementation of inspection activities is accomplished by the Veterinarian-in-Charge of each official establishment, with oversight from the regional offices and headquarters. Verification of implementation is accomplished by periodic supervisory reviews conducted by the RIS.

There is a formal system for information dispatch from the Livestock Protection Division to the Regional Directorates; the latter send the new information to the local offices and from there it is forwarded to the inspection teams. Often the information is copied electronically by the Sub-Department of Industry & Technology and sent directly to the Regional Export Supervisor; he, in turn, provides them the Official Veterinary Inspectors in the establishments. Each RIS further verifies, during his/her monthly supervisory visits, that the information has been received by the officials at the plant level.

7.1.2 Ultimate Control and Supervision

The in-plant inspection personnel are supervised by the Veterinarian-in-Charge, who has the authority to suspend the establishment's production operation any time the safety or wholesomeness of the product is jeopardized. The VIC reports directly to the LVO and the RIS. The RIS is responsible for performing comprehensive periodic internal reviews of the establishments in his/her Region that are certified as eligible to produce products for export to the United States; an integral part of these reviews is the evaluation of inspection personnel's performance. In Chile, these reviews are conducted at least monthly. The Regional Inspection Supervisors' monthly reviews cover inspection team performance, certification programs, export requirements, and pathogen reduction programs; every 3 months there is a special additional review of the pathogen reduction programs at the Regional level. The RIS sends his/her report to the Regional Officer-In-Charge of Livestock and provides a copy with the in-plant inspection team. The RS's responsibilities also include verification of the national beef residue program, microbiological testing of surfaces, testing programs for *E. coli* O157:H7, species verification, export certification, and livestock traceability.

Furthermore, there is a central supervisory review program, under which the SAG headquarters officials review the activities of the regions (at least annually) regarding—among other matters—the latter's oversight of enforcement of compliance at the establishment level. In the event of noncompliance, the region not only must require corrective actions at the establishment level and verify their effectiveness, but also must implement their own corrective actions concerning their supervision of the establishments in which noncompliance was identified.

All inspection personnel assigned to establishments certified to export meat and poultry products to the United States are full-time government employees receiving no remuneration from either industry groups or establishment personnel.

All establishments in Chile that produce food for human consumption, regardless of whether they export their products, must be registered with the Ministry of Health. When the manager of an establishment wishes to become eligible to export, he/she requests export certification/inscription into the *Lista de Establicimientos Exportadores de Productos Pecuarios* (LEEPP), or List of Establishments Exporting Livestock Products. SAG performs an in-depth visit to determine if the establishment meets all the requirements demanded by the country to which the establishment wishes to have export access. If non-compliances are identified, they must be corrected and another visit by SAG is required. When SAG determines that all requirements are met, authorization is granted and SAG notifies the importing country.

7.1.3 Assignment of Competent, Qualified Inspectors

Each Regional Director is responsible for the initial hiring, training, and payment of veterinarians and non-veterinary meat inspectors. All inspection personnel participate in introductory training as well as on-the-job training under the supervision of experienced veterinarians. Continuing education is provided for all inspection personnel as needed. The Regional Offices maintain the individual training records of inspection personnel.

Government employees are prohibited by law from engaging in any activities that bear similarity to their public duties, with the exception of teaching. SAG veterinarians may be permitted to work in small-animal practice outside of official hours, but they are not allowed to engage in food-animal practice.

To maintain inspection coverage in the event of planned or unplanned absences of inspection personnel, each region has a pool of available, qualified veterinarians and inspectors. The regional supervisor can also work in the establishments in special cases.

7.1.4 Authority and Responsibility to Enforce the Laws

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

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

7.1.5 Adequate Administrative and Technical Support

There is a central accreditation unit that establishes regulations for the accreditation of all residue and microbiology laboratories. It develops technical instructions for the development and maintenance of accreditation. The Department of Laboratories and Quarantine Stations has a team that conducts audits of the ISO 17025 Quality-Assurance requirements in the laboratories and also verify compliance with technical requirements (including requirements for the use of FSIS-approved methods in laboratories in which US-eligible products are analyzed) at least once per year.

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

7.2 Headquarters Audit

The auditor(s) conducted a review of inspection system documents at the headquarters and regional offices, and also in inspection offices in the audited establishments. These document reviews focused primarily on food safety hazards and included the following:

- HQ review report for regional offices
- Internal review reports
- Supervisory visits to establishments that were certified to export to the U.S.
- Internal audit reports for microbiology laboratories
- Corrective action verification for the non-compliance reported in one microbiology laboratory during the previous audit (the same ID number had been used for samples from the two halves of a carcass for analysis for *Salmonella* species and generic *E. coli*)
- Training records for inspection personnel
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Sanitation, slaughter and processing inspection procedures and standards
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, hydatidosis, trichinosis (Technical Standard 62), etc., and of inedible and condemned materials
- Export product inspection and control including export certificates (These were maintained in a central database.)

- Enforcement records, including examples of suspending, the eligibility of an establishment whose product was found (in Korea) to contain dioxin (The problem was traced to the farm.)

One concern arose as a result of the examination of these documents (see Section 14.2, Testing for Salmonella Species).

7.3. Audits of Regional and Local Inspection Sites

The FSIS auditor(s) reviewed government oversight and enforcement activities at the SAG Regional and Local Offices in Osorno (Los Lagos Region) and Temuco (Araucanía Region), and in the inspection offices of the 10 establishments audited.

8. ESTABLISHMENT AUDITS

A total of 10 slaughter-and-processing establishments that were certified by the government of Chile as eligible to export to the US were audited. The four poultry establishments were delisted. No establishment received a NOID.

9. 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, intra-laboratory check samples, 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 samples. If private laboratories are used to test United States samples, the auditor(s) evaluate compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

No residue or microbiology laboratories were included in the scope of this audit.

10. SANITATION CONTROLS

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

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

In addition, 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, and outside premises.

10.1 Sanitation Standard Operating Procedures

Each of the establishments audited was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The SSOPs in all of the ten establishments audited were found to meet the basic FSIS regulatory requirements, with some exceptions: Some SSOP requirements were not adequately enforced in two of these 10 establishments.

- In one establishment, several small and large edible-product containers being used for product were cracked, deteriorated, and in need of replacement.

- In one establishment, non-compliant pre-operational sanitation by the establishment was noted by the Regional Supervisor leading the audit; numerous pieces of product-contact equipment needed to be re-cleaned and one large conveyor belt had to be disassembled for thorough cleaning. Two boning rooms were rejected for complete re-cleaning and reinspection before operations were allowed to begin.

10.2 Sanitation Performance Standards

Sanitation Performance Standards in all establishments were found to meet the basic FSIS regulatory requirements, with some exceptions.

- In four establishments, maintenance and cleaning of ceilings and over-product equipment and structures did not meet regulatory requirements in several areas.

    - In one of these (the establishment that had received the NOID in 2008), the deterioration was extensive and this was a repeat finding. For this and other reasons, the establishment was delisted by SAG
    - In another establishment, the SAG inspection team had identified the problems and the ceilings were being systematically replaced. In the other two, some of the problem areas had been identified by SAG in advance; others had not.

- In one establishment, several small and large plastic trays and combo bins containing edible product were observed to be cracked, broken, and in need of repair or replacement.

- In one establishment, work clothes were stored together with street clothes in several lockers in the men's changing rooms.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor(s) reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor(s) determined that Chile's inspection system had adequate controls in place.

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

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor(s) reviewed was Slaughter/ Processing Controls. The controls include the following areas: Ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

The controls also included the implementation of HACCP systems and implementation of generic *E. coli* testing programs in all of the establishments audited.

12.1 Humane Handling and Humane Slaughter

No non-compliance was reported.

12.2 HACCP Implementation

Each slaughter and processing establishment certified to export meat products to the US is required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the U.S. domestic inspection program.

The HACCP programs in all 10 establishments were found to meet the basic FSIS regulatory requirements; however, some requirements were not met in seven of these. The following non-compliances were reported:

- In four establishments, pre-shipment document reviews were being performed as required, but the documentation did not contain the actual times when the individual reviews were performed.

- In three establishments, the monitoring documentation contained one notation representing absence of feces/ingesta for all units in the monitoring sample.

- In three establishments, the times when the record review portion of verification were performed were not recorded.

- In one establishment, the written frequencies for verification of monitoring of a Critical Control Point were not being consistently followed. This was a repeat non-compliance in this establishment from the 2008 FSIS audit.

- In one establishment, a full description of procedures for verification of monitoring activities was missing in the description of one CCP. These non-compliances had been identified by the Veterinarian-In-Charge and were in the process of being corrected.

12.3 Testing for Generic *E. coli*

Chile has adopted the FSIS regulatory requirements for testing for generic *E. coli,* with the exception of the following equivalent measures, which have been determined to be equivalent by FSIS (the details of these alternative programs are provided in Section 4 of this report).

- Chile has an equivalence determination to collect an additional generic *E. coli* sample in addition to the three set forth in the FSIS requirements.
- There are two verifications for generic *E. coli*: the establishment carries out a daily sampling following FSIS frequencies, and SAG takes weekly verification samples.
- If there are more than 3 out of a series of 13 samples which have generic *E. coli* results between "m" and "M," then the establishment must identify take certain proscribed corrective actions. (Chile's values for "m" and "M" were determined statistically as part of a national sampling program to determine the baseline.)
- Each time that "M" is exceeded the Official Veterinary Inspector issues a Non-Compliance Report to the establishment.
- The daily samples for generic *E. coli* that are collected by the establishment are analyzed by a private laboratory. The weekly verification samples that are collected by the Official Veterinary Inspector can be sent either to a government laboratory or to a private laboratory.
- Alternative methods for sample analysis have been recognized as equivalent.

All of the 10 establishments audited were required to meet the regulatory requirements for the alternative generic *E. coli* testing program and were evaluated according to the criteria set out in this program.

Testing for generic *E. coli* was conducted properly in all of the 10 establishments.

12.4 Testing for *Listeria monocytogenes*

None of the 10 establishments audited was required to meet the basic FSIS regulatory requirements for testing for *Listeria monocytogenes.* Chile had only recently received FSIS approval to export ready-to-eat products to the United States, and none were as yet being produced for US export.

13. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor(s) 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.

Chile's residue testing program was evaluated at the establishment level. No non-compliance was reported. The National Residue Testing Plan for 2009 was on schedule.

14. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor(s) reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements such as required inspection coverage, the testing programs for *Salmonella,* and species verification.

- Non-compliances that should have been identified in advance by SAG and corrected prior to this audit were reported in all of the ten establishments audited.

14.1 Daily Inspection in Establishments

Inspection was being conducted daily, whenever US-eligible products were being produced, in all of the 10 establishments audited.

14.2 Testing for *Salmonella* species

Chile has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measures:

- Chile has implemented a zero tolerance for *Salmonella* on raw products produced in official establishments.

- Chile uses private laboratories to test product for the presence of *Salmonella* in meat and poultry products produced by U.S. certified plants.

- Samples are collected for testing for *Salmonella* from the leg (ham), abdomen (belly), head (jowl), and neck for swine; and from the lap (flank), chest (brisket), hip (rump), and neck for bovines and ovines.

- Samples for testing for *Salmonella* for swine and bovines are collected using the sponge (swab) method in each of 4 100-cm2 areas for a total area of 400 cm2.

- In the Chilean *Salmonella* testing program for meat, 5 samples are collected each week by the VIC. These 5 samples are all collected on the same day of the week, with the day of the week such collection is made rotated each week of the month, so in a four-week month a total of 20 samples are collected.

- When a positive *Salmonella* sample occurs for the first time, the Official Veterinary Inspector issues a Non Conformity Notification within 24 hours of obtaining the results from the laboratory. The establishment must present a contingency plan of corrective actions within 48 hours. The VIC then takes 28 samples, 48 hours after implementation of the corrective actions. If all samples are negative, then the establishment returns to a normal sampling regime. If one or more are positive then this process is repeated. If, during the second round of follow up testing, there is a positive, then the VIC notifies the SAG Regional Director, and the export certification is to be suspended.

All of the 10 establishments audited were required to meet the basic FSIS regulatory requirements and the equivalent measures for *Salmonella* testing and were evaluated according to the criteria employed in the U.S. domestic inspection program and those recognized by FSIS as equivalent.

Testing for *Salmonella* was properly conducted in all of the establishments in which it was required; however, one of these equivalent procedures was not followed consistently:

- In one establishment, when positive results were reported for a second follow-up sample set, a meeting was called involving SAG headquarters officials, one of the two Regional Supervisors, and establishment management. During the meeting, the establishment management proposed further corrective actions and further testing instead of suspension of its export certification. The proposed corrective actions included disassembling machinery, using different disinfectants on evisceration machinery over the weekend, and chlorination of the chiller water up to the highest levels permitted by Chilean regulations. (The chiller water had not been chlorinated when the first positive sample occurred because the establishment was producing product for export to Europe and the European Union does not permit the use of chlorine.) SAG had accepted the establishment's proposal and had collected another set of 28 samples (the day before the FSIS audit) and was awaiting the results. Meanwhile, export certification remained intact. The VIC explained that the reason why export certification had not been suspended when the second follow-up sample set had tested positive was that the problem had been traced to the farm and not to deficiencies within the establishment.

If the CCA intends to deviate from an alternative program accepted by FSIS as equivalent, the details of the deviation—and the reasons for the decision not to follow the measures submitted to FSIS for an equivalence determination—should be provided to FSIS promptly for review and comment.

14.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

14.4 Periodic Supervisory Reviews

In all of the establishments audited, supervisory reviews of certified establishments were being performed and documented as required; however, a number of areas of non-compliance that were identified during the audit should have been identified during the supervisory reviews.

14.5 Inspection System Controls

The CCA had controls in place for ante-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. Also, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

The following post-mortem inspection non-compliances were reported:

- In two of the three beef establishments audited, lateral retropharyngeal (atlantal) lymph nodes were not incised and inspected as required.

- In one beef establishment, the viscera inspector was not inspecting one of the two tracheobronchial lymph nodes.

- A system-wide non-compliance was identified by the FSIS auditor regarding Chile's implementation of both FSIS and Chilean requirements for post-mortem inspection procedures in poultry. In all four of the poultry establishments certified by SAG as eligible to export to the United States, some of the required parts of post-mortem inspection were not being performed.

- In all four poultry establishments, due to the small space between birds, the inspectors were unable to observe completely the outsides of the shackled carcasses that were facing away from them on the moving chain in the mirrors.

- All of the inspectors in two of the three chicken establishments, one of the three inspectors in the third chicken establishment, and one of the three inspectors in the turkey establishment, were not routinely inspecting the insides of all the birds presented to them, as required.

- In one chicken establishment, an inspector failed to perform any inspection of five birds in a row that were assigned to him to inspect.

- In the three chicken establishments, the ability of the inspectors to view the outside surfaces that were turned away from them was further impeded by heavy fogging and smearing of the mirrors as a result of contact with numerous carcasses.

After the post-mortem inspection non-compliances were found in both of the first two chicken establishments audited, SAG officials proposed to FSIS immediate suspension of their export certification for the United States, an immediate review of the post-mortem inspection procedures in the other two US-eligible poultry establishments and suspension of their certification as well if the same non-compliances should be found, and a full review of establishment facilities and the program for assignment of inspectors, in order to determine how to correct the non-compliances.

Later the same day (July 30, 2009), SAG informed FSIS that communications with the in-plant inspection staff at the two remaining poultry establishments had resulted in the information that, in both establishments, post-mortem inspection procedures were being performed as required. One of these was scheduled for audit on August 3; the FSIS auditor proposed substituting the fourth poultry establishment for the swine establishment scheduled the following day (July 31). SAG approved the proposal.

During the audit of the newly-substituted establishment, the FSIS auditor determined that one of the three inspectors failed to conduct inspection of the insides of the birds as required and none of the inspectors was able to view the complete outside surfaces of the birds, due to the lack of space between the birds to see the surfaces turned away from them and the smeared condition of the reflective surface intended to allow them to do so.

Based on the information that several aspects of the post-mortem inspection procedures, as required by both FSIS and Chilean regulations, were found to be noncompliant in multiple poultry establishments, FSIS upper management officials determined that Chile's poultry inspection system had failed to meet basic FSIS requirements. As a result, FSIS initiated delistment of all Chilean poultry establishments, effective July 30, 2009.

On Monday, August 3, SAG provided assurances to FSIS that corrective actions had been taken in the first two chicken establishments that had been audited and requested verbally that the auditor re-visit these two establishments to verify that the post-mortem inspection was now being performed in conformance with requirements. FSIS responded that this

request must be made in writing; SAG sent the request by e-mail and FAX on August 4 and included a summary of the corrective actions. FSIS provided authorization on August 4 for the auditor to return to these establishments.

On August 6, the FSIS auditor evaluated post-mortem inspection in one of the two establishments and verified that the following corrective actions, which had been communicated to FSIS, were indeed in place and functioning effectively:

- Installation of railings that modify the position of the carcass allowing its cavity to be exposed and to be in full view of the official inspector
- The carcass enters the inspection point at an angle of approximately 45°.
- Increased lighting at inspection points to eliminate the shadow cast in the abdominal cavity of the carcass, thus facilitating inspection by the official inspector
- Shortened and modified the position of the structure at the inspection point facing the official inspector, so that SAG technical inspectors can approach the carcass line within less than 2 feet
- Instructions to increase diligence in official inspection of carcass interiors and to mark and un-hang from the slaughter line any carcass that is not visible in its interior, which is to be re-hung on the shackles and reinspected by the veterinary medical officer

In addition to these corrections that had been provided in writing, the auditor also noted the following:

- A new mirror-washing facility had been installed which, together with the extra space between the mirror and the carcasses provided by the stainless steel bar that re-positions the carcasses that provides for excellent visibility of the entire outer surface of the carcasses.
- The automatic eviscerating machinery has been adjusted to enlarge the abdominal opening, providing improved visibility of the abdominal cavities.
- The line speed has been reduced from 50 to 42 chickens per minute per inspector.

During the auditor's stay in this establishment, SAG proposed a change in the schedule. They gave verbal assurances that they had been informed the previous day that corrective actions were now also in place in a third chicken establishment, which was in a different Region, and proposed that he travel to this establishment in lieu of the planned second establishment, to verify more effectively the scope of the corrections to the system. FSIS agreed.

The auditor evaluated post-mortem inspection in this third establishment and noted the following:

- Carcasses had previously been hung on every shackle; they were now hung on alternate shackles, with an empty shackle in between carcasses.
- The birds were now presented at a rate of 24 per minute per inspector, as opposed to 47 per minute per inspector on the day of the original audit.

- Three new glass mirrors had been installed.
- Signals were now given by inspectors to assistants via hand signals rather than by means of a manually-applied purple marker.

Furthermore, SAG gave assurances that the following additional steps were planned:

- The structure of the slaughter line would be modified by September 1, 2009 to allow the inspectors to be closer to the carcasses.
- A new inspection station would be installed for an additional (fourth) inspector; each inspector would inspect every 4th bird.
- The line speed would be maintained at the rate of 35 birds per minute per inspector.
- There would be sufficient space between the birds that the inspectors would have a clear view of the far sides of the carcasses.

The auditor concluded that, in both of the re-visited establishments, post-mortem inspection had been in full compliance with both FSIS and Chilean requirements: In addition to the improvements noted above, the post-mortem inspectors were grasping the carcasses, reflecting the skin flaps, and observing the abdominal cavities of the birds, in addition to observing the viscera and the outsides of the carcasses.

A teleconference was held on the afternoon of August 6, in the headquarters offices of SAG, between upper-level SAG officials and the Directors of FSIS' International Audit Staff and International Equivalence Staff. During this meeting FSIS requested documentation in writing of the instructions that had been provided to inspectors regarding the step-by-step details of how post-mortem inspection of poultry was to be carried out and also an outline of what further steps SAG would take to ensure that supervisors would perform on-going verification activities to ensure that the inspection procedures would remain in full compliance with both FSIS and Chilean requirements. SAG provided the requested information to FSIS that same evening.

FSIS reviewed the information provided and authorized SAG to re-list the four poultry establishments, effective as of the afternoon of August 7, 2009.

15. CLOSING MEETING

A closing meeting was held on July 7 in Santiago with the CCA. In this meeting, the auditor presented the primary findings.

The CCA understood and accepted the findings.

10/30/09 (Gary D. Bolstad, DVM)

15. ATTACHMENTS

- Individual Foreign Establishment Audit Forms
- (No Foreign Country Response to the Draft Final Audit Report was provided by October 30, 2009, when this report was finalized.)

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sopraval S.A. Panamericana Norte Km 12 La Calera	08/03/2009	509	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 08/03/2009 Est #: 509 (Sopraval S.A. [S/P/CS]) (La Calera, Chile)

22/51. The monitoring documentation contained one "0" representing absence of feces/ingesta on the 10 turkey carcasses in each monitoring sample. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

51/55. A thorough post-mortem inspection of the turkey carcasses was not possible under the conditions observed during the audit. The FSIS auditor made the following observations: (1) Birds over 16 pounds were being processed at a rate of 18 birds per minute per inspector, but they were hung on every shackle; the space between the birds varied from 1/2 inch to approximately 3 inches. From their positions, the post-mortem inspectors were unable to see the anterior portions of the breasts. The inspectors were not turning the birds to be able to inspect the parts of the outsides of the carcasses that faced away from them. (2) The size of the openings in the abdominal cavities resulting from the mechanical evisceration varied greatly, resulting in many poor presentations: Approximately 20% of the openings were very small, in the range of 1-1.5 inches laterally and 2-3 inches dorso-ventrally. The inspectors were wearing helmet-mounted flashlights, but they were not consistently grasping the skin flaps and spreading the abdominal openings to inspect the insides of the carcasses. Both inspectors failed to examine the full internal surfaces of approximately 15-20% of the birds assigned to them for inspection. [9 CFR §327.2(a)(2)(i)(D), 381]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Faenadora Lo Miranda Carretera H-30 N. 3814 Donihue	07/30/2009	602	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. Delistment	X
59.	

60. Observation of the Establishment

Date: 07/30/2009 Est #: 602 (Faenadora Lo Miranda [S/P/CS]) (Donihue, Chile)

11/51. Rust and inadequately-sealed openings and vents were observed) on ceilings and over-product structures in several areas of the establishment. Some of the deficiencies had been identified by SAG in advance and scheduled for correction. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 416.14, 416.17]

51/55. Post-mortem carcass inspection was not being performed in compliance with either FSIS or Chilean requirements, both of which clearly specify mandatory inspection of the outside surfaces, inside surfaces (abdominal cavities), and viscera of 100% of the birds presented for inspection. Each inspector was inspecting every 3rd bird (both carcass and viscera), at a rate of 47 birds per minute per inspector. The inspectors were unable to see into the abdominal cavities of the passing carcasses from their positions: The birds were hung by their hocks and the opening to each abdominal cavity was at a level slightly below that of the inspectors' eyes. Lighting at the inspection station met regulatory requirements, but the insides of the birds were in complete shadow and were hidden from the inspectors' observation capabilities. There was a physical separation between the inspectors and the passing carcasses of approximately 2 feet. The Regional Supervisor (who performed internal supervisory reviews monthly) had not identified these deficiencies, although evaluation of in-plant inspectors' performance was an integral part of each Regional Supervisor's routine review activities. [9 CFR §310.1, 327.2(a)(2)(i)(D)]

58. Inspection officials of Chile voluntarily removed this establishment from the list of establishments certified as eligible to export to the United States, effective 07/30/09. The FSIS auditor was in agreement with this decision.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Faenadora El Milagro S.A. Camino Fundo Peuco 3400 San Francisco de Mostazal, Libertador Bernardo O'Higgins	08/04/2009	603	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment | Date: 08/04/2009 Est #: 603 (Faenadora El Milagro S.A. [S/P/CS]) (San Francisco de Mostazal, Chile)

22/51. The monitoring documentation for CCP-1 contained one notation representing absence of feces/ingesta for all of the units in the monitoring sample rather than the actual observed results for each unit monitored. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

22/51. The establishment was performing pre-shipment document reviews but the documentation did not contain the actual times when the individual reviews were performed. [9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	GD Bolstad DVM 10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Faenadora Rosario Ltda. Ruta H-50 Km. 04 Rosario, Libertador Bernardo O'Higgins	07/27/2009	606	Chile
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 07/27/2009 Est #: 606 (Faenadora Rosario Ltda. [S/P/CS]) (Rosario, Chile)

10. Several small and large plastic trays and combo bins containing edible product were observed to be cracked, broken, and in need of repair or replacement. The Regional Supervisor ordered a complete reinspection of all edible-product containers, repair of those that were reparable, and rejection of those that were not. [Regulatory reference(s): 9 CFR §416.13, 416.17]

22/51. The pre-shipment document reviews were performed at the end of each shift (there were two shifts per day), but the establishment was not recording the signature of the individual performing the rewiews or the times when they were performed, as required. The documentation of the pre-shipment reviews was performed weekly, and this document contained one signature to cover the entire week's production, but did not document the time when the review was performed. The Regional Supervisor ordered immediate correction. [9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

39/51. Varying degrees of rust, flaking paint, and deteriorated silicone sealing material were seen on over-product strucures and equipment. No direct product contamination or adulteration was observed. The Regional Supervisor ordered corrective actions to be taken after the day's operations and before the next day's operations would be allowed to start. [9 CFR §327.2(a)(2)(i)(D), 416.17, 416.2(b)]

40/51. FSIS requires a minimum of 50 foot-candles (fc), or 538 Lux, of shadow-free lighting at the inspection surfaces. Lighting levels as low as 16 fc (175 Lux) and 23 fc (250 Lux) were measured at the inspection surfaces of the posterior abdominal cavities and of the head lymph nodes, respectively. The SAG officials ordered prompt installation of lighting sufficient to provide the required intensity at the inspection surfaces. [9 CFR §307.2(m)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Faenadora San Vicente Carretera H-66 G San Vicente de Tagua, Libertador Bernardo O'Higgins	07/28/2009	608	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D.Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. Delistment	X
59.	

60. Observation of the Establishment Date: 07/28/2009 Est #: 608 (Faenadora San Vicente [S/P/CS]) (San Vicente de Tagua, Chile)

22/51. The documentation of pre-shipment document reviews did not contain the actual times when the reviews were performed. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

51/55. Post-mortem carcass inspection was not being performed in compliance with either FSIS or Chilean requirements, both of which clearly specify mandatory inspection of the outside surfaces, inside surfaces (abdominal cavities), and viscera of 100% of the birds presented for inspection. Each inspector was inspecting every 4th bird, at a rate of 50 birds per minute per inspector. The inspectors were unable to see into the abdominal cavities of the passing carcasses from their (seated) positions: The birds were hung by their hocks and the opening to each abdominal cavity was at a level slightly below that of the inspectors' eyes. Lighting at the inspection stations met regulatory requirements, but the insides of the birds were in complete shadow and were hidden from the inspectors' observation capabilities. There was a separation between the inspectors and the passing carcasses of approximately 2 feet. The Regional Supervisor (who performed internal supervisory reviews monthly) had not identified these deficiencies, although evaluation of in-plant inspectors' performance was an integral part of each Regional Supervisor's routine review activities. [9 CFR §327.2(a)(2)(i)(D), 381]

58. Inspection officials of Chile voluntarily removed this establishment from the list of establishments certified as eligible to export to the United States, effective 07/28/09. The FSIS auditor was in agreement with this decision.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D.Bolstad, DVM	10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Faenadora Las Pataguas, Comercial Maxagro Ltda. Ruta H - 886 Km 2 Sector El Toco Pichidegua, Libertador Bernardo O'Higgins	07/29/2009	617	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 07/29/2009 Est #: 617 (Faenadora Las Pataguas, Comercial Maxagro Ltda. [S/P/CS]) (Pichidegua, Chile)

19/51. Full descriptions of the verification procedures for the 3 CCPs were not included in the written HACCP plan. This had already been identified by the SAG Veterinarian-In-Charge and was in the process of being corrected by the establishment. [Regulatory reference(s): 9 CFR §327.2(a)(2)(i)(D), 417.2(c)(7), 417.8]

22/51. Neither the documentation of the records-review aspect of verification of monitoring nor the pre-shipment document reviews contained the actual times when they were performed. The establishment presented revised documents containing clear provision for the mandatory recording of the times when these activities are performed prior to the end of the audit. [9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	GD Bolstad DVM 10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico Temuco S.A. Altamira 01825 Temuco, Araucania	07/24/2009	912	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D.Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 07/24/2009 Est #: 912 (Frigorifico Temuco S.A. [S/P/CS]) (Temuco, Chile)

40/55. Lighting at two inspection stations did not meet regulatory requirements. FSIS regulations require a minimum of 50 foot-candles (fc), or 538 Lux, of shadow-free lighting at the inspection surfaces. Lighting levels of only 9.3 fc (100 Lux) were measured at the inspection surfaces of the posterior abdominal cavities at the final carcass-inspection station and on the exterior surfaces of a carcass at the retained-rail reinspection station. The SAG officials ordered prompt installation of additional light to meet the requirement. [Regulatory reference(s): 9 CFR §307.2(m)]

55. An establishment employee preparing beef plucks for inspection trimmed away and discarded most of the mediastinal lymph nodes on one pluck before presenting it to the SAG inspector. The Regional Supervisor, who was leading the audit, immediately identified the problem and instructed the inspector to require presentation of plucks containing the entire set of intact lymph nodes and also instructed the establishment officials to require the person preparing the plucks to do so in such a manner that all parts requiring inspection remain intact with the plucks. [9 CFR §310.1]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D.Bolstad, DVM	10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico de Osorno S.A. Francisco del Campo 200, Osorno, Los Lagos	07/21/2009	1026	Chile
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	X
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. Delistment	X
59.	

60. Observation of the Establishment

Date: 07/21/2009 Est #: 1026 (Frigorifico de Osorno S.A. [S/P/CS]) (Osorno, Chile)

10. Pre-operational sanitation inspection by the Veterinarian-In-Charge (VIC) was observed. Numerous instances of product residues from the previous day's operations were identified on product-contact equipment; the VIC rejected two boning rooms pending complete re-cleaning by the establishment and re-inspection by the in-plant inspection staff. [Regulatory reference(s): 9 CFR §416.13]

10/51. Many instances of readily-visible flaking paint and various degrees of rust were observed on equipment and ceilings directly above exposed product areas and traffic areas used by edible-product workers throughout the establishment. This was a repeat finding from the previous FSIS audit on July 14, 2008. Neither in-plant nor supervisory inspection records reflected the conditions observed on the day of the audit. [9 CFR §327.2(a)(2)(i)(D), 416.13, 416.17]

19/51. The written HACCP plan required two direct-observation verification activities and one review of records per week. The auditor reviewed records for the first week in June 2009 and found that a second direct-observation verification activity had not been performed. This was a repeat deficiency: During the 2008 FSIS audit, it was reported that "the establishment did not follow its verification frequency for direct observation of monitoring procedures." This deficiency had been overlooked by the SAG inspector who had verified and countersigned the week's records. [9 CFR §327.2(a)(2)(i)(D), 417.2(c)(7), 417.8]

39/51. The door to the receiving area for cardboard cartons did not form a complete seal when closed. Live spiders and numerous cobwebs were observed in the corners of the area. [9 CFR §327.2(a)(2)(i)(D), 416.17, 416.2(b)]

40/51. Lighting at the post-mortem head-inspection station did not meet regulatory requirements. Lighting levels of only 350 Lux (32.5 Lux) were measured at the inspection surfaces of medial retropharyngeal and parotid lymph nodes. This was a repeat deficiency: Inadequate lighting at the final carcass-inspection station had been reported in the FSIS audit of this establishment on July 14, 2008. FSIS requires 50 foot-candles (fc), or 538 Lux, of shadow-free lighting at the inspection surfaces. [9 CFR §307.2(m), 327.2(a)(2)(i)(D)]

44. Work clothes were stored together with street clothes in several employees' lockers, in violation of establishment policy. [9 CFR §416.17, 416.2(h)]

51/55. The final carcass inspector was unable to view the inspection surfaces of the posterior aspects of the beef carcasses from closer than approximately 7 feet: The inspector stood on the floor to observe beef carcasses hung on a moving conveyor that were so high above him that the lowest portion of the carcasses that he was able to observe at eye level was tht of the anterior pleural cavities and shoulders. [9 CFR §310.1, 327.2(a)(2)(i)(D)]

51/55. Post-mortem inspectors were not routinely incising and inspecting either left tracheobronchial lymph nodes on beef lungs or lateral retropharyngeal (atlantal) lymph nodes on beef heads. [9 CFR §310.1, 327.2(a)(2)(i)(D)]

58. Inspection officials of Chile voluntarily removed this establishment from the list of establishments certified as eligible to export to the United States, effective 07/21/09. The FSIS auditor was in agreement with this decision.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	GD Bolstad DVM 10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorifico O Higgins S.A. Camino a Melipilla 8139 Santiago, Metropolitano	07/17/2009	1303	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 07/17/2009 Est #: 1303 (Frigorifico O Higgins S.A. [S/P/CS]) (Santiago, Chile)

40/51. Lighting at the carcass inspection station did not meet regulatory requirements. Light levels of 150 Lux (13.9 foot-candles) were measured in the posterior abdominal cavities of beef carcasses and 100 Lux (9.3 fc) on the anterior shoulders and necks. The FSIS requirement is a minimum of 50 fc of shadow-free lighting at the inspection surfaces. The SAG officials ordered prompt installation of adequate lighting. [Regulatory reference(s): 9 CFR §307.2(m), 327.2(a)(2)(i)(D)]

51/55. Lateral retropharyngesl (atlantal) lymph nodes were not routinely incised and inspected by the SAG head inspector. The SAG officials were unaware of this requirement but gave assurances that this would be corrected promptly. [9 CFR §310.1, 327.2(a)(2)(i)(D)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	10/30/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agroindustrial El Paico LTD Los Libertadores 1714 El Monte	07/31/2009	1307	Chile
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	X
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. Delistment	X
59.	

60. Observation of the Establishment

Date: 07/31/2009 Est #: 1307 (Agroindustrial El Paico LTD [S/P/CS]) (El Monte, Chile)

11/15. Rust, flaking paint, inadequately-sealed ceiling tiles, and deteriorating silicone sealant were observed on over-product structures and equipment in several areas. The Regional Supervisor had documented identification of the problem and all ceilings in the production areas were in the process of being replaced. [Regulatory reference(s): 9 CFR §416.14]

19/30/51. A routine official set of 5 samples was taken by SAG on April 28, 2009 for testing for Salmonella species. A report that a sample had tested positive was received by the Veterinarian-In-Charge (VIC) one week later. The VIC issued a Noncompliance Report within 24 hours of receiving the report. The establishment submitted a corrective action contingency plan within 48 hours of notification by the VIC of the positive report. The VIC took 28 more samples as required and submitted them for analysis. The establishment's corrective action plan called for an investigation into the cause of the violation; the investigation determined that the cause lay in the farm where the chickens had originated. Further corrective actions included training of personnel on the farm of origin, disinfection of the trucks that transport the birds to the slaughter facility, and training of establishment personnel regarding good manufacturing practices for slaughter with a special emphasis on evisceration. SAG collected a further 28 samples and submitted them for analysis. There were again positive results, and the VIC repeated the above procedure. All of the above steps complied with the procedures submitted by SAG to FSIS and determined to be equivalent to FSIS requirements. The procedures recognized as equivalent by FSIS also called for the regulatory control action of suspending export certification in the event of a third positive result. However, when positive results were again reported for the second follow-up sample set, a meeting was called involving SAG headquarters officials, one of the two Regional Supervisors, and establishment management. During the meeting, the establishment management proposed further corrective actions, including disassembling machinery, using different disinfectants on evisceration machinery over the weekend, and chlorination of the chiller water up to the highest levels permitted by Chilean regulations. At the time of this audit, the establishment was continuing to chlorinate the water to 10-50 ppm. (The chiller water had not been chlorinated when the first positive sample occurred because the establishment was producing product for export to Europe and the EU does not permit the use of chlorine.) SAG accepted the establishment's proposal and collected another set of 28 samples (the day before this audit) and was awaiting the results. Meanwhile, export certification remained intact. The VIC explained that the reason why export certification had not been suspended when the second follow-up sample set had tested positive was that the problem had been traced to the farm and not to deficiencies within the establishment. [9 CFR §310.25, 327.2(a)(2)(i)(D)]

22/51. The records documenting the pre-shipment document reviews did not contain the actual times when the activities were performed. [9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

22/51. The documentation of the (hourly) monitoring of 10 birds for the CCP regarding zero tolerance for contamination with ingesta/feces did not contain the actual observations for each bird, but rather one summary number for the findings on all 10 birds. [9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

51/55. Post-mortem carcass inspection was not being performed in compliance with either FSIS or Chilean requirements, both of which clearly specify mandatory inspection of the outside surfaces, inside surfaces (abdominal cavities), and viscera of 100% of the birds presented for inspection. The FSIS auditor observed that (1) none of the three post-mortem inspectors was able to observe the anterior surfaces of the breasts because there was no space between the shackled birds to view these surfaces in the stainless-steel mirror provided, (2) due to fogging and smearing of the mirror from contact with numerous carcasses, the surfaces turned away from the inspectors were not adequately visible to them, (3) none of the three inspectors was turning the birds to view the outside surfaces they were otherwise unable to see, (4) neither of the two Regional Supervisors (each of whom performed internal supervisory reviews on alternate months) had identified these deficiencies, although evaluation of in-plant inspectors' performance was an integral part of their routine review activities, and (5) one of the three inspectors was not opening the abdominal cavities of all birds to inspect the inside surfaces; furthermore, the auditor observed that this inspector failed to examine 5 birds in a row. [9 CFR §310.1, 327.2(a)(2)(i)(D)]

58. Inspection officials of Chile voluntarily removed this establishment from the list of establishments certified as eligible to export to the United States, effective 07/31/09. The FSIS auditor was in agreement with this decision.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Gary D. Bolstad, DVM	10/30/09