



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

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Dr. Oscar Videla  
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Servicio Agrícola y Ganadero  
Ministry of Agriculture  
Avda. Bulnes 140  
Santiago  
Republic of Chile

Dear Dr. Videla,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Chile's Meat and Poultry inspection system from April 10 through April 27, 2012. Enclosed is a copy of the draft final audit report. You are invited to provide comments regarding the information in the audit report. Comments received from the government of Chile will be included as an attachment to the final report. Comments must be provided within 60 days of the receipt of this letter.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at [internationalaudit@fsis.usda.gov](mailto:internationalaudit@fsis.usda.gov).

Sincerely,

Dr. Shaukat Syed  
Director  
International Audit Staff  
Office of International Affairs

Enclosure

DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN  
CHILE  
APRIL 10 THROUGH APRIL 27, 2012

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
THE PRODUCTION OF MEAT AND POULTRY  
PRODUCTS INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service  
United States Department of Agriculture

### *Executive Summary*

This report describes the outcome of a routine on-site verification audit conducted by the Food Safety and Inspection Service (FSIS) from April 10 through April 27, 2012, to determine if Chile's food safety system governing the production of meat and poultry products continues to be equivalent to that of the United States, with the ability to produce products which are safe, unadulterated, and properly labeled.

The focus of the audit was on the ability of the Central Competent Authority (CCA), Servicio Agrícola y Ganadero (SAG), to regulate meat and poultry products production. FSIS reviewed and verified the information provided by the CCA in the Self-Reporting Tool (SRT). The audit scope included one central, two regional and five local government offices; one porcine slaughter and processing establishment, three poultry (one chicken, one turkey and one turkey and chicken) slaughter and processing establishments, and one bovine and ovine establishment producing ready-to-eat (RTE) product; and one government microbiological and chemical residue laboratory. Determinations concerning the effectiveness of Chile's meat and poultry inspection system focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs.

The audit outcome showed that the CCA is able to meet the established criteria for five of the components. Government oversight must be improved based on the following findings:

- Statutory Authority and Food Safety Regulations Component:  
SAG has the regulatory authority for a verification program for net weights; however, they have not written and implemented such a program. They have just begun producing consumer vs. bulk sized packaged products.
- Sanitation Component:  
There is inconsistent application of implementation requirements for operational sanitation by industry and inconsistent verification activities for operational sanitation by in-plant SAG personnel.
- HACCP Component:
  1. Flow chart steps were missing
  2. Of more importance is the plant did not include the verification activities appropriate to the processes. The activity was either monitoring or record keeping but never calibration of monitoring equipment.
- In the Microbiological Testing Programs component  
The testing program does not have a random selection process for carcasses for generic *Escherichia Coli* (*E. coli*) analysis. The CCA provided corrective actions during the audit.

The CCA must still submit a program for the testing of *E. coli* non-O157 Shiga-toxin producing *Escherichia coli* (STECs).

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority, Agriculture and Livestock Service, Servicio Agrícola y Ganadero (SAG)
CFR	United States Code of Federal Regulations
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
<i>Lm</i>	<i>Listeria monocytogenes</i>
NOID	Notice of Intent to Delist
POE	Point-of-Entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
RIS	Regional Inspection Supervisor
RTE	Ready-to-Eat
SAG	Servicio Agrícola y Ganadero (Agriculture and Livestock Service)
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
SRT	Self-Reporting Tool
STEC	<i>Shiga-toxin</i> producing <i>Escherichia coli</i>
VIC	Veterinarian-in-Charge

## **1. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Chile's meat and poultry food safety inspection system from April 10 through April 27, 2012.

The audit began with an entrance meeting in Santiago, Chile on April 10, 2012, with representatives from the Central Competent Authority (CCA) – Servicio Agrícola y Ganadera (SAG) and the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS).

## **2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

This was a routine ongoing equivalence verification audit. The audit objective was to ensure that Chile's food safety system for meat and poultry continues to be equivalent to that of the United States, with the resultant capacity to produce products which are safe, unadulterated, and properly labeled.

FSIS used a risk-based procedure to determine the audit scope which included an analysis of country performance within six equivalence components, production types and volumes, frequency of prior audit-related on-site visits, point-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included data collected by FSIS over a three year timeframe in addition to information obtained directly from the CCA, through a self-reporting process, outlining the current structure of the country's inspection system and identifying any significant changes which have occurred since the last audit.

The FSIS auditor was accompanied throughout the audit by representatives from the CCA or from the regional and local inspection offices. Program effectiveness determinations focused on performance within the following six equivalence components: (1) Government oversight, (2) Statutory authority and food safety regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems (HACCP), (5) Chemical residues, and (6) Microbiological testing programs.

Administrative functions were reviewed at the CCA headquarters, two regional offices, and five local inspection offices. The FSIS auditor evaluated the implementation of those management control systems in place which ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

A sample of five establishments was selected from a total of fourteen establishments certified to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety. Emphasis was placed on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2 / 381.96.

Additionally, one government central reference laboratory, supporting both microbiological and chemical residue functions, was audited to verify its ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	SAG Headquarters, Livestock Protection Division (LPD), Santiago
	Regional	2	Región Metropolitana, Región XIII, Santiago Región Los Ríos, Región XIV, Rio Bueno
Laboratories		1	Government central reference laboratory supporting both microbiological and chemical residue functions, Lo Aguirre
Establishments			
<ul style="list-style-type: none"> <li>• Meat Slaughter/Processing</li> <li>• Meat Processing (RTE)</li> <li>• Poultry Slaughter/Processing</li> </ul>		1	Est. 06-06, Alimentos del Sur, Rosario, O'Higgins
		1	Est. 14-01, Campos La Unión, La Unión, Los Ríos
		3	Est. 05-09, Sopraval, La Calera, Valparaíso Est. 06-08, San Vicente, San Vicente, O'Higgins Est. 13-07, El Paico, Santiago, Metropolitana

### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
- The Poultry Products Inspection Regulations (9 CFR Part 381]

The audit standards applied during the review of Chile's meat and poultry inspection system included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Chile has equivalence determinations in place for the following:

- For generic *Escherichia coli* (*E. coli*), four sampling sites for cattle and swine
- For *Salmonella*:
  - Year-round, on-going testing
  - Any positive result requires immediate corrective actions by the establishment followed by additional sampling by the SAG to verify the effectiveness of the establishment's corrective actions
  - Four sampling sites for cattle and swine
    - 400 cm<sup>2</sup> are sampled, 100 cm<sup>2</sup> from each sampling site
  - Private laboratories analyze samples.

- For the Pathogen Reduction Program:
  - Control of generic *E. coli* in raw product
  - Control of *Salmonella* in raw product
- For *Listeria monocytogenes (Lm)*:
  - The *Lm* control program
  - Screening method for RTE in meat and poultry VIDAS *Listeria monocytogenes* Xpress (03/09/11)
  - Detection and confirmation method VIDAS LMO2 (07/06/09)
- For *E. coli* O157:H7:
  - The National Program for *E. coli* O157:H7
    - Screening method VIDAS ECO (07/08/09)
    - Confirmatory method VIDAS ICE (07/08/09)
    - Screening method in RTE meat VIDAS ECPT (03/09/11)

#### 4. BACKGROUND

Chile is eligible to export meat and poultry to the United States. Between October 1, 2010 and September 30, 2011, Chile exported 40,857,947 pounds of meat and poultry products to the United States of which 21,685,333 pounds were re-inspected at United States point-of-entry (POE). A total of 317,663 pounds were rejected at POE, of which 4,138 pounds were for failures of public health significance (presence of feces/ingesta).

The findings of the last on-site audit conducted during 2009 resulted in no Notices of Intent to Delist (NOIDs) and five delistments of establishments certified by Chile for export to the United States. Four of the five delistments were lifted before the FSIS auditor left the country because of corrective actions taken by the CCA. This audit confirmed that those corrective actions were in place and effective.

The FSIS final audit reports for Chile's Food Safety System are available on the FSIS's website at:

[http://www.fsis.usda.gov/Regulations\\_&Policies/ForeignAuditReports/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/ForeignAuditReports/index.asp)

#### 5. GOVERNMENT OVERSIGHT

The first of the six equivalence components that the auditor reviewed was Government Oversight. The auditor verified that the inspection system was organized and administered by the national government of Chile and provided standards equivalent to those of the Federal system of meat and poultry inspection in the United States (U.S.). The CCA has recently reorganized the headquarters unit. Although some changes were made at higher levels, this reorganization mainly involves the Livestock Protection Division which is part of the Technical Unit under the National Directorate of the SAG. The other parts of the Technical Unit are the Division of Plant Protection, the Division of Laboratories and Quarantine Stations, the Natural Resource Protection Division and the Seed Division. In addition to the Technical Unit, there is an Administrative Unit and 15 Regional Directorates. Under the Regional Directorates are 64 Local Offices, the Regional Laboratories and the Border Control Points.

The Chief Veterinary Officer (CVO) is located within the Livestock Protection Division which has input from the Risk Assessment Group. The CVO has the responsibility of monitoring international issues (such as the World Organisation for Animal Health) as well as the oversight of three sub-departments: Food Safety and Certification, Animal Health, and Integrated Management. Through these sub-departments, the CVO oversees the 15 Regional Directorates each of which includes a Livestock Regional Director-in-Charge and Regional Export Supervisors. The Regional personnel oversee the Local Offices (which may or may not be located in establishments). The Food Safety and Certification sub-department includes control at the farm level, control of animal feed and supplies, food safety controls, and certification process controls. The Animal Health sub-department includes maintenance activities such as the prevention of the introduction of foreign diseases, endemic disease surveillance, and the registry of veterinary medical products. This sub-department also includes improvement activities such as improving health status, bovine brucellosis eradication, and tuberculosis control and eradication. The Integrated Management sub-department includes technical and budget planning, the livestock information system, animal welfare, and the quality management system.

Official verification and inspection activities are conducted at all certified establishments in accordance with uniform instructions disseminated from the CCA to the field via email, intranet, fax, telephone, and hard copy. Updates and additional instructions to personnel concerning established regulations, programs, and manuals are published and disseminated as circulars. These programs and manuals contain procedures to assist official personnel to uniformly assess the adequacy of food safety measures implemented by establishments certified to export meat and poultry products from Chile to the U.S. and enforce the regulations of the Chilean inspection system. The FSIS auditor performed on-site observations and reviewed records maintained by inspection personnel at all levels, headquarters, regional offices and in-plant SAG inspection offices. These records are detailed in the following equivalence components. The FSIS auditor determined that regulatory verification and inspection activities were not consistently implemented at all establishments audited. Officials use the authority conferred upon them by the laws of Chile to enforce the rules of the meat and poultry inspection system, identify and document non-compliances, and verify the adequacy of corrective actions and preventive measures.

A schedule for all of the training for the whole system for the year 2011 was provided as well as the training plans for 2012. The FSIS auditor reviewed some of the training records which are kept for each individual in SAG. The 2011 training subjects included:

- Sanitary and phytosanitary measures
- Pathogen Reduction Programs
- Medical Veterinarians and food safety
- Production of safe food from animals
- The Meat Law
- Small ruminant diseases
- Safety and biosecurity of food
- Bovine pathology and necropsy findings
- Techniques of inspection and recognition of pathologic lesions in livestock species
- Standardization of criteria and controls for Decree 94/2008 (Regulations for Slaughterhouses)

- Refresher on rendering
- Medical Veterinarians and recognition of exotic diseases
- Upgraded inspection standards and techniques for birds and wild game
- Biotechnology and its impact on food animals and food safety
- Contamination and food preservation
- Quality assurance programs, accreditation systems and audits
- Risk analysis
- Dioxin residues in food
- Revisions in the procedures for certification of slaughterhouses for export
- Standardization of the criteria for the inspection of meat in slaughterhouses
- Standardization of criteria for inspection, monitoring and certification of livestock sectors
- Standardization of knowledge and technical aspects of brucellosis
- Simulation of a livestock emergency event
- Narcotics control for establishments importing and retailing veterinary pharmaceuticals
- Animal welfare in transit
- The Animal Protection Law and its regulations
- Animal Quarantine Management in Malaysia
- Strengthening the process of exports of animal products for human consumption
- Strengthening the program for control of residues and contamination by dioxins
- National diagnostic laboratories and food safety
- Management control system for residue samples
- Knowledge updates for the diagnosis of disease in livestock

The 2011 SAG training program also included sending attendees to the following conferences:

- The International Congress for Veterinary Medical Studies for the Year of the Veterinarian VET 2011
- The Humane Slaughter Association International Symposium
- International Workshop on the Assessment of Animal Welfare,

The 2012 training subjects include:

- Quality Control Systems
- ISO systems, the techniques of resolution of non-conformances, corrective actions and preventive measures
- The use of work equipment
- HACCP systems for export products
- Residue analysis and control of residues in emergencies
- The Meat Law
- Medical Veterinarians and inspection of cattle, poultry and their meats
- Procedures for certification and qualification
- Fundamentals of microbiology
- Updates on sanitary inspection of meat
- Food safety in meat
- Strengthening the program for control of residues and contamination by dioxins
- Quality control system for residue samples

- Strengthening the process of exports of animal products for human consumption
- *Salmonella* and *Mycoplasma* in birds
- Contaminants in animal feed

The 2012 SAG training program also included sending attendees to the following conferences:

- VIII RAPAVE 2012 – Congress on Veterinary Pathology
- Latin American Conference on Microbiology and Food Safety 2012

The FSIS auditor reviewed documentation to ascertain that Veterinary Medical Doctors had the required veterinary degree and that inspectors had the required pre-employment training program and education. This documentation was reviewed for a sampling of individuals including both veterinarians and inspectors at the headquarters, regional office, and in-plant levels. All training records reviewed showed that veterinary personnel had degrees in veterinary medicine and that inspectors had certificates attesting to their required pre-employment training programs.

The FSIS auditor reviewed the two types of contracts for SAG personnel along with some of the resultant performance evaluations. The first contract is the Provision of Services Agreement on Lump Sum Permanent and covers headquarters, regional, some upper level laboratory personnel, and chief-of-service veterinarians and includes a benefits package. The Provision of Services Agreement on Lump Sum Temporary covers in-plant inspection personnel and some laboratory personnel and does not include benefits. The agreements in both contracts set the duties, obligations, and responsibilities of the employee, how many hours they can work, the salary for those hours, how billing is to be done and when payment will be made, whether or not the position has public servant status and under what conditions that status is provided, the effective dates of the contract, provisions for information security, paid holidays, training activities to be provided if so budgeted, and the use and return of government equipment in the performance of their duties.

These contracts can be terminated with one day prior notice and that the cause for termination does not have to be indicated. Reasons for termination include:

- Contracts with the SAG for more than two hundred monthly tax units
- Remaining litigations with the SAG
- Owning 10 percent or more of an organization that has more than two hundred monthly tax units with the SAG
- Conviction of a crime or felony
- The breach of any of the obligations established in the information security provisions

A contract can also be terminated for poor performance of the duties listed in the contract; however, the Administrative State Law provides for a time period to correct that performance. If poor performance continues, the contract can be terminated during the year or not renewed for the following year at the discretion of the SAG office issuing the contract.

In addition, the Services Agreement on Lump-Sum Temporary also provides specific duties for inspection personnel in terms of support of the export of livestock products and support of their supervisors in the performance of inspection

Although contracts may come from either the CCA or regional level, all personnel are employees of the government. Yearly performance evaluations determine who will be offered a contract for the following year.

The FSIS auditor reviewed the laboratory personnel performance evaluations on national and international intra- and inter-laboratory samples, international check samples and proficiency programs. All analysts reviewed did well in these testing programs for 2011. These evaluations are in addition to the contract performance evaluation and help determine if a new contract will be offered.

Staffing levels at establishments are determined by a combination of regulatory direction and regional determinations. The regulations for staffing are very general and give the authority for the staffing of individual establishments to the regional offices. Norma Technica 117 from the Undersecretary of Public Health, Public Policy Division is the General Technical Rule for Veterinary Medical Inspection of Poultry and its Meats. In Annex 1, Guideline for the official veterinary Health inspection it states that the veterinary medical inspection of poultry and its meat should be done by the inspection team under the responsibility of the Medical Inspector Veterinary Officer, supported by its team of technical assistants. Annex 1 of P-PP-IT-005 (Procedures for Inspection in Slaughterhouses) provides a reference guide for calculating staffing for bovine and swine slaughter lines. This guide provides staffing numbers as fractions of veterinary days both for slaughter numbers per month and for line speeds. These veterinary days are divided into ante mortem, carcasses, heads, green viscera, red viscera, re-inspection and, in the case of swine, additional veterinary days for *Trichina* collection and testing. These individual establishment staffing decisions are based on the species slaughtered or processed, the slaughter versus processing type of establishment, the type of processes conducted in each establishment, and a consideration of food safety risk for all of the preceding elements. Both regional offices explained their decisions for staffing establishments and were consistent with each other and with the above mentioned regulatory guidance.

The following laws, regulations and resolutions provide the CCA the legal authority to oversee production activities of establishments that intend to export meat and poultry products to the U.S:

- Law 18755 (Organic Law of the Agriculture and Livestock Service),
- Law 19162 (Establishment of the Mandatory System for the Classification of Livestock, the Identification and Naming of Meat, and the Regulation of the Operation of Slaughterhouses, Refrigerators and Plants for the Meat Industry),
- Decree 94-2008 (Approves Regulations Regarding Slaughterhouses, Refrigerating Establishment, Refrigerating Chamber and Butchering Plant Structure and Operations and Establishes Minimum Equipment Requirements for Those Establishments)
- Resolution 1767-2009 (Creation of the Under-Department of Animal Health)

- P-PP-IT-003 (Procedure for Registration of Human Consumption Livestock Product Establishments for Exportation)
- I-PP-IT-001 (Instructions for Certification Inspection for Livestock Products for Human Consumption for Exportation)
- Resolution 2561-2003 (The National Export Establishment Registration System for Livestock Products is Created, the Conditions to be Registered as Such are Set Forth and Powers are Delegated as Indicated)
- Resolution 2592-2003 (Establishment of the Requirements for the Health Inspection and Certification of Exports of Edible Products and By-products of Animal Origin)

Initial and yearly ongoing certification of establishments for export to the U.S. is performed by the headquarters component of the CCA. Integral to these certifications are Resolution 2561-2003 (The National Export Establishment Registration System for Livestock Products is Created, the Conditions to be Registered as Such are Set Forth and Powers are Delegated as Indicated) and Resolution 2592-2003 (Establishment of the Requirements for the Health Inspection and Certification of Exports of Edible Products and By-products of Animal Origin). Establishments are required to fulfill all Chilean regulatory requirements governing the physical aspects of the establishment as well as the production of products certifiable for export according to the requirements listed in the above laws and regulations and meet the specific requirements of the importing country.

The initial reviews and ongoing reviews are conducted by representatives from the regional office component of the CCA who then send a recommendation to the headquarters component of the CCA. The Evaluation Form for Slaughter Establishments for Poultry for the United States and Evaluation Form for Slaughter Establishments for Red Meat for the United States must be completed for initial certification and again during the yearly reviews. The forms include sections that correspond to the sanitation requirements in 9 CFR 416, for facility maintenance and SSOP procedures, for HACCP as specified in 9 CFR 417, for humane handling, and for generic *E. coli* testing. All sections of the forms must be in compliance for either initial certification or yearly re-certification to be granted.

The program for Certification of Ready-to-Eat (RTE) Establishments contains the following steps: (1) the establishment must first be accepted into the national export system (LEEPS) and (2) the establishment must pass further inspections (using the evaluation form listed above) by the SAG regional supervisor to be considered as an RTE establishment. The RTE certification program requires the implementation of establishment self-sampling programs for *Lm*, *Salmonella*, and *E. coli* O157:H7 in RTE product. The requirements are based on 9 CFR 430.4 and FSIS Directive 10,240.1, Revision 1. The establishment must demonstrate that their choice of an Alternative for the *Lm* control program is appropriate and effective and that they are conducting the self-sampling program for that Alternative. The series of letters and reports for the one RTE establishment was reviewed by the auditor. The documentation reviewed of the certification of the RTE establishment confirmed the system was in place and being properly implemented. The activities detailed in the reports (processing specifications for the products

certified for export) and the *Lm*, *Salmonella*, and *E. coli* O157:H7 testing programs with specifications for product and frequencies of testing as well as results were verified at the new RTE establishment.

The FSIS auditor gathered information about the implementation of a Food Defense Plan by the CCA. The SAG received the formal presentation from FSIS and has begun the process of creating a national Food Defense Plan. This plan had not been completed at the time of the audit.

In conclusion, there were no system findings in Chile's adherence to the criteria for organizational structure and staffing, ultimate control and supervision, the assignment of competent qualified inspectors, the authority and responsibility to enforce the laws and adequate administrative and technical support including laboratory oversight and the application of procedures and standards that are equivalent to the U.S. requirements. However, government oversight must be improved based on the findings in the following components of Statutory Authority and Food Safety Regulations, Sanitation, HACCP and Microbiological Testing Programs.

## **6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations (SAFSR). The auditor verified that the inspection system was organized and administered by the national government of Chile. The auditor also verified that the system provided for:

- Humane handling and slaughter of livestock
- Ante-mortem inspection of animals
- Post-mortem inspection of carcasses and parts
- Controls over condemned materials
- Controls over establishment construction, facilities, and equipment
- Daily inspection
- Periodic supervisory visits to official establishments

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the on-site audit of the system. In addition to the regulatory documents and guidance identified in section 5, the following documents were reviewed:

- Standard 62 (General Technical Standards on Veterinary Inspection of Livestock for Food and Meat with Aptitude Qualification Criteria for Human Consumption)
- P-PP-IT-005 (Procedure for Inspection in Slaughter Establishments [and updates from 2010])
- Law 20380 (On Animal Protection)
- Fax 523-09 (Animal Welfare in Bovine, Ovine and Swine Establishments)

- Law 54 (General Technical Standards on Veterinary Inspection of Poultry and their Meats)
- Instructions to Apply Veterinary Inspection Procedures to Poultry and Their Meat for Exporting Purposes)
- F-PP-IT-034 (Supervision Guidelines for the Integrated Official Inspection System and Response Report)
- Resolution 5338-2005 (Resolution Setting Health Measures for the Destruction of Ruminant Offal)

FSIS equivalence criteria require that the CCA has the legal authority and associated responsibility to ensure that adulterated or misbranded product is not prepared for export to the U.S. The FSIS auditor reviewed the above documentation furnished in the 2010 Self-Reporting Tool (SRT), compared it to the equivalence criteria, and found that the CCA has not established net weight in-plant verification procedures.

The FSIS auditor verified that official inspection and verification activities followed responses from the SRT and supporting documentation. Furthermore, in response to the findings of the 2009 audit, the auditor verified that the regulations governing poultry establishments do require bird-by-bird inspection. The FSIS auditor observed post-mortem inspection activities in the three poultry slaughter establishments audited and found that these activities, including the coordination with the required establishment helpers, followed the regulations for bird-by-bird inspection.

Periodic supervisory reviews were completed based on a risk-based schedule for differing types of establishments and products produced; this schedule mandated a frequency of at least one review every four months for export slaughter establishments, and at least once every six months for export processing establishments even if the processing establishment was under sporadic inspection because of their inherent processes.

## **7. SANITATION**

The FSIS auditor reviewed Sanitation as the third of the six equivalence components. The auditor verified that the inspection system provided requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. These requirements are contained in the following documents:

- Law 18755 (Organic Law of the Agriculture and Livestock Service)
- Resolution 2561-2003 (The National Export Establishment Registration System for Livestock Products)

- Resolution 2592-2003 (Establishment of the requirements for the health inspection and certification of exports of edible products and by-products of animal origin)
- Instruction for the Application of Veterinary Inspection Procedures for Poultry and Meat Exports
- Law 54 (General Technical Standards on Veterinary Inspection of Poultry and their Meats)
- P-PP-IT-005 (Procedure for Inspection in Slaughter Establishments)

The FSIS auditor verification of this component included a review and analysis of the information provided by the CCA in the SRT and observations during the on-site audit. The auditor reviewed legislation, regulations, official instructions and guidelines and verified that the CCA requires and verifies that the establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. Records reviews included monitoring and corrective action records of the establishments as well as verification, non-compliance, and supervisory review records of SAG.

In addition, the FSIS auditor observed pre-operational sanitation and operational sanitation and compared the conditions of the establishments to SAG documentation. The auditor determined the establishments met sanitary requirements and the documentation matched the observed conditions.

However at one establishment the FSIS auditor determined that the plant did not have monitoring records for operational sanitation even though monitoring and documentation were required by the SSOP.

At another establishment operational sanitation was only monitored after the mid shift clean-up, before employees returned to their work stations. The associated SSOP called for a monitoring event during operations; this SSOP did not state that the monitoring would occur only after mid-shift clean-up. The FSIS auditor observed that additional operational sanitation monitoring may be necessary as insanitary conditions were found during operations; these included product build-ups on conveyor belts, tote inserts not properly placed so that product contacted non-contact surfaces, grease-contaminated belts, and excessive product on the floor.

In neither case was there recognition of the lack of implementation of the SSOPs as they were written by the SAG at either the in-plant or supervisory review levels.

The FSIS auditor also evaluated supervisory reviews at all establishments and regional offices. These reviews contained sections on sanitation and SSOPs, HACCP, supervisory controls, ante mortem, post mortem, removal and control of specified risk materials, facility construction and maintenance, in-plant SAG supervision, non-compliance reports, and the follow-up to previous findings. The reviews showed that supervisory reviews were being conducted as scheduled (Norma tecnica SITEP 2012), that the reviews covered the required categories, and that the reviews accurately reflected the conditions of the establishments. The reviews had appropriate

follow-up and findings had corrective actions and preventive measures furnished by the establishments.

In conclusion, the FSIS equivalence criteria applicable to Sanitation Performance Standards and pre-operational sanitation were met. However, the CCA must address documentation by SAG personnel of implementation and documentation of non-compliances in operational sanitation.

## **8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The auditor verified that the inspection system required that each official establishment develop, implement and maintain a HACCP plan.

The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations during the on-site audit. The documents provided by the CCA in the SRT included:

- Law 18755 (Organic Law of the Agriculture and Livestock Service)
- Decree 94 (Approves Regulations Regarding Slaughterhouse, Refrigerating Establishment, Refrigerating Chamber and Butchering Plant Structure and Operations and Establishes Minimum Equipment Requirements for Those Establishments)
- P-PP-IT-005 (Procedures for Inspection in Slaughter Establishments and Updates)
- SAG Fax 5338(2005 – Resolution Setting Health Measure for the Destruction of Ruminant Offal as Stated)
- Resolution 2592 (Establishment of the requirements for the health inspection and certification of exports of edible products and by-products of animal origin),
- Fax 1363 (Meat Exports to the U.S.), and Instructions on Official Verification and Self-Regulation of E. coli O157:H7 in Ground Beef, Trimming, Tenderized Meat, Marinated Meat, and Beef Hamburgers for Export to the United States
- Project no. 322 (Generic Manual Quality Assurance Systems)
- I-PP-IT-001 (Instructions Certification Inspection for Livestock Products for Human Consumption for Exportation)

The auditor verified that the certified establishments had developed, implemented, and maintained HACCP systems in accordance with the above Chilean laws and regulations. The auditor reviewed HACCP programs and monitoring, verification and corrective action records of the establishments as well as verification, non-compliance, and periodic supervisory review records of SAG.

During the establishment review, the FSIS auditor determined the establishment's HACCP program did not include all processes in the flow chart (receipt and storage of packaging materials) and hazard analysis. The establishment also did not include all three on-going verification activities (direct observation of the monitoring activities and corrective actions, review of records, and calibration of process-monitoring instruments) for each of the Critical Control Points (CCP) identified in the HACCP plan. Each CCP contained only one verification activity, either observation of the monitor or review of records. None of the CCPs contained the on-going verification activity for calibration of process-monitoring instruments. During the audit, the establishment said they were calibrating thermometers, but did not have a written program.

The establishment has provided a written program for the checking and calibration of monitoring instruments in their corrective actions which has been evaluated by the FSIS auditor and found to meet HACCP requirements.

The previous supervisory reviews had not identified either of these deficiencies. (This is a new establishment and supervisory reviews are only required every six months.) The assigned inspector who visits the establishment for each CCP-related step in the production of this dried whole muscle product also had not identified these deficiencies during her documented verification activities and as a result there the non compliances were not documented

The Chile zero tolerance program is based on the requirements of FSIS Directives 6420.2 and 5000.1 as well as 9 CFR 307.2(g)(m), 310.3, 310.17(a), 310.18(a) and 318.4(b). The inspection officials must include zero tolerance verification in their daily activities according to "General Document of Quality Assurance Verification in Exporting Slaughter Establishments and is additionally supervised by the team chief veterinarian in each establishment. Implementation direction was provided to all regions with slaughter establishments in 2009.

Activities of the daily verification by SAG include random selection of carcasses, verification of the CCP prior to washing of the carcasses, done in the same area that the establishment does their verification, internal and external visual inspection, verification of adequate light intensity, control for visible milk, ingesta and feces (as well as the other contaminations listed above), recording of the results as well as review of the establishment's records, and verifying corrective actions. When zero tolerance violations are found for visible fecal material, ingesta, or milk ( or urine, bile, hair, dirt, or foreign material), the in-plant SAG personnel verify that the corrective actions consider all points of 9 CFR 417.3 and that all measures are carried out before the carcass can be washed. In those establishments that do zero tolerance on every carcass, those actions would be for just that carcass. The SAG has the authority to retain all carcasses back to the previous acceptable SAG check for zero tolerance. The establishment must inspect every one of the retained carcasses and then the SAG will verify their inspection.

The auditor reviewed the implementation and documentation of establishment and SAG zero tolerance programs during the on-site audits of the four establishments conducting slaughter operations and found no non-compliances.

Slaughter dressing procedures and SAG inspection procedures were reviewed in the four slaughter establishments (one pork, one turkey, one chicken, and one chicken and turkey) included in the audit. All three poultry establishments were conducting bird-by-bird inspection by SAG personnel in accordance with the procedures established prior to the end of the 2009 audit (Instructions to Apply Veterinary Inspection Procedures to Poultry and their Meat for Exporting Purpose [August 2009]). The FSIS auditor observed SAG post mortem inspection at all three stations in the swine slaughter establishment and reviewed the SAG records of zero tolerance verification. There were no findings from the observations of the SAG inspection procedures.

In conclusion, HACCP criteria were met in most establishments. The CCA must address the flow chart non-compliances and the inadequate plant verification procedures and assure that SAG personnel have the knowledge, skills and ability to assure compliance with the Chilean HACCP regulations.

## **9. CHEMICAL RESIDUES**

The FSIS auditor reviewed Chemical Residues as the fifth of the six equivalence components. The FSIS criteria for chemical residues include a program managed by the CCA and established to carry out effective regulatory activities to prevent contamination of food products with chemical residues. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of the basis for its residue plan and the process used to design the plan. The plan must describe the actual operations of its residue plan. The CCA must provide a description of the actions taken to deal with unsafe residues as they occur. The CCA must have access to and supervision of analytical laboratories that have the capability to assure the validity and reliability of test data.

The auditor verified that the inspection system has an organized governmental program established to carry out effective regulatory activities to prevent contamination of food products with chemical residues; that the SAG manages this program and provides direction, coordination and oversight; that the various elements of the program are conducted by the SAG in conjunction with the central laboratory at Lo Aguirre; and that the program has sufficient resources from Headquarters, the central laboratory at Lo Aguirre, other governmental and various private laboratories, and regional and in-plant personnel as well as funding to carry out the program. The auditor also verified the previously submitted laws, regulations and implementation documents defining the legal authority of the SAG to organize and implement a residue control program. This legal authority prescribes the conditions for the use of chemicals in the production of meat and poultry products, prohibits the use of compounds that may present unacceptable public health risks, provides the ability to control and monitor industrial and environmental chemicals that may lead to contamination and provides the ability to enforce these laws and regulations.

The internal SOPs for the laboratory were reviewed and the records provided as well as the on-site observations of the auditor showed that these SOPs were being properly implemented. The ISO 17025 certification report from an outside audit of the laboratory as well as the audits that

the laboratory performs on other government and private laboratories were reviewed. The auditor also reviewed the corrective action reports following these certification audits and the follow-up actions that were taken before certification was granted or extended.

The auditor verified that the design of the Chile National Residue Program includes the required criteria including a description of the basis for the residue plan and the process used to design the residue plan. The residue plan also describes the various sampling schemes, lists the selected matrices for each compound, and includes a rationale and process for the choice of chemical compounds. Much of the choice of compounds and numbers for sampling are based on Council Directive 96/23/EC of 29 April 1996.

The auditor verified that the implementation of the plan at the headquarters, laboratory, regional, and in-plant levels was proceeding in the manner outlined in the plan and that sampling was occurring on time and in the manner designated, analyses were completed in a timely manner, and results were distributed as directed. Additionally the auditor verified that the plan contained appropriate internal actions to be taken if a result was in question, what screening methods were involved and what confirmation methods could be used.

Enforcement measures are delegated to another agency, Animal Health, and all violative results are immediately reported to them and they act by retaining products, destroying products, recalls, farm quarantines, risk communication as appropriate to the violative substance. Research is done at the farm level to determine the probable cause of the residue's presence. The veterinarian doing the investigation focuses on the possession and use of veterinary drugs, the animal feed and any environmental aspects. The veterinarian also emphasizes to the private companies the proper use of veterinary drugs as the label proscribes, respect for the proper withdrawal times, and the necessity of a veterinary prescription for the use of the drug.

In the case of a prohibited substance, an investigation related to the acquisition, distribution and sale of the substance is initiated. Although Chile does not publish a violators list as in the U.S., the establishment can be removed from the list of farms eligible to take animals to SAG-certified establishments. Any violative residue results are transmitted to all of the slaughterhouses so that the violator cannot choose to bring animals to a different slaughterhouse. The PABCO farm registry program (which is voluntary) establishes sanctions in situations when a farm has violative residues. These sanctions go from suspension to elimination of participation in the PABCO program. All of the farms are aware of these potential actions following a violative result.

The residue laboratory audit also focused on the general capabilities of the central reference laboratory as well as what the capabilities are of the other government laboratory used, the private laboratories certified within Chile, and the laboratories used in other countries for confirmatory analyses of positive results found at the central reference laboratory. This included the ability to assure the validity and reliability of test data.

The central laboratory audit also focused on the facility, equipment, personnel organization and qualifications. In addition, the auditor reviewed analytical methods, recordkeeping requirements, sample handling and traceability, corrective actions, inter-, intra-, and international proficiency testing programs and results, and accreditation. All above criteria for the operation of a residue laboratory were in place and operating effectively. All certifications, including ISO 17025, were current.

Results of Chile's current year's residue sampling program were reviewed at the laboratory, regional offices and in-plant levels. The program was operating as specified, results were delivered on time, and results were available at all levels.

The 2012 Chile National Residue Program has been submitted to OIA and has been reviewed by the FSIS auditor. The number of samples per compound per species is based on European Union directives. One set (porcine) was incorrectly calculated. The FSIS auditor was assured that this calculation will be corrected for the next year's program.

All of the above listed criteria for this component were met.

## **10. CCA MICROBIOLOGICAL TESTING PROGRAMS**

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs used by the CCA. Chile has microbiological testing programs for generic *E. coli* in all slaughter species, *E. coli* O157-H7 in beef, *Salmonella* in raw and RTE products, *Campylobacter* in raw poultry products, and *Listeria monocytogenes (Lm)* in RTE products. The auditor verified that the system has implemented certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

The audit of the Central Reference Laboratory focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. No deficiencies were identified in the review of these criteria. Although private laboratories are used for many of the microbiological analyses set out in the National Pathogen Reduction Program, no private microbiological laboratories were reviewed during this audit.

The testing for *Salmonella* in raw products met criteria. According to the Procedure for Microbiological Sampling of Meat Processed in Slaughter Establishments for Export (P-PP-IT-I-Version 5.0), "the presence of *Salmonella spp.* signals deficiencies in the control system at the slaughter establishment. The criteria for the evaluation of *Salmonella spp.* shall be the absence or presence of this pathogen." Sampling includes four locations for beef and pork carcasses, the same as is conducted in the European Union. FSIS has previously found that the Chilean *Salmonella* sampling program is equivalent to that of FSIS. All positive *Salmonella spp.* samples are then serotype sub-typed and then sent to the Ministry for Public Health to complete the serotyping process. In slaughter establishments, carcasses were being sampled once a week (five samples) per the national plan. Results were reviewed in each slaughter establishment as well as observing the sampling technique in two establishments. None of the results reviewed (CY 2012 and CY 2011) included any failures of a set. Set limits are established to be the same

as those listed in 9 CFR 310.25. There is an Excel database of results maintained at the CCA for all slaughter establishments. This database includes results back to the beginning of the *Salmonella* pathogen reduction testing program. There are specific steps designated for both industry and SAG to follow in the case of a set failure. The interpretation of the results will be done in cycles and each cycle will hold 50 samples which will be taken as groups of five each week. Each species (pigs, chickens, turkeys, bovines, and mutton and goat) have a set acceptance level of the number of positive samples allowed per cycle. Once the cycle exceeds the acceptance criteria, the system will automatically be considered as a FAIL. When a FAIL occurs, the SAG veterinarian-in-charge (VIC) will generate a non-compliance report (NR) to the establishment. The establishment will have a maximum of 72 hours to carry out immediate corrective actions described in the response to the NR. These corrective actions are to be communicated daily to the SAG VIC and verified by the SAG VIC. At 48 hours following the corrective actions, the VIC will take five samples once the first half of slaughter has finished. The VIC will take five samples every other day until a total of 15 samples have been taken. The acceptance criteria for these 15 samples are designated according to species. If the acceptance criteria are reached, a new cycle of 50 samples is begun. If the acceptance criteria are not met, the VIC will generate a new NR and the establishment must carry out new corrective actions within 96 hours. After the new corrective actions have been in effect for 48 hours, the VIC will take another five samples every other day to obtain a total of 15 samples. The acceptance criteria are the same as for the previous set of 15 samples. Again, if the acceptance criteria are met, a new cycle of 50 samples is begun. If the acceptance criteria are not met, the establishment has 96 hours to:

- Apply a contingency plan for cleaning and sanitization, which will be evaluated through a microbiological analysis using the traditional diagnostic methodology or using the bioluminescence
- Carry out GMP, SOP and SSOP analyses
- Evaluate the HACCP Plan and the Risk Analysis
- Complete an Accident Report (per Annex 9 to the Procedure for Microbiological Sampling in Exportation Slaughterhouses P-PP-IT-I-Version 8.0)

If the acceptance criteria are still not reached, the Region together with the VIC and official inspection team will send notification to the establishment that they will not be allowed to export product to any other country from the date of the notification until the suspension of certification is lifted. This is the application of Resolution No. 2592, (the requirements for the health inspection and certification of exports of edible products and by-products of animal origin). Once the Resolution No. 2592 is applied, the establishment must apply a contingency plan determined by the establishment in order to re-obtain export certification.

Once they have established this plan, the establishment will notify the VIC who will then verify the plan. This verification is accomplished by taking five samples per day for five consecutive days for a total of 25 samples. Acceptance criteria are established for this 25 sample set. If the criteria are met, the suspension is lifted and a new cycle of 50 samples is begun. If the criteria are not met, the establishment must re-calculate their HACCP Plan. Once the changes to the HACCP Plan are implemented and 48 hours have passed, a supervisory visit to the establishment will be conducted by someone from the Central Level of the CCA to determine what actions are to be taken.

The testing program for *E. coli* O157:H7 in raw beef products had previously been determined as equivalent. Chile samples raw beef trimmings and cuts designated for grinding by SAG approved frequencies and methods. The updated program for *E. coli* O157:H7 was just published in April 2012 and the auditor was furnished a copy. A translated copy was furnished following the audit. The updated program is currently under review by the FSIS. This document did not contain information on the testing program for non-O157 *Shiga*-toxin producing *E. coli* (STECs). This will be furnished to FSIS as soon as the new commercial methods and materials have been procured and validated. The SAG has communicated to the FSIS that this should be in November or December of 2012.

Testing of RTE products for *Listeria monocytogenes* (*Lm*) and *Salmonella* from the one establishment certified to produce RTE products met the criteria established in the Assessment Guideline for the Approval of Manufacturing Establishments of Meat Products Ready for Human Consumption to the U.S as well as the Pathogen Reduction Program. The establishment uses *Lm* Alternative 3, Sanitation only, and the products are sampled on a monthly basis when a completed product is available. Results were reviewed at the laboratory and at the establishment and no positive results were found. Testing followed the established protocols.

The establishment program for pathogens contains the following:

- *Lm* and *Salmonella* are considered in the hazard analysis as hazards reasonably likely to occur in the curing stage of production.
- Sodium lactate is incorporated into the conditioning stage to kill or limit pathogen growth.
- Sodium nitrate and nitrite are incorporated into the product in the curing stage, this is represented as a CCP (measurement of weight of additive).
- The temperature of the chilling chamber is not allowed to exceed eight degrees Celsius, this is represented as a CCP (measurement of chamber temperature).
- Water activity must be below 0.96 to prevent pathogen growth.
- *Lm* is not considered likely to occur at the packaging stage of production.
- Anaerobic vacuum packaging (modified atmosphere) is used to inhibit pathogen growth.

- Each batch of product is sent to a SAG certified laboratory (using the SAG approved methods) for testing for the presence of *Lm* and *Salmonella* and must receive negative results before the product is released for export.
- There is a program for the testing of product contact surfaces and for environmental testing in the post-lethality exposure area for *Lm* or an indicator organism. The samples must be sent to a SAG certified laboratory using SAG approved methods. These results are available to the SAG official inspection personnel.

The SAG program for control of *Listeria monocytogenes* (*Lm*) in products ready for consumption exposed to the environment after a lethal step contains the following provision:

- Alternative 1 – The establishment uses a post-lethal treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms in the product and an antimicrobial agent of process that suppresses or limits the growth of *Lm*. This treatment and agent must be incorporated into the HACCP plan, SSOP, or a prerequisite program, must be implementing these as described, and must have validation data for post-lethality treatment including the effectiveness of the agent or process in suppressing or limiting the growth of *Lm*.
- Alternative 2 – The establishment uses a post-lethal treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms in the product or an antimicrobial agent or process that suppresses or limits the growth of *Lm*. The agent or process used in the post-lethality treatment must be incorporated in the HACCP plan, SSOPs, or a prerequisite program, the establishment must have validated the effectiveness of the agent or process, the establishment must take samples of food contact surfaces in the post-lethality environment for *Lm* or an indicator organism to ensure those surfaces are sanitary, and the establishment must identify the conditions under which the establishment will implement retention and sampling procedures when they receive a positive test result for *Lm* or an indicator organism. The establishment's program must include a frequency for sampling (including a justification for sufficiency of that frequency) and the size and specific locations where samples will be taken.
- Alternative 3 – The establishment performs control of *Lm* only through sanitation measures. The establishment must have continuous sampling procedures for *Lm* or an indicator organism for verification of food contact surfaces incorporated into the HACCP plan, SSOPs, or a prerequisite program and have implemented those procedures. The establishment must identify the conditions under which they will implement retention and sampling procedures when they receive a positive test result for *Lm* or an indicator organism. The establishment's program must include a frequency for sampling (including a justification for sufficiency of that frequency) and the size and specific locations where samples will be taken.

- Alternative 3 – (deli or hot-dog type products) Additionally to the provisions included above for Alternative 3, these establishments must verify whether the corrective actions taken after an initial positive result are effective by taking follow-up samples and additional sampling of the area. If they receive a second positive result during the follow-up sampling, they must hold the batches of product possibly contaminated. Before marketing batches of product that are possibly contaminated, they must conduct sampling using a sampling method and frequency that will provide a statistical confidence level to ensure that no adulteration with *Lm* is present in each batch including documenting the results of this sampling. Alternatively the establishment could reprocess the product using a process that is destructive to *Lm*.
- For all alternatives, the establishment must use verification tests including tests for *Lm* or an indicator organism to verify the effectiveness of sanitation procedures in the post-lethality processing environment. The establishment must incorporate sanitation measures to control *Lm* and procedures for the use of antimicrobial agents or processes into their HACCP plans, SSOPs or prerequisite programs. If these are not included in the HACCP plan as a CCP, but included in SSOPs or prerequisite programs, the establishment must have supporting documentation to show that *Lm* is a hazard not likely to occur. The establishment must maintain sanitation in the post-lethality processing environment. If the *Lm* control measures are included in the HACCP plan, they must be verified and validated for effectiveness. If the *Lm* control measures are included in the SSOPs, they must be assessed for effectiveness. If the *Lm* control measures are included in a prerequisite program other than the SSOPs, the program and results must be included in the supporting documentation for HACCP. For post-lethality exposed products, all results must be available to official inspection officials and have an estimate of production furnished to official inspection officials at a regular interval, at least annually.

For RTE products, the official SAG sampling plan tests five samples monthly for each microorganism (*Lm*, *Salmonella*, and *E. coli* O157:H7[if appropriate]). This is destructive sampling using the methods that have already been deemed equivalent. The samples are taken by a SAG veterinarian. The program includes self-sampling by the establishments of product sampling for Alternative 1, product and direct food contact surface sampling for Alternative 2, and product, direct food contact surface and environmental surface sampling for Alternative 3. The public health decision criteria include notifying the establishment and the Regional Health Ministry of a positive sample. Export certification will only be granted for batches of product that test negative for all samples in accordance with the Alternative. Product batches with positive results will be segregated and identified as non-exportable to the U.S. Once an establishment implements corrective actions following a positive result, the SAG veterinarian will conduct the sampling contingency two times per week for two weeks. In the event of one or more positive results in the follow-up sampling, the regional directorate will suspend export certification.

The SAG began testing for *Campylobacter* in raw poultry in early April 2012. Some of the establishments had begun testing on their own during the previous months. At this point in time, these are pilot programs. Data gathered through 2013 will be evaluated in order to set a

baseline for further testing. There are not limits set at this time. The 2011 Pathogen Reduction Program was furnished to the auditor.

In two of the four establishments audited that were required to conduct generic *E. coli* testing, there were deficiencies in the methods used to select samples which resulted in the lack of true randomness. In one establishment, only the birds on the hangers representing the end of each set of 3000 were eligible for selection. This was corrected immediately by instituting a two-step selection process: step one included random selection from all eligible hangers within each set of birds; step two included random selection from each location (18-22) on the selected hanger. In another establishment, the correct number of samples was chosen for the total slaughter of the day; however, the birds chosen to be sampled were not chosen from each set of 22,000 birds but rather from the entire day's slaughter. This was immediately corrected so that a bird was chosen from each 22,000 birds slaughtered and therefore represented random sampling throughout the day. SAG recognized that this misunderstanding of true random selection could also affect other establishments and immediately sent out a letter to all slaughter establishments instructing them to assure that their method of selecting carcasses for generic *E. coli* testing provided for true randomness. A copy of this letter was provided to the auditor.

In conclusion, the National Pathogen Reduction Program for Chile and the operation of the microbiological laboratories are in accordance with the established equivalence criteria. The CCA must now verify the effectiveness of their direction for the selection of generic *E. coli* samples. The CCA must also furnish FSIS with their program for *E. coli* non-O157 STECs in beef. At a later date, FSIS will be requesting data from the newly established *Campylobacter* program.

## **11. EXIT MEETING**

An exit meeting was held on April 27, 2012 in Santiago with the SAG Livestock Protection Division. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

The CCA understood and accepted the findings.

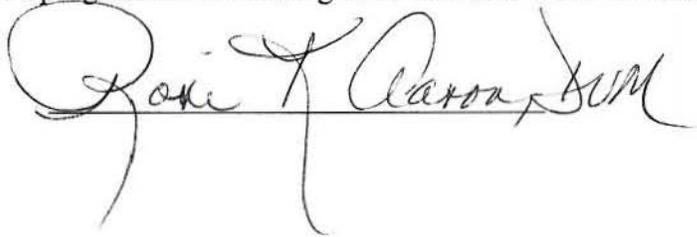
A presentation was given on the new system of electronic export certification.

## **12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS**

The audit outcome showed that Chile's meat and poultry food safety inspection system maintains equivalence. However, as described in the corresponding sections of this report, there are concerns related to the Government Oversight of Statutory Authority and Food Safety Regulations, Sanitation, the Hazard Analysis and Critical Control Point System, and Microbiological Testing Programs components of the system that require the attention of the CCA. Short term corrective actions were being implemented throughout the audit, but the effective implementation of long term corrective actions to address the findings summarized below remains pending.

- In the component of Statutory Authority and Food Safety Regulations, the CCA must address the lack of a SAG program for the verification of net weights.
- In the Sanitation component, the CCA must address the inconsistent application of implementation requirements for operational sanitation by industry and inconsistent verification activities for operational sanitation by in-plant SAG personnel.
- In the Hazard Analysis and Critical Control Point System component, the CCA must address why SAG personnel failed to identify missing basic HACCP elements in an establishment HACCP plan.
- In the Microbiological Testing Programs component, the CCA has already addressed the issue concerning the randomness of selection of carcasses for generic *E. coli* analysis. The CCA must still submit a program for the testing of *E. coli* non-O157 STECs.

Rori K. Aaron, DVM  
Senior Program Auditor

A handwritten signature in black ink, appearing to read "Rori K. Aaron, DVM". The signature is written in a cursive style with a horizontal line drawn through the middle of the letters.

### **13. ATTACHMENTS TO THE AUDIT REPORT**

Foreign Country Response to Draft Final Audit Report (when it becomes available)

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sopraval S.A. Panamericana Norte, Km. 112 La Calera Valparaiso Region Chile	2. AUDIT DATE 04/13/2012	3. ESTABLISHMENT NO. 05-09	4. NAME OF COUNTRY CHILE
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Chile Est. 05-09, 04/13/2012

27/51 The choice of the samples for generic *E. coli* analysis was done with the use of a computer-based random number generator. For turkeys, the requirement is for one sample from each 3000 turkeys slaughtered. The establishment uses an air chill system where 14 or 20 birds are hung on each hanger, depending on gender. The establishment marked the hangers that would represent the end of each group of 3000 birds, selecting by the gender slaughtered to select the correct hanger. Then the random number generator was used to select the bird for testing from that hanger. This system is not true randomness, as the bird can only be selected from the last hanger of each set of 3000 birds. The SAG personnel who were present also did not understand that this was not true randomness and had not noted a problem with the system. I explained that this left over 2980 birds from each group that could never be selected. The system was immediately amended so that the random number generator will first select the hanger from the number of hangers used to hang each 3000 birds and then select the position on the hanger to select the bird for testing. 9 CFR 381.94(a)(2)(i)

61. NAME OF AUDITOR  
Rori K. Aaron. DVM

62. AUDITOR SIGNATURE AND DATE

*Rori K. Aaron, DVM* 5/7/12

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Procesador de Alimentos del Sur Limitada Ruta H-50 Km 0,304, camino Quinta Tilcoco Rosario Libertador Bernardo O'Higgins Region Chile	2. AUDIT DATE 04/19/2012	3. ESTABLISHMENT NO. 06-06	4. NAME OF COUNTRY CHILE
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Chile Est. 06-06 4/19/2012

There were no findings of food safety significance reported for this establishment during this audit.

61. NAME OF AUDITOR

Rori K. Aaron. DVM

62. AUDITOR SIGNATURE AND DATE

*Rori K. Aaron, DVM* 5/7/12

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Faenadora San Vicente Limitada Carretera H-66 G km. 19,2 San Vicente de Tagua Tagua Libertador Bernardo O'Higgins Region Chile	2. AUDIT DATE 04/20/2012	3. ESTABLISHMENT NO. 06-08	4. NAME OF COUNTRY CHILE
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Chile Est. 06-08, 04/20/2012

10/51 The monitoring of operational SSOPs only occurred following the mid-shift clean-up while no operations were in progress. SAG in-plant personnel had not identified this as a non-compliance. Establishment officials assured the auditor that the program would be re-written to include monitoring during actual operations. 9 CFR 416.13(c) and 416.17

61. NAME OF AUDITOR  
Rori K. Aaron. DVM

62. AUDITOR SIGNATURE AND DATE  
*Rori K. Aaron, DVM* 5/7/12

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agroindustrial El Paico Ltda. Avenida Los Libertadores #1714 Comuna El Monte Metropolitan Region of Santiago Chile	2. AUDIT DATE 04/17/2012	3. ESTABLISHMENT NO. 13-07	4. NAME OF COUNTRY CHILE
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

Chile Est. 13-07, 04/17/2012

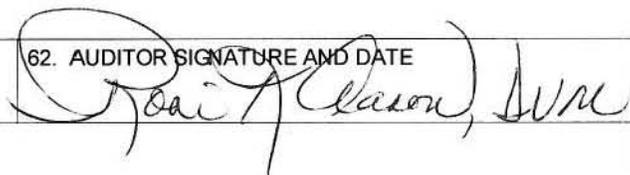
27/51 The choice of the samples for generic *E. coli* analysis was done with the use of a computer-based random number generator. For turkeys, the requirement is for one sample from each 3000 turkeys slaughtered and for chickens the requirement is for one sample from each 22,000 chickens. The establishment is selecting the correct number of birds per species to sample from each day's total production; however, the samples are not selected within the sets of 3000 or 22,000 birds slaughtered. This system does not assure the selection of a bird within each production set. The SAG personnel who were present also did not understand that this was not the correct way to select samples and had not noted a problem with the system. The system was immediately amended so that the random number generator will select the birds for testing from each set of production. 9 CFR 381.94(a)(2)(i)

51 The verification of net weights is not a part of the SAG requirements for verification. 9 CFR 381.196(a)(2)(i)(G). In a conversation with the SAG HQ representative accompanying the auditor, it was related that this is a not a SAG in-plant responsibility. This is a systemic finding.

61. NAME OF AUDITOR

Rori K. Aaron. DVM

62. AUDITOR SIGNATURE AND DATE

 Rori K. Aaron, DVM 5/7/12

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agricola y Comercial Campos de La Union S.A. Predio San Carlos s/n, Lote C, Casilla #339 La Union Los Rios Region Chile	2. AUDIT DATE 04/24/2012	3. ESTABLISHMENT NO. 14-01	4. NAME OF COUNTRY CHILE
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

Chile Est. 14-01, 04/24/2012

10/13/51 The establishment had no records to document the monitoring of operational sanitation. SAG said that they had discussed this with the establishment previously, but had not written an NR on the non-compliance. 9 CFR 416.13(c), 416.16(a), 416.17

13/51 The establishment HACCP flow chart and hazard analysis did not include the receipt and storage of packaging materials. SAG had not noted this non-compliance. 9 CFR 417.2(a), 417.8

19/51: The HACCP plan did not include all three parts of verification for each of the CCPs; all CCPs involved the measurement of temperatures. SAG had not noted this non-compliance. 9 CFR 417.4(a)(2), 417.8

51 SAG personnel were not performing net weight verification. On further conversation with the SAG HQ representative, this is not a requirement for SAG personnel anywhere.

61. NAME OF AUDITOR

Rori K. Aaron. DVM

62. AUDITOR SIGNATURE AND DATE

*Rori K. Aaron DVM*, 5/7/12