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

FEB 15 2013

Dr. Oscar Videla
Chief, Departmento Proteccion Pecuaria
Servicio Agricola 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 final audit report. The comments received from the government of Chile are included as an attachment to the final report.

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 international.audit@fsis.usda.gov.

Sincerely,

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

Enclosure



EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

# 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 Agricola y Ganadera (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 Agricola y Ganadera (SAG) |
| CFR | United States Code of Federal Regulations |
| *E. coli* | *Escherichia coli* |
| FSIS | Food Safety and Inspection Service |
| *Lm* | *Listeria monocytogenes* |
| 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 Agricola y Ganadera (Agriculture and Livestock Service) |
| *Salmonella* | *Salmonella* species |
| SPS | Sanitation Performance Standards |
| SSOP | Sanitation Standard Operating Procedures |
| SRT | Self-Reporting Tool |
| STEC | *Shiga*-toxin producing *Escherichia coli* |
| 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 Agricola 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<br>Región Los Ríos, Región XIV, Rio Bueno |
| Laboratories | | 1 | Government central reference laboratory supporting both microbiological and chemical residue functions, Lo Aguirre |
| Establishments<br>• Meat Slaughter/Processing<br>• Meat Processing (RTE)<br>• Poultry Slaughter/Processing | | <br>1<br>1<br>3 | <br>Est. 06-06, Alimentos del Sur, Rosario, O'Higgins<br>Est. 14-01, Campos La Unión, La Unión, Los Ríos<br>Est. 05-09, Sopraval, La Calera, Valparaíso<br>Est. 06-08, San Vicente, San Vicente, O'Higgins<br>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 cm2 are sampled, 100 cm2 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/Foreign_Audit_Reports/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, Revision1. 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 cased 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 c 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 bio-luminescence

- 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 anti-microbial 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

## 13. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Chile Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

# Foreign Establishment Audit Checklist

| 1. ESTABLISHMENT NAME AND LOCATION | 2. AUDIT DATE | 3. ESTABLISHMENT NO. | 4. NAME OF COUNTRY |
|---|---|---|---|
| Sopraval S.A.<br>Panamericana Norte, Km. 112<br>La Calera<br>Valparaiso Region<br>Chile | 04/13/2012 | 05-09 | CHILE |
| | 5. NAME OF AUDITOR(S) | | 6. TYPE OF AUDIT |
| | Rori K. Aaron, 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 | X |
| 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 | |
| 57. Monthly Review | |
| 58. | |
| 59. | |

60. Observation of the Establishment



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 | 62. AUDITOR SIGNATURE AND DATE |
| --- | --- |
| Rori K. Aaron. DVM | Rori K Aaron DVM |

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 Limitada<br>Carretera H-66 G km. 19,2<br>San Vicente de Tagua Tagua<br>Libertador Bernardo O'Higgins Region<br>Chile | 04/20/2012 | 06-08 | CHILE |
| | 5. NAME OF AUDITOR(S) | | 6. TYPE OF AUDIT |
| | Rori K. Aaron, 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. | 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. | |
| **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 | |
| 57. Monthly Review | |
| 58. | |
| 59. | |

60. Observation of the Establishment



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 | 62. AUDITOR SIGNATURE AND DATE |
| --- | --- |
| Rori K. Aaron. DVM | Rori K Aaron DVM |

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 Ltda.<br>Avenida Los Libertadores #1714<br>Comuna El Monte<br>Metropolitan Region of Santiago<br>Chile | 04/17/2012 | 13-07 | CHILE |
| | 5. NAME OF AUDITOR(S) | | 6. TYPE OF AUDIT |
| | Rori K. Aaron, 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 | X |
| 25. General Labeling | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | |
| **Part D - Sampling Generic *E. coli* Testing** | |
| 27. Written Procedures | X |
| 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 | |
| 57. Monthly Review | |
| 58. | |
| 59. | |

60. Observation of the Establishment



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

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 |
|---|---|---|---|
| Agricola y Comercial Campos de La Union S.A.<br>Predio San Carlos s/n, Lote C, Casilla #339<br>La Union<br>Los Rios Region<br>Chile | 04/24/2012 | 14-01 | CHILE |
| | 5. NAME OF AUDITOR(S) | | 6. TYPE OF AUDIT |
| | Rori K. Aaron, 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. | 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. | X |
| **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. | |
| **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** | |
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| 37. Import | |
| 38. Establishment Grounds and Pest Control | |
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| 40. Light | |
| 41. Ventilation | |
| 42. Plumbing and Sewage | |
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| 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 | |
| 57. Monthly Review | |
| 58. | |
| 59. | |

60. Observation of the Establishment



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 | 62. AUDITOR SIGNATURE AND DATE |
| --- | --- |
| Rori K. Aaron. DVM | Rori K Aaron DVM |

SAG
Ministerio de Agricultura
Gobierno de Chile

000147

SANTIAGO, 04 FEB. 2013

**SENIOR PROGRAM AUDITOR**
**RORI K. AARON, DVM**
**USDA/FSIS/OIA/IAS**
**EMAIL: AURORA.CRAVER@FSIS.USDA.GOV**
**PRESENTE**

Estimada Ms. Rori K. AARON:

Junto con saludarle muy cordialmente, en relación al "DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN CHILE, APRIL 10 THROUGH APRIL 27, 2012" envío a Ud. comentarios y acciones al respecto.

Saluda atentamente a Ud.,

SERVICIO AGRICOLA Y GANADERO
JEFE
DIVISION PROTECCION PECUARIA

**OSCAR VIDELA PÉREZ**
**MÉDICO VETERINARIO**
**JEFE DIVISIÓN PROTECCIÓN PECUARIA**

DGM/ECR/SJF
02.02.2013
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Teléfono: (02) 345 1423
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SAG
Ministerio de Agricultura
Gobierno de Chile

Courtesy translation

**SANTIAGO,**

**SENIOR PROGRAM AUDITOR**
**RORI K. AARON, DVM**
**USDA/FSIS/OIA/IAS**
**EMAIL: AURORA.CRAVER@FSIS.USDA.GOV**
**PRESENT**

Dear Ms. Rori K. AARON:

Along with my best greetings, and regarding the "DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN CHILE, APRIL 10 THROUGH APRIL 27, 2012", I am directing myself to you in order to attach comments and measures implemented as requested by the FSIS.

Thanking your time and consideration, sincerely yours,

**ÓSCAR VIDELA PÉREZ**
**CHIEF**
**LIVESTOCK PROTECTION DIVISION**

## Agricultural and Livestock Service Comments

In relation to the comments given in the FINAL DRAFT REPORT OF AN AUDIT IN CHILE conducted APRIL 10 THROUGH APRIL 27, 2012, relative to Quality Assurance Systems implemented at national level in 2012, it must be indicated that Exempt Resolution No. 4577 of August 3, 2012 (attached) was issued, and establishes specific requirements for prerequisite programs and HACCP, for the implementation of Quality Assurance System, including within its scope all the establishments registered on the Livestock Products for Exportation Establishments List (LEEPP) including those authorized for the United States.

Among the issues covered in this regulation, we can highlight those which establish that "The operator of each establishment registered in the LEEPP, should guarantee that during every stage of production, the transformation, storage and distribution of food under their control, the hygiene requirements are complied with regarding national regulations and those of the countries or markets where the products are destined."

Regarding item 7. SANITATION of the report, it must be indicated that the development and implementation of the prerequisites are established from point 12 to 21 and from 29 to 34 the resolution regarding the official control done by SAG is explained. The monitoring Activities Registry are indicated specifically in the provisions in section 14, 15 and 18 while the Official verification done by the Official Inspection Team are indicated in point 29.

- Regarding item 8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS of the report, related to the verification activities, the resolution establish in paragraph 26, c), vii) that verification activities are at least:

1) Calibration of the monitoring instruments of the process,
2) Direct observations of the monitoring activities and corrective actions,
3) The review of records,
4) Review of the consumer complaints that have been received by the establishment, in order to determine if these are related to the execution of the HACCP plan or if these reveal unidentified critical control points, and
5) Carrying out periodically the analysis during a process and of the finished product.

In addition, paragraph 26 c), viii), 1), establishes that:

"The establishment should, at least, develop, implement and maintain:

1) Records that document: hazard analysis, determination of the CCP, determination of the critical limits, including the records of real time data, temperature and other quantifiable values, according to the HACCP plan of the establishment; deviations and corresponding corrective actions, the calibration of the instruments for the monitoring process; verification procedures and results; modification of the HACCP, product codes; name or identity of the products or production batch."

In relation to the observation on item 8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS, regarding the Official Verification, the Resolution establishes the actions done by SAG Inspector in Service Control Issues, from point 29 to 34.

- In relation to the observations on item 12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS of the report:

  - Upon verification of net weights: this in under the Ministry of Economy, however the Resolution N° 4577, states the Prerequisite Programs in point 12 and in point 20 the following:

    e): "Regarding the program of traceability, the establishments, should develop and implement systems, procedures and records, auditable that, at least, allow: ..... e) Identify the final product,...."

    Therefore, establishments authorized for the United States will be instructed to implement a prerequisites program for the verification of net weights.

- Regarding the implementation requirements for operational sanitation by industry and inconsistent verification activities for operational sanitation by in plant SAG personnel: The SAG estates in the Resolution N° 4577, from point 29 to 34 the Service Control Activities are established.

- In relation to the Observation on the Hazard Analysis and Critical Control Point System component, the Official Inspection Team must address why SAG personnel failed to identify missing basic HACCP elements in an establishment HACCP plan: El SAG states the Resolution N° 4577 denominated "Establishes specific requirements of the prerequisite programs and hACCP for the implementation of the quality assurance system and abolishment Resulutions Nº 3.360 and N°3.685 of 1999. (Attached)

**ESTABLISHES SPECIFIC REQUIREMENTS OF THE PREREQUISITE PROGRAMS AND HACCP FOR THE IMPLEMENTATION OF THE QUALITY ASSURANCE SYSTEM AND ABOLISHMENT**

**RESULUTIONS Nº 3.360 AND N°3.685 OF 1999**

**Santiago,**

N° _____/ CONSIDERING: Law N° 18.755, Organic Agricultural and Livestock Service; DFL RRA N° 16 of 1963, on Health and Animal protection; Law Nº 19.162, which Establishes Mandatory Livestock Classification System, Classification and Nomenclature of its meats and Regulates the Functioning of Slaughterhouses, Meat Industry Refrigeration and Establishments; Decree N° 94 of 2008, which Approves Regulation on Structure and Functioning of Slaughterhouses Refrigeration Establishments, Refrigeration Chambers and Deboning and Fixed Plants minimum equipment of such Establishments, Decree N° 240 from 1993, General Regulation of Cattle and Meat Transportation; Decree N° 682 from 1942, which Regulates the Export of Livestock Products; the Resolutions N° 3,360 and 3,685, both from 1999, N° 2,592 from 1999, N° 2,592 of 2003 and N° 7,078 of 2011, all of the Agricultural and Livestock Services.

## CONSIDERING

1. That the Agricultural and Livestock Services (SAG initials in Spanish) is the official and competent organism to certify the suitability of human consumption of primary agricultural products destined for export.

2. That the safety of the processes observes Good Manufacturing Practices, Standardized Operational Procedures, Standardized Operational Procedure of Sanitation Programs and the Hazard Analysis Systems and Critical Control Points.

3. That it is important to make a clear distinction between the role that the establishments play and the competent authorities, respectively, in the validation of the control measures.

4. That the Quality Assurance Systems (QAS) compose prerequisite programs and Systems of Hazard Analysis and Critical Control Points (HACCP).

5. That the HACCP system, that has scientific base and systematic nature, allows us to identify specific hazards and control measures with the purpose of guaranteeing the food's safety.

6. That the HACCP is an instrument to evaluate the hazards and establish control systems that focus on prevention instead of basing itself mainly on showing the finished product.

7. That the Standardized Sanitation Operational Procedure Programs (SSOP) document and describe the method and mode of procedure in an orderly and efficient way, hygiene, cleaning and sanitation that is carried out in the different stages of the process.

8. That the recorded establishments in the Exporting Establishments of Livestock Products List (LEEPP), subscribe to the SAG an operational agreement which states the obligations that they commit to.

**RESOLVE**

1. For the purpose of this Resolution, the following expressions have the meaning that is stated below:

   a) **Control Measure:** Any action or activity that can be used to prevent or eliminate a hazard for the food safety or reducing it to an acceptable level.

   b) **Validation:** The procurement of proof that shows that a control measure or combination of control measure, if it is applied correctly, is able to control the hazard with a specific result.

   c) **Verification:** The application of methods, procedures, proof and other evaluations, and also monitoring, in order to determine if a control measure is or has been functioning in the way it was foreseen.

   d) **Monitoring:** to carry out the planned sequence of observation or measurements of the control parameters established in the system, requiring that corresponding associated records exist.

   e) **Hazards that have a reasonable probability of happening:** Is the reason why an establishment establishes controls, because this has happened historically, or because there exists a possibility that this will occur in the type of product in particular that is being processed in the absence of these controls.

   f) **Operator:** Natural person or legal owner or a person in charge of an establishment who is responsible for assuring compliance with the food legislation requirements.

   g) **Quality Assurance Systems,** QAS, entails:
      i. SSOP (Standardized Sanitation Operational Procedure)
      ii. HACCP (Hazard Analysis Critical Control Points System).

iii. SOP (Standardized Operational Procedures).

2. The operator of each establishment registered in the LEEPP, should guarantee that during every stage of production, the transformation, storage and distribution of food under their control, the hygiene requirements are complied with regarding national regulations and those of the countries or markets where the products are destined.

3. The operator of each establishment who carries out his activity at slaughter, elaboration, processing, packaging or storage of export foods of livestock origin destined for human consumption, registered in the LEEPP should implement, apply and maintain a Quality Assurance System (QAS), based on the principles of hazard analysis and critical control points (HACCP) and in prerequisites, such as food hygiene quality assurance system. The mentioned programs should comply with the requirements established in this resolution.

4. The establishment will be responsible of the validation of:
   a) The control measures or combination of the control measures, implemented in its Quality Assurance System (QAS).
   b) The capacity of the HACCP plan to control the food safety hazards that is reasonably likely to happen.
   c)
5. The validation of the Quality Assurance Systems (QAS) should be carried out at the moment in which a control measure or a food safety control system is designed or when the changes taken place indicate the need for a revalidation.

6. The establishment will be responsible that the Quality Assurance System (QAS) is effectively implemented.

7. The establishment should demonstrate before the Service, at the moment when it is required, that the QAS, installations and production processes, comply with the current national regulation, with the general and specific demands of the Service, the requirements of the countries or markets where the products are destined, and that the products are produced under a functioning HACCP system.

8. The documentation of the established Quality Assurance Systems should be available to the Service at any moment for revision and should also have the validation of the established control measures by this.

9. All the procedures and amendments of the QAS programs of the establishments should be signed and dated by the responsible person of the establishment; moreover being notified to the Service, prior to the implementation.

10. The establishment should assure that at all stages of the production the traceability is: from the animals destined for food production, slaughter, elaboration, transformation, packaging and distribution of the foodstuff and any other substance destined to be incorporated in the food or is likely to be so.

11. The SAG will verify the adequacy of the establishment's QAS and the compliance of the requirements of this resolution. The Service, with the purpose of guaranteeing the compliance to the regulations, demands or requirements, of the importing countries, can:

    a) Solicit corrections to the QAS or QAS programs.
    b) Establish special requirements for the development, implementation, application and maintenance of the HACCP system principles and prerequisite programs.

**Prerequisite Programs**

12. The establishments should develop and implement their Prerequisite Programs, according to the Foods Sanitary Regulations, the conditions that are established by the destination countries or markets of their products and the following conditions:

    a) Present the programs in written form, communicating clearly its objectives, the application sphere, definitions, references, detailed production flow and elaboration of foodstuff, when the latter is applicable, the procedures that are to be executed (SOP and SSOP), with what frequency, who has the responsibility and the actions that will be taken if the procedures are not executed in agreement with the written protocols or if the procedures do not have the expected results.

    b) Be implemented and executed by qualified personnel in its execution.

    c) Include the verification procedures and monitoring (where it is applicable).

    d) Submit the programs to regular revisions in order to assure that the foreseen objective is being complied with and it is being modified when it is necessary.

    e) Sign and date by the person with general responsibility in the establishment or by the member of staff of the highest level. The signature has to indicate that the establishment will implement and maintain the prerequisites according to the requirements of this resolution.

13. The establishments should establish, implement and permanently maintain, at least the prerequisite programs considered in the current national regulations and the following:

a) Information proof regarding the food chain, for the establishments that receive the animals for slaughter.

b) Specifications of the raw materials and conditions of reception.

c) Storage and distribution of the foodstuff.

d) Personal hygiene: personal cleanliness, hygienic-sanitary attitudes of personnel, health condition, sicknesses and injuries, and visitors.

e) Handling of condensation.

f) Specifications in the quality control and production.

g) Specific instruction of work for the individual jobs or specialized (GMP)
h) Investigation system and complaint feedback and lawsuit from the consumers.

i) Handling of solid and liquid residues.

j) Training and instruction in the procedures of hygiene and work.

k) Cleaning and sanitation of equipment, utensils and structures.
l) Traceability.

m) Any other that sustains the decisions in relation to the HACCP.

14. The program of Standardized Sanitation Operational Procedures (SSOP) should observe, at least, daily hygiene, cleaning and sanitation which both personnel and the establishment, equipment, transportation, etc. should be subjected to before and after operations. It should also include methodology that is used for the control of rodents and vectors.

15. Regarding the indicated program in the numeral 13 letter k of the present Resolution, the establishments should develop, implement and maintain written SSOPs, that comply, with the following requirements:

    a) Written development

        i) Describe all the procedures that will be carried out daily, before and during the operations, which are sufficient to prevent the direct contamination or adulteration of the products.
        ii) Identify the procedures that are carried out before beginning the operations and consider, at least, the cleaning of surfaces that are in contact with the food of the installations, equipment and utensils.

iii) Specify the frequency with which each procedure in the SSOP is carried out, identifying the employees responsible for the implementation and maintaining each procedure.

b) Implementation

i) All the preoperational procedures should be carried out before beginning operations.
ii) All the specific procedures in the SSOP should be carried out with the specified frequencies.
iii) Each establishment should monitor daily the implementation of all the procedures included in the SSOP.

c) Maintenance

The SSOPs and the identified procedures within these, should be evaluated routinely in order to determine their effectiveness in direct contamination prevention or adulteration of the products and should be modified as many times as is needed in order to keep them updated and effective, in a way that reflects the changes in the installations, equipment, utensils, operations or personnel.

16. The establishments should take appropriate corrective action when they determine that the hygiene and disinfection procedures and processes are not effective in avoiding product contamination, or allow the creation of unhealthy conditions. The corrective actions of the hygiene and disinfection procedures and processes should at least:

a) Identify and dispose adequately of the products that can be contaminated.
b) Restore the sanitary conditions.
c) Prevent that the reoccurrence of the faults in the systems do not happen.

17. Without detriment to what is put forth in N° 15 of this Resolution, each time that the official verification determines that the SSOP, or the specific procedures, or the implementation, or the maintenance of the SSOP have failed to prevent the direct contamination or adulteration of the products, the establishment should, at least, take corrective action as stated in the last article.

18. The establishments should establish and maintain daily records adequate, of the indicated minimum prerequisites programs, in order to allow evaluate the efficiency, and showing documented monitoring, the verification and all the corrective action that is taken.

The data record should be carried out at the moment that the controls are executed and these should be dated and signed by the person responsible for the action. The records can be maintained in data systems as long as the establishment implements appropriate controls that assure the integrity of the electronic data. The Service could determine the periods of maintenance of the records, if they consider convenient, these should be available for the official verification when it is required.

19. Regarding the program indicated in the numeral 13, letter a, of this Resolution, the Service may establish the minimum elements of the information on the food chain that the owner of the property that dispatches the animals should communicate to the establishment that receives the animals for slaughter.

20. Regarding the program of traceability, the establishments, should develop and implement systems, procedures and records, auditable that, at least, allow:

    a) The identification of the origin of the raw materials and persons that provide these, an animal destined for food production, or any substance that is incorporated in the food or with a probability of being so.
    b) Confirm in the case of the elaboration of processed products starting with the raw materials, proceeding from other establishments, that this is in compliance with the demands of the destination countries or markets.
    c) Assuring that the raw materials, the ingredients, additives, supplements, technological coadjutant, semi-elaborated or intermediate products and any other substance destined to be incorporated in the livestock origin export food, or with the likelihood of being so, will be adequately labeled or identified, in order to facilitate their traceability by means of documentation or pertinent information. This is also valid for the commercialized food or with the likelihood of being commercialized.
    d) Relate the products that have been received to the establishment, the operations or processes that these have followed (equipment, lines, chambers, mixing, divisions, etc.) within this.
    e) Identify the final product.
    f) Identify the Establishments to which have had products delivered.
    g) Recuperate the products when it is required.
    h) Place the information described in this numeral at the disposition of the competent authorities, if these request it.

21. The establishments should periodically revise the traceability systems in order to prove its functioning and efficiency, in at least the accuracy of the stored information and the response time.

## DIRECTIONS FOR THE APPLICATION OF THE HACCP SYSTEM

22. The establishment should have the prerequisite program implemented and functioning according to what is specified in this Resolution for the application of the HACCP system.

23. The establishments should develop, implement, validate, apply and maintain a permanent QAS based on the principals of Hazard Analysis and Critical Control Points (HACCP), according to the current national regulation and considering that they establish the requirements of the countries or markets of the products' destination, if they correspond.

24. The management of the establishment should develop all the actions that are at its reach, in order for the management to implement, apply and maintain a HACCP system.

25. The establishments should implement the HACCP system principals, indicated in the national regulation, through the sequential application of the following twelve (12) steps.

    a) Forming a HACCP team.
    b) Product description.
    c) Determining the use of the product's foreseen use.
    d) Elaborating a flow diagram.
    e) On site confirmation of the flow diagram.
    f) Carry out hazard analysis. (Principle 1).
    g) Determine the critical control points (Principio 2).
    h) Establishing the critical limits for each CCP (Principle 3).
    i) Establishing a monitoring system for each CCP (Principle 4).
    j) Establishing corrective actions (Principle 5).
    k) Establishing verification procedures (Principle 6).
    l) Establishing a documentation and record system (Principle 7).

26. The development of the twelve (12) steps, should accord with:

    a) The current national regulation.
    b) The considerations that establish the requirements of the destination markets of the products, and
    c) The requirements of the Service in relation to:
        i. <u>Product description.</u>
        The establishment should include use instruction and any other applicable microbiological or chemical criteria.
        ii. <u>Elaboration of a flow diagram.</u>
        To elaborate a flow diagram, the following information techniques should be included at least:

1) Plan of the work installations and the auxiliary equipment,
2) Distribution and character of the equipment,
3) Sequence of all the stages of the process (including the incorporation of raw materials, ingredients and additives and the hold-ups, delays during or between stages),
4) Technical parameters the operations (in particular, time and temperature, including the stoppages and delays during or between steps.
5) Product flow (including potential crossed contamination),
6) Separation of clean and dirty areas (or high and low risk) and
7) Subsequent to determining the Critical Control Points (CCP), these should be indicated in the flow diagram.

iii. Carry out hazard analysis (Principle 1). The establishment should:

1) Consider the repercussions of the raw materials, the ingredients, food production practices on the product's safety and the function of the production processes on the hazard control, that have a reasonable likelihood of occurring. Furthermore, the likely end use of the product, the consumer categories affected and the epidemiological information relative to the food's safety.

2) Include in its hazard analysis:
   - The production or persistence of toxins in the food and allergens,
   - Contamination and (or recontamination) of biological nature (microorganisms, parasites), chemical or physical of the raw products, intermediate products or end products.

3) Regarding the control measures for some hazards, the establishment, should consider the need to develop, implement and maintain specific procedures (special cleaning programs, precise specifications for thermal treatment, special requirements for go-between countries, etc.).

4) Once the hazard analysis is finished it should indicate the evaluated potential hazards, associating them with the production stage and the measures that will be used in order to control the hazard(s).

iv) <u>Establishment of critical control points for each CCP</u> (principle 3) They should be based on the evidence founded on which the values chosen will give as result a process under control.

v) Establishment of a monitoring system for each CCP (Principle 4).

The establishment should, at least, describe the methods, sampling plan, the frequency of the observations or measurements, the record procedure and the person responsible for carrying out the monitoring.

In the case of establishing sampling plans and monitoring intervals these should guarantee responsibly that the hazard is under control.

vi) Establishment of corrective actions (Principle 5). The establishment should:

1) Describe the corrective action and assign a person responsible of adapting this in order to assure that:
   - The cause of deviation is identified and eliminated.
   - The CCP (Critical Control Point) is under control after applying the corrective action.
   - Measures are established to prevent its reoccurrence.
   - Identify and segregate the affected product as a result of the deviation from the critical limit.

2) If an unforeseen event occurs that compromises the safety or the fitness for food consumption, the establishment should segregate and separate the affected product, and should:
   - Carry out or obtain a revision of the product in order to determine its acceptability for distribution,
   - Take action when needed, with regards the affected product to assure that no product hurtful to health is commercialized or it is adulterated due to the deviation,
   - Perform a re-evaluation in order to determine if the recently identified deviation or other unforeseen hazard should be incorporated to the HACCP system.

3) Evaluate the efficiency of the corrective measures, if for the same procedure, corrective actions have had to be taken repetitively.

4) All the corrective actions taken must be totally documented in the records, which are subject to verification.

vii. Establishments of verification procedures (Principle 6).

The establishment should include in the verification activities, at least:

1) Calibration of the monitoring instruments of the process,
2) Direct observations of the monitoring activities and corrective actions,
3) The review of records,
4) Review of the consumer complaints that have been received by the establishment, in order to determine if these are related to the execution of the HACCP plan or if these reveal unidentified critical control points, and
5) Carrying out periodically the analysis during a process and of the finished product.

viii. Establishment of a documentation system and record (Principle 7).

The establishment should, at least, develop, implement and maintain:

1) Records that document: hazard analysis, determination of the CCP, determination of the critical limits, including the records of real time data, temperature and other quantifiable values, according to the HACCP plan of the establishment; deviations and corresponding corrective actions, the calibration of the instruments for the monitoring process; verification procedures and results; modification of the HACCP, product codes; name or identity of the products or production batch.
2) Recording data should be done at the moment the controls are executed and should include the date and hour of annotation, and should be signed by the employee of the establishment who performs it or contains the initials of it.
3) Prior to the solicitude of product certification, the establishment should have, through a revision of its records, the fulfillment with the national sanitary requirements, the critical limits, the fulfillment of the destination market requirements and of the Service. This revision should be performed, dated and signed by a corresponding competent person.
4) In the record system of the plant it should be clearly expressed the non-productive shifts or days, by product, in order to guarantee the records of those days or shifts where there was no production.
5) The establishment could use computerized records as long as the appropriate controls are implemented in order to assure the integrity of the electronic records and the signatures.
6) The Service, without compromising the current legislation, could establish minimum storage times for the establishments and the protection of all the required records in point 1 of this article.

7) Without compromising the current legislation, the storage of the required records in point 1 outside the establishments, are allowed having passed 6 months, as long as these records can be recuperated and are available at the establishment within 24 hours after having been solicited for official verification.
8) All records, plans and procedures should be available on petition by the official verification for their revision and copy.
9) The HACCP plan should be signed and dated by the responsible person of the establishment when it is initially accepted and when modified.

**Re-evaluation HACCP plan and Prerequisites**

27. The establishment should re-evaluate, at least, its HACCP plan and Prerequisites:

a) At least once a year,
b) Each time there is a modification that can alter its applications, modification related to the raw materials, to the product and its formulation, to the process or any phase of this, control measures, structural in the establishment, distribution systems of the finished product or, in its foreseen use or consumers of the finished product; that have probabilities of influencing decisively the control or the introduction of a hazard.
c) When there is information that indicates a risk for human health associated with the food product,
d) The product o product category is linked to an outbreak of food transmitted illness, that has not been considered,
e) Reiterated deviations from a critical limit,
f) Product withdrawal due to problems of their safety,
g) Changes in national legislation or in legislation of the destination countries or markets of its products, and
h) new scientific information, such as: greater concentration of hazard than what was originally found and were taken into account in the design of the control measures, a change to the response of the hazard control (e.g. due to adaptation), the rise of a new previously unidentified hazard, the availability of new information that indicates that the danger is not being controlled on the foreseen level, or a new result regarding the safety of the food.

Once the finalized the re-evaluation the HACCP team should generate a report stating their finds. If the re-evaluation indicates that it is necessary to modify the plan, this should be carried out immediately in order to assure the consumers' health. Every change and re-evaluation should be recorded.

28. In case of the establishments, that in their hazard analysis show that all hazards can be controlled by the implementation of prerequisite programs, they should at least comply with the following requirements:

a) Formation of a HACCP team, product description, determining the foreseen use of the product, the elaboration of a flow diagram, on site confirmation of the flow diagram. They should also develop, implement and maintain appropriate corrective actions, in order to face possible faults that may occur in the prerequisite programs, which sustain the decisions related to the HACCP.
b) The corrective actions should at least consider:
   (1) The adequate identification and availability of the products that may be contaminated.
   (2) Restore the sanitary conditions.
   (3) Prevent the reoccurrence of the faults in the programs.
c) Establish verification procedures in order to determine if the prerequisite programs, that sustain the decision related to the HACCP system, function correctly.
d) Establish a documentation and record system.
e) Proceed to re-evaluate the validity of the hazard analysis, according to what is stated in number 27.

**Control of the Service**

29. The QAS, will be subject to the Service's control, according to the risk level or the requirements determined by the Service, due to the negotiations with third party countries. The Service will establish the frequency, the procedures of these controls, and the personnel that will perform them.

These controls are composed of, as a minimum:

a) An integral supervision of the establishment's QAS, with the objective to determine:
   (1) The competency of the establishments QAS,
   (2) If the activities and their resulting outcomes are adjusted to the objectives foreseen by the QAS, and
   (3) Honoring the requirements of this resolution.
b) Official periodic verifications of the functioning of the QAS programs, in order to determine the fulfillment of the specific requirements that this resolution states.

30. In order to determine the level of risk, the Service, will take into account:
a) The identified risks in relation to: the food, any process, material, substance, activity or operation that may affect the safety of the food.
b) The quality systems implemented by the Establishments.
c) The Establishments' records, regarding the fulfillment of the programs, norms and actions of the System.

d) The reliability of the quality control that have been carried out, and any data that might indicate its incompliance.
e) The consumer level risks.

31. The Service may request the establishment the re-evaluation of a control measure or a combination of the control measures, in case of:

a) Confirm the faults for the ones that have not been identified a cause of the deviation from the process,
b) Failure to meet Service's vigilance criteria or the verification of the establishment,
c) Detecting an inadequate analysis of the hazard,
d) That the establishment has not carried out a re-evaluation, according to numeral 27 of this Resolution.

32. If it is confirmed that the establishments cannot assure the compliance of the specific requirements, guarantee that the products will not be contaminated or cannot avoid the generation of unhealthy conditions, according to the commitment signed in the operational agreement, they will be notified through a Non-compliance Notification, Verification Act or other official document.

33. If the implemented actions by the establishments do not give guarantees or it persists in the non-compliance the Service will suspend the certification until the establishment show that it has returned to taking control of the process.

34. The Service may consider the QAS inadequate if the establishment is not performing the specific duties specified in the QAS or does not comply with the requirements established by this resolution.

35. In case the Service has not defined specified sampling or analysis methods for some microbiological, chemical or other parameter, the establishment can use internationally recognized methods, or scientifically validated methods that offer equivalent results to those established by an organism or standard with international reference recognized by the Service.
36. Repealing of the Resolutions N° 3.360 of 1999, that created the QAS project for Products with Livestock Origin and N° 3.685 of 1999, that Declares the official manuals that establishes procedures for the validation and verification of QAS for products of livestock origin.

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