



United States Department of Agriculture

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Food Safety and  
Inspection Service

AUG 30 2018

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Dr. David Guerra  
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Servicio Agrícola y Ganadero (Agricultural and Livestock Service)  
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Santiago  
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Dear Dr. Guerra,

The FSIS on-site audit conducted from April 2 through April 17, 2018, supports that Chile's inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Chile are included as an attachment to the report.

Sincerely,

A handwritten signature in black ink that reads "Janell Kause".

Janell Kause  
Acting International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

CHILE

APRIL 2-17, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
BEEF, PORK, LAMB, MUTTON, CHICKEN, AND TURKEY PRODUCTS  
EXPORTED TO THE UNITED STATES OF AMERICA

August 29, 2018

Food Safety and Inspection Service  
United States Department of Agriculture

## Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from April 2-17, 2018. The purpose of the audit was to determine whether Chile's food safety inspection system governing meat and poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Chile is eligible to export raw intact and raw non-intact beef, pork, lamb, mutton, chicken, and turkey, as well as heat treated-not fully cooked-not shelf stable poultry to the United States. Currently, Chile exports the following categories of products: raw intact beef, pork, lamb, mutton, chicken, and turkey; raw non-intact chicken and turkey; and heat treated-not fully cooked-not shelf stable chicken.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

### **Government Statutory Authority and Food Safety and Other Consumer Protection Regulations**

- The post-mortem inspection procedures for poultry did not consistently include observation of the interior of the carcasses nor surfaces of the tibiotarsal joints. The incomplete observation of surfaces of the tibiotarsal joints is a repeat finding from the 2016 audit.

### **Government Hazard Analysis and Critical Control Points (HACCP) System**

- The Central Competent Authority (CCA) is not requiring establishments to incorporate pre-chill sampling of poultry carcasses for microbial organisms within their HACCP systems. All three audited poultry slaughter establishments lacked written programs and procedures to conduct pre-chill sampling.
- The two beef establishments with confirmed positive STEC results have not identified STEC as a hazard reasonably likely to occur in the slaughter process.

### **Government Chemical Residue Testing Programs**

- The CCA conducts residue analysis on primary samples but defers confirmation until the National Reference Laboratory (NRL) determines and officially reports positive results for secondary and tertiary samples. This methodology is not consistent with FSIS requirements for which a collected sample and corresponding analytical result is expected to be representative of the sampled animal.

### **Government Microbiological Testing Programs**

- At one establishment, the CCA's methodology for collecting samples of raw beef trim for purposes of STEC analysis does not target surface tissue and is not equivalent to FSIS sampling methods for slaughter operations.
- The CCA's official STEC reports are insufficient to accurately document the analytical methods and results for inspection personnel at the establishment level.

During the audit exit meeting, the Central Competent Authority (CCA) provided evidence that they immediately began addressing some of these systemic findings by revising inspection procedures for poultry to consistently include observation of the interior of the carcasses and surfaces of the tibiotarsal joints, issuance of instructions for inspection teams to ensure that inspection is being done on the abdominal cavity, issuance of instructions for poultry pre-chill sampling and preparation of instructions to adopt FSIS N60 sampling protocols. FSIS will evaluate the adequacy of the CCA's documentation of further submitted corrective actions upon receipt, and base future equivalence verification activities on the information provided.

# TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY .....	1
III.	BACKGROUND.....	3
IV.	COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION) .....	3
V.	COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING) .....	6
VI.	COMPONENT THREE: GOVERNMENT SANITATION.....	8
VII.	COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM.....	9
VIII.	COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS.....	10
IX.	COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS.....	12
X.	CONCLUSIONS AND NEXT STEPS .....	14
	APPENDICES .....	16
	Appendix A: Individual Foreign Establishment Audit Checklists	
	Appendix B: Foreign Country Response to the Draft Final Audit Report	

## **I. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Chile's food safety inspection system from April 2-17, 2018. The audit began with an entrance meeting held on April 2, 2018, in Santiago, Chile, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA), the Agriculture and Livestock Service (*Servicio Agrícola y Ganadero (SAG)*).

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

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety inspection system governing meat and poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Chile is eligible to export raw intact and raw non-intact beef, pork, lamb, mutton, chicken, and turkey, as well as heat treated-not fully cooked-not shelf stable poultry to the United States. Currently, Chile exports the following categories of products: raw intact beef, pork, lamb, mutton, chicken, and turkey; raw non-intact chicken and turkey; and heat treated-not fully cooked-not shelf stable chicken.

The USDA's Animal and Plant Health Inspection Service (APHIS) identifies Chile as free of African swine fever, highly pathogenic avian influenza, and exotic Newcastle disease. Chile is also listed as free of classical swine fever, foot-and-mouth disease, rinderpest, and swine vesicular disease with special restrictions, and negligible risk for bovine spongiform encephalopathy. According to APHIS, Chile is eligible to export meat and poultry products to the United States.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

Representatives from the CCA accompanied the FSIS auditors throughout the entire audit. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, three regional offices, and ten local inspection offices. The FSIS auditors evaluated the implementation of control systems in

place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of ten slaughter and processing establishments was selected from a total of 21 establishments certified to export to the United States. During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors examined the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2 and §381.196.

Additionally, one microbiological and chemical residue laboratory was audited to verify its ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>• SAG Headquarters, Santiago</li> </ul>
	Regional Directorates	3	<ul style="list-style-type: none"> <li>• O’Higgins Regional Directorate, Rancagua</li> <li>• Punta Arenas Regional Directorate, Punta Arenas</li> <li>• Valparaiso Regional Directorate, Quillota</li> </ul>
Laboratory		1	<ul style="list-style-type: none"> <li>• SAG Chemistry and Food Safety Laboratory, Santiago</li> </ul>
Beef slaughter and processing establishments		2	<ul style="list-style-type: none"> <li>• Establishment 10-15, Osorno</li> <li>• Establishment 10-26, Osorno</li> </ul>
Lamb and mutton slaughter and processing establishments		3	<ul style="list-style-type: none"> <li>• Establishment 12-01, Punta Arenas</li> <li>• Establishment 12-05, Punta Arenas</li> <li>• Establishment 12-10, Porvenir</li> </ul>
Pork slaughter and processing establishments		2	<ul style="list-style-type: none"> <li>• Establishment 06-02, Donihue</li> <li>• Establishment 06-06, Rengo</li> </ul>
Chicken slaughter and processing establishments		2	<ul style="list-style-type: none"> <li>• Establishment 06-08, San Vicente de Tagua</li> <li>• Establishment 13-07, El Monte</li> </ul>
Turkey slaughter and processing establishment		1	<ul style="list-style-type: none"> <li>• Establishment 05-09, La Calera</li> </ul>

FSIS performed the audit to verify that the food safety inspection system met requirements equivalent to those under the specific provisions of United States’ laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq.*);
- The Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*);
- FSIS Regulations for Imported Meat (9 CFR Part 327); and
- FSIS Regulations for Imported Poultry (9 CFR Part 381, Subpart T).

The audit standards applied during the review of Chile's 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 World Trade Organization's Sanitary/Phytosanitary Agreement.

### **III. BACKGROUND**

Chile currently exports raw and processed beef, lamb, mutton, goat, chicken, and turkey to the United States. From October 1, 2015 to August 31, 2017, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,822,813 pounds of raw intact beef, 1,871,081 pounds of raw intact lamb, 544,868 pounds of raw intact mutton, 7,287,542 pounds of raw intact pork, 3,653,315 pounds of raw intact chicken, 134,971,905 pounds of raw non-intact chicken, 1,254,132 pounds of heat treated-not fully cooked-not shelf stable chicken, 34,075,205 pounds of raw intact turkey, and 2,999,448 pounds of non-intact turkey exported by Chile to the United States. Of these amounts, additional types of inspection were performed on 18,701,573 pounds of raw beef, lamb, mutton, pork, chicken, and turkey including testing for chemical residues and microbiological pathogens including *E. coli* O157:H7 and non-O157 STEC. A total of 53,181 pounds of raw, intact pork offal was rejected due to fecal contamination. An additional 132,407 pounds of the products listed above were refused entry for shipping damage, label, and certification issues.

The previous FSIS audit in 2016 identified findings under the Government Oversight component related to the lack of standardized performance assessment procedures for evaluating the competence of inspection personnel. In addition, a systemic finding was identified in the Government Statutory Authority and Food Safety and Other Consumer Protection Regulations component due to the failure of inspection personnel to observe surfaces of the tibiotarsal joints during post-mortem inspection of poultry. The FSIS auditors verified that the previously reported audit findings had been adequately addressed by the CCA with the exception of examination of the surfaces of the tibiotarsal joints in poultry.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Chile's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Chile's food safety inspection system governing raw intact and raw non-intact beef, pork, lamb, mutton, chicken, turkey, and heat treated-not fully cooked-not shelf stable poultry, is being implemented as documented in the country's SRT responses and supporting documentation.

The FSIS final audit reports for Chile's food safety system are available on the FSIS Web site at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

### **IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)**

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be

organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The meat and poultry food safety inspection system in Chile is organized and managed by the national government as mandated by national statutes. The CCA for the Chilean meat and poultry inspection system is SAG. The Ministry of Health is responsible for the safety of all food products destined for human consumption and has delegated responsibility for meat and poultry inspection to SAG, which is part of the Ministry of Agriculture. The CCA is responsible for veterinary drugs, pesticides, and other chemical residues in the production of agricultural products, including meat and poultry. The CCA has the responsibility for carrying out Chile's inspection program, including oversight and enforcement of the FSIS regulatory requirements in meat and poultry establishments certified by the CCA as eligible to export to the United States. Additionally, the CCA has oversight over the residue and microbiology laboratories that analyze products eligible to be exported to the United States.

The CCA's regulatory oversight of its meat and poultry inspection system consists of four levels: central, regional, local (sectorial), and establishment. The national directorate at the central level includes the strategic management division, law division, internal audit division, and communications department. Also at the national level are the technical support, business management, and administrative support departments. The inspection activities are overseen from regional offices, each managed by a Regional Director that reports to the National Director. Within each region are multiple local (sectorial) offices, with responsibilities for all commodities and including animal health. The Regional Supervisor for inspection and certification provides oversight of establishments certified to export to the United States including periodic supervisory visits, administrative decisions, and performance evaluation of inspection personnel. In each certified establishment is a government inspection team headed by the Chief Veterinary Medical Officer, (*Médico Veterinario Oficial* (MVIO)) and comprised of Veterinary Medical Officers (MVOs) and Technical Inspection Officials (TIOs) responsible for post-mortem inspection.

The CCA has the authority and responsibility to enforce the laws and regulations governing meat and poultry inspection including the authority to certify establishments as eligible to export products to the United States. Resolutions N° 1722 and N° 1045 are new since the last FSIS audit. Resolution N° 1722 provides the CCA with enhanced enforcement authority and administrative procedures to refuse registration and authorization of establishments certified to export to the United States, suspend establishments or processes, or refuse certification of specific products or production. The resolution also confers upon the CCA responsibility for verifying that third country requirements are met. Resolution N° 1045 defines establishment responsibility for ensuring compliance with national regulations, market regulations, and provides the requirement for HACCP systems including reassessment of the HACCP plan and prerequisite requirements.

The FSIS auditors verified that the CCA implements procedures in accordance with Resolution N° 1722 in order to certify eligibility to export to the United States. Once the CCA has

confirmed that an establishment complies with national and United States requirements, the establishment is incorporated into the List of Exporting Establishments of Livestock Products.

The CCA utilizes Ceropapel, an electronic document management system, to communicate requirements throughout all levels of the food safety inspection system. Ceropapel includes controls to determine which employees have opened and read transmitted information. In this manner the Regional Supervisors ensure that the MVIOs at each certified establishment are informed. The FSIS auditors verified that the use of Ceropapel was consistently implemented and effective by evaluating records at regional and establishment level offices.

The CCA implements procedures to maintain adequate staffing at each certified establishment to ensure official inspection coverage of every slaughter period and during every shift requiring inspection. Resolution N° 2592 states that every authorized establishment shall be subjected to the inspection of the CCA. Each certified establishment has approved operating hours and must inform the CCA and request its approval for operations. In accordance with Memo N° 236, the daily distribution of the hours and days to be worked at each certified establishment are determined in each region by the Regional Director together with the MVIO and the establishment. The FSIS auditors reviewed documented staffing records and observed government staffing levels at each establishment and confirmed that the CCA is ensuring sufficient staffing to perform ante-mortem and post-mortem inspection and to verify all other requirements during all establishment operations requiring inspection.

The national government of Chile through the Ministry of Agriculture funds the meat and poultry food safety inspection system, partially through fees assessed to industry for services rendered. The MVIO at each certified establishment is responsible for submitting the weekly hours worked by each member of the inspection team to the Chief of Office in the regional office for accounting purposes. Inspection personnel are paid directly from the financial department in SAG headquarters through direct deposit. Official inspection and supervisory personnel are employed on an annual basis by SAG through the ratification of their employment contracts. Continued employment is partially dependent upon successful performance evaluations by each employee's direct supervisor. The employment system is consistent with the Chilean statutes governing civil servants.

The CCA is responsible for hiring all inspection personnel and requires appropriate credentials including graduation from a recognized veterinary school for all MVOs. In addition, the CCA has coordinated with three Chilean universities to design the curriculum for a meat and poultry inspection course offered by the universities. Each MVO is required to successfully complete the course and present their training certificate prior to being hired by the CCA. The CCA utilizes central, regional, and local (sectorial) level training courses to ensure all inspection personnel are adequately trained, and the CCA is also utilizing eLearning courses to address training needs.

Each regional office is responsible for assessing its own training needs, and training may be conducted by universities, technical experts such as veterinary pathologists, Regional Supervisors, and MVIOs to ensure the entire inspection team is sufficiently trained to perform inspection and verification activities. Information obtained by the FSIS auditors through reviews

of training records and interviews of inspection personnel and Regional Supervisors demonstrated that the CCA has the ability to provide specialized and ongoing training for United States requirements.

The CCA maintains oversight of the national reference laboratories for microbiology and chemical residue analysis. Chile's network laboratories are comprised of SAG and Ministry of Health laboratories as well as private laboratories authorized by the CCA to perform microbiological analyses for the Pathogen Reduction Program (PRP). The official laboratories are organized within the Laboratory and Quarantine Stations Department of SAG, and those laboratories provide technical support to the inspection system. In accordance with Resolution N° 90/2014, the CCA implemented the *Specific Regulation for the Authorization of Analytical Laboratories* (D-GF-CGP-PT-012, Version 04) that requires private laboratories to have a Quality Assurance System based on International Organization for Standardization (ISO) 17025 standards.

The national accrediting organization, the National Standardization Institute (*Instituto Nacional de Normalización*, INN), conducts initial accreditation audits as well as ongoing audits every 18 months to verify that ISO 17025 standards are met in laboratories. The CCA ensures that only approved analytical methods are used for analyses of samples. Quality assurance staff from the SAG National Reference Laboratory (NRL) are responsible for assessing the performance of approved laboratories including annual audits of approved laboratories. Each approved laboratory is required to conduct proficiency testing annually, and results are reported to the CCA. For purposes of chemical residue analyses, the CCA utilizes international reference laboratories for some confirmatory analyses. Prior to use of these external laboratories, the CCA conducts an onsite visit to verify analyses and reports.

The FSIS auditors verified that the CCA's meat and poultry food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

**V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)**

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide 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; inspection at least once per shift during processing and continuous on-line inspection during slaughter operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified that each certified establishment has an assigned inspection team that performs duties under the coordination and direct supervision of an MVIO who directs and coordinates the verification activities of the establishments' food safety inspection programs and

the delivery of ante-mortem inspection conducted by MVOs and post-mortem inspection conducted by MVOs and TIOs. Government MVOs verify that establishments comply with regulatory requirements that apply to humane handling and slaughter of livestock as well as good commercial practices for poultry slaughter. Decree N° 28 includes provisions for construction of facilities and equipment used for handling and slaughtering of animals, competency of establishment personnel, and humane handling and slaughter.

Requirements for the ante-mortem and post-mortem inspection of livestock and poultry are detailed in Decree N° 977. The official inspection team performs ante-mortem and post-mortem inspection of livestock according to the requirements detailed in General Technical Rule N° 62 and of poultry according to General Technical Rule N° 117. The instructions for performing ante-mortem and post-mortem inspection of livestock and poultry are outlined in I-CER-VPE-PP-001, *Guidelines - Inspection of Slaughter Facilities*. The FSIS auditors assessed ante-mortem and post-mortem inspection through onsite record reviews, interviews, and observations of the inspection personnel performing these procedures in audited livestock and poultry slaughter establishments. The FSIS auditors identified the following finding:

- The post-mortem inspection procedures for poultry did not include observation of the interior of the carcass nor surfaces of the tibiotarsal joints. The incomplete observation of surfaces of the tibiotarsal joints is a repeat finding from the 2016 audit. At two of the three audited slaughter establishments inspection personnel did not observe the interior of each carcass, therefore failing to inspect for conditions within the interior of the carcass that would impact the wholesomeness of the product and eligibility for the mark of inspection, contrary to the CCA's General Technical Regulation N° 117 and "*Instructions to Apply Veterinary Inspection Procedures to Poultry and Their Meat for Exporting Purposes*" that instructs inspection personnel to check 100 percent of carcasses, internally and externally. In addition, inspection personnel at all audited poultry slaughter establishments were not presented birds for inspection with the tibiotarsal joint exposed, therefore precluding post-mortem inspection of the joint surfaces for pathology. The CCA failed to implement effective corrective actions to ensure post-mortem inspection of poultry meets FSIS requirements.

The FSIS auditors reviewed staffing assignments at establishments certified as eligible to export to the United States at the regional and establishment levels, and the auditors confirmed that the CCA requires inspection of each and every livestock and poultry carcass during all slaughter operations and at least once per shift during processing, as well as shifts where only shipment and certification for export take place. The FSIS auditors verified that inspection personnel are inspecting each poultry and livestock carcass. Supervisory officials visit the certified establishments a minimum of every four months to assess the adequacy of the design and implementation of the food safety programs maintained by the certified establishments, and evaluate delivery of ante-mortem and post-mortem inspection activities, HACCP and sanitation standard operating procedures (Sanitation SOPs) and control over condemned materials.

In response to the 2016 audit finding associated with a lack of standardized performance assessment, the FSIS auditors verified the implementation of Circular N° 803/2017, describing the evaluation of each member of official inspection teams using a standardized form. Records of supervisory visits reviewed by the FSIS auditors document the results of these activities and

demonstrate that this activity is conducted in accordance with instructions issued by the CCA that are consistent with United States requirements.

Establishments certified to export to the United States are required to maintain identity of products, and to control and segregate product destined for the United States from other products. In addition, the CCA has controls to prevent any imported meat from being further processed and certified for export to any third country, including the United States. The Electronic System for Issuing Export Certificates is used by both industry and official inspection personnel to document each and every export certificate, including all traceability and other supporting documents. In addition, the Electronic System is used to validate controls for the eligibility of establishments and products. The MVOs evaluate each request for export to ensure the documentation supports eligibility, and official inspection personnel re-inspect export lots at the time of loading. If the MVO determines the export lot meets all requirements, including eligibility of product, the electronic system is used to generate an export certificate with a unique certificate number. The FSIS auditors verified in each audited establishment the official inspection security of controls associated with the export process including certification records, security paper, and official seals.

The CCA has legal authority to establish regulatory controls over certified meat and poultry establishments that export their products to the United States. However, the CCA did not implement corrective actions in response to previous audit findings to ensure the post-mortem inspection of poultry meets FSIS requirements.

## **VI. COMPONENT THREE: GOVERNMENT SANITATION**

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions.

The CCA requires certified establishments to develop and adhere to written programs that prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions. Each certified establishment must develop procedures to address sanitary requirements including cleaning, facility construction and maintenance, equipment maintenance, and pest control consistent with the FSIS regulations for Sanitation Performance Standards at 9 CFR §416.2-416.6. The MVOs verify compliance of establishments certified to export to the United States with sanitation requirements on a daily basis by direct observation and reviewing records.

The FSIS auditors verified the adequacy of official verification and inspection activities related to sanitation programs at establishments certified to export to the United States by observing official inspection personnel as they assessed the implementation of the establishments' sanitation procedures. The FSIS auditors assessed the adequacy of pre-operational sanitation by observing official inspection personnel conducting pre-operational verification of the establishment's sanitation program at two of the audited establishments. The in-plant inspection personnel conducted this activity in accordance with the established procedures including an

organoleptic inspection of food contact surfaces of facilities, equipment, and utensils. The FSIS auditors also reviewed inspection records and assessed the overall sanitary conditions of production areas and storage rooms, and auditors observed the production processes conducted in slaughter and processing (cutting/deboning) areas of the establishments.

Lastly, the FSIS auditors evaluated official inspection personnel verification of establishment sanitary dressing procedures in slaughter establishments. Official inspection personnel routinely verify establishment sanitary dressing, and they also perform daily verification of zero tolerance for fecal material, ingesta, and milk on livestock carcasses and fecal material in poultry. Overall, the CCA has written requirements and verification procedures sufficient to ensure that each slaughter establishment adheres to sanitary dressing principles.

FSIS verified that the meat and poultry food safety inspection system of Chile requires that all establishments certified to export to the United States implement sanitation programs to prevent the creation of insanitary conditions and to prevent direct product contamination. Inspection personnel conducting verification on the implementation adequacy of sanitation programs assess the risks posed by conditions that could cause direct product contamination and, when a noncompliance is identified, they require the establishment to implement adequate corrective actions. The food safety inspection system has an effective enforcement program that includes suspension and withdrawal of inspection for those establishments that fail to prevent product contamination or fail to take corrective actions.

The CCA's meat and poultry food safety inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

## **VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM**

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

The FSIS auditors verified that the CCA requires establishments to design, implement, and maintain HACCP systems as required by Resolutions N° 2592 and N° 1045. The evaluation standards (F-PP-IT-047) for meat and (F-PP-IT-058) for poultry address the verification of HACCP requirements consistent with 9 CFR §417 that establishments are required to meet in order to be eligible to export product to the United States. The FSIS auditors reviewed programs and records maintained by inspection personnel and the audited establishments, and the auditors also observed the implementation of the HACCP systems.

The FSIS auditors verified that the audited establishments have developed flow charts and conducted hazard analyses. For specific hazards that are reasonably likely to occur, the establishments have instituted critical control points (CCPs) described in HACCP plans. The FSIS auditors also verified that official inspection personnel conduct daily verification of zero tolerance for fecal material, ingesta, and milk in livestock and fecal material in poultry to verify

establishment compliance with sanitary dressing and the establishments' CCPs for zero tolerance.

The CCA requires that establishments implement corrective actions when deviations from established critical limits occur that result in food safety hazards. The FSIS auditors verified that establishments' HACCP plans identify the CCPs, the critical limits to be monitored, the monitoring frequency, the corrective actions to be implemented when a deviation occurs, and verification activities to be implemented. The official inspection team conducts verification activities for HACCP requirements according to general document D-PP-IT-003, *Verification of the Quality Assurance System in Slaughterhouses for Export*. The FSIS auditors reviewed inspection records associated with their daily verification of compliance of HACCP requirements to ensure the adequacy of their food safety controls in accordance with verification instructions.

The FSIS auditors verified that the CCA requires establishments certified to export to the United States to develop and implement HACCP systems. However, during review of establishments' HACCP systems and records, the FSIS auditors identified the following findings:

- The CCA is not requiring establishments to incorporate pre-chill sampling of poultry carcasses for microbial organisms within their HACCP systems. All three audited poultry slaughter establishments lacked written programs and procedures to conduct pre-chill sampling, therefore, not meeting the FSIS requirements.
- The two beef establishments with confirmed positive STEC results have not identified STEC as a hazard reasonably likely to occur in the slaughter process. Confirmed positive STEC findings are evidence that the hazard is reasonably likely to occur, and HACCP requires incorporation of a CCP designed to prevent, eliminate, or reduce STEC below detectable levels at the end of the slaughter process. The two audited beef slaughter establishments cannot support decisions in the hazard analysis, and those establishments failed to design and implement CCPs to control the STEC hazard.

The FSIS auditors determined that the CCA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP systems. However, the audit findings listed above demonstrate that the CCA's food safety inspection system did not effectively verify the adequacy of HACCP systems at some establishments certified to export to the United States.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS**

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed Chile's national Residues Control Program (RCP) for 2017, results for 2016, associated methods of analysis, and additional SRT responses outlining the structure of Chile's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit in 2016.

The CCA maintains the legal authority and responsibility to develop and implement an annual RCP in accordance with the CCA's requirements, including Decree N° 977, in order to prevent and control the presence of residues of veterinary drugs and contaminants in the tissues of livestock and poultry slaughtered for human consumption. The program is designed to meet the requirements of all countries that import meat and poultry products from Chile and provides data that the CCA analyzes to identify developing trends and any need for corrective actions. Suppliers of animals destined for slaughter are required to comply with government regulations that apply to the use, manufacturing, importing, and selling of veterinary drugs prohibited for use in animals destined for human consumption. For other compounds that are permitted for use in primary production, the program has established maximum tolerance levels, analytical methodology, and sampling protocols to be implemented throughout the year at ranches and establishments to verify compliance with equivalent requirements.

The FSIS auditors' verification of this component occurred at all audit sectors of the inspection system which included central, regional, and local (sectorial) inspection offices at establishments, and at the NRL, the SAG Chemistry and Food Safety Laboratory. The CCA has approved six laboratories to conduct official chemical residue testing. The NRL is responsible for the official laboratory network including the oversight and auditing of approved laboratories as well as management of technical activities with international reference laboratories. The CCA ensures that only approved analytical methods are used for analysis of samples and requires proficiency testing at all approved laboratories, as well as quality assurance systems meeting ISO 17025 standards.

The FSIS auditors verified that the MVOs were collecting random residue samples in accordance with the RCP and instructions provided by the CCA at meat and poultry slaughter establishments. The MVOs were ensuring consistent sampling methodology, identification of animals, traceability, and sample security. In addition to the RCP sampling, inspectors also collect targeted samples from livestock and poultry suppliers with a history of residue violations. Unscheduled sampling is also performed when MVOs detect suspect animals during ante-mortem or post-mortem inspection. The results of the residue analyses are communicated to MVIOs, the CCA headquarters, and Regional Supervisors to ensure that only products that comply with Chilean and United States requirements are certified for export. In addition, residue results that are in violation of Chilean standards are subject to action in accordance with established procedures that are designed to educate the producers, monitor their compliance, and penalize them if they fail to comply with the laws and regulations of the system.

The NRL laboratory audit included interviews with the officials, document reviews, and a visit to the chemical residue testing portion of the laboratory. This laboratory is ISO 17025 accredited by INN. The FSIS auditors reviewed the most recent accreditation audits of the laboratory and verified the laboratory's corrective action plans in response to the audits. The FSIS auditors verified that the Quality Manual included all expected chapters, including organization, staff

qualifications, credentials, and training. The FSIS auditors also reviewed proficiency testing associated with the methods, and they found the results of the proficiency testing to be acceptable. The FSIS auditors verified that the audited laboratory ensured traceability throughout sample receipt, analysis, and reporting. The FSIS auditors identified the following finding:

- The CCA conducts residue analysis on primary samples but defers confirmation until the NRL laboratory determines and officially reports positive results for second and tertiary samples. This methodology is not consistent with FSIS requirements for which a collected sample and corresponding analytical result are expected to be representative of the sampled animal. A paired sample is collected at the establishment by the MVO, of which one sample is sent to the laboratory, while keeping the “counter sample” under official control at the establishment. The laboratory splits the submitted sample and tests one portion. If the initial sample portion tests positive, the laboratory then analyzes the second portion, and if positive the laboratory then requests the MVO to submit the “counter sample” from the establishment. The CCA only confirms official residue samples as positive if all three of the tests are positive. The auditors confirmed that there have been no presumptive positive residue analyses since the prior audit so no immediate threat to public health is identified.

Except for the above finding, the FSIS auditors’ analysis and onsite audit verification indicated that the CCA continues to meet the core requirements for this component.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The last equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat and poultry products prepared for export to the United States are safe and wholesome. The FSIS auditors reviewed the programs implemented by the CCA as part of its PRP that includes generic *E. coli*, *Campylobacter*, and *Salmonella* sampling, as well as Chile’s STEC control programs.

The CCA has written procedures for the collection, analysis, and verification of generic *E. coli* and *Salmonella* performance standards in livestock slaughter establishments as well as generic *E. coli*, *Salmonella*, and *Campylobacter* performance standards in poultry slaughter establishments. The establishment is responsible for collecting generic *E. coli* samples in accordance with frequencies consistent with 9 CFR §310.25 for livestock and 9 CFR §381.65 for poultry. All samples are required to be analyzed in official SAG laboratories using the Association of Analytical Chemists (AOAC) 991.14 analytical method. The results are reported to the establishment and CCA and the MVIO in each establishment generates statistical process control charts to verify establishment process control.

The CCA has established *Salmonella* performance standards for livestock and poultry as described in the general document D-CER-VPE-PP-003, *Microbiological Sample of Bovine and Carcasses in Export Slaughtering Plants*. In addition, the CCA has established *Campylobacter* performance standards and sampling in poultry as described in general document D-BB-CC.

The MVO is responsible for collecting five weekly samples from livestock and poultry. Livestock carcasses are sampled using sponge methodology; chickens are sampled using whole bird rinse, and turkeys are sampled using excision of neck skin. Samples are submitted to the approved laboratories that analyze samples for the presence of *Salmonella spp.* using VIDAS® Easy SLM methodology. The poultry samples are also analyzed for *Campylobacter* using VIDAS® CAM. Results are reported directly to the CCA at the regional and establishment levels, and the MVIO tabulates results to document each sample set. If an establishment fails a set, then the CCA requires immediate corrective actions including reassessment of the HACCP system; if a third set fails, then the CCA is authorized to suspend operations at the facility.

The FSIS auditors verified that official inspection personnel conducted sampling according to written procedures, and that results clearly documented completion of performance standard sets in each establishment. In addition, the FSIS auditors assessed the CCA response to failed sets including documenting noncompliance and verifying establishment corrective actions.

The CCA's testing program for STEC in raw beef had been determined as equivalent by FSIS. No certified beef establishments are producing non-intact beef for export to the United States. The general document D-CER-VPE-PP-004, *Official and Self-monitoring Verification of E. coli O157:H7 and STEC No-O157 on Bovine Ground Meat, Trimming and Its Precursors, Tenderized Meat, Marinated Meat and Hamburgers to be Exported to the United States, Israel, Canada and Costa Rica*, describes the official sampling procedure, sampling methodology, identification and transportation of samples, analytical techniques, interpretation of results, submission of results, decision criteria and corrective actions.

The official inspection personnel collect monthly verification samples of raw beef trimmings for STEC analysis comprising five samples for *E. coli* O157:H7 and five samples for non-O157 STEC analysis. Official STEC verification samples are submitted to the official SAG laboratory; and 325 g samples are analyzed for *E. coli* O157:H7 using VIDAS® UP AFNOR BIO 12/25-05/09 and 375 g samples are analyzed for non-O157 STEC using Assurance GDS MPX Top 7 STEC AOAC Performance Tested Method 071301. According to the CCA's testing program, screen positive results must be confirmed using methodologies determined equivalent by FSIS. The FSIS auditors observed official STEC sample collection at one beef slaughter establishment and identified the following finding:

- At one establishment, the CCA's methodology for collecting samples of raw beef trim for purposes of STEC analysis does not target surface tissue and is not equivalent to FSIS sampling methods for slaughter operations. As a result, the sampling method is not designed to maximize the opportunity to detect the pathogen, if present.

When conducting government official sampling for STEC, the CCA does not allow certification of product until the results of the microbiological tests are received. The FSIS auditors verified that production lots of raw beef trimmings are held by official inspection personnel pending acceptable sample results and the sampled production is declared ineligible in the export certification database. The test results related to official verification of microbiological control programs for pathogens are reported directly to the government in a timely manner, generally via email to the appropriate officials. However, review of multiple

STEC results reported by the SAG laboratory at the government inspection offices of two beef slaughter establishments resulted in the following finding:

- The CCA's official STEC reports are insufficient to accurately interpret the analytical methods and results for inspection personnel at the establishment level. Laboratory records failed to clearly identify results for analyzed samples. In addition, the laboratory records documenting 'confirmatory' STEC results list the screening analytical methods rather than the confirmatory methodologies that were expected to be utilized. Therefore, based on review of laboratory records at the establishment, either the laboratory is failing to follow the confirmatory methodology or the laboratory is not ensuring accurate reporting according to ISO 17025 requirements.

For every confirmed positive STEC result, official inspection personnel verify destruction of the sampled production lot according to Ministry of Health orders as well as establishment corrective actions, implementation of establishment corrective actions, and conduct follow-up sampling. The FSIS auditors verified that, in response to confirmed positive results, two sets of official follow-up sampling were conducted.

The Government Microbiological Testing Programs component of the meat and poultry food safety inspection system of Chile is organized and administered by the national government to verify that meat and poultry products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. There have not been any POE violations related to this component since the last FSIS audit. Except for the findings noted above, the CCA's meat and poultry inspection system continues meet the core requirements for this component.

## **X. CONCLUSIONS AND NEXT STEPS**

An exit meeting was held with SAG on April 17, 2018, in Santiago, Chile. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

### **Government Statutory Authority and Food Safety and Other Consumer Protection Regulations**

- The post-mortem inspection procedures for poultry did not consistently include observation of the interior of the carcasses nor surfaces of the tibiotarsal joints. The incomplete observation of surfaces of the tibiotarsal joints is a repeat finding from the 2016 audit.

### **Government Hazard Analysis and Critical Control Points (HACCP) System**

- The Central Competent Authority (CCA) is not requiring establishments to incorporate pre-chill sampling of poultry carcasses for microbial organisms within their HACCP systems. All three audited poultry slaughter establishments lacked written programs and procedures to conduct pre-chill sampling.
- The two beef establishments with confirmed positive STEC results have not identified STEC as a hazard reasonably likely to occur in the slaughter process.

### **Government Chemical Residue Testing Programs**

- The CCA conducts residue analysis on primary samples but defers confirmation until the National Reference Laboratory (NRL) determines and officially reports positive results for secondary and tertiary samples. This methodology is not consistent with FSIS requirements for which a collected sample and corresponding analytical result is expected to be representative of the sampled animal.

### **Government Microbiological Testing Programs**

- At one establishment, the CCA's methodology for collecting samples of raw beef trim for purposes of STEC analysis does not target surface tissue and is not equivalent to FSIS sampling methods for slaughter operations.
- The CCA's official STEC reports are insufficient to accurately document the analytical methods and results for inspection personnel at the establishment level.

During the audit exit meeting, the CCA provided evidence that they immediately began addressing some of these systemic findings by revising inspection procedures for poultry to consistently include observation of the interior of the carcasses and surfaces of the tibiotarsal joints, issuance of instructions for inspection teams to ensure that inspection is being done on the abdominal cavity, issuance of instructions for poultry pre-chill sampling, and preparation of instructions to adopt FSIS N60 sampling protocols. FSIS will evaluate the adequacy of the CCA's documentation of further submitted corrective actions upon receipt, and base future equivalence verification activities on the information provided.

# **APPENDICES**

## **Appendix A: Individual Foreign Establishment Audit Checklists**

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sopraval S.A. Panamericana Norte, Km 112 La Calera Región de Valparaíso	2. AUDIT DATE 04/06/2018	3. ESTABLISHMENT NO. 05-09	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

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**60. Observation of the Establishment**

55. The post-mortem inspection procedures for turkeys did not include a consistent observation of the surfaces of the tibio-tarsal joints or observation of the interior of the carcass.

**The following noncompliances were not identified by Chile's inspection officials during the establishment review:**

10/14/51. The establishment was not able to visualize the insertion of a thermometer into product at the temperature monitoring CCP of product in refrigerated storage. The thermometer was inserted into a stack of crates wrapped in plastic which is opaque and does not allow the monitor to see if the thermometer is inserted into product or ambient air. This practice could also introduce contamination into the product from exterior packaging material.

14/51. The establishment was not collecting and analyzing samples for microbial organisms at the pre-chill point in the poultry slaughter process as required.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

**62. DATE OF ESTABLISHMENT AUDIT**04/06/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Faenadora Lo Miranda Ltda. Carretera H-30, No 3814 Donihue Libertador General Bernardo O'Higgins	2. AUDIT DATE 04/12/2018	3. ESTABLISHMENT NO. 06-02	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

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60. Observation of the Establishment

**The following noncompliance was not identified by Chile's inspection officials during the establishment review:**

10/51. Carcasses in the chiller that had been reprocessed after falling on the ground destined for the domestic market were on rail next to and kept in close proximity to carcasses destined for export markets.

12/51. The SSOP records did not document the disposition of product or preventative measures as a part of corrective actions.

22/51. The direct observation of monitoring that is documented on the HACCP records does not correspond with the monitoring record for which the verification activity occurred, including time and result.

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61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

04/12/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Procesadora de Alimentos del Sur Limitada Ruta H-50 Km. 0.304 Camino Quinta de Tilcoco Rengo Libertador General Bernardo O'Higgins	2. AUDIT DATE 04/11/2018	3. ESTABLISHMENT NO. 06-06	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

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**60. Observation of the Establishment**

51. Inspection personnel identified multiple SPS issues and the establishment's failure to segregate reprocessed product during their daily inspection however did not issue a written record of noncompliance to the establishment and only verbally notified the establishment.

**The following noncompliance was not identified by Chile's inspection officials during the establishment review:**

16/51. A HACCP record documented by the establishment did not include in the corrective actions, visual inspection of product involved in a deviation at the critical control point for zero tolerance for visual fecal matter.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

**62. DATE OF ESTABLISHMENT AUDIT**04/11/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Faenadora San Vicente Ltda. Ruta H-66G, Km. 19.2 San Vicente de Tagua Libertador General Bernardo O'Higgins	2. AUDIT DATE 04/10/2018	3. ESTABLISHMENT NO. 06-08	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

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**60. Observation of the Establishment**

55. The post-mortem inspection procedures for broilers do not include a consistent observation of the surfaces of the tibio-tarsal joints or observation of the interior of the carcass.

**The following noncompliances were not identified by Chile's inspection officials during the establishment review:**

14/51. The establishment was not collecting and analyzing samples for microbial organisms at the pre-chill point in the poultry slaughter process as required.

14/51. The establishment's hazard analysis did not identify chemical hazards at a process step in which chlorine was being used for reprocessing.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

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**62. DATE OF ESTABLISHMENT AUDIT**04/10/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Matadero Frigorifico del Sur S.A. Ruta U 55 Camino Pichidamas km 1.7 Osorno Región de Los Lagos	2. AUDIT DATE 04/12/2018	3. ESTABLISHMENT NO. 10-15	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

**The following noncompliances were not identified by Chile's inspection officials during the establishment review:**

10/51. Three carcass sides were being moved on the retention rail by an establishment employee, and were coming into direct contact with other sides prior to trimming and release, providing the distinct possibility for directly contaminating additional product. Further, the air line hoses on the trim stand of the retention rail were observed directly in contact with a carcass side.

10/51. During the bunning process, extensive spillage of urine was observed directly onto exposed carcass surfaces. No immediate actions were noted by the employee. In addition, the employee at the first legging station was observed to use the same knife for hide cuts and skinning without sanitizing between cuts or switching his knife, which was the expectation according to the establishment's own instructions.

14/51. The establishment had a confirmed positive E. coli O157:H7 in August of 2017 but had not designed or implemented a CCP to eliminate or reduce the hazard below detectable levels at the end of the process.

39/51. Multiple product storage areas had product stacked directly up to the walls with no ability to access and visualize the wall/floor junctures to assess sanitary conditions.

41/51. Extensive beaded condensation was observed below the three ventilation units in carcass cooler #5, directly over carcasses on a rail. No evidence of direct product contamination was observed.

45/51. A stainless steel trolley cart used for edible product in the deboning room had multiple protruding points with open seams precluding thorough cleaning and sanitizing.

58. The CCA's methodology for collecting samples of raw beef trim for the purposes of STEC analysis does not target surface tissue and is not equivalent to FSIS sampling methods for slaughter operations

58. The CCA's official STEC reports are insufficient to accurately document the analytical methods and results for inspection personnel at the establishment level.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

04/12/2018

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorífico de Osorno S.A. Francisco del Campo 200 Osorno Región de Los Lagos	2. AUDIT DATE 04/11/2018	3. ESTABLISHMENT NO. 10-26	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

**The following noncompliances were not identified by Chile's inspection officials during the establishment review:**

14/51. The establishment had multiple positive STEC results, however their hazard analysis concludes that STEC are not reasonably likely to occur, therefore the establishment was unable to support decisions made in the hazard analysis. While the establishment had incorporated an antimicrobial control point, they had not designed and implemented a CCP to eliminate or reduce the hazard below detectable levels at the end of the process.

38/51. Gaps were observed under three shipping doors in the product load-out room, providing the potential for entry of pests and rodents.

39/51. Extensive degradation of concrete was observed outside of freeze tunnels and in a transfer hallway with resultant rough surfaces of missing concrete, irregular surfaces and accumulation of dirt and water resulting in insanitary conditions.

39/51. In an establishment freezer, product was stored on racks directly against the walls on both sides, preventing access or ability to visualize the wall to floor juncture to assess sanitary conditions.

58. The CCA's methodology for collecting samples of raw beef trim for the purposes of STEC analysis does not target surface tissue and is not equivalent to FSIS sampling methods for slaughter operations

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

04/11/2018

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorífico Simunovic S.A. Km. 13.7 Norte Punte Arenas Región de Magallanes y la Antartica Chilena	2. AUDIT DATE 04/06/2018	3. ESTABLISHMENT NO. 12-01	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

**The following noncompliances were not identified by Chile's inspection officials during the establishment review:**

10/51. Sheep carcasses were observed coming into contact with nozzles and water tubing that were not able to be thoroughly cleaned and sanitized within the carcass wash. for sheep were not able to be thoroughly cleaned and sanitized to prevent the creation of insanitary conditions. Additionally, two establishment employees were cross-contaminating the hide with the exposed carcass during the dehiding process, creating an insanitary condition.

19/51. The establishment's review of records for the zero tolerance CCP did not include the time and results of the ongoing verification activity.

19/51. The establishment's HACCP plan for CCP2, cold storage, did not identify the calibration of thermometer procedure and frequency.

41/51. Beaded condensation was observed below the ventilation unit in Carcass Chiller 2, immediately above a carcass rail. In addition, there was extensive rust of the overhead ventilation and a loose metal covering exposing insulation. However, no evidence of direct product contamination was observed.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

04/06/2018

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Soc. Com. Jose Marin Antonin y Cia. Ltda. Los Calafates No. 415 Sitio 7-11 Barrio Industrial Punta Arenas Región de Magallanes y la Antartica Chilena	2. AUDIT DATE 04/05/2018	3. ESTABLISHMENT NO. 12-05	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

**The following noncompliances were not identified by Chile's inspection officials during the establishment review:**

10/51. An establishment employee was not sanitizing his knife between his hide opening cut at the neck and skinning of the fore shank, creating an insanitary condition. In addition, a slaughter employee was cross-contaminating the hide with the exposed carcass during the dehiding process, creating an insanitary condition.

12/51. The SSOP pre-operational corrective actions were not addressing whether sanitary conditions were restored and verified.

15/51. The HACCP plan for the zero tolerance CCP failed to list procedures and frequency for the ongoing verification activity of review of records. The establishment was performing a review, however the records did not include the time and results of the verification activity.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

04/05/2018

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorífico Patagonia S.A. John Williams No 1 Porvenir Región de Magallanes y la Antartica Chilena	2. AUDIT DATE 04/09/2018	3. ESTABLISHMENT NO. 12-10	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

## 60. Observation of the Establishment

**The following noncompliances were not identified by Chile's inspection officials during the establishment review:**

10/51. The establishment was stacking edible crates on top of inedible crates in the cutting room in order to facilitate sliding of crates across the floor.

10/51. An establishment employee was observed cutting the hind legs from the carcass resulting in subsequent drop of the carcass such that the head, neck, and wool would contact the housing from the head hide puller, resulting in direct contamination on individual carcasses as well as between carcasses.

16/51. The establishment's direct observation of monitoring records did not include time and initials. The establishment's HACCP records failed to document the results of two hourly monitoring events. Despite the lack of monitoring results, the establishment had completed the review of records and indicated they were compliant, thereby failing to identify the lack of monitoring results demonstrating the critical limits had been met.

42/51. Extensive standing water was observed on the floor in the cutting room due to the apron wash for which there was no associated drain. The water pooled across approximately 8 x 20 feet of flooring as the nearest drain was approximately 30 feet away. In addition, at several stations on the slaughter floor the water supply pipes or drain pipes from sinks/sterilizers were leaking from multiple points.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

04/09/2018

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Agroindustrial el Paico S.A. Av. Los Libertadores 1714 El Monte Región Metropolitana de Santiago	2. AUDIT DATE 04/04/2018	3. ESTABLISHMENT NO. 13-07	4. NAME OF COUNTRY Chile
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

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60. Observation of the Establishment

55. The post-mortem inspection procedures for broilers do not include a consistent observation of the surfaces of the tibio-tarsal joints. =

**The following noncompliances were not identified by Chile's inspection officials during the establishment review:**

14/51. The establishment was not collecting and analyzing samples for microbial organisms at the pre-chill point in the poultry slaughter process as required.

39/51. Styrofoam insulation covering pipes above the carcass chiller and packaging areas was not covered and was observed to have areas that were degrading.

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61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

04/04/2018

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**Appendix B: Foreign Country Response to the Draft Final Audit Report**



**Santiago,**

COURTESY TRANSLATION

**JANELL KAUSE  
ACTING INTERNATIONAL COORDINATION EXECUTIVE OFFICE OF INTERNATIONAL  
COORDINATION  
FSIS - USDA  
1400 INDEENCE AVENUE, SW. WASHINGTON, D.C. 20250,**

Dear **JANELL KAUSE,**

Along with my cordial greetings, I am writing you in order to send the comments and actions taken by the Agricultural and Livestock Service in front of the detected findings indicated in the draft final report of the audit conducted in Chile, between April 02th to 17th of 2018 in which the Chilean food safety system governing the production of meat and poultry products intended for export to the United States of America was evaluated.

I will be glad to answer or clarify any doubt or concern that you may have.

Best regards,

**MIGUEL EDUARDO PEÑA BIZAMA  
DEPUTY CHIEF OF LIVESTOCK DIVISION  
AGRICULTURAL AND LIVESTOCK SERVICE**



**COMMENTS OF THE AGRICULTURAL AND LIVESTOCK SERVICE (SAG) ON THE DRAFT OF THE FSIS  
AUDITING REPORT PREPARED BETWEEN APRIL 2 AND 17 OF 2018**

**REGARDING THE FINDINGS POINTED OUT IN THE ASSESSED CONTENT**

**I. Content two: state statutory authority, food safety, and other consumer protection regulations (inspection system, product and labeling and human handling standards)**

Scope:

- a) The post-mortem inspection procedures for poultry did not consistently include observation of the interior of the carcasses nor surfaces of the tibiotarsal joints. The incomplete observation of surfaces of the tibiotarsal joints is a repeat finding from the 2016 audit**

The Competent Central Authority (CCA) through Circular 344/2018, instructs official inspection teams in poultry slaughterhouses to conduct inspections on carcasses in accordance with the provisions of current regulations.

Circular N° 335/2018, which instructs Official Inspection Teams (OIT) of establishments permitted to export to USA, that amidst the implementation of definitive corrective measures to properly expose the tibiotarsal joints, the corresponding measures are required to be met in order to correct this breach. These corrections include calibrating the cut at the joint, which, in turn, may involve slowing down or stopping the processing line, if necessary.

The foregoing must be confirmed by the Official Inspecting Veterinarian twice per work shift and per line. These must be recorded in the Form F-PP-IT-032. Should there be other breaches in the process that prevent from conducting an appropriate inspection of the joint facet, a non-compliance report must be written. Follow-up and control of the corrective action of this report must be registered in form F-PP-IT-032. |

The definitive corrective action defined by broiler establishment authorized to export to USA in order to comply with CCA requirements was the purchase of an equipment intended for cutting the tibiotarsal joints. In the case of turkeys this machine is currently operating in the processing line. As for broilers, this equipment will be fully operational between October 2018 and January 2019. Please, find attached the purchase orders for the latter.

Please find attached **Annex I a)**, as evidence of the foregoing.

## II. CONTENT FOUR: GOVERNMENT “HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM:

Scope:

- a) **The CCA is not requiring establishments to incorporate pre-chill sampling of poultry carcasses for microbial organisms within their HACCP systems. All three audited poultry slaughter establishments lacked written programs and procedures to conduct pre-chill sampling, therefore, not meeting the FSIS requirements.**

Through Circular N° 243/2018, CCA instructs to the official inspection teams in poultry slaughterhouses authorized to export to USA to meet the regulatory requirements, in compliance with 9 CRF 381.65. This aims to proof the effectiveness of their process control procedures.

These facilities must develop, implement and maintain written procedures to prevent carcasses and their parts from being contaminated with enteric pathogens. This must be controlled by the official inspection teams, and recorded in form F-PP-IT-032.

Please find attached **Annex II a)**, as evidence of the foregoing.

- b) **The two beef establishments with confirmed positive STEC results have not identified STEC as a hazard reasonably likely to occur in the slaughter process. Confirmed positive STEC findings are evidence that the hazard is reasonably likely to occur, and HACCP requires incorporation of a CCP designed to prevent, eliminate, or reduce STEC below detectable levels at the end of the slaughter process. The two audited beef slaughter establishments cannot support decisions in the hazard analysis, and those establishments failed to design and implement CCPs to control the STEC hazard.**

Due to the findings related to the microbiological risk of STEC, the Agricultural and Livestock Service implemented the official actions described in the various sections of this report.

As for Hazard Analysis and the decisions that support the implementation of control measures against STEC in facilities permitted to export to USA, the Agricultural and Livestock Service proceeded to:

- Through Circular N ° 453/2018, the beef product export certification for the United States of (trimming, patties, ground beef or cuts that will be used to make these products) was suspended. Given suspension will continue until the official inspection program is updated and the authorized establishments duly address STEC risks in their HACCP plan.
- Through Circular N° 471/2018, the Agricultural and Livestock Service proceeded to give its Regional SAG Teams the following instruction: "Exporting establishments must include in their Quality Assurance System the requirements of the markets, to which they are authorized to export, as well as the re-assessments of their HACCP plans, provided that control measures designed are insufficient to control the risk". This instruction is governed by Exempt Resolution No. 1045/2013.



The SAG Inspection Teams assigned to the slaughterhouses authorized to export to the United States, controlled in the field the compliance with the instructions of circular 471/2018, and analyzed the re-assessments of HACCP plans regarding STEC findings indicated in the draft report. Furthermore, when dealing with an inadequate hazard analysis, the personnel of the Service may request a re-assessment, considering factors such as severity and frequency, in addition to the official microbiological and internal quality control results available.

The results of the Official Verification determined that the slaughterhouse and cold storage facility Matadero Frigorífico del Sur (10-15) completed their HACCP re-assessment and implemented a Critical Control Point (CCP) for STEC risks. It was also determined that the Frigorífico de Osorno S.A. (10-26) y Frigorífico Simunovic S.A (12-01) are still in the process of re-assessing their HACCP. The Service will maintain the suspension of the certification of bovine meat (trimming, hamburgers, ground beef or cuts that will be used for the elaboration of these products) of the latter facilities until the re-assessments conclude are completed, and the staff of the Service confirms the correct fulfillment of the requirements.

Please find attached **Annex II b)**, as evidence of the foregoing.

### III. CONTENT FIFTH: GOVERNMENT PROGRAMS FOR THE ANALYSIS OF CHEMICAL RESIDUES

Scope:

- a) **The CCA conducts residue analysis on primary samples but defers confirmation until the National Reference Laboratory (NRL) determines and officially reports positive results for secondary and tertiary samples. This methodology is not consistent with FSIS requirements for which a collected sample and corresponding analytical result is expected to be representative of the sampled animal.**

The analysis of the sample conducted by the laboratory authorized by CCA generates a single result without a secondary sample. The foregoing is due to the positive result of that sample being always produced by the laboratory, once all the actions leading to determine that the result obtained is positive are carried out by applying the quality controls associated with the corresponding analytical test.

On the other hand, the Service, taking into account the finding indicated by FSIS, will consider as a definitive result, the one obtained from the sample (referred to in the FSIS report as a primary sample), and will immediately perform all the actions described in points 8.2 and 8.3 of the 2018 Residues Control Program, such as, suspension of certification, containment or disposal of products, exclusion for export of the farms involved, among others.

Simultaneously, the Service will have a Counter Sample (a duplicate sample), whose purpose will be to correct logistical problems such as the loss or deterioration of the primary sample and, probably, to perform a second analysis only at the request of the producer, which will be conducted in an authorized laboratory, in the presence of the professionals responsible for the Chemistry and Food Safety Laboratory of the Service and at the private expense. This result will be considered as the final result.

Notwithstanding the foregoing, specifically for the United States, the Service will not consider the result of the analysis requested by the producer. Therefore, the counter sample will not be used for a second analysis. This definition will be informed through a Circular at the regional level, specifying that products compromised in residues findings will not be certified, if positive results are obtained from the samples analyzed (primary samples).

#### IV. CONTENT SIX: GOVERNMENT PROGRAMS FOR MICROBIOLOGY TESTING

##### Clarification:

The Agricultural and Livestock Service, on June 29, 2017, updated the pathogen reduction program (PRP), and was named "official microbiological verification".

Please, find attached D-CER-VPE-PP-009\_v01 and its amending circulars (406/2017, 446/2017, 640/2017, 105/2018).

In relation to the sampling of Official Verification of *Salmonella* and *Campylobacter*, the Agricultural and Livestock Service has not established the same frequency or matrix for both microorganisms:

##### a) *Salmonella spp.*

Since the beginning of this official program, the sampling has been non-destructive. The official inspection team is responsible for collecting five weekly samples of livestock and poultry for Salmonella analysis (n = 5).

- In the case of cattle and turkey carcasses, this is done by means of the sponge swabbing method.
- The sampling of broilers is done by the whole carcass rinsing method.

The samples are sent to the SAG regional laboratories and laboratories authorized by the SAG, which test them for Salmonella spp. using the VIDAS® Easy SLM method.

##### b) *Campylobacter spp.*

In poultry slaughterhouses (chicken and turkey) authorized to export to the United States, the official inspection team collects five monthly sampling units (n = 5) to detect the presence of *Campylobacter* and analyzes them using the VIDAS® CAM method.

- Non-destructive sampling method is used in poultry (whole carcass rinsing).
- For turkeys, neck tissue samples are collected (destructive).

These samples are analyzed in the SAG's central livestock laboratory.

Please find attached **Annex IV**, as evidence of the foregoing.

Scope:

**a) In a facility, CCA methodology for obtaining samples of beef trimming intended for STEC testing is not applied to superficial tissues and is not equivalent to FSIS sampling methods for processing operations.**

The Agricultural and Livestock Service, in compliance with the requirements established in the FSIS regulatory framework, made a proposal to update its official microbiological verification program of Shiga toxin producing *Escherichia coli* (STEC) and *E. coli* O157: H7. Consequently, the use of a sampling methods equivalent to the N60 of the FSIS was strengthened and made explicit in the instructions, as well as the sampling process of superficial tissue, as established by the FSIS Directive 10,010.1, related to sampling verification activities for Shiga toxin-producing *Escherichia coli* (STEC) in raw beef products. Furthermore, in order to standardize the application of this new instruction, In August 2018, SAG central level carried out theoretical-practical training session for all regional work teams (regional supervisors and heads of inspection team) working in establishments authorized to export non-intact meat products to the United States.

Please, find attached the proposal for the official microbiological verification program of Shiga toxin producing *Escherichia coli* (STEC) and *E. coli* O157: H7.

Please, find attached **Annex IV a)**, as evidence of the foregoing.

**b) ACC official reports on STEC are insufficient to accurately document the analytical methods and results for the inspection staff at establishment level.**

The Agricultural and Livestock Service modified the official STEC verification protocol, in which the methodologies in use are recorded in separate cells, both for the screening method and for those used for confirming cases of *E. coli* O157: H7 and STEC. On the other hand, the protocol incorporates new fields to record the results obtained in each stage, thus allowing the professionals to interpret the results delivered (separate cells for "Screening" and "Confirmation" results).

Furthermore, in order to standardize the understanding of the interpretation of result protocols, SAG central level carried out theoretical-practical training session in August 2018 for all regional work teams (regional supervisors and heads of inspection team) working in establishments authorized to export non-intact meat products to the United States.

Please, find attached the new version protocol for delivering results of the official microbiological verification program of Shiga toxin producing *Escherichia coli* (STEC) and *E. coli* O157: H7.

Please, find attached **Annex IV b)**, as evidence of the foregoing.

## REGARDING THE FINDINGS IN ASSESSED FACILITIES

Below, you will find the actions implemented according to the Audit findings for each visited facility, which verified by the Agricultural and Livestock Service (SAG):

➤ **ESTABLISHMENT SOPRAVAL S.A., LEEPP<sup>1</sup> Registration N°: 05-09**

- **55. The post-mortem inspection procedures for turkeys did not include a consistent observation of the surfaces of the tibio-tarsal joints or observation of the interior of the carcass.**

**Corrective action:**

- The official entity carries out 2 controls per shift, pursuant to circular 335/2018, which addresses the correct inspection of the joint facet.
- The company develops and installs a machine for automatic cutting of the joint. This machine consists of a guide that allows flexing the joint and an automatic circular knife that performs the cutting of the joint. This allows in depth and height (Male and Female) to be adjusted. This was verified by SAG and it is possible to request a calibration when required by the Official Inspecting Veterinarian (OIV).  
Inspected by SAG on July 3, 2018.
- The official entity instructs that the Official Inspecting Veterinarian in line trains the Official Technical Inspectors, in order to carry out a systematic inspection of the inner surface of carcasses. This is controlled by Veterinarians, which must take place once per work shift, as established. This must be recorded in the Internal Quality Assurance Control sheet F-PP-IT-032.
- In addition, the company made 2 changes to improve the official inspection inside the abdominal cavity:
  - The inspection point was extended 50 cm more. This provides more space for the Inspector Technician to perform the systematic inspection of the abdominal cavity.
  - Additionally, two chairs were installed to allow the inspector to reach the necessary height to efficiently inspect the abdominal cavity.  
Inspected by SAG on August 13, 2018.

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<sup>1</sup> LEEPP, by its initials in Spanish, stands for National List of Establishments authorized to Export Livestock Products.

- **10/14/51. The establishment was not able to visualize the insertion of a thermometer into product at the temperature monitoring CCP of product in refrigerated storage. The thermometer was inserted into a stack of crates wrapped in plastic which is opaque and does not allow the monitor to see if the thermometer is inserted into product or ambient air. This practice could also introduce contamination into the product from exterior packaging material.**

**Corrective action:**

- The establishment trained the personnel in charge of temperature monitoring, instructing that it should be measured directly in the product and in the absence of material covering the product.

Inspected by SAG on April 13, 2018.

- The establishment modified HACCP - CCP 3, where it is indicated that the temperature should be measured directly in the product and not through a material that covers it.

Inspected by SAG on May 3, 2018.

- **14/51. The establishment was not collecting and analyzing samples for microbial organisms at the pre-chill point in the poultry slaughter process as required.**

**Corrective action:**

- The documents of Operation and determination of Carcass Microbiological Samples are modified, including Pre-cooling and Post-cooling samples (ACL-SOP-00-17), whose indicator is E. coli. This action is controlled by the official service on a monthly basis.

Inspected by SAG on April 18, 2018.

➤ **ESTABLISHMENT LO MIRANDA LTDA., LEEPP Registration N°: 06-02**

- **10/51. Carcasses in the chiller that had been reprocessed after falling on the ground destined for the domestic market were on rail next to and kept in close proximity to carcasses destined for export markets.**

**Corrective action:**

- Modification of line 1 of equalization is coordinated by moving in 15 cm of line 2, avoiding contact between reprocessed and normal carcasses  
Inspected by SAG on August 3, 2018.
- **12/51. The SSOP records did not document the disposition of product or preventative measures as a part of corrective actions.**

**Corrective action:**

- SOP records are reviewed in order to verify that the product arrangement or preventive measures are documented as part of the corrective measures. Therefore, the record PC-RG-DTE-035 Product dropped to the floor is modified, indicating the pre-defined actions that must be carried out according to what is provided in procedure PC-ISOP-GEN-001  
Inspected by SAG on August 3, 2018.
- **22/51. The direct observation of monitoring that is documented on the HACCP records does not correspond with the monitoring record for which the verification activity occurred, including time and result.**

**Corrective Action:**

- The Official Service controls HACCP records, thus evidencing that the control activity of the HACCP supervisor is recorded, including the time and result thereof.  
Inspected by SAG on August 3, 2018.

➤ **ESTABLISHMENT PROCESADORA DE ALIMENTOS DEL SUR LTDA., LEEPP registration N°: 06-06**

- **51. Inspection personnel identified multiple SPS issues and the establishment's failure to segregate reprocessed product during their daily inspection however did not issue a written record of noncompliance to the establishment and only verbally notified the establishment.**

**Corrective actions:**

- A written notification system was implemented in the establishment through the Inspection Report (registration F-PP-IT-020). This document is numbered to avoid adulteration and is received by the establishment and signed by the quality assurance manager, who holds a copy of given document.  
Inspected by SAG on August 3, 2018.

- **16/51. A HACCP record documented by the establishment did not include in the corrective actions, visual inspection of product involved in a deviation at the critical control point for zero tolerance for visual fecal matter.**

**Corrective action:**

- The establishment incorporated the written record of evidence regarding the visual inspection of the effectiveness of the corrective actions for visible fecal contamination.  
Inspected by SAG on July 24, 2018.

➤ **ESTABLISHMENT FAENADORA SAN VICENTE LTDA., LEEPP registration N°:06-08**

- **55. The post-mortem inspection procedures for broilers do not include a consistent observation of the surfaces of the tibio-tarsal joints or observation of the interior of the carcass.**

**Corrective action:**

- The establishment calibrated claw cutting knives to the tibio-tarsal joints, so that through the cut joint facets are exposed for an adequate inspection by the official inspectors.
- As a preventive measure, the visual inspection of the operation of cutting machines was implemented, with maintenance and constant calibration during work shifts, especially when chicken size changes, to ensure the correct cut.  
Inspected by SAG on May 31, 2018.
- Leg Feet process & multihead machine purchase order is issued 06-07-2018 to definitively improve the tarsus cutting.
- The Official Inspectors were instructed to control the correct cutting of the tarsus during line inspections and the immediate action, should joint-inspection problems arise. This action is conducted by the Veterinarians during each work shift, which is recorded in the form F-PP-IT-032.  
Inspected by SAG on May 28, 2018.
- The corrective action for the finding of non-systematic inspection of the inner surface of carcasses was a theoretical and practical training at the inspection point for the Official Technical Inspectors (OTI).
- In addition, the veterinarians responsible for the post-mortem health inspection were instructed to control the correct revision of the external surfaces and the abdominal cavity of carcasses by the Official Technical Inspectors. It was established that this action should be carried out once per work shift and per line, after the inspection point.  
Inspected by SAG on April 18, 2018.
- Furthermore, the lighting in the inspection stations was improved and the location of the guides that affect the inclination of the carcasses was corrected.  
Inspected by SAG el May 31, 2018.

- **14/51. The establishment was not collecting and analyzing samples for microbial organisms at the pre-chill point in the poultry slaughter process as required.**

**Corrective action:**

- The quality assurance department of the plant implemented the processes of pre- and post-cooling sampling, pursuant to the provisions in CFR point 381.65 (g). E. coli was determined as an indicator.

Inspected by SAG on April 28, 2018.

- **14/51. The establishment's hazard analysis did not identify chemical hazards at a process step in which chlorine was being used for reprocessing.**

**Corrective action:**

The establishment included in the hazard analysis the chemical risk when chlorine is used in cases of setbacks at CCP1, as a corrective action of this. As a result, now it does not represent a chemical hazard in the process.

Inspected by SAG on May 31, 2018.

➤ **ESTABLISHMENT MATADERO FRIGORÍFICO DEL SUR S.A, LEEPP registration N°:10-05**

- **10/51. Three carcass sides were being moved on the retention rail by an establishment employee, and were coming into direct contact with other sides prior to trimming and release, providing the distinct possibility for directly contaminating additional product. Further, the air line hoses on the trim stand of the retention rail were observed directly in contact with a carcass side.**

**Corrective action:**

- The establishment assigned and instructed the line operator to carry out activities specific to the area of re-inspection, in accordance with the slaughtering SOP. (Implementation date 04-12-18). Inspected by SAG on 04/12/18, where the content of the training and its execution were displayed.
- The establishment modified the infrastructure of this hall, therefore eliminating cross-contamination sources. (Implementation date 08-20-18). Inspected by SAG on 08-20-18.
- The establishment prepared a sanitation station in this area, which includes: sterilizer, sinks, soap dispenser, sanitizers, disposable blanket dispenser, caps, masks, waste container. (Implementation date 08-13-18). Inspected by SAG on 08-14-18.
- **10/51. During the bunging process, extensive spillage of urine was observed directly onto exposed carcass surfaces. No immediate actions were noted by the employee. In addition, the employee at the first legging station was observed to use the same knife for hide cuts and skinning without sanitizing between cuts or switching his knife, which was the expectation according to the establishment's own instructions.**

**Corrective action:**

- The establishment instructs the personnel responsible for this operation to give immediate notice to the direct supervisor or quality assurance monitor of the area, in case of any accidental breach of good practices, in order to take corrective actions in a timely manner, thus minimizing the contamination risk in the product. (Implementation date 04-12-18). Inspected by SAG on 04-12-18.
- The establishment strengthens sanitary practices by training the operator on the sanitation of utensils between each operation. (Implementation date 04-12-18). Inspected by SAG on 04-12-2018.
- The establishment has included in the Cattle Processing Line Control record the inspection of bladder emptying in the stages of ligation of rectum and gutting. (Implementation date 08-13-18). Inspected by SAG on 08-14-18.

- **14/51. The establishment had a confirmed positive E. coli O157:H7 in August of 2017 but had not designed or implemented a CCP to eliminate or reduce the hazard below detectable levels at the end of the process.**

**Corrective action:**

- The establishment determined to incorporate the monitoring of the Carcass Sanitization process into the Processing Line Workstation Control sheet. (Implementation date 08-13-18). Inspected by SAG on 08-14-18.
- The establishment re-assessed its Processing HACCP Plan to include the carcasses Sanitation stage as CCP. (Implementation date -08-1318). Inspected by SAG on 08-14-18.
- The establishment record to inspect the concentration of the sanitizer (Peracetic Acid at a concentration of 200ppm) considering its effectiveness on E. coli O157: H7 demonstrated in the study of effectiveness and bibliographic background. The same dosing equipment (industrial spray pump) will be used for all carcasses. One of the points to be evaluated is the correct application of the sanitizer on the carcass. In addition, training will be provided to the operators responsible for this activity. (Implementation date 08-20-18). Inspected by SAG on 08-20-18.

- **39/51. Multiple product storage areas had product stacked directly up to the walls with no ability to access and visualize the wall/floor junctures to assess sanitary conditions.**

**Corrective action:**

- The establishment, through its logistics headquarters, gave instructions to the cold storage staff in order to maintain the transitory spaces that allow an adequate inspection, thus allowing controlling the hygienic and sanitary conditions of the stored products. In the same way, the company generated a weekly chamber cleaning program, in addition it elaborates an order and cleaning register of refrigerated and frozen chambers, where the involved structures are indicated, camera identification, date / time, frequency, result of the monitoring ( Comply or Not Comply).

Complementing the above, the company has said that it will consider in future camera constructions, the existence of a space between racks and walls thus facilitating the inspection of the wall / floor junctions. (Date of implementation of corrective action: 08-20-18). Inspected by SAG on 08-24-18.

- **41/51. Extensive beaded condensation was observed below the three ventilation units in carcass cooler #5, directly over carcasses on a rail. No evidence of direct product contamination was observed.**

**Corrective action:**

- The establishment trains the personnel involved in the arrangement of carcasses in cooling chambers, considering clear instructions of cleanliness in relation to the correct and effective removal of moisture from floors, ceilings, walls and evaporator pans, as described in the corresponding SOP document. (Implementation date 08-17-18).  
Inspected by SAG on 08-17-18.
- In compliance with the internal program of preventive maintenance, the establishment prepares a work schedule to improve the findings observations. This aims to improve the tightness of the plant thus minimizing and avoiding conditions that are favorable for condensation. Simultaneously, the establishment creates work instructions for the chamber cleaning department and carcass storage area, where it is expected to correctly store carcasses and clean of chambers before, during and after the loading of the chamber. The implementation date will be set pursuant to the preventive maintenance program presented by the company. The SAG official verification will be carried out according to this program, in parallel with the work performed by the maintenance department of the company, until the problem of these findings is solved.
- The establishment implemented a record for the revision of receiving trays and condensate reception drains of evaporators. (Implementation date 08-20-18).  
Inspected by SAG on 08-20-18.
- **45/51. A stainless steel trolley cart used for edible product in the deboning room had multiple protruding points with open seams precluding thorough cleaning and sanitizing.**

**Corrective action:**

- The establishment immediately identifies the cart as "OUT OF ORDER" and is taken away from the processing room for repair. Maintenance personnel are notified regard the prohibition of the use of rivets on carts or other containers in direct contact with the product. (Implementation date 04-12-18). Inspected by SAG on 08-12-18.
- **58. The CCA's methodology for collecting samples of raw beef trim for the purposes of STEC analysis does not target surface tissue and is not equivalent to FSIS sampling methods for slaughter operations.**

This situation is addressed in **Point IV a)** of this report.

- **58. The CCA's official STEC reports are insufficient to accurately document the analytical methods and results for inspection personnel at the establishment level.**

This situation is addressed in **Point IV b)** of this report.

➤ **ESTABLISHMENT FRIGORÍFICO DE OSORNO S.A, LEEPP register n°: 10-26**

- **14/51. The establishment had multiple positive STEC results, however their hazard analysis concludes that STEC are not reasonably likely to occur, therefore the establishment was unable to support decisions made in the hazard analysis. While the establishment had incorporated an antimicrobial control point, they had not designed and implemented a CCP to eliminate or reduce the hazard below detectable levels at the end of the process.**

As indicated in **Point II b)** of this report, the Frigorífico Osorno S.A establishment (10-26) is in the process of re-evaluating the HACCP plan. Therefore, the suspension of the export certification to the United States will be maintained for bovine meat products (trimming, hamburgers, ground beef or cuts that will be used for the elaboration of these products) until this re-evaluation process concludes and the service staff verifies the proper support of the decisions applied in their hazard analysis. Once this process is concluded, the result of the re-evaluation and/or the official actions implemented by the SAG will be reported to the FSIS authorities.

- **38/51. Gaps were observed under three shipping doors in the product load-out room, providing the potential for entry of pests and rodents**

**Corrective Action:**

- The establishment, through its maintenance staff, sealed the points where lack of tightness was detected. Preventively the establishment set a guideline for monthly revision of tightness to complement the current program. This guideline considers the sectors to be monitored, the items such as (skies, baseboards, grills, ducts, etc.) and if the result is satisfactory or unsatisfactory, plus the observation box and corrective actions in case the result indicates non-conformity. (Date of structural repair 05-07-18). Inspected by SAG on 05-08-18.

- **39/51. Extensive degradation of concrete was observed outside of freeze tunnels and in a transfer hallway with resultant rough surfaces of missing concrete, irregular surfaces and accumulation of dirt and water resulting in insanitary conditions.**

**Corrective Action:**

- The establishment will repair the floors in the indicated areas. In an immediate and preventive way, the personnel in charge were instructed on the cleaning and sanitation methods of the sector to minimize health risks. Said re-instruction is carried out on 04/13/2018. The works area will opt for the best quality of the production supplies to be used for the improvements execution. Said structural repair will be carried out on 12/31/2018. In parallel, the establishment notifies the Official Inspection Team of the establishment of the budgets for the floor repairing, as well as the quotation and finally the associated purchase order and invoice. The SAG control for re-instruction is done on 04/16/2018. During the official monthly SAG control, the status of the tunnels and corridor is incorporated into the condition of the freezing of products (boxes) until the final correction.

- **39/51. In an establishment freezer, product was stored on racks directly against the walls on both sides, preventing access or ability to visualize the wall to floor juncture to assess sanitary conditions.**

**Corrective Action:**

- The establishment, once indicated, immediately proceeds to give the instructions to establish margins or enough room to be able to walk and see. The establishment during the repair process of the industrial racks, will allow the replacement of spaces for inspection processes through structural movement. The installation of the racks will begin to be carried out sequentially and the dates contemplated for this definitive correction go from 08-13-18 to 10-30-18. All future industrial projects of storage chambers will contemplate the space of 70 cm of circulation or inspection. The SAG control is being carried out from day 04-13-18 until the end of the project, for this it has incorporated in the monthly control sheet of Traffic SOPs and in this way to be able to guarantee the optimal conditions the chamber must have in and thus ensure the product safety.
- **58. The CCA's methodology for collecting samples of raw beef trim for the purposes of STEC analysis does not target surface tissue and is not equivalent to FSIS sampling methods for slaughter operations**

The present observation is addressed in **Point IV a)** of this report.

➤ **ESTABLISHMENT FRIGORÍFICO SIMUNOVIC S.A, LEEPP registry N°: 12-01**

- **10/51. Sheep carcasses were observed coming into contact with nozzles and water tubing that were not able to be thoroughly cleaned and sanitized within the carcass wash. for sheep were not able to be thoroughly cleaned and sanitized to prevent the creation of insanitary conditions, Additionally, two establishment employees were cross-contaminating the hide with the exposed carcass during the dehiding process, creating an insanitary condition**

**Corrective Action:**

- The establishment makes the modification in the installation of water pipes and sprinklers, to avoid that the carcasses that pass through this area have contact with the structure. Inspected by SAG on 04-12-18.
  - Punshing operational area personnel is instructed so that each operator examines one side of the carcass, thus avoiding the danger of cross contamination and for them to have the time to wash hands and arms with soap, to give compliance with the washing and disinfection process of hands and arms between carcasses. Adjustment is made in the SOP manual. Inspected by SAG on 04-06-18.
  - The establishment will purchase "flanking tool" machinery to prevent the passage of punshing to be done manually, in this way the machine will be sterilized between each carcass. Complementing the support of this measure, the company notifies the catalog of the equipment sent by the client, which is already in quotation. The official SAG control will be carried out at the beginning of the season. The planned date for the installation and operation of the machinery will be 01-02-2019.
- **19/51. The establishment's review of records for the zero tolerance CCP did not include the time and results of the ongoing verification activity**

**Corrective Action:**

- The establishment includes in the documentary review of the CCP 1 the time and result of the control for the records in the same way as the direct control is carried out. This is done by stamping the CCP 1 monitoring record form. For this purpose, the information of the documentary control stamp includes the date, time, name of the responsible person and result (complies or does not comply). At the same time, the inclusion of this stamp has been indicated in its HACCP manual. Inspected by SAG on 04-09-18.
- **19/51. The establishment's HACCP plan for CCP2, cold storage, did not identify the calibration of thermometer procedure and frequency**

**Corrective Action:**

- The establishment makes a detailed description of the steps of equipment calibration including frequency through "General Traceability Scheme of Plant Temperature

Measurement Equipment". This scheme has been incorporated into the Calibration and Testing Program of Temperature, Pressure and Weight Measuring Equipment.  
Inspected by SAG on 04-11-18.

- **41/51. Beaded condensation was observed below the ventilation unit in Carcass Chiller 2, immediately above a carcass rail. In addition, there was extensive rust of the overhead ventilation and a loose metal covering exposing insulation. However, no evidence of direct product contamination was observed.**

**Corrective Action:**

- The establishment immediately removes the condensation, restricting the use of aeration rails 2, close to the evaporator, identifying the RESTRICTED USE by means of a sign, a measure that is considered in its Removal or condensation drying procedure.  
Inspected by SAG on 04-06-18.
- Maintenance personnel in charge removes rust in the upper ventilation area and repairs the aeration evaporator packing 2.  
Inspected by SAG on 04-07-18.
- To provide greater security, the establishment installs a sanitary area under the evaporators in order to avoid the formation of condensation and to separate the areas.  
Inspected by SAG on 04/14/18.

- **ESTABLISHMENT SOC. COM. JOSÉ MARIN ANTONIN Y CIA. LTDA., LEEPP registration N°: 12-05**
  - **10/51. An establishment employee was not sanitizing his knife between his hide opening cut at the neck and skinning of the fore shank, creating an insanitary condition. In addition, a slaughter employee was cross-contaminating the hide with the exposed carcass during the dehiding process, creating an insanitary condition.**

**Corrective Action:**

- The establishment immediately performs a verbal instruction to the operators through quality assurance staff, in order to perform the cuts correctly avoiding cross contamination. Verified in the field during the audit on 04-05-2018.
- As a final corrective measure, the concept of sterilizing the knife in between animals is changed in these jobs by the sterilization of the knife in between cuts, since they are two cuts that are made on the skin. The monitoring will be done by the recording of the control of operations. Inspected by SAG on 07-25-2018.
- Training is carried out to supervise the area and the operators involved in the process, which is supported in its respective registry, where the objectives are to instruct the measures to avoid contamination of the carcasses during the skinning, as well as the concept of sterilization of the knife in between cuts or the use of two different knives and sterilization of both. Inspected by SAG on 07-23-2018.
- The company will train the new operators who will work in these positions at the beginning of the season, if that is the case.
  - **12/51. The SSOP pre-operational corrective actions were not addressing whether sanitary conditions were restored and verified.**

**Corrective Action:**

- The establishment makes the change of pre-operational and post-operational cleaning registry, where a check-box is included for the initial check-up and another for when the corrective action was already executed. The above is documented in the corresponding registry. The new version will take effect from the next slaughter season (12-15-18). Inspected by SAG on 07/25/18.
  - **15/51. The HACCP plan for the zero tolerance CCP failed to list procedures and frequency for the ongoing verification activity of review of records. The establishment was performing a review, however the records did not include the time and results of the verification activity.**

**Corrective Action:**

- The establishment changes the version of the record "channel monitoring sheet for pollution zero tolerance", from version 15 to 16, which includes a table with the control time of the document (time), observations and corrective actions if necessary. The above is documented in the corresponding record. Inspected by SAG on 04-09-18.



- The establishment also notifies the entry into force of the new version of the Quality Assurance System Manual No. 16, which indicates the way in which the document is verified, as well as the time and final condition of the document, the observations and corrective actions, if any. Inspected by SAG on 04-09-18.

➤ **ESTABLISHMENT FRIGORÍFICO PATAGONIA S.A., LEEPP registration n°: 12-10**

- **10/51. The establishment was stacking edible crates on top of inedible crates in the cutting room in order to facilitate sliding of crates across the floor.**

**Corrective Action:**

- Due to the harvesting period specific to ovine species, this establishment is not currently processing. The establishment has decided to implement a movable surface to transport the product. Additionally, preoperational records will be modified once the date to use the movable surface is set. The latter will be fixed as soon as the new harvesting period starts, as well as the official SAG inspection, which took place on 12-27-2018.
- **10/51. An establishment employee was observed cutting the hind legs from the carcass resulting in subsequent drop of the carcass such that the head, neck, and wool would contact the housing from the head hide puller, resulting in direct contamination on individual carcasses as well as between carcasses.**

**Corrective Action:**

- The establishment decides to put up a sign on the cattle abattoir automatic over-head convey rail, which indicates when the legs will be cut to avoid the neck to touch the cattle skinning machine. The SOP Manual for the slaughtering yard production area is also modified, where the aforementioned convey rail sign is included. Additionally, the proper conduct of the procedure included in the corresponding record is monitored.  
Inspected by SAG on 04-20-2018.
- **16/51. The establishment's direct observation of monitoring records did not include time and initials. The establishment's HACCP records failed to document the results of two hourly monitoring events. Despite the lack of monitoring results, the establishment had completed the review of records and indicated they were compliant, thereby failing to identify the lack of monitoring results demonstrating the critical limits had been met.**

**Corrective Action:**

- The establishment conducts a retroactive investigation for their HACCP records, emphasizing their proper fill-out. Thus, seeking to standardize a better order that allows for a full and proper fill-out of the report sheet, before the register can be arranged in its folder. Likewise, and considering the retroactive analysis made, the establishment trained the Quality Assurance staff, where the advisor of the establishment instructs the chief and supervisor of the Quality Assurance Team of the company. The objective of this activity consisted of instructing the correct fill-out of CCP monitoring forms and records according to 9CRF 417.5 (b). The official SAG inspection was conducted on 04-20-2018, confirming the content of the training and its execution.

- **42/51. Extensive standing water was observed on the floor in the cutting room due to the apron wash for which there was no associated drain. The water pooled across approximately 8 x 20 feet of flooring as the nearest drain was approximately 30 feet away. In addition, at several stations on the slaughter floor the water supply pipes or drain pipes from sinks/sterilizers were leaking from multiple points.**

**Corrective Action:**

- The establishment and its maintenance area carry out the anchoring of the apron washing area and make the direct connection to the drain to avoid the accumulation of water.
- The establishment and its maintenance department unclog sinks and change the flexible hose that protects the structure, in order to avoid the dripping of water in multiple points. Additionally, all the sinks and sterilizers pipes will be sealed. For all the above, the establishment presents to SAG the preventive maintenance program which endorses each of the improvements implemented. Additionally, the establishment has implemented monitoring and controls in order to ensure and maintain the effectiveness of the corrective action. The official SAG control of the anchoring of the apron washing area to the drain, and the unclogging of the sinks and change of the flexible ones takes place on 04-20-2018. The SAG official verification of the sealing of all the sinks and sterilizers pipes will be carried out on 12-27-2018, before the beginning of the season.

➤ **ESTABLISHMENT AGROINDUSTRIAL EL PAICO LTDA, LEEPP registration N°:13-07**

- **55. The post-mortem inspection procedures for broilers do not include a consistent observation of the surfaces of the tibio-tarsal joints.**

**Corrective action:**

- The official inspectors were instructed to include an observation and verification of the correct cut of the tarsus for its inspection and immediate corrective action in case of setbacks. This is controlled by the Veterinarians twice per work shift in accordance with instruction of Circular 335/2018, who record this in the form F-PP-IT-032.  
Inspected by SAG on May 16, 2018.
- As a complementary action to the aforementioned, the establishment determines the purchase of a Q-HAM-VI-B joint pre-cutting machine.
  - **14/51. The establishment was not collecting and analyzing samples for microbial organisms at the pre-chill point in the poultry slaughter process as required.**

**Corrective action:**

- The sampling of pre- and post- cooling of carcasses was incorporated in compliance with the provisions in CFR point 381.65 (g). Enterobacteria was chosen as an indicator.  
Inspected by SAG on June 7, 2018.
  - **39/51. Styrofoam insulation covering pipes above the carcass chiller and packaging areas was not covered and was observed to have areas that were degrading.**

**Corrective action:**

- Maintenance personnel repairs pipes and equipment whose insulation had signs of deterioration.  
Inspected by SAG on July 28, 2018.