



United States Department of Agriculture

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Food Safety and  
Inspection Service

September 26, 2023

1400 Independence  
Avenue, SW.  
Washington, D.C.  
20250

Dr. Carlos Orellana  
Livestock Protection Division, Chief  
Agricultural and Livestock Service (SAG)  
Ministry of Agriculture  
Avda. Bulnes 140, Piso 7  
Santiago, Republic of Chile

Dear Dr. Orellana,

The U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Chile's inspection system April 3–24, 2023. 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.

Chile's actions in response to the FSIS audit findings will guide the scope and frequency of future equivalence verification activities, including the frequency at which FSIS reinspects products from Chile at the U.S. point-of-entry. For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by email at [InternationalCoordination@usda.gov](mailto:InternationalCoordination@usda.gov).

Sincerely,

MICHELLE  
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Date: 2023.09.26 10:27:03  
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Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF CHILE

APRIL 3–24, 2023

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT AND POULTRY PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

September 26, 2023

Food Safety and Inspection Service  
U.S. Department of Agriculture

## Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Chile conducted by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) from April 3–24, 2023. The purpose of the audit was to verify whether Chile's food safety inspection systems governing meat and poultry remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Chile currently exports raw chicken, turkey, beef, lamb, and pork and not-ready-to-eat otherwise processed chicken to the United States.

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 Point (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 OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)**

- The official laboratory analyzing samples of raw beef products for Shiga toxin-producing *Escherichia coli* maintains acceptance criteria allowing receipt of frozen samples, which is not permitted according to the Central Competent Authority's (CCA's) written instructions.

### **GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)**

- Government inspection personnel did not identify that lambs had no access to water in the holding pens at two establishments. The establishments immediately took corrective actions by transferring the lambs into different pens with available water.
- Government inspection personnel were not verifying that the label declares the percentage of retained water on product labels for non-marinated products.
- Government inspection personnel were not ensuring adequate post-mortem inspection at multiple beef and pork slaughter establishments.

### **GOVERNMENT SANITATION**

- Government inspection personnel did not identify deficiencies related to the verification of sanitation standard operating procedures (Sanitation SOPs) at multiple establishments (e.g., verification of pre-operational sanitation, maintenance of product contact surfaces, and incomplete documentation of corrective actions).

### **GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM**

- Government inspection personnel did not identify deficiencies related to HACCP requirements at multiple establishments.

### **GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

- Government inspection personnel were not collecting raw beef trimming samples using the sampling method described in the documentation submitted by the CCA prior to the audit.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Chile's food safety inspection system April 3–24, 2023. The audit began with an entrance meeting April 3, 2023, in Santiago, Chile, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA)—the Servicio Agrícola y Ganadero (SAG). Representatives from SAG accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference April 24, 2023.

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection systems governing meat and poultry remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Chile is eligible to export the following categories of products to the United States:

<b>Process Category</b>	<b>Product Category</b>	<b>Eligible Products<sup>1</sup></b>
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Beef	Beef - All Products Eligible except Advanced Meat Recovery Product (AMR); Beef Patty Product; Finely Textured Beef (FTB); Ground Beef; Hamburger; Partially Defatted Chopped Beef (PDCB); Partially Defatted Beef Fatty Tissue (PDBFT); and Low Temperature Rendered Product (LTRP)
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Chicken	Chicken - All Products Eligible except Mechanically Separated
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Meat-other (sheep, goat)	Lamb and Mutton - All Products Eligible except Mechanically Separated and AMR
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and AMR
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Turkey	Turkey - All Products Eligible except Mechanically Separated

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<sup>1</sup> All source meat and poultry used to produce products must originate from eligible countries and establishments certified to export to the United States.

<b>Process Category</b>	<b>Product Category</b>	<b>Eligible Products<sup>1</sup></b>
Raw - Intact	Raw Intact Beef	Beef - All Products Eligible except Cheek Meat, Head Meat, Heart Meat, and Weasand Meat; and Boneless Manufacturing Trimmings
Raw - Intact	Raw Intact Chicken	Chicken - All Products Eligible
Raw - Intact	Raw Intact Meat-Other (Sheep, Goat)	Lamb and Mutton - All Products Eligible
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Raw - Intact	Raw Intact Turkey	Turkey - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Poultry	Chicken and Turkey - All Products Eligible

USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Chile as free of African swine fever, classical swine fever, foot-and-mouth disease, and swine vesicular disease (with special restrictions in place with the exception of African swine fever). Chile is affected by highly pathogenic avian influenza and free of Newcastle disease. Chile is classified as negligible risk for bovine spongiform encephalopathy.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Chile's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify whether Chile's food safety inspection systems governing meat and poultry are being implemented as documented in the country's SRT responses and supporting documentation.

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 3-year period, in addition to information obtained directly from SAG through the SRT.

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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at SAG headquarters, 2 regional offices, and 10 local inspection offices within the establishments. 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 10 establishments was selected from a total of 19 establishments certified to export to the United States. This included two beef slaughter and processing establishments; one chicken and turkey slaughter and processing establishment; one chicken, turkey and pork slaughter and processing establishment; three lamb and mutton slaughter and processing establishments; two pork slaughter and processing establishments; and one turkey slaughter and processing establishment. The products these establishments produce and export to the United States include raw intact beef, pork, lamb, mutton, chicken and turkey; raw ground, comminuted, or otherwise non-intact pork, chicken, and turkey; and NRTE otherwise processed chicken and turkey.

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 assessed SAG's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2 and 381.196.

The FSIS auditors also visited one government microbiological and chemical residue laboratory to verify that this laboratory is capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>• Servicio Agrícola y Ganadero, Santiago</li> </ul>
	Regional	2	<ul style="list-style-type: none"> <li>• Magallanes y Antártica Chilena (Región XII), Punta Arenas</li> <li>• Valparaíso (Region V), Quillota</li> </ul>
Laboratory		1	<ul style="list-style-type: none"> <li>• Laboratorio y Estación Cuarentenaria de Lo Aguirre, Government Microbiological and Residue Laboratory, Santiago</li> </ul>
Beef slaughter and processing establishments		2	<ul style="list-style-type: none"> <li>• Establishment No. 10-15, Matadero Frigorífico del Sur S.A., Osorno</li> <li>• Establishment No. 10-26, Frigorífico de Osorno S.A., Osorno</li> </ul>
Chicken and turkey slaughter and processing establishment		1	<ul style="list-style-type: none"> <li>• Establishment No. 13-07, Agroindustrial El Paico S.A., El Monte</li> </ul>
Chicken, turkey and pork slaughter and processing establishment		1	<ul style="list-style-type: none"> <li>• Establishment No. 06-02, Faenadora Lo Miranda Ltda., Lo Miranda</li> </ul>
Lamb and mutton slaughter and processing establishments		3	<ul style="list-style-type: none"> <li>• Establishment No. 12-01, Frigorífico Simunovic S.A., Punta Arenas</li> <li>• Establishment No. 12-05, Soc. Com. José Marín Antonín y Cía. Ltda. Punta Arenas</li> </ul>

		<ul style="list-style-type: none"> <li>Establishment No. 12-10, Frigorífico Patagonia S.A., Porvenir</li> </ul>
Pork slaughter and processing establishments	2	<ul style="list-style-type: none"> <li>Establishment No. 06-06, Procesadora de Alimentos del Sur Limitada, Rengo</li> <li>Establishment No. 06-17, Faenadora Las Pataguas, Comercial Maxagro S.A., Pichidegua</li> </ul>
Turkey slaughter and processing establishment	1	<ul style="list-style-type: none"> <li>Establishment No. 05-09, Sopraval SPA, La Calera</li> </ul>

FSIS performed the audit to verify that Chile's food safety inspection systems meet 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.) Section 601 et seq.);
- The Poultry Products Inspection Act (21 U.S.C. Section 451 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1906);
- The Meat Inspection Regulations (9 CFR parts 301 to the end); and
- The Poultry Products Inspection Regulations (9 CFR part 381).

The audit standards applied during the review of Chile's inspection systems for meat and poultry 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 Agreement on the Application of Sanitary and Phytosanitary Measures.

### III. BACKGROUND

From August 1, 2019, to July 31, 2022, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 29,810,107 pounds of meat and 408,032,208 pounds of poultry from Chile. This included 881,609 pounds of raw intact beef; 5,417,873 pounds of raw intact lamb; 1,516,929 pounds of raw intact mutton; 21,898,354 pounds of raw intact pork; 95,342 pounds of raw non-intact pork; 14,496,308 pounds of raw intact chicken; 363,392,345 pounds of raw non-intact chicken; 1,885,468 pounds of NRTE otherwise processed chicken; 26,840,517 pounds of raw intact turkey; and 1,417,570 pounds of raw non-intact turkey exported by Chile to the United States.

Of these amounts, additional types of inspection were performed on 4,099,799 pounds of meat and 41,675,779 pounds of poultry (99,215 pounds of raw intact beef; 490,623 pounds of raw intact lamb; 244,788 pounds of raw intact mutton; 3,172,247 pounds of raw intact pork; 92,926 pounds of raw non-intact pork; 1,428,948 pounds of raw intact chicken; 37,006,467 pounds of raw non-intact chicken; 176,881 pounds of NRTE otherwise processed chicken; 2,909,658 pounds of raw intact turkey; and 153,825 pounds of raw non-intact turkey). These additional types of inspection included physical examination, testing for chemical residues and microbiological pathogens including Shiga toxin-producing *Escherichia coli* (STEC), including serogroups O157, O26, O45, O103, O111, O121, and O145, in raw beef products. As a result of this additional testing, 127,479 pounds of meat were rejected for issues related to public health,



including fecal contamination, ingesta and extraneous materials. FSIS evaluated SAG's corrective action responses, found them sufficient, and closed the POE violations.

The previous FSIS audit in 2020 identified the following findings:

<b>Summary of Findings from the 2020 FSIS Audit of Chile</b>	
<b>Component 1: Government Oversight (e.g., Organization and Administration)</b>	
<ul style="list-style-type: none"> <li>The CCA did not have a mechanism or procedure in place requiring that livestock carcasses and parts subjected to routine chemical residue testing be precluded from export to the United States until receipt and confirmation of acceptable testing results.</li> </ul>	
<b>Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)</b>	
<ul style="list-style-type: none"> <li>Government inspectors did not observe the interior of the poultry carcasses during post-mortem inspection. The incomplete observation of the interior of the carcass is a repeat finding from the FSIS 2018 audit.</li> </ul>	
<b>Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System</b>	
<ul style="list-style-type: none"> <li>Government inspectors did not verify that the hazard analyses addressed chemical hazards associated with restricted ingredients (e.g., sodium phosphate and potassium phosphate).</li> <li>Government inspectors did not verify the HACCP plans complied with the CCA's requirements for HACCP plan content.</li> <li>Government inspectors did not verify the establishments complied with the CCA's requirements for HACCP recordkeeping.</li> </ul>	

The FSIS auditors verified that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The most recent final audit reports for Chile's food safety inspection system are available on the FSIS website at: [www.fsis.usda.gov/foreign-audit-reports](http://www.fsis.usda.gov/foreign-audit-reports).

#### **IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)**

The first equivalence component 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 national government of Chile organizes and manages the food safety systems governing meat and poultry products. The CCA is SAG, which falls under the Ministry of Agriculture and has the responsibility for developing and implementing Chilean policy in the fields of food safety and animal health and welfare under the authority of Decree No. 977, Sanitary Food Regulations. 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. The national directorate at the central level includes the strategic management division, the legal division, internal audit division, and communications department. Also at the central level are the technical support, business management, and administrative support departments. The FSIS auditors determined that there have been updates to the organizational structure of the Livestock Protection Division of SAG under Resolution No. 2843/2021 which essentially included changes of names of the subdepartments since the previous FSIS audit in 2020.

SAG's regulatory oversight of its meat and poultry inspection systems consists of four levels under the Livestock Protection Division: central, regional, local (sectorial), and establishment. The inspection activities are managed from 15 regional offices, 7 of which contain establishments that export to the United States. Regional offices are led by a Livestock Regional Officer-in-Charge and a Regional Inspection Supervisor (RIS). The RIS provides oversight of establishments certified to export to the United States including periodic supervisory visits, administrative decisions, and performance evaluation of government inspection personnel. The government inspection personnel team assigned to slaughter and processing establishments is headed by the Chief Veterinary Medical Officer (Médico Veterinario Inspector Oficial (MVIO)) providing oversight and supervision of subordinate Veterinary Medical Officers (MVOs) and Technical Inspection Officials (TIOs) responsible for post-mortem inspection.

SAG 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. Resolution No. 1722 provides SAG with 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 SAG responsibility for verifying that export requirements are met. Resolution No. 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 SAG implements procedures in accordance with Resolution No. 1722 to certify establishments to export to the United States. Once SAG has confirmed that an establishment complies with national requirements, the establishment is incorporated into the List of Exporting Establishments of Livestock Products (LEEPP). Once listed in the LEEPP, establishments must then meet import requirements of the specific country in accordance with Resolution No. 1722.

The Electronic System for Issuing Export Certificates is used by both industry and government inspection personnel to document every export certificate, including all traceability and other supporting documents. The system is used to validate controls for the eligibility of establishments and products. MVOs evaluate each request for export to ensure the documentation supports eligibility, and government inspection personnel reinspect 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 official controls

associated with the export process, including certification records, security paper, and official seals.

The FSIS auditors verified that information regarding FSIS requirements is conveyed to government inspection personnel and establishments certified to export to the United States through the utilization of Ceropapel, an electronic document management system. Ceropapel includes controls to determine which employees have opened and read transmitted information. In this manner, the RIS ensures that 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.

SAG implements procedures to maintain adequate staffing to ensure continuous inspection at slaughter establishments and once-per-shift inspection at processing establishments. Resolution No. 2592 states that every authorized establishment shall be subjected to inspection by SAG. In accordance with Memo No. 236, the daily distribution of the hours to be worked at each establishment certified to export to the United States is determined in each region by the Regional Director together with the MVIO and the establishment. The FSIS auditors reviewed staffing records and observed actual government staffing levels at each establishment and confirmed that SAG ensures sufficient staffing to perform ante-mortem and post-mortem inspection and to verify all other requirements during all establishment operations requiring inspection.

The FSIS auditors verified that the national government of Chile through the Ministry of Agriculture funds the meat and poultry food safety inspection systems. 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. Government inspection personnel are paid directly from the financial department in SAG headquarters.

The FSIS auditors reviewed the hiring process of government inspection personnel and verified that MVOs are required to hold a Doctorate of Veterinary Medicine degree in order to qualify for their positions. In addition, SAG 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 SAG. TIOs are required to complete training on General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats for livestock and Technical Regulation No. 117 Medical Veterinary Inspection of Poultry and its Meats for poultry prior to starting their assignment. The FSIS auditors verified that annual training on FSIS import requirements including training on procedures in FSIS Directives is held once per year at the regional level for all MVOs assigned to establishments that export to the United States.

The FSIS auditors verified that SAG ensures adequate enforcement of establishments that do not meet requirements for export to the United States through a review of noncompliance records. Additionally, the FSIS auditors reviewed an enforcement action and product recall of an establishment implicated in a POE violation since the previous FSIS audit in 2020. SAG delisted

the establishment from export to the United States and did not allow it to be relisted until corrective actions were taken and the corrective actions were verified in accordance with Resolution No. 2592. The FSIS auditors verified that traceability was maintained to ensure recall effectiveness.

The National Reference Laboratory (NRL) is the primary laboratory that conducts microbiological and chemical residue analyses as well as diagnostics for animal diseases. The NRL is accredited by the National Standardization Institute (Instituto Nacional de Normalización), which conducts initial accreditation audits as well as ongoing audits every 18 months to verify that International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards are met in laboratories. The FSIS auditors reviewed the most recent laboratory audits and verified that when deficiencies were found, corrective actions were taken and subsequently verified. The FSIS auditors also verified that the scope of accreditation included laboratory methods implemented for analyzing products intended for export to the United States.

In addition to the NRL, the greater Chilean laboratory network is comprised of SAG and Ministry of Health laboratories as well as private (third-party) laboratories authorized by SAG to perform microbiological analyses for the Pathogen Reduction Program. 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 No. 90/2014, SAG implemented the Specific Regulation for the Authorization of Analytical Laboratories (D-GF-CGP-PT-012, Version 04) which requires private laboratories to have a quality assurance system consistent with ISO/IEC 17025 standards. For purposes of chemical residue analyses, SAG also utilizes international reference laboratories for some confirmatory analyses. Prior to use of these international reference laboratories, SAG conducts an onsite audit. SAG has approved six laboratories to conduct official chemical residue testing.

SAG ensures that only approved analytical methods are used for analyses of samples. Quality assurance staff from the 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 SAG. The FSIS auditors verified that the NRL conducts both internally and externally administered proficiency testing for methods that are used to analyze official samples. The FSIS auditors verified that proficiency testing covers the methods used by laboratory personnel to analyze official samples of products that are destined for the United States and found no concerns. Additionally, the FSIS auditors verified that the NRL was meeting most of the requirements for sample handling, receipt, and traceability. However, the FSIS auditors observed that the laboratory criteria for the receipt of STEC samples taken in conjunction with the verification program for products intended for export to the United States was in conflict with SAG's written instruction for submission of these samples (D-CER-VPE-PP-009, General Document – Official Microbiological Verification in Livestock Establishment of Export). Whereas SAG's written instruction indicated that samples should not be frozen prior to submission, the criteria maintained at the laboratory indicated that frozen samples would be acceptable, however no frozen samples have been received since this change in instruction.

- The official laboratory analyzing samples of raw beef products for Shiga toxin-producing *Escherichia coli* maintains acceptance criteria allowing receipt of frozen samples, which is not permitted according to the Central Competent Authority's (CCA's) written instructions.

The NRL audit included interviews with the officials, document reviews, and a visit to the chemical residue testing portion of the laboratory. 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 verified that SAG's meat and poultry food safety inspection systems have the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component. Except for the finding noted above, SAG's meat and poultry inspection systems continue to meet the core 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 equivalence component the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for good commercial practices in poultry; humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors confirmed that MVOs verify humane handling requirements of Decrees 28, 30 and 94 on a daily basis. MVOs verify truck unloading, water and feed availability, handling of suspect and disabled livestock, handling during livestock movement, electric prod/alternative object use, observations for slips and falls, stunning effectiveness, checks for conscious animals on the rail, as well as good commercial practices for poultry. However, the FSIS auditors identified the following finding:

- Government inspection personnel did not identify that lambs had no access to water in the holding pens at two establishments. The establishments immediately took corrective actions by transferring the lambs into different pens with available water.

Ante-mortem inspection of livestock is conducted according to the requirements detailed in General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats and of poultry according to General Technical Rule No. 117 Medical Veterinary Inspection of Poultry and its Meats. Additional requirements for the ante-mortem inspection of

livestock and poultry are detailed in Decree No. 977, Sanitary Food Regulations. 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 verified that ante-mortem inspection is performed on all livestock and poultry to determine whether animals are fit for slaughter, and the MVO identifies and segregates livestock with disease conditions. The FSIS auditors assessed ante-mortem inspection through onsite record reviews, interviews, and observations of the government inspection personnel performing these procedures in audited livestock and poultry slaughter establishments.

The FSIS auditors verified that post-mortem inspection procedures were conducted in accordance with Decree No. 977 Sanitary Food Regulations; General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats for livestock and General Technical Rule No. 117 Medical Veterinary Inspection of Poultry and its Meats for poultry. The FSIS auditors observed and verified proper presentation, identification, examination, and disposition of carcasses and parts are being implemented during post-mortem inspection. MVOs and TIOs are inspecting every livestock carcass, head, and viscera through incision, palpation, and observation, and inspecting every carcass for contamination with fecal material, ingesta, or milk contamination and every poultry carcass and parts for fecal contamination. The establishments have mechanisms in place to divert carcasses from the slaughter line for further disposition if pathology or the need for trimming is identified. The FSIS auditors verified that SAG maintains line speed requirements and that the line speed at the time of the audit was appropriate for the staffing level of government inspection personnel as observed. However, the FSIS auditors identified the following findings:

- Government inspection personnel were not ensuring adequate post-mortem inspection at multiple beef and pork slaughter establishments.
  - Government inspection personnel were not palpating the mesenteric lymph nodes in swine during post-mortem inspection activities as written in the General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats.
  - Government inspection personnel were not verifying the removal of bruises from beef carcasses prior to receiving the mark of inspection.

The FSIS auditors verified that SAG conducts supervisory review visits once per quarter to evaluate the performance of government inspection personnel and the establishment. Government inspection personnel are evaluated on humane handling, ante-mortem and post-mortem inspection; microbiological and residue sample collection, verification of humane handling in livestock and good commercial practices in poultry, condemned materials, HACCP, sanitation standard operating procedures (Sanitation SOP), sanitation performance standards (SPS), and FSIS import requirements. Supervisory reviews are conducted in accordance with Decree No. 94/2008 and Resolution No. 1045 by an RIS. The reviews include MVIOs, MVOs, and TIOs and are documented on form F-CER-PP-002. The FSIS auditors reviewed the most recent supervisory reviews and verified that corrective actions were taken and confirmed when deficiencies were identified.

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 products

intended for other markets. In addition, SAG has controls to prevent any imported meat from being further processed and certified for export to any third country, including the United States.

The FSIS auditors verified through interviews and record reviews that SAG requires certified establishments to properly label products intended for export to the United States. SAG government inspection personnel are to verify labeling requirements within the context of the establishment's quality system at least once per month. Labels must include the product name, company authorization number, shipping identification mark, country of origin, name and address of the manufacturer or distributor, net weight of the product, and safe handling instructions. However, the FSIS auditors identified a deficiency related to the verification of labeling requirements for retained water. During the audit of one of the poultry facilities using water as part of the chilling process, it was noted that government inspection personnel were not verifying the percentage of retained water on product labels for non-marinated products. A review of the establishment's protocol for the analysis of retained water resulting from the chilling process indicated acceptable limits without the need to declare these on the product label. Discussion with representatives from SAG indicated that the cause of this omission was related to the adherence to domestic regulations which permit for a certain percentage of retained water to be maintained without the need for additional labeling. However, this practice is not consistent with U.S. labeling requirements in 9 CFR 441.10 and the systemic application of a domestic tolerance level could ultimately impact labeling of water-chilled products of other establishments certified for export to the United States.

- Government inspection personnel were not verifying that the label declares the percentage of retained water on product labels for non-marinated products.

SAG has legal authority to establish regulatory controls over certified meat and poultry establishments that export their products to the United States. However, the FSIS auditors identified deficiencies related to post-mortem inspection and labeling that do not meet FSIS equivalence requirements.

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

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written Sanitation SOP to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

The FSIS auditors verified that SAG requires establishments certified to export to the United States to develop, implement, and maintain Sanitation SOP to prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions, as required by Resolution No. 1045. SAG requires that establishments develop procedures to address sanitary dressing requirements, facility construction and maintenance, equipment maintenance, and pest control consistent with FSIS regulations. MVOs verify compliance of establishments certified to export to the United States with sanitation requirements daily by direct observation and reviewing records.

The FSIS auditors verified that MVOs conduct a review of SPS daily by observing areas of the establishment and through a records review. MVOs monitor the establishment for condensation control, chemical use and storage, employee hygiene, water potability, pest control, outside premises, and lighting. The FSIS auditors verified that this was conducted, in accordance with evaluation standards F-PP-IT-047 for meat and F-PP-IT-058 for poultry, which are consistent with FSIS requirements in 9 CFR part 416.

The FSIS auditors observed MVOs performing pre-operational and operational Sanitation SOP verification and verified that MVOs conduct daily verifications consisting of both direct observation and a records review, and results are documented on their daily verification records. The FSIS auditors reviewed records and verified that deficiencies were identified, documented as noncompliance, corrected by the establishment, and verified by MVOs.

When deficiencies are identified, MVOs have the authority to restrict an area from operating and to require immediate corrective actions when deficiencies are identified involving direct product contamination or product contact surfaces. However, the FSIS auditors determined that government inspection personnel were not identifying deficiencies during pre-operational sanitation inspection, including the presence of residue from the previous days' production and frayed cutting boards. Additionally, government inspection personnel did not identify establishment records that were lacking documentation of corrective actions in response to deficiencies. The FSIS auditors therefore identified the following finding:

- Government inspection personnel did not identify deficiencies related to the verification of Sanitation SOP at multiple establishments (e.g., verification of pre-operational sanitation, maintenance of product contact surfaces, and incomplete documentation of corrective actions).

Sanitary dressing verification is conducted by MVOs daily at multiple points in the slaughter process where contamination is likely to occur. The FSIS auditors evaluated government inspection personnel verification of establishment sanitary dressing procedures in slaughter establishments. Additionally, MVOs perform daily verification of zero tolerance for fecal material, ingesta, and milk on livestock carcasses and fecal material in poultry. The FSIS auditors verified that SAG has implemented written requirements and verification procedures sufficient to ensure that each slaughter establishment adheres to sanitary dressing principles.

SAG's meat and poultry food safety inspection systems continue to maintain sanitary regulatory requirements that meet the core requirements for this component. However, the audit finding listed above demonstrates that SAG's food safety inspection system did not effectively verify SPS and Sanitation SOP requirements at some establishments certified to export to the United States.

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



The fourth equivalence component 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 SAG requires establishments certified to export to the United States to develop, implement, and maintain a HACCP system in accordance with Resolutions No. 2592 and No. 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 part 417, which establishments are required to meet in order to be eligible to export product to the United States. SAG has the authority to take enforcement measures when an establishment does not implement a HACCP system in accordance with SAG requirements. The FSIS auditors verified that MVOs verify HACCP activities daily in accordance with document D-PP-IT-003. MVOs also review basic HACCP requirements (hazard analysis, flowchart, HACCP plans) when initially developed or when modified by the establishment. The FSIS auditors verified through direct observation and records review that MVOs conduct daily zero tolerance verification for fecal material, ingesta, and milk contamination in livestock prior to the final wash and daily verification for fecal contamination in poultry prior to the entering the chiller.

The FSIS auditors reviewed documents and records to assess the establishment's HACCP monitoring and verification activities, and the MVO's implementation of regulatory enforcement. The review of documents showed that the establishment maintained a written hazard analysis for each step in the slaughter process, flow chart, and HACCP plan. The FSIS auditors verified that the HACCP plan addressed hazards identified as reasonably likely to occur, critical control points (CCPs), critical limits, monitoring frequency, corrective actions, and verification procedures. The HACCP plans included a CCP for the monitoring of zero tolerance for fecal material, milk, and ingesta contamination in livestock located prior to the final wash, and fecal contamination in poultry located prior to entering the chiller. The FSIS auditors verified that HACCP records include a pre-shipment review to confirm that all HACCP requirements are met prior to export and HACCP corrective action records in response to deviations from a critical limit.

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

- Government inspection personnel did not adequately identify deficiencies related to HACCP requirements at multiple establishments, which included:
  - Government inspection personnel did not verify that the hazard analyses addressed biological (removal of stick wound) and physical hazards (weasand banding).
  - Government inspection personnel did not verify that all corrective actions are taken in response to deviations from the critical limit.
  - Government inspection personnel did not identify deficiencies related to HACCP verification requirements (HACCP plan did not include thermometer calibration).
  - Government inspection personnel did not identify deficiencies related to HACCP monitoring requirements (results of monitoring and signature).

The FSIS auditors determined that SAG requires establishments certified to export to the United States to develop, implement, and maintain HACCP systems. However, the audit findings listed above demonstrate that SAG's food safety inspection system did not effectively implement verification activities to evaluate 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 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, or muscle of carcasses for chemical residues identified by the exporting country's meat and poultry products inspection authorities or by FSIS as potential contaminants.

Chile's Residue Control Program (RCP) specifies the analytes included in the testing program, methods of analysis to be used, matrices to be collected, and the total number of samples to be collected and tested.

The RCP is developed by SAG under the authority of Law No. 18755 Established Norms of the Agriculture and Livestock Service and Decree No. 977 Sanitary Food Regulations, 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. Government inspection personnel are responsible for carrying out the sampling plan. SAG headquarters and regional offices ensure that sampling is carried out according to the prescribed plan during quarterly supervisory reviews. If violative residues are identified, the MVO will ensure appropriate disposition of product, (e.g., verifying condemnation). 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.

The FSIS auditors reviewed the routine and targeted residue sampling procedures and associated records and verified that samples are collected by MVOs in accordance with the RCP and instructions provided by SAG at meat and poultry slaughter establishments. MVOs ensure consistent sampling methodology, identification of animals, traceability, and sample security. If the MVO identifies animals suspected of residues on ante-mortem inspection, those animals are segregated, slaughtered last, and sampled for chemical residue testing once slaughtered. MVOs may also identify carcasses upon post-mortem inspection that warrant targeted residue sampling, which are then retained and sampled. Traceability information is collected on the sampled animal for both routine and targeted residue sampling and product is held until negative sample results are received. Results are reported to the MVOs as well as regional offices and SAG headquarters.

Circular No. 389/2020 requires that livestock carcasses and viscera subjected to routine official government chemical residue testing under the RCP are not to be exported to the United States

until acceptable test results are obtained. Circular No. 294/2021 requires that government inspection personnel must check that the results available from either the RCP or any other establishment testing for chemical residues must comply with U.S. tolerances for products intended for export to the United States.

The FSIS auditors' onsite audit verification activities indicate that SAG continues to maintain overall authority for a chemical residue testing program, which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in meat and poultry products exported to the United States. There have not been any POE violations related to this component since the previous FSIS audit in 2020.

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

The last equivalence component the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat, and poultry prepared for export to the United States are safe and wholesome.

SAG implements D-CER-VPE-PP-009 which includes requirements for establishment indicator organism sampling for cattle and sheep consistent with 9 CFR 310.25(a), for swine consistent with 9 CFR 310.18, including sampling at both pre-evisceration and post-chill, and for poultry consistent with 9 CFR 381.65, including sampling at both pre-chill and post-chill. The sampling requirements are verified by MVOs assigned to the establishment. All samples are required to be analyzed in official SAG laboratories using the Association of Analytical Chemists (AOAC) 991.14 analytical method for generic *E. coli*. The FSIS auditors observed carcass sampling by the establishment and verified that MVOs observe sample collection and review the establishment's test results. MVOs verify that indicator organism carcass testing is performed at the required frequency and generate statistical process control charts to verify establishment process control.

SAG has developed *Salmonella* performance standards in livestock and poultry slaughter establishments as described in D-CER-VPE-PP-009. The FSIS auditors observed an MVO performing sample collection for official *Salmonella* sampling and verified that sampling procedures were consistent with SAG requirements. Sample results are sent to the MVIO, the regional office and SAG. The MVO evaluates results to verify process control and ensure that corrective actions are taken by the establishment when performance criteria are not met. The FSIS auditors reviewed the records documenting sample collection and results. Samples are submitted to the approved laboratories that analyze samples for the presence of *Salmonella* using the VIDAS® Easy SLM (AFNOR BIO 12/16-09/05) and ISO 6579-1:2017 amended 1:2020 methods.

SAG's verification testing program for STEC in raw beef is described in document D-CER-VPE-PP-004, Official and Self-monitoring Verification of *E. coli* O157:H7 and STEC Non-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. D-CER-

VPE-PP-004 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 FSIS auditors verified that official government sampling for *E. coli* O157:H7 and non-O157 STEC is conducted by MVOs, who collect monthly verification samples of raw beef trimmings for STEC analysis. Each sample comprises five sub-samples for *E. coli* O157:H7 analysis and five sub-samples for non-O157 STEC analysis. The FSIS auditors observed official STEC sample collection at both eligible beef slaughter establishments and noted that the sampling method (grab sample) differed from that reported (N60 sample) in Chile's most recent SRT submission and found equivalent by FSIS. Conversations with local inspection personnel indicated that this resulted from recent instruction issued by SAG. However, this change in sampling methodology had not yet been submitted to FSIS for equivalence review, for which the use of sampling methods not determined to be equivalent can compromise the accuracy of testing results. Consequently, the FSIS auditors identified the following finding:

- Government inspection personnel were not collecting raw beef trimming samples using the sampling method described in the documentation submitted by SAG prior to the audit.

Official STEC verification samples are analyzed by the official SAG laboratory. The laboratory analyzes a 325 g test portion for *E. coli* O157:H7 using the VIDAS® UP (AFNOR BIO 12/25-05/09) method and a 375 g test portion for non-O157 STEC using the Assurance GDS MPX Top 7 STEC (AOAC Performance Tested Method 071301) method.

When conducting government official sampling for STEC, SAG 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 are held by government 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 in a timely manner to MVIOs, the regional office, and SAG.

The FSIS auditors verified that SAG maintains overall authority to implement an official microbiological sampling program organized and administered by the national government to verify that meat and poultry products intended for export to the United States are unadulterated, safe, and wholesome. There have not been any POE violations related to this component since the previous FSIS audit in 2020.

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

A remote exit meeting was held April 24, 2023, with officials from SAG. 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 OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)**

- The official laboratory analyzing samples of raw beef products for Shiga toxin-producing *Escherichia coli* maintains acceptance criteria allowing receipt of frozen samples, which is not permitted according to the Central Competent Authority's (CCA's) written instructions.

#### **GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)**

- Government inspection personnel did not identify that lambs had no access to water in the holding pens at two establishments. The establishments immediately took corrective actions by transferring the lambs into different pens with available water.
- Government inspection personnel were not verifying that the label declares the percentage of retained water on product labels for non-marinated products.
- Government inspection personnel were not ensuring adequate post-mortem inspection at multiple beef and pork slaughter establishments.

#### **GOVERNMENT SANITATION**

- Government inspection personnel did not identify deficiencies related to the verification of Sanitation SOP at multiple establishments (e.g., verification of pre-operational sanitation, maintenance of product contact surfaces, and incomplete documentation of corrective actions).

#### **GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM**

- Government inspection personnel did not identify deficiencies related to HACCP requirements at multiple establishments.

#### **GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

- Government inspection personnel were not collecting raw beef trimming samples using the sampling method described in the documentation submitted by SAG prior to the audit.

During the audit exit meeting, SAG committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of SAG's documentation of proposed corrective actions 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 04/05/2023	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.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			



Establishment Operations:	Turkey slaughter and processing.
Prepared Products:	Raw non-intact turkey (ground product, and other non-intact); and raw intact turkey (boneless and/or skinless parts, and poultry parts (giblets).

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations. This audit was conducted remotely from the Agricultural and Livestock Service (SAG) headquarters due to biosecurity concerns associated with a recent outbreak of highly pathogenic avian influenza in a flock of broiler breeding hens.

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 Lo Miranda Donihue Libertador General Bernardo O'Higgins	2. AUDIT DATE 04/10/2023	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.		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.	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. Periodic Supervisory Reviews	
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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork (primals, sub-primals, cuts)

60. Observation of the Establishment

The following non-compliances were not identified by Chile's inspection officials during the establishment review:

15. The establishment had not identified hazards associated with the sticking (bleeding) and dehairing of swine carcasses within the context of its HACCP system. The tissues surrounding the stick wound can become contaminated during subsequent phases of the dehairing process with pathogenic microorganisms or otherwise unwholesome material. A review of the establishment production records indicated that the meat from this area was not currently being exported to the United States.

United States Department of Agriculture  
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## 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 04/11/2023	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.	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.	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. Periodic Supervisory Reviews	
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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork (back ribs, pork bellies, tenderloin, livers)

60. Observation of the Establishment

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

10. Verification of Pre-operational SSOP: Numerous cutting boards presented frayed edges, creating the potential for product adulteration. Upon notification of this defect by the FSIS auditor, Chilean inspection officials took immediate corrective action to address reconditioning of these surfaces.

15. The establishment had not identified hazards associated with the sticking (bleeding) and dehairing of swine carcasses within the context of its HACCP system. The tissues surrounding the stick wound can become contaminated during subsequent phases of the dehairing process with pathogenic microorganisms or otherwise unwholesome material. A review of the establishment production records indicated that the meat from this area was not currently being exported to the United States.

**In addition, FSIS identified the following findings related to the implementation of Chile's inspection system:**

55. The viscera inspector was not palpating the mesenteric lymph nodes during post-mortem inspection activities in a manner consistent with General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	04/11/2023

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Faenadora Las Pataguas, Comercial Maxagro S.A. Ruta H - 886 Km. 2 Sector El Toco Pichidegua Libertador General Bernardo O'Higgins	2. AUDIT DATE 04/06/2023	3. ESTABLISHMENT NO. 06-17	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.	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. Periodic Supervisory Reviews	
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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw intact pork (back-ribs and bellies)

60. Observation of the Establishment

The following non-compliances were not identified by Chile's inspection officials during the establishment review:

10. In the processing area, several white bins carrying exposed product presented frayed bits of plastic on their interior surfaces, creating the potential for product adulteration. Upon notification of this defect by the FSIS auditor, Chilean inspection officials took immediate corrective action to address potential product adulteration and reconditioning of bins in this area.

15. The establishment had not identified hazards associated with the sticking (bleeding) and dehairing of swine carcasses within the context of its HACCP system. The tissues surrounding the stick wound can become contaminated during subsequent phases of the dehairing process with pathogenic microorganisms or otherwise unwholesome material. A review of the establishment production records indicated that the meat from this area was not currently being exported to the United States.

In addition, FSIS identified the following findings related to the implementation of Chile's inspection system:

55. The viscera inspector was not palpating the mesenteric lymph nodes during post-mortem inspection activities in a manner consistent with General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats.

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. Rute U-55 Camino Pichidamas Km 1,7 Osorno Region de Los Lagos	2. AUDIT DATE 04/11/2023	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.		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.	X	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. Periodic Supervisory Reviews	
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. STEC Sampling	X
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			



Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (primals, sub-primals, cuts)

60. Observation of the Establishment

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

19. Government inspection personnel did not identify a missing result for a direct observation verification activity for CCP 2, antimicrobial concentration.
20. Government inspection personnel did not verify that the establishment documented all parts of corrective actions for CCP 1, zero tolerance in response to a deviation.
41. Government inspection personnel did not identify frozen condensate at the entrance to freezing tunnel #3. No product was observed to be affected by the condensation. The condensation was in a doorway where boxed product is transported to the loading dock.
41. Government inspection personnel did not identify dripping condensation in the boning room adjacent to a carousel with exposed product, in a product transit area. No direct product contamination was observed.

**In addition, FSIS identified the following findings related to the implementation of Chile's inspection system:**

55. Government inspection personnel are not ensuring that bruises are removed from beef carcasses at the final rail. Two beef carcasses were observed with bruises passing post mortem inspection, entering the final wash.
57. Government inspection personnel were not collecting N60 samples for STEC according to instructions in D-CER-VPE-PP-009 Verificación Microbiológica Oficial en Establecimientos Pecuarios de Exportación.

61. AUDIT STAFF OIEA International Audit Staff (IAS)	62. DATE OF ESTABLISHMENT AUDIT 04/11/2023
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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 N°200 Osorno Region de Los Lagos	2. AUDIT DATE 04/12/2023	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	
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. Periodic Supervisory Reviews	
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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Raw beef intact cuts

60. Observation of the Establishment

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

15. Government inspection personnel did not identify that the HACCP plan was missing the frequency of the calibration of thermometers.

**In addition, FSIS identified the following findings related to the implementation of Chile's inspection system:**

55. Government inspection personnel are not ensuring that bruises are removed from beef carcasses at the final rail. One beef carcasses was observed with bruises passing post mortem inspection, entering the final wash.

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 Punta Arenas Region de Magallanes y de la Antartica	2. AUDIT DATE 04/10/2023	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.	X	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 .		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.	X	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. Periodic Supervisory Reviews	
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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Lamb slaughter and processing
Prepared Products:	Raw intact lamb (carcasses, primals, sub-primals, cuts)

60. Observation of the Establishment

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

10. After the MVIO completed pre-operational inspection, the FSIS auditor identified wool in multiple locations on the carcass rail from the previous day's production and blood was observed on the floor adjacent to the slaughter line from the previous day's production.
12. Government inspection personnel did not identify that on one operational SOP record, corrective actions were not documented in response to a n identified deficiency, however the establishment took corrective actions for this deficiency.
16. Government inspection personnel did not identify that one CCP monitoring record did not include the result for the zero tolerance CCP
16. Government inspection personnel did not identify that one CCP monitoring record did not include a signature for the zero tolerance CCP
16. Government inspection personnel did not verify that two CCP verification records did not include the daily document review as required by the HACCP plan.
39. Government inspection personnel did not identify peeling paint was observed on a metal surface above the carcass rail at the exit of the chiller. No direct product contamination was observed.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Soc. Com. José Marín Antonín y Cía. Ltda. Los Calafates N°0415 Sitio 7-11 Barrio Industrial Punta Arenas Región de Magallanes y de la Antártica	2. AUDIT DATE 04/06/2023	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 SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	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 .		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. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	X
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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Lamb and mutton slaughter and processing
Prepared Products:	Raw intact lamb (carcasses, primals, sub-primals)

60. Observation of the Establishment

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

10. Government inspection personnel did not identify several lamb carcasses covered in fabric shrouds that were torn, leaving the product exposed in the finished product freezer. Additionally, black grease/dirt residue was observed on the exposed portions of the carcasses. The carcasses were subsequently diverted for use only in the domestic market.
10. Government inspection personnel did not identify multiple lamb heads with hide on were observed contacting the backs exposed carcasses from the dehiding to the hock cutting areas. The carcasses observed were then diverted for use only in the domestic market.
13. On three different operational sanitation records, government inspection personnel did not identify that corrective actions were not documented in response to deficiencies identified.
22. Government inspection personnel did not identify multiple CCP monitoring records for zero tolerance that did not include the time of event.
22. Government inspection personnel did not identify multiple CCP verification records for direct observation for zero tolerance that did not include the result of the verification activity.
39. Government inspection personnel did not identify standing water that was adjacent to carcasses on the trimming stand in the cutting room. No direct product contamination was observed.
39. Government inspection personnel did not identify standing water at the entrance to carcass chiller from slaughter no direct product contamination was observed.
52. Government inspection personnel did not identify that approximately 40 lambs were observed in a holding pen with no access to water. The establishment took immediate corrective action by transferring the lambs into a different pen with water available.

61. AUDIT STAFF OIEA International Audit Staff (IAS)	62. DATE OF ESTABLISHMENT AUDIT 04/06/2023
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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 N°1 Porvenir Region de Magallanes y de la Antartica	2. AUDIT DATE 04/05/2023	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	X
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.	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. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	X
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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			



Establishment Operations:	Lamb slaughter and processing
Prepared Products:	Raw intact lamb (carcasses, primals, sub-primals, cuts and offal)

60. Observation of the Establishment

The following non-compliances were not identified by Chile's inspection officials during the establishment review:

10. At the reinspection station for carcasses with contamination and pathology, government inspection personnel did not identify potentially contaminated carcasses that were contacting each other in addition to a handwashing sink, providing a risk of cross contamination.
15. Government inspection personnel did not verify that the establishment did not identify physical hazards at the weasand banding step, where plastic weasand clips are introduced.
38. Government inspection personnel did not identify gaps on both sides of the door to the loading dock, leading to the exterior premises.
41. Government inspection personnel did not identify beaded condensation at the exit to chiller #3. No product was observed to be affected by the condensation. The condensation was in a doorway where boxed product is transported to the loading dock.
52. Government inspection personnel did not identify approximately 15 lambs in a holding pen with no access to water. The establishment took immediate corrective action by transferring the lambs into a different pen with water available.

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 Región Metropolitana El Monte Región Metropolitana de Santiago	2. AUDIT DATE 04/12/2023	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	
<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. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling	X	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.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Chicken and turkey slaughter and processing.
Prepared Products:	Raw intact and non intact chicken wings, drumsticks, breasts, tenders (marinated/not marinated) [Not currently exporting turkey]

60. Observation of the Establishment

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

22. The establishment was documenting an average temperature of the 10 carcasses measured during monitoring of CCP2 (carcass temperature with a critical limit of  $\leq 4\text{ }^{\circ}\text{C}$ ) rather than the specific temperature for each carcass.

25. The establishment did not report the percentage of retained water on the product label for non-marinated products. A review of the establishment's protocol for the analysis of retained water resulting from the chilling process indicated the following values: entire carcass (4.83%); whole breast (3.87%); whole wing (4.13%); drumstick (3.89%).

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

**COMMENTS OF THE AGRICULTURAL AND LIVESTOCK SERVICE (SAG) ON THE DRAFT OF THE FSIS  
AUDITING REPORT (APRIL 3– 24, 2023)**

**RESPONSES TO FINDINGS POINTED OUT IN THE ASSESSED CONTENT**

**I. Component one: government oversight (e.g., organization and administration)**

- a. The official laboratory analyzing samples of raw beef products for Shiga toxin-producing *Escherichia coli* maintains acceptance criteria allowing receipt of frozen samples, which is not permitted according to the Central Competent Authority's (CCA's) written instructions.

**Response:**

The SAG Official Laboratory, Food Microbiology Section (Livestock) has modified its Procedure "Entry of Samples and Report of Results Subdepartment of Chemistry and Food Safety" code QIA/PT - 01/21, effective September 1, 2023, annex N°19, page 23, table "Official Verification of STEC for export to the United States", updating the criteria for sample acceptance as established in the document "Official Microbiological Verification in Livestock Export Establishments" D-CER-VPE-PP-009, current version, where it stipulates that official samples for STEC analysis must be received in a refrigerated state. Attached is the new version of Procedure QIA/PT-01/21 and its respective Annex N°19 (**Annexes 01 and 02**).

**II. 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)**

- a. Government inspection personnel did not identify that lambs had no access to water in the holding pens at two establishments. The establishments immediately took corrective actions by transferring the lambs into different pens with available water.
- b. Government inspection personnel were not ensuring adequate post-mortem inspection at multiple beef and pork slaughter establishments.
  - i. Government inspection personnel were not palpating the mesenteric lymph nodes in swine during post-mortem inspection activities as written in the General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats.
  - ii. Government inspection personnel were not verifying the removal of bruises from beef carcasses prior to receiving the mark of inspection.

**c. Government inspection personnel were not verifying that the label declares the percentage of retained water on product labels for non-marinated products.**

**Response:**

Decree No. 94/2009 (**Annex 03**) states that reception and holding pens for cattle must have drinking water available. In that sense, Official Inspection Teams (EIO) verified the implementation of immediate corrective actions. The preventive measures implemented by the establishments included installation of livestock drinkers in all holding pens and the reinforcing of requirements for water availability and animal housing through training of the working staff of those areas.

Regarding the post mortem inspection, specifically in pork slaughtering facilities, the mesenteric lymph nodes of the gastrointestinal tract were only partially inspected, as observed by the FSIS Auditors. Official Technician Inspectors (TIO) must perform the inspection process in the gastrointestinal viscera according to the General Technical Rule No. 62 (**Annex 04**), which clearly states that the mesenteric lymph nodes must be palpated and that, in case of visible lesions in the submaxillary lymph nodes, their internal structure must be inspected through an incision. To address this finding, the corrective action consists of constant training of Official Inspectors, especially in the involved establishments. Also, Regional Supervisors (SRIC) oversee the correct execution of the official inspection performed by the EIOs.

To address the finding about the removal of bruises, circular No. 590/2023 (**Annex 05**) was issued, which instructs the EIOs in authorized establishments in the Region of Los Lagos to verify the implementation of Standard Operating Procedures (SOP) that ensure the removal of bruises from beef carcasses prior to receiving the official stamp, in addition to the monitoring activities to control the correct execution of these procedures.

Finally, EIOs were instructed to verify the implementation of 9 CFR § 441.10 requirements on each slaughter facility's Quality Assurance System via circular No. 647/2023 (**Annex 06**). As such, effective from October 2nd, 2023, EIO must verify the following:

- Implementation of a protocol for the determination of retained water, according to the requirements states in 9 CFR § 441.10(d).
- Any modification to said protocol informed by the establishment.
- Inclusion of a statement indicating the percentage of water retained on the label of non-marinated products that, as determined by the protocol, fall under this category.

These official verification activities will be recorded on the F-PP-IT-032 registry. In addition, circular No. 360/2019 (**Annex 07**) instructs that EIOs must have a copy of all the certificates of compliance for the labels of the products destined to the United States, to verify the compliance of the label of the products on each shipment.

### **III. Component three: government sanitation**

- a. Government inspection personnel did not identify deficiencies related to the verification of Sanitation SOP at multiple establishments (e.g., verification of pre-operational sanitation, maintenance of product contact surfaces, and incomplete documentation of corrective actions).**

#### **Response:**

The competent authority through the EIOs, requires establishments authorized to export products to the United States that they must develop and implement their prerequisite programs. Resolution No. 1045/2013 (**Annex 08**) stipulates that these must be submitted in writing, detailing procedures to be executed, frequency, responsibilities, and actions to be taken if these procedures are not executed in accordance with the written protocols.

Establishments are also required to be implemented and executed by trained personnel, including verification and monitoring procedures and that they must be signed and dated by the person responsible for them.

In relation to the detected findings, the root cause was identified in each of them and corrective and preventive actions were implemented in order to avoid their recurrence. First this was done by each individual establishment and then it was verified by the EIOs on site.

Additionally, in the establishments, internal training sessions were given by the Head of Quality Assurance to the quality monitors involved in the process. Regarding the Competent Authority, training was also carried out by the EIO Leader (JEIO) to the Official Veterinary Inspectors (MVIO).

### **IV. Component four: government hazard analysis and critical control point (HACCP) system**

- a. Government inspection personnel did not adequately identify deficiencies related to HACCP requirements at multiple establishments, which included:**
  - **Government inspection personnel did not verify that the hazard analyses addressed biological (removal of stick wound) and physical hazards (weasand banding).**
  - **Government inspection personnel did not verify that all corrective actions are taken in response to deviations from the critical limit.**
  - **Government inspection personnel did not identify deficiencies related to HACCP verification requirements (HACCP plan did not include thermometer calibration).**
  - **Government inspection personnel did not identify deficiencies related to HACCP monitoring requirements (results of monitoring and signature).**

#### **Response:**

The Agricultural and Livestock Service has evaluated the observation made by the FSIS auditor and has considered carrying out an instruction to the team destined for pork slaughter plants authorized to export to the U.S., based on the following foundation:

- The bleeding process, in which a knife is used to cut the arteriovenous trunk and thus cause the animal to bleed to death, can potentially allow the entry of biological and physico-chemical contaminants in the scalding and depilation processes, which have not been addressed by the establishments.
- In the throat wound from the cut, there is a trace of clot and rupture of muscle tissue. In this area, a product of possible contamination, a mechanism must be implemented to control the risk of contamination.

Due to the above, pig slaughter establishments must implement a system that demonstrates that there is control over this possible risk of contamination. This must be included in the hazard analysis of the establishment, explicitly. EIO on authorized establishments must verify this as instructed in circular No. 300/2023 (**Annex 09**).

The inclusion of the weasand banding process in the hazard analysis by the correspondent establishments was verified by the EIOs on site.

Regarding the verification of the HACCP plan, specifically to include in the monthly program the verification of the contrasting of the thermometers, the service has instructed the EIO through the SRIC that this action be carried out periodically. In the same way, it has been emphasized that the monitoring must be named and signed by the official inspector.

Finally, the deficiencies related to the results of the monitoring procedures and the signage of records was addressed by the correspondent establishments and verified by the EIOs.

## **V. Component six: government microbiological testing programs**

- a. Government inspection personnel were not collecting raw beef trimming samples using the sampling method described in the documentation submitted by SAG prior to the audit.**

### **Response:**

Currently, the official microbiological verification program for the determination of STEC, is the “VERIFICACIÓN MICROBIOLÓGICA OFICIAL – *Escherichia coli* productora de Shiga toxinas (O26, O45, O103, O111, O121, O145, O157:H7) por requisito de Estados Unidos”, which is included in the General Document Microbiological Verification in Establishments Exporters of Livestock Products (D-CER-VPE-PP-009) in its version that is in force (V04) (**Annex 10**).



The D-CER-VPE-PP-009 v04, Chapter I point H point 5.2 f and g, establishes that the sampling procedure applies to sampling of beef trim by official government personnel is the N60 sampling methodology when samples are obtained from pieces large enough to be subjected to this methodology. Otherwise, the samples shall be obtain using the aseptic grab samples method. In this case, the MVIO should obtain enough product to fill each of the bags.

## RESPONSES TO FINDINGS IN ASSESSED FACILITIES

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

### I. Faenadora Lo Miranda Ltda. (Official LEEPP Registration Number 06-02)

- 1. The establishment had not identified hazards associated with the sticking (bleeding) and dehairing of swine carcasses within the context of its HACCP system. The tissues surrounding the stick wound can become contaminated during subsequent phases of the dehairing process with pathogenic microorganisms or otherwise unwholesome material. A review of the establishment production records indicated that the meat from this area was not currently being exported to the United States.**

#### Response:

Faenadora Lo Miranda Ltda. has made changes to the evisceration process, generating a new operational step "Extraction of the sticking wound", described as operational step No. 32. Associated with this step, a hazard analysis validated by the company has been carried out. The description of the operational step is as follows:

"An employee using a traditional knife and/or circular saw removes and eliminates the anatomical area where the knife was inserted in the operational step of bleeding in the slaughter process, starting from the base of the first rib to the point of entry of the bleeding knife"

### II. Procesadora de Alimentos del Sur Limitada (Official LEEPP Registration Number 06-06)

- 1. Verification of Pre-operational SSOP: Numerous cutting boards presented frayed edges, creating the potential for product adulteration. Upon notification of this defect by the FSIS auditor, Chilean inspection officials took immediate corrective action to address reconditioning of these surfaces.**

#### Response:

The EIO was re trained on the role of the SAG inspector regarding the correct verification of the food safety system of an establishment, based on the Code of Federal Regulations, Title 9 CFR, subchapter E – Part 416 Sanitation and based on FSIS directive 5000.1, chapter 2, part III. In addition, the EIO added the verification of the monitoring of infrastructure and sanitary conditions (RO-RG-ACL-243) in the Official Verification Program with a monthly frequency.

- 2. The establishment had not identified hazards associated with the sticking (bleeding) and dehairing of swine carcasses within the context of its HACCP system. The tissues surrounding the stick wound can become contaminated during subsequent phases of the dehairing process with pathogenic microorganisms or otherwise unwholesome material. A review of the establishment production records indicated that the meat from this area was not currently being exported to the United States.**

**Response:**

Establishment incorporates in risk matrix RO-DC-HACCP-005 possibility of cross-contamination through the sticking wound during the scalding process and added the operational step “sticking wound extraction” in the flow diagram R0-RG-HACCP-028. This step was also incorporated in the SOP for the evisceration area (RO-ISPO-FAE-052). The verification of its execution is registered in the RO-RG-ACL-005 form and is also included in the operational document RO-DC-GEN-070. The EIO added the verification of this activity to the monthly verification program.

- 3. The viscera inspector was not palpating the mesenteric lymph nodes during post-mortem inspection activities in a manner consistent with General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats.**

**Response:**

EIO is re-trained on correct post mortem inspection according to General Technical Standard No. 62 Veterinary Medical Inspection of Carcasses and their Meats, and also on post mortem inspection based on the Code of Federal Regulations, Title 9 CFR, Chapter III, Part 311 Elimination of carcasses and diseased parts.

**III. Faenadora Las Pataguas, Comercial Maxagro S.A. (Official LEEPP Registration Number 06-17)**

- 1. In the processing area, several white bins carrying exposed product presented frayed bits of plastic on their interior surfaces, creating the potential for product adulteration. Upon notification of this defect by the FSIS auditor, Chilean inspection officials took immediate corrective action to address potential product adulteration and reconditioning of bins in this area.**

**Response:**

All the white bins were immediately removed from the area by Quality Assurance Area personnel. The registry form LP-RG-SSOP-01-033 was updated, and the item “verification of the condition of bins” was added to the checklist. Bin maintenance personnel were trained on the verification of the

condition of bins at the exit of the washing machine. Packing area personnel were trained on notifying the area in charge when bins in poor condition are detected.

- 2. The establishment had not identified hazards associated with the sticking (bleeding) and dehairing of swine carcasses within the context of its HACCP system. The tissues surrounding the stick wound can become contaminated during subsequent phases of the dehairing process with pathogenic microorganisms or otherwise unwholesome material. A review of the establishment production records indicated that the meat from this area was not currently being exported to the United States.**

**Response:**

The establishment included the possible cross-contamination through the sticking wound during the dehairing process considering *Salmonella* and *Escherichia coli* as potential biological hazards. Also, the sticking wound area will be removed in the cutting stage, prior to the removal of the head of the carcass. This was verified by the EIO on site.

- 3. The viscera inspector was not palpating the mesenteric lymph nodes during post-mortem inspection activities in a manner consistent with General Technical Rule No. 62 on Medical Veterinary Inspection of Carcasses and its Meats.**

**Response:**

The EIO personnel were re-trained on “Inspection of mesenteric lymph nodes” according to the General Technical Standard No. 62.

**IV. Matadero Frigorífico del Sur S.A. (Official LEEPP Registration Number 10-15)**

- 1. Government inspection personnel did not identify a missing result for a direct observation verification activity for CCP 2, antimicrobial concentration.**

**Response:**

Root Cause:

By unintentional error, the quality monitor responsible for CCP 2 did not enter the data obtained by direct verification in his record.

Corrective Action:

A meeting was held after the audit with personnel responsible for filling out the register, to reinforce how to fill it out and its importance. SAG personnel at the establishment verified compliance on 08-08-2023.

Preventive Action:

Reinduction is carried out for the quality monitors who carry out direct verification. Likewise, the personnel responsible for documentary verification were re-induced by the head of Quality and Safety Assurance. SAG personnel verified the implementation of these preventive actions on 08-08-2023.

Action by the Official Team:

SAG personnel at the establishment verify once a week in-situ the correct entry of the data obtained in the self-control monitoring at the time of a verification by direct observation, which is recorded in the SAG form F-PP-IT-032.

**2. Government inspection personnel did not verify that the establishment documented all parts of corrective actions for CCP 1, zero tolerance in response to a deviation.**

**Response:**

Root Cause:

Because the manual was made specifically for the verification and follow-up of the CCP, it only describes the immediate corrective action and did not consider the corrective and preventive action components, so the document is incomplete.

Corrective Action:

HACCP Team meeting is held where the finding is made known and the CCP 1 record is modified to comply with the requirements of 9 CFR § 417.3 - Corrective Actions, which incorporates:

- (1) The cause of the deviation is identified and eliminated;
- (2) The CCP will be under control after corrective actions are taken;
- (3) Measures are put in place to prevent recurrence; and
- (4) No product enters commerce that is injurious to health or otherwise adulterated as a result of the deviation.

The above actions were verified as compliant by the EIO on 09-01-2023.

Preventive Action:

- The monitoring log detailing the root cause, corrective and preventive actions related to the CCP is implemented.
- Along with the above, those responsible for its implementation are defined.
  - o Responsible for determining the root cause will be the area supervisor.
  - o For the corrective action the CCP1 operator.
  - o Preventive action the Quality Monitor.
- All responsible personnel are trained.
- SAG staff verifies it as per 07-25-2023, 08-04-2023 and 08-08-2023.

Action of the Official Team:

SAG personnel at the establishment, verify once a week in-situ that they keep the register updated, which is recorded in SAG's F-PP-IT-032.

- 3. Government inspection personnel did not identify frozen condensate at the entrance to freezing tunnel #3. No product was observed to be affected by the condensation. The condensation was in a doorway where boxed product is transported to the loading dock.**

**Response:**

Root Cause:

Due to the obstruction of a potable water pipe over the roof of the deboning area, with a break in the pipe, which caused constant dripping of water, which was not detected by Quality Assurance personnel.

Corrective Action:

- Condensation is removed from the sector and two specific people are available to perform the work of drying the condensation found. The origin of the condensation is reviewed with machine room personnel and the leak is corrected immediately.
- Quality and safety monitors verify the correct execution of this task. Condensation problems are recorded on the area's operational monitoring form (observations), which is verified in accordance with the same document.
- The SAG personnel at the facility verify compliance for the last time on 08-08-2023.

Preventive Action:

- It is verified daily during the pre-operational cleanliness review by the company's Quality Assurance which is recorded in the area's pre-operational form.
- In the event of findings, infrastructure deviations will be reported immediately to the maintenance area.
- Quality personnel are re-instructed on the correct execution of this action.
- SAG staff performs the conformance check on 08-08-2023.

Action by the Official Team:

SAG personnel at the facility, implements an operational verification of an area of the facility with a frequency of 2 times per week, this area will not be repeated more than once a week, this verification includes the observation of the presence of condensation, which is recorded on form F-PP-IT-032.

- 4. Government inspection personnel did not identify dripping condensation in the boning room adjacent to a carousel with exposed product, in a product transit area. No direct product contamination was observed.**

**Response:**

Root Cause:

Due to the obstruction of a potable water pipe over the roof of the deboning area, with a break in the pipe, which caused constant dripping of water, which was not detected by Quality Assurance personnel.

Corrective Action:

- Condensation is removed from the sector and two specific people are available to perform the work of drying the condensation found.
- The origin of the condensation is reviewed with machine room personnel and the leak is corrected immediately.
- Quality and safety monitors verify the correct execution of this task.
- The condensation problem is recorded on the area's operational monitoring form (observations), which is verified in accordance with the same document.
- The SAG staff at the establishment verifies compliance for the last time on 08-08-2023.

Preventive Action:

- It is verified daily during the pre-operational cleanliness review by the company's Quality Assurance which is recorded in the area's pre-operational form.
- In the event of findings, infrastructure deviations will be reported immediately to the maintenance area.
- Quality personnel are re-instructed on the correct execution of this action.
- SAG staff performs the conformance check on 08-08-2023.

Action by the Official Team:

SAG personnel at the facility, implements an operational verification of an area of the facility with a frequency of 2 times per week, this area will not be repeated more than once a week, this verification includes the observation of the presence of condensation, which is recorded on form F-PP-IT-032.

- 5. Government inspection personnel are not ensuring that bruises are removed from beef carcasses at the final rail. Two beef carcasses were observed with bruises passing post mortem inspection, entering the final wash.**

**Response:**

Root Cause:

SAG inspection personnel and slaughter personnel of the establishment corresponding to the high and low areas of the carcasses, did not notice the presence of bruises on the affected rods.

Corrective Action:

The establishment's slaughter supervisor removed the bruises from the carcasses observed during the slaughter line audit, which was verified by the area's quality monitor.

SAG personnel on inspection duty verified the result of the expungement for the elimination of the bruises on 04-11-2023.

Preventive Action:

The establishment instructed that when faced with a carcass that presents this type of deviation during the production process, the personnel in charge of trimming will verbally inform the SAG



personnel who is responsible for indicating referral to the re-inspection area or, failing that, perform online expurgation by the qualified operator.

If the carcass is found bruised at CCP 1, it will be sent to the holding chamber for corrective actions. Likewise, if line stoppage is required, it will be requested in order to carry out the action more effectively. To implement these instructions, training was provided to the responsible personnel.

SAG personnel verified compliance on July 25<sup>th</sup> and August 29<sup>th</sup>, 2023.

#### Action by the Official Team:

Faced with the finding by the FSIS auditor, the establishment was requested to divert the affected carcass and apply the expungement to eliminate the bruising, which was verified on the same day of the audit on April 11, 2023 by the veterinarian on duty responsible for the inspection.

The EIO assigned to the establishment held an internal meeting to report the finding of bruises by the FSIS auditor on 04-12-2023. A second meeting was held on 08-17-2023 with the establishment to report the entry into force of the instruction.

On 08-18-2023, the SAG inspection team of the establishment held an internal meeting to implement the instruction sent by Circular No. 590/2023 for the control of bruises in the slaughter process, which includes the following actions:

- Stopping the slaughter line.
- Notifying the MVIO shift supervisor.
- Notifying the company's slaughter manager to divert the affected carcasses and remove the bruises detected.
- Notification of non-compliance to the establishment.

Circular No. 590/2023 instructs EIOs to verify that establishments implement procedures for company personnel to remove and eliminate any bruises or hematomas present prior to the official inspection of carcasses, as well as the implementation of the establishment's SAC self-monitoring system to comply with this requirement.

#### **6. Government inspection personnel were not collecting N60 samples for STEC according to instructions in D-CER-VPE-PP-009 Verificación Microbiológica Oficial en Establecimientos Pecuarios de Exportación.**

#### **Response:**

The EIO was re-trained in the correct selection of the type of sampling, according to the size of products available to collect the sample for microbiological verification of STEC, according to the



current instructions for OFFICIAL MICROBIOLOGICAL VERIFICATION - Shiga toxin-producing *Escherichia coli* (O26, O45, O103, O111, O121, O145, O157:H7), D-CER-VPE-PP-009 v04.

#### **V. Frigorífico de Osorno S.A. (Official LEEPP Registration Number 10-26)**

- 1. Government inspection personnel did not identify that the HACCP plan was missing the frequency of the calibration of thermometers.**

##### **Response:**

##### Root Cause:

Due to a misinterpretation of the requirement presented in the 2020 audit, a corrective action was implemented that did not resolve the observation.

##### Corrective Action:

To correct the deficiency, the service, requested the company to perform a review of the internal manuals of its HACCP plan, in order to update its manuals to incorporate the frequency of calibration of thermometers.

Compliance with the inclusion in the company's HACCP manuals and verification by the self-monitoring of the establishment of the frequency of calibration of equipment related to CCPs, was included in version 5 of the internal manual CODE: M-BRCGS-HACCP-03 and verified as compliant by the SAG inspection team at the establishment, on June 28, 2023.

##### Preventive Action:

As a preventive measure, the self-control of the establishment, incorporated this update to the digital system of the company, with which this new version is available to all units of the company related to this control (heads, supervisors and monitors), along with the above the company performs training for its reinforcement of the application criteria, which was verified as compliant by the SAG inspection team at the establishment on July 24, 2023.

##### Action by the Official Team:

Additionally the EIO assigned to the facility held a meeting with the Regional Supervisor of Inspection and Certification to review the updates, on the occasion a weekly frequency of official

verification was defined which includes: instruments, verification of calibration frequency and contrasting.

**2. Government inspection personnel are not ensuring that bruises are removed from beef carcasses at the final rail. One beef carcasses was observed with bruises passing post mortem inspection, entering the final wash.**

**Response:**

Corrective Action:

Faced with the finding by the FSIS auditor, the establishment was requested to divert the affected carcass and apply the expungement to eliminate the bruising, which was verified on the same day of the audit on July 11, 2023 by the veterinarian on duty responsible for the inspection.

Preventive Action:

To prevent its recurrence the establishment, reinforced in the company's personnel training booklets the recognition and form of expurgation, for control before the carcasses leave the slaughter line.

Action by the Official Team:

For its part, the EIO assigned to the establishment, holds an internal meeting to implement the instruction sent by circular No. 590/2023 for the control of bruises in the slaughter process, which contemplates the following actions:

- Stopping the slaughter line.
- Notifying the MVIO shift supervisor.
- Notifying the company's slaughter manager to divert the affected carcasses and remove the bruises detected.
- Notification of non-compliance to the establishment.

Circular No. 590/2023 instructs EIOs to verify that establishments implement procedures for company personnel to remove and eliminate any bruises or hematomas present prior to the official inspection of carcasses, as well as the implementation of the establishment's SAC self-monitoring system to comply with this requirement.

#### **VI. Frigorífico Simunovic S.A. (Official LEEPP Registration Number 12-01)**

- 1. After the MVIO completed pre-operational inspection, the FSIS auditor identified wool in multiple locations on the carcass rail from the previous day's production and blood was observed on the floor adjacent to the slaughter line from the previous day's production.**

**Response:**

Root Cause:

Inadequate verification of the cleaning procedure on the day prior to the review, deficiency in the final cleaning process.

Corrective action:

Removal, cleaning and immediate disinfection of the points found with observations are carried out before starting the production process.

Preventive action:

- Training in SSOP cleaning and disinfection procedures for personnel in the slaughter line area, supervisors, and quality control, which was verified by the EIO on 04-14-2023.
- Training is carried out with an external company for operators in the process area, with respect to prerequisites, what was verified by the EIO on 07-31-2023.
- JEIO trains MVIO offline in pre-operational SSOP verification procedures (Exempt Resolution No. 1045/2013 "Specific requirements of prerequisite programs and HACCP for the implementation of a quality assurance system", SSOP Plan of the establishment, verification of the quality assurance in export slaughterhouses).

- 2. Government inspection personnel did not identify that on one operational SOP record, corrective actions were not documented in response to an identified deficiency, however the establishment took corrective actions for this deficiency.**

**Response:**

Root Cause:

Deficiency in completing the SSOP record by the Quality Monitor, since it did not record the corrective action taken.

Corrective action:

The establishment is notified and requested through inspection report 0003/2023 for the final review of the day with special emphasis on all corrective actions implemented being reflected in the record.

Induction to the quality manager of the deboning area focused on the fact that all corrective actions carried out must be registered in the SSOP-1 record, what was verified by the EIO on 04-11-2023.

Preventive action:

- The quality control personnel in charge of the records are instructed on the correct filling of the record, what was verified by the EIO on 04-12-2023.
- Training is carried out with an external company Eurofins for personnel from the Quality Control areas, Supervisors, and those in charge of HACCP, what was verified by the EIO on 07-31-2023.
- JEIO trains MVIO offline in review of SSOP records (Training Resolution 1045 "Specific requirements of prerequisite programs and HACCP for the implementation of a quality assurance system", SSOP Plan of the establishment, verification of the quality assurance system in export slaughterhouses).

**3. Government inspection personnel did not identify that one CCP monitoring record did not include a signature for the zero tolerance CCP.**

**Response:**

Root Cause:

Deficiency in filling out the CCP Monitoring record by the quality monitor by not including the result of monitoring for a period.

Corrective action:

The establishment is notified and requested through inspection certificate 0003/2023 that special emphasis is to be placed in the daily review of Zero Tolerance CCP monitoring records to verify that all results are included.

The online record of the CCP1 that the plant has as a backup of the documentary record is reviewed, to verify the monitoring period where the result was not written, to correct.

Preventive action:

- The quality control personnel in charge of the records are instructed on the correct filling of the record, what was verified by the EIO on 04-12-2023.
- Training is carried out with an external company Eurofins for personnel from the Quality Control areas, Supervisors, and those in charge of HACCP, what was verified by the EIO 07-31-2023.
- JEIO trains MVIO offline on verification "Review of CCP monitoring records" (Training: Monitoring the CCP "how to perform the review of records along with what minimum aspects should be verified", correct filling of the F-PP-IT-032 form, HACCP Plan of the establishment)

- 4. Government inspection personnel did not verify that two CCP verification records did not include the daily document review as required by the HACCP plan.**

**Response:**

Root Cause:

Deficiency in filling out the CCP monitoring record by the quality monitor by not including the daily review of the CCP monitoring.

Corrective action:

The record is reviewed and compared with the day the fault was evidenced in the online backup where the daily observation is recorded.

Preventive action:

- The quality control personnel in charge of the records are instructed on the correct filling of the record, what was verified by the EIO on 04-12-2023.
- Training is carried out with an external company Eurofins for personnel from quality control areas, what was verified by the EIO on 07-31-2023.

- 5. Government inspection personnel did not identify peeling paint was observed on a metal surface above the carcass rail at the exit of the chiller. No direct product contamination was observed.**

**Response:**

Root Cause:

Personnel in charge of preventive maintenance did not detect peeling paint in the sector.

Corrective action:

Peeling paint is removed and painted immediately after business hours by maintenance personnel.

Preventive action:

A check list is built for the maintenance area so that those in charge of the area carry out according to the frequency established in each process area in search of structural observations to keep controlled and solve structural observations in a preventive way, what was verified by the EIO on 04-14-2023.

**VII. Soc. Com. José Marín Antonín y Cía. Ltda. (Official LEEPP Registration Number 12-05)**

- 1. Government inspection personnel did not identify several lamb carcasses covered in fabric shrouds that were torn, leaving the product exposed in the finished product freezer. Additionally, black grease/dirt residue was observed on the exposed portions of the carcasses. The carcasses were subsequently diverted for use only in the domestic market.**

**Response:**

Root cause:

When the carcasses are too large, the stockinette must be stretched too much, which is why these holes may appear. In relation to the findings related to cleanliness, greater awareness is required on the part of the supervision and the camera personnel of the establishment.

Corrective action:

The EIO (EIO) requests the establishment to immediately replace both the stocks and the damaged containers and the purge of the exposed parts of the carcasses contaminated with black residue of fat/dirt. Subsequently, the EIO verifies that the affected carcasses were identified, expunged, and excluded from export to the United States.

Preventive action:

For broken stockinettes, the instructions for Carcass Tunneling (IT-AC.-22) version 7 are modified, indicating that when the carcasses are large, double packaging and container (bag and stockinette) must be used. For cleaning issues, a new SSOP is established: Procedure for Cleaning and Sanitizing Platforms and Chambers (P-C A-02) version 00 with its respective monitoring record (R-AC-02) version 21 and the Head of Assurance of Quality trains camera staff and headquarters regarding the cleaning conditions that must be met. The control record of Products in the Chamber is reformulated, (R-AC-17) version 14, which includes the verification of the findings detected.

This was verified by the EIO on 04-14-2023. The EIO Leader (JEIO) trains the MVIOs offline regarding the verification of the Food Safety System of an Establishment (**Annex No. 11**).

- 2. Government inspection personnel did not identify multiple lamb heads with hide on were observed contacting the backs exposed carcasses from the dehiding to the hock cutting areas. The carcasses observed were then diverted for use only in the domestic market.**

**Response:**

Root Cause:

The head scalper is not in good condition and better-trained operators are required to handle this equipment.

Corrective action:

EIO request the establishment to repair the affected equipment and take palliative measures to avoid direct contact of the heads with the skin and the backs of the skinned carcasses. Subsequently, the EIO verifies that the affected carcasses were identified, purged, and excluded from export to the United States.

Preventive action:

The affected equipment was checked and repaired. It is established through the SOP: Operational Procedure for Sheep Slaughtering (P-FAE-02) version 21, allowing two possibilities; with head cut or without head cut. In the latter case, it is established that the use of the head scalper is mandatory to avoid contamination of the back and that it is applied only when it is necessary to stick out the tongue for commercial reasons. This was verified by the EIO on 04-17-2023.

Quality Assurance Manager conducts training for supervisors, managers and quality monitors.

The JEIO trains MVIOs offline regarding the verification of procedures for process control and sanitary dressing (**Annex No. 11**).



- 3. On three different operational sanitation records, government inspection personnel did not identify that corrective actions were not documented in response to deficiencies identified.**

**Response:**

Root Cause:

Lack of training for quality assurance monitors on the activities that need to be recorded on their respective registry form.

Corrective action:

The Head of Quality Assurance is requested to review the affected internal records and train the quality monitors in the correct documentation of the corrective actions carried out in the Pre-operational Cleaning and Sanitation Control Record (R-AC-02).

Preventive action:

The Head of Quality Assurance trains quality monitors in the use of records. This was verified by the EIO on 04-17-2023.

The JEIO trains MVIOS offline regarding System Verification for Food Safety of an Establishment (**Annex No. 11**).

- 4. Government inspection personnel did not identify multiple CCP monitoring records for zero tolerance that did not include the time of event.**

**Response:**

Root Cause:

The quality monitor is unable to complete the form in a timely manner to generate the record.

Corrective action:

The Head of Quality Assurance is requested to review the affected internal records and train the quality monitors in the correct documentation of the time of the events carried out during the CCP monitoring of Zero-Tolerance Contamination on carcasses (registry form R-AC-22).

Preventive action:

The Head of Quality Assurance trains the quality monitors to record each monitored carcass one by one. This was verified by the EIO on 04-17-2023.

JEIO trains MVIOS offline on Verification of Control Procedures for Fecal Material, Intake and Milk in Slaughterhouse Operations (**Annex No. 11**).

- 5. Government inspection personnel did not identify multiple CCP verification records for direct observation for zero tolerance that did not include the result of the verification activity.**

**Response:**

Root Cause:

Each time a field verification of the CCPs monitoring operation is carried out, it must be indicated whether or not there are observations. If there were any, the design of the form indicated that they should be recorded, but not in the case in which there were no observations, which is why it is a flaw in the design of the record.

Corrective action:

The Head of Quality Assurance is requested to review the affected internal records and train the quality monitors in the correct documentation of the results obtained after the verification activity in the Channel Monitoring form for Zero Contamination Tolerance (R-AC-22).

Preventive action:

The Head of Quality Assurance trains quality monitors so that in the event that there are no observations, a line is recorded, indicating this situation. This was verified by the EIO on 04-17-2023.

The JEIO trains MVIOS offline on Verification of Control Procedures for Fecal Material, Intake and Milk in Slaughterhouse Operations (**Annex No. 11**).

- 6. Government inspection personnel did not identify standing water that was adjacent to carcasses on the trimming stand in the cutting room. No direct product contamination was observed.**

**Response:**

Root Cause:

Deficiency in the maintenance program, which does not consider water ponding.

Corrective action:

The establishment is requested to remove the standing water and repair the root cause of the ponding. Subsequently, the EIO verifies that the standing water was immediately removed.

Preventive action:

The metallic ladder is repaired and its parts are adjusted so that it does not accumulate water. Ponding will be controlled via operational cleaning. The Head of Quality Assurance trains quality monitors to verify the absence of ponding and the Operations Control Record (R-AC-19) version 21 was modified. This was verified by the EIO on 04-28-2023.

The JEIO trains MVIOS offline regarding System Verification for Food Safety of an Establishment (**Annex No. 11**).

**7. Government inspection personnel did not identify standing water at the entrance to carcass chiller from slaughter no direct product contamination was observed.**

**Response:**

Root Cause:

Deficiency in the establishment maintenance program. A water leak was not considered in the sink of the place.

Corrective action:

The establishment is required to remove standing water and repair the root cause of the ponding (sink repair). Subsequently, the EIO verifies that the pooled water was immediately removed.

Preventive action:

The water ponds are controlled via operational cleaning and the Operations Control record (R-AC-19) version 19 was modified. The Head of Quality Assurance trains the quality monitors to verify this aspect of operational cleaning. This was verified by the EIO on 04-28-2023.

The JEIO trains MVIOS offline on System Verification for Food Safety of an establishment (**Annex No. 11**).

- 8. Government inspection personnel did not identify that approximately 40 lambs were observed in a holding pen with no access to water. The establishment took immediate corrective action by transferring the lambs into a different pen with water available.**

**Response:**

Root Cause:

Lack of training of pen managers in animal welfare. It should be reinforced that access to water by animals must be permanent, regardless of the waiting time.

Corrective action:

The establishment is required to provide observed lambs with access to water in holding pens. Subsequently, the EIO verifies that the affected animals were immediately transferred to a pen with water availability in drinkers.

Preventive action:

Quality Monitor trains pen managers on access to water and animal housing conditions. This was verified by the EIO on 04-28-2023. The JEIO trains MVIOS offline regarding Humane Slaughter and Livestock Slaughter (**Annex No. 11**).

## **VII. Frigorífico Patagonia S.A. (Official LEEPP Registration Number 12-10)**

- 1. At the reinspection station for carcasses with contamination and pathology, government inspection personnel did not identify potentially contaminated carcasses that were contacting each other in addition to a handwashing sink, providing a risk of cross contamination.**

**Response:**

Root Cause:

At the time of the inspection, the contaminated carcass was inappropriately moved by the employee, who replaced the employee who usually works in that operational step, which produced an error in the movement of the carcasses.

Corrective action:

Carcasses are arranged on the reinspection rail so as not to touch each other.

The affected carcass is purged and the sink is moved to another place so that it does not touch the product.

Preventive action:

Personnel working in the area were trained to correctly carry out the operational step, handling and distribution of carcasses on the reinspection rail, and personnel were also instructed so that carcasses do not come up against structures, thus avoiding product contamination. This was verified by the EIO on 04-10-2023.

**2. Government inspection personnel did not verify that the establishment did not identify physical hazards at the weasand banding step, where plastic weasand clips are introduced.**

**Response:**

Root Cause:

The establishment did not list the plastic clip as a physical hazard. This product is detailed in the flow chart, so it was not considered a danger *per se*.

Corrective action:

A comprehensive verification of the HACCP plan was carried out to detect deficiencies with respect to the requirements established in Exempt Resolution No. 1045/2013. The clip input is incorporated into the risk matrix, evaluating severity and probability of hazard. This was verified by the EIO on 05-17-2023.

Preventive action:

A periodic review of plant procedures is performed. Update of the verification program designed by the EIO.

**3. Government inspection personnel did not identify gaps on both sides of the door to the loading dock, leading to the exterior premises.**

**Response:**

Root Cause:

The bellows of the loading dock door had been overlapped and poorly closed, in addition to presenting a crack in the rubber bands of this, which generated the entry of light from the outside.

Corrective action:

Loading dock area was sealed and the deteriorated rubber was changed.

Preventive action:

Maintenance personnel were trained on correct verification of the preventive maintenance program. This was verified by the EIO on 04-06-2023.

**4. Government inspection personnel did not identify beaded condensation at the exit to chiller #3. No product was observed to be affected by the condensation. The condensation was in a doorway where boxed product is transported to the loading dock.**

**Response:**

Root Cause:

At the time of entering the chambers, personnel from the correspondent area had carried out a product movement in order to prepare a shipment. The door was left open for the forklift to pass through, which caused a temperature change that generated condensation above the door between the loading dock and the maintenance chamber.

The area was protected by plastic slats, therefore, the place where the condensation occurred did not contain the finished product.

Corrective action:

The affected area at the entrance to the maintenance chambers is cleaned and sanitized.

Preventive action:

Area supervisor trains the personnel in charge in handling condensation and cleaning it. This was verified by the EIO on 04-06-2023.

JEIO increases the frequency of verification of these structures, reviewing each time a shipment is made.

- 5. Government inspection personnel did not identify approximately 15 lambs in a holding pen with no access to water. The establishment took immediate corrective action by transferring the lambs into a different pen with water available.**

**Response:**

Root Cause:

The aforementioned corral was used as a waiting corral, since the animals had to be accommodated and the order of the batches for slaughter, which led to their waiting in the corral.

Corrective action:

Animals are immediately moved to a holding pen with available water.

Preventive action:

The staff is reinforced that during recess hours the permanence of animals in this area is not allowed. Drinkers are installed in all pens.

This was verified by the EIO on 04-06-2023.

**VIII. Agroindustrial El Paico S.A. (Official LEEPP Registration Number 13-07)**

- 1. The establishment was documenting an average temperature of the 10 carcasses measured during monitoring of CCP2 (carcass temperature with a critical limit of  $\leq 4^{\circ}\text{C}$ ) rather than the specific temperature for each carcass.**

**Response:**

Root cause:

The CCP monitoring procedure indicates that the average temperature obtained from the 10 measurements must be recorded on the registry, but not each individual measurement.

Corrective action:

The CCP description in the HACCP plan (HACCP-FA-PO), monitoring procedure (I-DAC-09) and the registry form (RM.02.15) were updated according to the audit observations, so that the monitor performing the activity must record each individual temperature. This was verified by the EIO on site.

- 2. The establishment did not report the percentage of retained water on the product label for non-marinated products. A review of the establishment's protocol for the analysis of retained water resulting from the chilling process indicated the following values: entire carcass (4.83%); whole breast (3.87%); whole wing (4.13%); drumstick (3.89%).**

**Response:**

Root cause:

Although the label on marinated products indicated the percentage of solution added, non-marinated products did not state the percentage of retained water, even when water was used during the post-evisceration process, which could potentially cause water retention in the final product.

Corrective action:

The establishment will determine the percentage of retained water in non-marinated products through the protocol I-TRPO-10, considering 9 CFR § 441.10 requirements. Also, the HACCP-CR-PO plan was updated to include U.S. labeling requirements in point 1.1.1.2.

Preventive action:

The EIO will verify the aforementioned corrective actions as instructed in circular No. 647/2023. Labels will be updated to include a retained water percentage statement, which will be verified by EIO starting October 2<sup>nd</sup>, 2023. These changes will also be verified as part of the product certification procedures for each shipment, as instructed in circular No. 360/2019.