USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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Washington, D.C.
20250

JUN 0 2 2022

Dr. José Carlos Martín Camperchioli
President
SENACSA
Avda. Ciencias Veterinarias No. 265
Asunción, Paraguay

Dear Dr. Martín,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a reinstatement of equivalence verification audit of Paraguay's meat inspection system from November 1 to November 17, 2021. Enclosed is a copy of the final audit report. The comments and corrective actions received from the Government of Paraguay are included as an attachment to the report.

FSIS plans to conduct a targeted onsite verification audit to verify the implementation of Paraguay's corrective actions outlined in your March 15, 2022, and May 11, 2022, submissions. Specifically, the scope of the upcoming FSIS audit will focus solely on the implementation of the corrective actions taken in response to FSIS' November 2021 audit findings. Based on the written documentation provided by the National Service for Quality and Animal Health (Servicio Nacional de Calidad y Salud Animal [SENACSA]), FSIS concludes that Paraguay's documented meat inspection system appears to be providing an equivalent level of public health protection as the FSIS inspection system. However, the targeted on-site verification audit is critical to verify full implementation of the written controls within your country's meat inspection system.

FSIS will verify SENACSA's implementation of specific corrective actions related to the audit findings listed below:

- SENACSA did not implement its enforcement program at an establishment failing to take required corrective actions, including reassessing the adequacy of its Hazard Analysis and Critical Control Point (HACCP) plan or making changes to its production process to address repeated positive Shiga toxin-producing *Escherichia coli* (STEC) samples.

- SENACSA did not implement its requirement that would ensure that livestock carcasses and parts subjected to routine chemical residue testing and production lots subjected to official STEC sampling be precluded from export

to the United States until receipt of acceptable testing results, should Paraguay become eligible to export raw intact beef products to the United States.

- SENACSA did not ensure that laboratories conducting official government analyses of microbiological and chemical residue samples report the results to SENACSA officials in a timely manner.

- SENACSA did not ensure that its official microbiology laboratory (General Directorate of Laboratories - DIGELAB) personnel calibrate the equipment at the frequency required by the laboratory's written quality assurance program.

- Government inspection personnel did not ensure that the HACCP plans' design at establishments complied with SENACSA's requirements for HACCP plan content.

- Government inspection personnel did not ensure that establishments' implementation of their HACCP plans complied with SENACSA's requirements for HACCP plan execution.

- Government inspection personnel did not ensure that establishments' HACCP records complied with SENACSA's requirements for HACCP recordkeeping.

- Government inspection personnel did not ensure that establishments' hazard analyses, flow charts, and supporting documentation complied with SENACSA's requirements.

- DIGELAB personnel were not analyzing the entire 60 trim pieces of the N60 sample submitted to the laboratory when the sample portion collected is greater than the size of the prescribed laboratory test portion of 375 grams.

- Government inspection personnel were not collecting *Salmonella* samples from chilled beef carcasses as specified in SENACSA's Microbiological Control Program.

We appreciate SENACSA's continued commitment to resolve these issues. FSIS will coordinate with SENACSA to establish dates for the targeted on-site verification audit. If you have any questions, please feel free to reach out by e-mail to the Office of International Coordination at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN PARAGUAY

NOVEMBER 1–17, 2021

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING RAW INTACT BEEF PRODUCTS

INTENDED FOR EXPORT TO THE UNITED STATES OF AMERICA

June 2, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a reinstatement-of-equivalence verification audit of Paraguay conducted by the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) from November 1 to17, 2021. Paraguay had been previously eligible to export meat products to the United States; however, in 1997, FSIS revoked the country's equivalence because it had not implemented requirements equivalent to those established in the FSIS' Pathogen Reduction (PR)/Hazard Analysis and Critical Control Points (HACCP) Systems final rule.

The purpose of the audit was to verify that Paraguay's food safety inspection system governing raw intact beef products is being implemented as documented in the Self-Reporting Tool (SRT) and is functioning in a manner equivalent to that of the United States, producing products which are safe, wholesome, unadulterated, and correctly labeled and packaged.

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

The Central Competent Authority – the National Service for Quality and Animal Health (Servicio Nacional de Calidad y Salud Animal [SENACSA]) - has required establishments that will be certified as eligible to export raw intact beef products to the United States to implement sanitation and HACCP requirements to ensure the safety of their products. In addition, SENACSA has implemented chemical residue and microbiological testing programs to verify its food safety inspection system. FSIS auditors identified the following findings in three of the six equivalence components:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- SENACSA did not implement its enforcement program at an establishment failing to take required corrective actions including reassessing the adequacy of its HACCP plan or making changes to its production process to address repeated positive Shiga toxin-producing *Escherichia coli* (STEC) samples.
- SENACSA did not implement its requirement that would ensure that livestock carcasses and parts subjected to routine chemical residue testing and production lots subjected to official STEC sampling be precluded from export to the United States until receipt of acceptable testing results, should Paraguay become eligible to export raw intact beef products to the United States.
- SENACSA did not ensure that laboratories conducting official government analyses of microbiological and chemical residue samples report the results to SENACSA officials in a timely manner.
- SENACSA did not ensure that its official microbiology laboratory (General Directorate of Laboratories - DIGELAB) personnel calibrate the equipment at the frequency required by the laboratory's written quality assurance program.

GOVERNMENT HACCP SYSTEM

- Government inspection personnel did not ensure that the HACCP plans' design at establishments complied with SENACSA's requirements for HACCP plan content.
- Government inspection personnel did not ensure that establishments' implementation of their HACCP plans complied with SENACSA's requirements for HACCP plan execution.
- Government inspection personnel did not ensure that establishments' HACCP records complied with SENACSA's requirements for HACCP recordkeeping.
- Government inspection personnel did not ensure that establishments' hazard analyses, flow charts, and supporting documentation complied with SENACSA's requirements.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- DIGELAB personnel were not analyzing all 60 trim pieces of the N60 sample submitted to the laboratory when the sample portion collected is greater than the size of the prescribed laboratory test portion.
- Government inspection personnel were not collecting *Salmonella* samples from chilled beef carcasses as specified in SENACSA's Microbiological Control Program.

The findings related to government oversight, government HACCP system and government microbiological testing programs will require SENACSA to submit revised procedures and laboratory methods for equivalence review before FSIS can allow the import of raw intact beef products. As part of the equivalence review process, FSIS will consider whether an additional on-site audit is necessary in order to verify the CCA's ability to implement the revised procedures and methods once they are submitted.

An exit meeting was held November 17, 2021, by videoconference with SENACSA. During the exit meeting, SENACSA committed to address the findings as presented. FSIS will evaluate the adequacy of SENACSA's proposed corrective actions once received and base future equivalence verification activities on the information provided. FSIS requests a written response within 60 calendar days of the date of the audit report.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an audit of Paraguay's food safety inspection system from November 1–17, 2021. The audit began with an entrance meeting held November 1, 2021, in Asunción, Paraguay, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the National Service for Quality and Animal Health (Servicio Nacional de Calidad y Salud Animal – [SENACSA]). SENACSA representatives accompanied the FSIS auditors throughout the entire onsite audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a reinstatement-of-equivalence verification audit. The audit objective was to verify that Paraguay's food safety inspection system governing raw intact beef products is being implemented as documented in the Self-Reporting Tool (SRT) and is functioning in a manner equivalent to that of the United States, producing products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

The USDA's Animal and Plant Health Inspection Service (APHIS) currently recognizes Paraguay as affected with foot-and-mouth disease, and with negligible risk for bovine spongiform encephalopathy (BSE).

Prior to the onsite reinstatement of equivalence verification audit, FSIS reviewed and analyzed Paraguay's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Paraguay's food safety inspection system governing raw intact beef products is being implemented as documented in the country's SRT responses and supporting documentation.

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 SENACSA headquarters and at nine local inspection offices within the establishments. The FSIS auditors evaluated the implementation of controls that ensure the national system of inspection, verification, and enforcement is being implemented as documented in their SRT and supporting documentation.

The FSIS auditors visited nine beef slaughter and processing establishments that have requested certification from SENACSA to export raw intact beef products to the United States. During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety. The FSIS auditors assessed SENACSA'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.

The FSIS auditors also visited one government microbiological laboratory and two private chemical residue laboratories that analyze official samples to verify that these laboratories can provide adequate technical support to the food safety inspection system.

Competent Authority Visits	#	Locations
Central Competent Authority	1	• SENACSA headquarters, Asunción
Laboratories	3	• The General Directorate of Laboratories [DIGELAB], Microbiological section (government), Asunción • Microbióticos Paraguay, S.R.L., Residue section (private), Asunción • EcoNatura, Residue section (private), Asunción
Beef slaughter and processing establishments	9	• Establishment No. 1, Frigorífico Neuland, Villa Hayes • Establishment No. 2, Matadero Frigorífico Frigomerc S.A., Asunción • Establishment No. 3, Matadero Frigorífico San Antonio, San Antonio • Establishment No. 9, Frigochorti, Pozo Grande • Establishment No. 10, Frigorífico Frigochaco, Limpio • Establishment No. 15, Frigorífico Norte S.A., Pedro Juan Caballero, Amambay • Establishment No. 17, Frigorífico Guarani S.A.C.I., Asunción • Establishment No. 23, Beef Paraguay S.A., Belén, Concepción • Establishment No. 38, Frigorífico Concepción, Concepción

FSIS performed the audit to verify that the food safety inspection system meets 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 Humane Methods of Livestock Slaughter Act (7.U.S.C. 1901, et seq.); and
- The Meat Inspection Regulations (9 CFR Part 301 to the end).

The audit standards applied during the review of Paraguay's food safety inspection system for raw intact beef products included all applicable legislation originally determined by FSIS as equivalent as part of the review process.

III. BACKGROUND

Paraguay was previously eligible to export beef products to the United States. In 1996, FSIS published the Final Rule requiring Pathogen Reduction (PR)/Hazard Analysis and Critical Control Point (HACCP) systems in all domestic meat and poultry establishments. On September 5, 1997, FSIS notified SENACSA that Paraguay was no longer eligible to export beef products to the United States because the country did not implement equivalent PR/HACCP requirements, specifically Sanitation Standard Operating Procedures (Sanitation SOPs) and generic *Escherichia coli* (*E. coli*) testing programs.

On November 12, 2015, SENACSA officials requested the reinstatement of equivalence for raw intact beef products. On March 7, 2019, Paraguay submitted responses and supporting documents as part of its SRT. On January 29, 2021, FSIS completed the review of Paraguay's SRT responses and the corresponding supporting documentation and reached a tentative determination pending an onsite audit by FSIS that Paraguay's food safety inspection system as documented in the SRT is equivalent to that of FSIS' inspection system.

FSIS' final audit report on Paraguay's food safety inspection system will be available on the FSIS website at https://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.

In 2004, the Paraguayan government created SENACSA through Law No. 2426/04. SENACSA is the CCA of Paraguay and its mission is to promote the safety and quality of products and by-products of animal origin. SENACSA is solely responsible for the preparation, regulation, coordination, implementation, and monitoring of the national policy on animal health, food safety, and quality management. The FSIS auditors confirmed through document review and interviews that SENACSA has the legal authority and the responsibility to issue, implement, and enforce inspection requirements in accordance with Resolution No. 277/83.

The administrative and technical structure of SENACSA includes the Presidency, 11 Supporting Units, and 5 General Directorates (Law No. 2426/04). The General Directorates play a primary role in the administration and oversight of the meat inspection system and consist of the:

- General Directorate of Quality and Safety of Products of Animal Origin (Dirección General de Calidad e Inocuidad de Productos de Origen Animal - DIGECIPOA), which is responsible for the preparation, proposal and management of quality control and safety

programs for products, by-products, and edible and non-edible derivatives of animal origin;

- General Directorate of Laboratories (Dirección General de Laboratorios - DIGELAB) whose role is to prepare, propose, and manage the necessary laboratory procedures for the diagnosis of animal diseases, the safetyof products, by-products, and derivatives of animal origin as well as the quality control of supplies and products for veterinary use;
- General Directorate of Technical Services (Dirección General de Servicios Técnicos - DIGESETEC) which is vested with the authority to prepare, propose, and manage measures to products and supplies for veterinary use and animal feed, as well as support for the institutional management system;
- General Directorate of Animal Health, Identity and Traceability (Dirección General de Sanidad Animal, Identidad y Trazabilidad - DIGESIT), which is responsible for the preparation, proposal, and management of sanitary measures for the protection, maintenance, and improvement ofanimal health; and
- General Directorate of Administration and Finance (Dirección General de Administración y Finanzas - DIGEAF) which manages the physical and financial resources assigned to SENACSA.

The FSIS auditors verified that each slaughterhouse has an official veterinary inspection (Inspección Veterinaria Oficial - IVO) team, which consists of a Chief Veterinary Inspector (Chief VI), a Deputy Chief Veterinary Inspector (Deputy Chief VI), Veterinary Inspectors (VI), and Veterinary Assistants (VA). Law No. 2426/04 provides the IVO team (hereinafter referred to as government inspection personnel [GIP]) with the authority to verify compliance with SENACSA's regulatory requirements at the slaughter and processing establishments. Resolution No. 277/83 provides GIP with the authority to take actions, such as attach a rejected tag to address insanitary conditions within the establishments. In addition, should GIP observe insanitary conditions that could lead to product contamination and/or adulteration, inhumane handling or slaughter of animals, failure by the establishment to destroy condemned materials, assault, intimidation of GIP or interference with their official duties, Resolution No. 277/83 provides GIP with the authority to withdraw or suspend inspection assignments at authorized establishments. Resolution No. 689/06 describes the requirements for establishments to take appropriate corrective or preventive actions to prevent direct contamination or spoilage of food products. Through direct observation, interviews and records review, the FSIS auditors verified GIP performing daily inspection and oversight of establishments' food safety systems as described in the Manual of the Functions and Procedures of the IVO (MIVO).

Resolution No. 689/06 provides SENACSA with the legal authority to suspend production processes, retain affected food products, and cancel the HACCP recognition resolution granted to an approved establishment in cases of major violations such as partial implementation or noncompliance with the HACCP plan, production of food that is unfit for human consumption, absence of records, false food labeling or records, failure to take required corrective action, or repeated (two consecutive times) minor violations in a period of no more than 60 days. Despite SENACSA having these additional enforcement measures at its disposal, the FSIS auditors found that:

- SENACSA did not implement its enforcement program at an establishment failing to take required corrective actions including reassessing the adequacy of its HACCP plan or making changes to its production process after repeated positive STEC samples.

As noted earlier, Law No. 2426/04 provides SENACSA with the legal authority and responsibility to verify compliance with regulatory requirements at authorized establishments. Resolution No. 277/83 defines adulterated products as products that bear or contain any poisonous or deleterious substances that may render the products injurious to health; products that consist of any dirty, putrid, or decomposed substance that make them unhealthy or unfit for human consumption; or products that were prepared, packaged, or stored under insanitary conditions. To ensure product is not adulterated, GIP perform daily verification and oversight tasks in accordance with SENACSA's requirements. When regulatory requirements are not met, the Chief VI has the authority to stop production, notify the establishment of the noncompliance, and demand immediate corrective actions and preventive measures.

Resolution No. 4757/13 sets the requirements for the labeling and packaging of bovine meat and outlines the enforcement actions SENACSA may take in the event of noncompliance with the labeling requirements. Resolution No. 277/83 defines misbranded products as products bearing false or misleading labels; products that are sold under another name; products that are an imitation of another product without any disclosure of such information on the product label; products whose container (package) was manufactured, shaped, or filled in a misleading or erroneous manner; or products that do not bear the official inspection legend or do not comply with the established regulations. SENACSA's Labeling Control (MIVO-FOR-23) document assigns the task of verifying product labels to the VI or designee at least once a week during production. The FSIS auditors observed the VIs perform label verification, which consisted of examining the labels of ten randomly selected boxes of different finished products, covering different markets.

SENACSA is authorized to issue animal health and quality certifications related to exports and maintains the control of exports of animal products and by-products, in accordance with Law No. 2426/04. The issuance of export certificates to foreign countries is performed using the Single Export Window (Ventana Única de Exportación – VUE*)* computer system. The purpose of the VUE system is to simplify the management of exports and to issue health certificates that are numbered, ink-sealed and embossed. The Chief VI records the unique seal numbers into the VUE system after closing each container at the establishment of origin. When not in use, Resolution No. 277/83 requires that official stamps, seals, and security paper be locked in the local government inspection office. Through interviews with GIP, the FSIS auditors ascertained that the Chief VI will be responsible for certifying raw beef products destined for export to the United States and for maintaining control over the export stamps, seals, and security papers, as described in the Manual of Procedures – Coordination of Certification DIGECIPOA (MPCC).

The FSIS auditors interviewed GIP and confirmed they are aware of the provisions of Resolution No. 1852/19, which approves the Procedure of Shipment Control (MIVO-PCE-10) and requires that GIP verify the physical and safety characteristics of products destined for export. The verification activity consists of checking the product temperature, the condition of the containers, and the product labels; and then documenting the findings on an official form. The Verification

of Processes Before Shipment (MIVO-FOR-10.1) procedure assigns the responsibility for performing and documenting this verification activity for exports to the Chief VI or a VI. In doing so, the Chief VI or VI is to review the documents of origin of the animals, the official verification records associated with the production process of the products being exported, and the results of both establishment and official microbiological and chemical residue testing. In this regard, the FSIS auditors found that:

- SENACSA did not implement its requirement that would ensure that livestock carcasses and parts subjected to routine chemical residue testing and production lots subjected to official STEC sampling would be precluded from export to the United States until receipt of acceptable testing results, should Paraguay become eligible to export raw intact beef products to the United States.

SENACSA is authorized to seize products that do not meet its sanitary requirements, in accordance with Law No. 2426/04. The Manual of Good Manufacturing Practices in the Production and Handling of Fresh Meat (MGMP) requires establishments approved for export to prepare and maintain written procedures for the recall of any contaminated and/or adulterated meat product produced and shipped by the establishment. The MGMP also requires written procedures that describe how the establishment will decide whether to conduct a product recall, and how the establishment will implement the recall. Additionally, DIGECIPOA Notice No. 1/14 requires that each establishment develop mock recall procedures, conduct mock recalls annually and notify SENACSA within 24 hours of the recall simulation. The FSIS auditors verified that each establishment has developed and implemented mock recall procedures and confirmed with SENACSA officials that, if adulterated and mislabeled products were shipped to the United States, they would inform FSIS within 24 hours.

Resolution No. 873/18 prohibits the entry of cattle and meat products from foreign countries to slaughter establishments authorized for export by SENACSA. The FSIS auditors verified through document review and interview of SENACSA officials and establishments' operators that all cattle and meat used in establishments that will be certified as eligible to export to the United States are from Paraguay. The FSIS auditors confirmed that on a daily basis, for every load of animals, before allowing them to be unloaded, a VI reviews the certificate of origin to ensure that the animals were born and raised in Paraguay.

The FSIS auditors verified all establishments that intend to export meat products to the United States are held to the same laws, regulations and policies emanating from SENACSA headquarters, especially those from DIGECIPOA. In addition, at the central level, the FSIS auditors verified that the Coordinator of Export Establishments (a veterinarian appointed by a SENACSA Resolution) is tasked with ensuring compliance with current national and international regulations related to the production of edible meat products at all establishments that plan to export meat products to the United States. Furthermore, as noted earlier, the auditors ascertained the assignment at each audited establishment of an official veterinary inspection team made of a Chief VI, a Deputy Chief VI, a VI and VAs who perform daily inspection verification activities from the receiving of the livestock to the shipping of the final product.

The MIVO states that the Chief VI is a veterinary professional appointed by a SENACSA Resolution at the proposal of DIGECIPOA and is in charge of animal health and animal welfare as well as the quality and safety of meat products and meat by-products. The Chief VI is also responsible for all documentation, stamps, seals, and signature of health certificates.

The Deputy Chief VI, who reports to the Chief VI, must also be a SENACSA appointee and verifies that incoming animals have the required documentation before being unloaded; conducts ante-mortem inspection on all animals destined for slaughter; supervises post-mortem inspection activities; controls the collection of tissues, organs or meat products for various laboratory analyses; ensures that animals are properly slaughtered; performs necropsies on animals that died of unknown causes; and collects biological materials for laboratory analysis. The MIVO requires the Deputy Chief VI to report to the Chief Veterinary Inspectorate any suspicious cases of contagious infectious diseases so that appropriate isolation, inspection, and disinfection measures are implemented.

As a SENACSA-appointed veterinary professional, the VI works under the supervision of the Chief VI. The VAs are not appointed but hired by and paid by the national government to perform post-mortem inspection on all carcasses and parts. VAs may also assist the Deputy Chief VI during ante-mortem inspection; comply with the directives of the Chief VI, Deputy Chief VI and VIs; notify the veterinary staff of any unfamiliar signs of disease or injuries; assist the veterinary staff in official verification activities; inform the Chief VI or Deputy Chief VI of any abnormality in terms of infrastructure, sanitary condition of the animals and/or carcasses; and perform administrative functions, as needed. The FSIS auditors verified through interviews, observation of their activities, and document review that GIP will be directly responsible for ensuring that FSIS requirements are implemented daily at all establishments that intend to produce products for export to the United States.

As noted earlier, SENACSA registers, authorizes, supervises, and would de-certify establishments that slaughter livestock, and process, condition, store, transport, market, or export meat products. To certify an establishment as meeting United States requirements, SENACSA will follow a two-pronged procedure: (1) at the establishment level and (2) at the DIGECIPOA level:

1. The establishment has to develop and implement Good Manufacturing Practices (GMP), Sanitation SOPs, and a HACCP system (hereinafter referred to as the programs) and submit them to the assigned Chief VI at the establishment, as required by SENACSA. The Chief VI then reviews and evaluates the programs and verifies implementation to determine compliance with regulatory requirements. If the programs or the implementation are not compliant with SENACSA's requirements, then the Chief VI documents the noncompliance and returns the application package to the establishment for corrective actions and resubmission. If the programs and their execution meet SENACSA's requirements, the Chief VI transmits the application to DIGECIPOA's Department of Safety Management (DSM) with a request for the approval and recognition of the establishment's programs.
2. At the DIGECIPOA level, DSM officials conduct a final document review of the establishment's programs and issue a certificate of approval and recognition if the programs are compliant. Should DSM officials determine that the establishment's programs do not meet regulatory requirements, they document the noncompliance and

return the package to the Chief VI for the establishment to take corrective actions and resubmit its application package. Once the establishment and its programs are approved, they will be added to a list of establishments that will be eligible to export raw beef products to the United States. The list will be communicated to FSIS by the SENACSA presidency. The FSIS auditors reviewed the certification process of an establishment that has been recently approved for export (should Paraguay become equivalent) and found that SENACSA officials followed the certification procedure as written.

The Director General of DIGECIPOA is responsible for collecting and disseminating information related to FSIS requirements to GIP and the establishments. The FSIS auditors reviewed communications that were sent by DIGECIPOA officials to GIP about United States import requirements. The Director General assigns a person with the responsibility of monitoring the FSIS and APHIS websites for any change or update of requirements. Any modification in FSIS' or APHIS' requirements is immediately communicated by e-mail to the Chief VIs who, in turn, inform the establishment officials.

The FSIS auditors verified that GIP possessed the appropriate educational credentials, training, and experience to carry out their inspection tasks. All veterinary staff stationed at establishments must have a Doctor of Veterinary Medicine or equivalent degree, and the VAs have specialized experience or education that allows them to perform their assigned duties. The FSIS auditors also verified through monthly payroll documents and government-issued identification cards that all GIP assigned to establishments intending to export to the United States are government employees who are hired and paid directly by the national government of Paraguay.

The FSIS auditors reviewed the annual performance appraisals of GIP and confirmed that their performance is assessed against pre-established performance standards. Law No. 2426/04 allows SENACSA to appoint, promote, transfer, and remove employees, apply disciplinary sanction to them and accept resignations from them as well.

The FSIS auditors verified SENACSA has implemented and conducted initial and ongoing training programs intended to ensure that GIP are aware of FSIS import regulations and of Paraguay's regulations for beef export to the United States. The FSIS auditors verified the training records of GIP and observed the VAs while they were performing their inspection activities. Each Chief VI is responsible for training VAs under their supervision. The FSIS auditors reviewed the recent training provided by SENACSA, which included requirements for Sanitation SOPs; GMPs; HACCP; ante-mortem and post-mortem inspection; and sample collection of beef manufacturing trimmings according to the N60 methodology; sample collection for *Salmonella*; and sample collection for chemical residue testing. The FSIS auditors verified that training materials (including program updates in inspection-related issues and procedures) and training participation records were maintained both at SENACSA headquarters and at government offices at the audited establishments.

Law No. 1626/04 and Resolution No. 1479/20 describe the ethical rules and values that apply to all of SENACSA's employees, including the prevention of conflict of interest. The FSIS auditors confirmed that GIP were solely acting in the interest of the public and found no cases of conflict of interest at the sites they visited.

The FSIS auditors observed the slaughter process from ante-mortem inspection to deboning, packaging, and shipping of the final product; and confirmed that government inspection occurs continuously during slaughter operations and at least once per production shift during the processing of raw beef products. SENACSA officials confirmed to the FSIS auditors that they will maintain the same level of staffing for products destined for export to the United States if they are granted equivalence. GIP are present at establishments during operating hours.

Through document review, interviews and observation, the FSIS auditors ascertained that every establishment that intends to export raw beef products to the United States is included in the official government chemical residue and microbiological sampling and testing programs. The FSIS auditors confirmed that GIP receive weekly or monthly e-mails from SENACSA headquarters directing them to collect the required chemical residue or microbiological samples.

The FSIS auditors also verified through record review and interviews that the policy of the SENACSA's DIGELAB is to have a quality management system using standards consistent with International Organization for Standardization (ISO) 17025, General Requirements for the Competence of Testing and Calibration Laboratories and on the Criteria and Policies of the National Accreditation Body (Organismo Nacional de Acreditación – ONA) as described in the General Certification of Accreditation (RG 001*)*. ONA is the national accreditation body of Paraguay. For this purpose, ONA has a Quality Management System implemented under the ISO/International Electrotechnical Commission (IEC) 17025 standard in force in all the laboratories that compose it, ensuring the quality of its tests, having competent and updated personnel on a permanent basis; and using validated documentation and methodology, in addition to adequate equipment and appropriate conditions of maintenance and calibration. During the visit of DIGELAB, the FSIS auditors found that:

- SENACSA did not ensure that DIGELAB personnel calibrate the laboratory equipment at the frequency required by the laboratory's written quality assurance program.

The FSIS auditors confirmed that, as required by law, SENACSA conducts annual laboratory quality system audits of DIGELAB, of the in-country private chemical residue testing laboratories (Econatura and Microbióticos) and of the foreign private chemical residue laboratory (Laboratorio Litoral S.A., Argentina). The FSIS auditors reviewed the annual audit reports issued by SENACSA auditors and confirmed that they were conducted at the established frequency. Moreover, the FSIS auditors were provided with and reviewed copies of the contractual agreements between SENACSA and the private laboratories and confirmed that the contracts outlined SENACSA's expectations and the obligations of the private laboratories.

The FSIS auditors verified that DIGELAB ensures the competence of contract laboratories in accordance with its Annual Training Program (RG-52), including the participation in laboratory proficiency testing (PT). The FSIS auditors verified that PTs are sourced from ISO 17034- or 17043-accredited reference material or PT providers.

The FSIS auditors confirmed that DIGELAB maintains a local electronic quality assurance system as well as a paper registry, and that traceability is maintained from sample receipt to

results reporting by laboratory personnel. DIGELAB, Econatura, and Microbióticos are externally accredited to ISO 17025:2017 standards by ONA; and each laboratory performs their own internal quality system audits. DIGELAB's *Salmonella* method is part of their ONA scope of accreditation, and they are pursuing the placement of their STEC detection method into their ONA scope of accreditation. Litoral laboratory (Laboratorio Litoral S.A.) in Argentina is accredited to the ISO 17025:2017 standard by National Accrediting Body of Argentina (Organismo Argentino de Acreditación – OAA). The FSIS auditors confirmed that violative or unacceptable results are not resampled or retested by the laboratories that analyze official samples.

The FSIS auditors verified that DIGELAB and the private laboratories directly report all positive official test results to SENACSA via e-mail while a VI or designee picks up all negative results directly from the laboratories. The FSIS auditors found that:

- SENACSA did not ensure that laboratories conducting official government analyses of microbiological and chemical residue samples report the results to SENACSA officials in a timely manner.

While the meat inspection system is organized and administered by the national government of Paraguay, the FSIS auditors found deficiencies related to the enforcement of SENACSA's requirements regarding repeated positive STEC samples at an establishment and a failure to implement the test and hold procedures for carcasses and production lots subjected to official chemical residue and microbiological sampling. Furthermore, DIGELAB is not implementing its quality assurance program, as required. The nature of these deficiencies indicates a need for SENACSA to continue to strengthen its oversight of its meat inspection system.

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 humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and 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 verified that Deputy Chief VIs, with the support of VAs, are required to conduct ante-mortem inspection daily, within 24 hours of the animals arriving at the slaughterhouse and less than 24 hours before slaughter, in accordance with the MIVO. The FSIS auditors confirmed that the Deputy Chief VI reviews the Official Animal Transit Certificate, the Guide for the Movement of Cattle, and the Certificate of Cleaning and Disinfection of Livestock Transportation Vehicle before allowing for the unloading of the animals, as required by the MIVO. Once those documents are found compliant, GIP observe the unloading of the animals and their movement into clean pens with access to water. Each establishment is required to have

a platform and adequate lighting for ante-mortem inspection, a designated isolation pen for further examination of suspect animals, an emergency slaughter room with the required equipment, and a digester or an incinerator. The FSIS auditors observed Deputy Chief VIs conduct ante-mortem inspection and confirmed that they observed all animals at rest and in motion and only animals that came with the proper documentation were eligible for slaughter.

The FSIS auditors also verified that GIP assign a lot number (based on slaughter date) to the loads of animals in the automated SIGOR (Sistema Informático de Gestión de Oficinas Regionales) system once they have verified that the animals come directly from the farm to the slaughter establishment. SIGOR is a specialized computer system designed to record relevant data related to owners; establishments of origin and destination; and number, class, type, and brand of animals for quick access in cases of health events. If the entire lot of animals is not slaughtered in one day, then a different lot number is assigned to the animals that are carried over to ensure proper traceability.

SENACSA has provided instructions describing disease conditions warranting condemnation of animals at ante-mortem inspection. The FSIS auditors verified that non-ambulatory, dying, diseased, and disabled cattle, as well as cattle showing neurological symptoms, are to be humanely slaughtered. Samples are collected from the brain tissues of animals with neurological symptoms for BSE testing. The condemned carcass is either incinerated or destroyed in the digester. In addition, as required by the MIVO, the FSIS auditors confirmed that animals that are dead on arrival or that die in the pens are declared unfit for human consumption and incinerated onsite.

Law No. 4840/12 mandates that the handling and slaughter of animals be carried out by humane methods. The same law provides SENACSA with the authority to control the slaughter of animals that are destined for human consumption and such slaughter must be carried out using humane methods. Sanctions that SENACSA could impose to any legal or natural person who violates this law are also outlined. Through interviews and direct observation, the FSIS auditors verified that stunning was effective and that the animals were rendered insensible to pain before shackling, hoisting, cutting, and bleeding.

The MIVO sets the requirements for the infrastructure of the areas used to hold and unload the animals, the stunning area, and stunning equipment, as well as prescriptive requirements for the unloading, holding, and driving of animals within the slaughterhouse. The MIVO describes the requirements for adequate access to water at all times and for feed if animals are held more than 12 hours. Additionally, Resolution No. 277/83 sets the requirements for the construction and maintenance of the holding pens, hallways and ramps used for livestock. The FSIS auditors verified that SENACSA's requirements for construction and good maintenance of the holding pens were being met at all the audited slaughter establishments. After observing the VIs perform ante-mortem inspection verification and reviewing the associated records, the FSIS auditors concluded that VIs were conducting ante-mortem inspection and humane handling verification in a manner that is consistent with FSIS requirements.

SENACSA has written and implemented post-mortem inspection programs that are equivalent to the FSIS food safety inspection system, as documented in the MIVO. Additionally, the MIVO

states that all parts of the animal, including blood, must be inspected immediately after slaughter to verify whether the meat or meat by-product is fit for human consumption. Furthermore, instructions to GIP on conducting post-mortem livestock inspection are provided in the MIVO and in Resolution No. 277/83.

The FSIS auditors observed the VAs and verified through a review of post-mortem reports and condemnation records that VAs conduct post-mortem inspection of every livestock carcass and parts, as required by the MIVO. The FSIS auditors observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented at the slaughter lines. The FSIS auditors observed VAs using incision, observation, and palpation of required organs and lymph nodes to perform examination of each bovine head, viscera, and carcass, in accordance with SENACSA's requirements. The FSIS auditors correlated the number of inspection personnel who conduct post-mortem inspection examination in each audited establishment with the maximum slaughter rate and concluded that SENACSA has provided enough inspection personnel for the existing production volume and slaughter line speeds.

Resolution No. 277/83 sets the requirements for the proper identification, handling, and separation of condemned carcasses identified with post-mortem disease conditions. This Resolution also describes the post-mortem disease conditions for livestock and identifies the condemnable disease conditions. At all audited establishments, the FSIS auditors confirmed that during post-mortem inspection, one VA is assigned at the feet and lips inspection station; at the head and tongue inspection station; at the red viscera inspection station; at the green viscera inspection station; at the pre-scapular ganglia, pre-femoral lymph nodes and diaphragm inspection station; and at the final inspection station. The FSIS auditors verified that line synchronization of carcasses, heads, and viscera was properly maintained, with the same number affixed to the carcass and the accompanying head and viscera.

The FSIS auditors reviewed supervisory records maintained at each local inspection office at the establishments and confirmed that SENACSA officials conduct supervisory visits twice a year, in accordance with Resolution No. 3346/16. Through interviews and records review, the FSIS auditors verified that the scope of the supervisory reviews include the establishments' infrastructure and sanitary facilities, application of procedures and sanitary hygienic controls (self-monitoring procedures) and the performance of the Chief VI. Additionally, SENACSA has a Technical Management Audit Unit that conducts monthly audits of all SENACSA's dependencies. Annual performance evaluations are conducted for all GIP by their immediate superiors and disciplinary issues are submitted to SENACSA's Legal Advisory Unit. The FSIS auditors concluded that the topics and areas that are evaluated during the periodic supervisory visits are consistent with FSIS' requirements.

SENACSA's General Requirements for the Export of Beef to the United States of America describe the requirements that are to be met by the establishments from the livestock receiving step to the shipment of the products to ensure separation of product destined to the United States market. The FSIS auditors verified that establishments have reserved designated areas for storage of products that will be destined for export to the United States in their cold chambers and some

of the audited establishments have even made “Products for USA” signs to ensure separation of products that will be destined for the United States from products destined to other markets.

The labeling requirements for products that will be destined for export to the United States are described in the Resolution No. 4757/13 and Notice No. 04. The FSIS auditors verified that GIP have received training on verification of FSIS’ labeling requirements from SENACSA and will ensure that FSIS labeling requirements are properly verified if FSIS reinstates the equivalence of Paraguay’s meat inspection system.

Resolution No. 1330/20 defines specified risk materials (SRM) in cattle 30 months of age and older as the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the sacral vertebrae), and dorsal root ganglia, while the distal ileum of the small intestine and the tonsils are SRMs in cattle of all ages. In addition, both Resolution No. 1330/20 and SENACSA’s Standard Operating Procedure for Handling Specified Risk Materials of Bovine Spongiform Encephalopathy (PNPVEEB) mandate that establishments develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. The FSIS auditors observed the slaughter operations at the audited establishments and confirmed that all identified SRMs were being removed and disposed of in the digesters or incinerators. The FSIS auditors also confirmed that GIP were verifying daily the removal, segregation, and disposal of SRMs and documenting their findings on an official record, as required by SENACSA.

The requirements for identifying, handling, and controlling inedible material are outlined in Resolution No. 277/83. The FSIS auditors reviewed official verification records and confirmed that condemned animals and other inedible materials were denatured and destroyed onsite at the audited establishments.

The FSIS auditors concluded that SENACSA has the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient regulatory control using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each establishment to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, maintain equivalent requirements for sanitation performance standards (SPS) and sanitary dressing.

In accordance with the Manual of Good Manufacturing Practices in the Production and Handling of Fresh Meat (MGMP), establishments are required to develop, implement, and maintain written GMP procedures designed to prevent contamination of livestock carcasses and parts by enteric pathogens, fecal material, ingesta, or milk. Furthermore, establishments that intend to export products to the United States must have their written GMPs, Sanitation SOP program, and other sanitary dressing procedures for livestock slaughter reviewed and approved by SENACSA.

The FSIS auditors observed slaughter and processing operations at all the audited establishments and observed slaughter establishments implementing practices and procedures to prevent potential carcass contamination during hide removal, direct contact between carcasses during dressing procedures, and carcass contamination with gastrointestinal contents during evisceration. In addition, the FSIS auditors confirmed through document review that GIP were verifying the implementation of GMPs by establishments weekly and sanitary dressing daily.

Resolution No. 3075/12 sets requirements for the establishments to incorporate and implement SPS requirements. Additionally, Resolution No. 689/06, as modified by Resolution No. 1151/19, states every establishment that slaughters, manufactures, or processes products of animal origin for human consumption must develop, implement, and maintain GMPs and Sanitation SOPs. The requirements for establishment construction, facilities, and equipment are described in SENACSA's Verification of Good Manufacturing Practices and Sanitary Performance Standards document. The FSIS auditors toured each of the audited establishments and found their construction, facilities, and equipment to be in sanitary conditions and in good repair. The FSIS auditors reviewed the official verification records and confirmed that GIP were verifying SPS implementation on a daily basis and documenting their findings on an official form.

While the FSIS auditors did not observe major SPS noncompliances, they discussed the requirements of Resolution No. 689/06 (modified by Resolution No. 1151/19) with the Chief VI at the audited establishments. The Chief VI explained that they notified the establishment management of minor violations (violations that do not lead to product contamination or adulteration) and increased the frequency of their SPS verification activities. However, in the event of a major violation, SENACSA would suspend the production processes and retain the affected food products. Major violations include a failure to implement the GMPs or noncompliance with the GMPs and Sanitation SOPs, production of food that is unfit for human consumption, failure to produce records, false food labeling or records, failure to implement corrective actions, or two consecutive minor violations in less than 60 days.

Resolution No. 1151/19 requires that establishments maintain written Sanitation SOPs (to include the daily sanitary activities to be performed before and during the production process as well as corrective actions in the event of direct product contamination). The resolution also requires the generation of daily sanitation records. The FSIS auditors assessed the adequacy of the pre-operational inspection verification by observing GIP conduct pre-operational sanitation verification inspection at two of the audited establishments. GIP's hands-on verification procedures occurred after the establishments had completed their pre-operational sanitation procedures and determined that the facility was ready for operations. GIP conducted pre-operational sanitation verification in accordance with SENACSA's established procedures.

The FSIS auditors observed GIP perform operational sanitation verification at all visited establishments. The FSIS auditors confirmed that the inspection verification activities included direct observation of the actual operations and review of the establishments' associated records. The FSIS auditors compared their overall observation of the sanitary conditions of the establishments with the official verification records. The FSIS auditors' records review included both the establishments' sanitation monitoring and corrective action records, in addition to the inspection records documenting inspection verification results, noncompliance, and reports of

supervisory reviews. The FSIS auditors' review of official records showed that GIP have identified and documented sanitation findings and associated corrective actions in their daily verification records. When Sanitation SOP requirements are not met, GIP require corrective actions that restore sanitary conditions, ensure appropriate disposition of products, and establish measures to prevent recurrence— including a reevaluation of the Sanitation SOPs.

The FSIS auditors verified that official inspection and establishment records mirrored the sanitary conditions of the establishments. The FSIS auditors identified minor deficiencies documented on the individual establishment checklists attached to this report (Appendix A), but these observations did not rise to the level of systemic findings. SENACSA's meat inspection system maintains sanitary regulatory requirements that meet the core requirements for this component.

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 establishment develop, implement, and maintain a HACCP system.

Resolution No. 689/06 sets the requirements for all establishments to develop, implement, and maintain a SENACSA-approved HACCP system that identifies, prevents, and controls the food safety hazards of concern. In addition, Resolution No.1151/19 expands the requirements for all slaughter and processing establishments to have GMPs, Sanitation SOPs and a HACCP system in place. The required HACCP system must integrate the seven principles of HACCP and include a flow chart, processing steps, hazard analysis, HACCP plan, intended use of product, monitoring and verification activities, corrective actions, reassessment (as per Resolution No. 2279/16), and records supporting the implementation of the HACCP system. In addition, SENACSA requires establishments to maintain documents supporting the decisions made in their hazard analysis and HACCP plan, including the initial validation of their HACCP system. The official livestock slaughter and processing establishments are required to establish a zero tolerance critical control point (CCP) for fecal, ingesta, or milk contamination, and establishments producing raw beef must address STEC in their hazard analyses.

The FSIS auditors reviewed records associated with GIP's verification of compliance with HACCP requirements and verified that GIP conduct daily verification of the establishments' critical limits established for all CCPs to ensure the adequacy of their food safety controls. The FSIS auditors also ascertained that GIP conduct daily verification of the zero tolerance CCP for fecal material, ingesta, and milk contamination. Through records review, the FSIS auditors verified all slaughter establishments have identified microbiological hazards associated with fecal material, ingesta, and milk contamination as reasonably likely to occur and established CCPs to control those hazards.

The FSIS auditors confirmed that GIP verify establishment personnel review records associated with the production of products to ensure all HACCP requirements are met prior to shipping.

However, during the record review of the audited establishments' HACCP systems, the FSIS auditors found multiple HACCP noncompliances and concluded that:

- Government inspection personnel did not ensure that the HACCP plans' design at establishments complied with SENACSA's requirements for HACCP plan content.
- Government inspection personnel did not ensure that establishments' implementation of their HACCP plans complied with SENACSA's requirements for HACCP plan execution.
- Government inspection personnel did not ensure that establishments' HACCP records complied with SENACSA's requirements for HACCP recordkeeping.
- Government inspection personnel did not ensure that establishments' hazard analyses, flow charts, and supporting documentation complied with SENACSA's requirements.

As noted in Component One, SENACSA did not implement its test and hold requirements for both establishment testing and government verification sampling of products tested for adulterants as defined by FSIS prior to completing and signing an export certificate.

The FSIS auditors' onsite verification activities and analyses indicate SENACSA requires all establishments that intend to export raw intact beef products to the United States develop, implement, and maintain a HACCP system. Considering the numerous HACCP design and implementation noncompliances found at the audited establishments, the FSIS auditors concluded SENACSA has *not* met the core requirements for the Government HACCP System that FSIS expects from foreign countries intending to export products to the United States. The nature of these findings indicates a need for SENACSA to continue to strengthen its oversight of HACCP requirements.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component 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 products inspection authorities or by FSIS as potential contaminants.

Decree No. 15-685/96, Law No. 2426/04, Resolution No. 1140/21, and Resolution No. 760/21 provide SENACSA with the legal authority and responsibility to develop, implement, and manage the National Program for Control of Residues of Veterinary Drugs, Environmental Contaminants and Pesticides in Foods of Animal Origin (hereinafter referred to as the National Residue Control Program [NRCP]). The objective of the NRCP is to monitor and ensure that products of animal origin intended for human consumption do not contain potentially dangerous chemical substances above established tolerance levels. The FSIS auditors confirmed through records review and interviews that while DIGECIPOA runs and oversees the execution of the program, GIP collect the chemical residue samples on a weekly basis and send them to the laboratory for analyses.

The FSIS auditors verified that Paraguay's NRCP is based on European Union Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products, which determines the minimum number of animals (0.4% of the total number of animals slaughtered the previous year) to be sampled, the products, and feed that must be checked each year for each type of residue or substances that must be monitored. The FSIS auditors also confirmed through interviews and documents review that DIGECIPOA officials prepare the annual sampling plan, coordinate the execution of the program, ensure sample collection, distribute the analytical results, oversee compliance, address non-compliant results, and prepare the annual report.

Through records review, the FSIS auditors verified that once a week, DIGECIPOA sends e-mails to all GIP stationed at establishments requesting the collection of samples and specifying the type of tissue to collect. The Chief VI then randomly selects the carcasses to sample from, collects the sample, and fills out a sample collection form which includes four copies of different colors: one copy for the laboratory, one copy for DIGECIPOA, one copy for the Chief VI's file, and one copy for the establishment. The FSIS auditors confirmed that the samples are either refrigerated or frozen until they are delivered to the laboratory. The FSIS auditors verified that sample integrity and proper chain of custody are maintained, in accordance with SENACSA's requirements.

Through interviews with DIGECIPOA officials, the FSIS auditors ascertained that the chemical compounds selected for sampling are based on national and international requirements or regulations, findings of residues or substances from the previous year, potential danger of exposure to the consumer, as well as the availability of validated analytical methods and appropriate equipment. The FSIS auditors also verified that the acceptable tolerance levels are based on the requirements of the importing countries and includes prohibited and permitted substances (such as veterinary medicines).

The FSIS auditors verified that Paraguay has implemented chemical compounds testing in accordance with its program documentation and at the required frequencies. The compound testing includes two groups: Group A which consists of anabolic (prohibited) substances and Group B which comprises authorized drugs. The FSIS auditors confirmed that 0.25% of the total slaughter volume is tested for Group A compounds while 0.15% of the total slaughter volume is tested for Group B compounds; and that the tissues tested include liver, fat, muscle, and kidneys. The FSIS auditors confirmed that the analytical methods used for screening and confirming the presence of chemical compounds in raw beef are consistent with FSIS' analytical methods outlined in the Chemical Laboratory Guidebook.

The FSIS auditors verified that DIGECIPOA addresses violative sample results based on whether the violation relates to prohibited (anabolic) substances or authorized products. For a prohibited substance violation, the farm that produced the animal is placed in a directed monitoring status. DIGECIPOA informs the owner of the livestock farm and requests that DIGESETEC block the livestock farm through the SIGOR computer system. Such blockade prevents the issuance of the official certificate of transit for animals coming from the affected farm. The restriction is only removed after three consecutive residue samples collected from animals of the same farm are confirmed negative.

Regarding violative results related to authorized products (such as veterinary medicines), the FSIS auditors verified that the General Technical Services Directorate requests that an alert be issued for the livestock farm or owner of the animals that exceeded the tolerance limit in the SIGOR system. Once the alert is emitted, it will be visible to all GIP stationed at establishments. GIP then are required to collect three samples from each lot of animals received belonging to the owner and/or affected livestock farm and retain the products derived from these animals until receipt of sample results. Should the result of the samples exceed the maximum residue limit, the retained product must be destroyed and animals of the same owner and/or livestock farm establishment shall remain under the directed monitoring status. The farm or owner is returned to the general monitoring regime only after two consecutive sample sets are negative. The FSIS auditors verified that DIGECIPOA informs the Chief VI at the official establishment by e-mail of violative results and the Chief VI informs the establishments' management. The FSIS auditors reviewed alerts related to farms that had exceeded the maximum residue levels for authorized products and confirmed that all samples were collected from lots of animals belonging to farms included in the alerts. The sample results reviewed by the FSIS auditors were all negative.

The FSIS auditors verified that Paraguay's meat inspection system maintains a chemical residue testing program organized and administered by the national government. SENACSA maintains the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of chemical residues of veterinary drugs and chemical contaminants in beef products that will be exported to the United States.

Despite the findings documented in Component One related to the test and hold procedures for carcasses sampled for chemical compounds and the delays in reporting sample results, the FSIS auditors confirmed that the government's chemical residue testing program has met the core requirements of this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth 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 products prepared for export to the United States are safe and wholesome.

The FSIS auditors verified Paraguay's microbiological sampling and testing programs through direct observation, document review, and interviews of SENACSA personnel at the local inspection offices within the visited slaughter and processing establishments as well as the microbiological laboratory personnel.

Resolution No. 1348/20 approves SENACSA's Microbiological Control Program in Establishments Producing Edible Products and By-Products of Animal Origin (hereinafter referred to as the Microbiological Control Program) and makes the program mandatory at all establishments authorized by SENACSA where beef products and beef by-products are produced or processed. The Microbiological Control Program sets the requirements for establishments to

develop and implement microbiological controls (generic *E. coli*) according to the regulations.

The FSIS auditors verified through records review that establishments are randomly selecting and collecting five weekly samples on carcasses before chilling. Those samples are analyzed for Aerobic Plate Count (APC), *Enterobacteriaceae*, and generic *E. coli* while GIP randomly select and collect five monthly samples that are analyzed for the same indicator organisms. The audited establishments are also collecting generic *E. coli* samples on chilled carcasses at the frequency of 1 sample out of every 300 carcasses. In addition to those analyses, SENACSA requires the establishments to conduct APC sampling on facilities, equipment, tools, and operators. The FSIS auditors also ascertained that GIP would sample chilled carcasses destined for export to the United States for generic *E. coli* at the frequency of 1 per every 300 chilled carcasses, in accordance with SENACSA's requirements.

The FSIS auditors confirmed that GIP conduct verification activities that ensure written generic *E. coli* testing programs meet requirements and include the location of sampling, randomness of sampling, and sample integrity. The FSIS auditors noted that GIP were verifying establishment sampling collection methodology for indicator organisms through direct observation of establishment sampling and the secure submission of each sample to the microbiological laboratory for analysis. GIP use the test results to verify establishment slaughter dressing controls for fecal contamination. Furthermore, the FSIS auditors confirmed that GIP verify that each establishment documents and correctly evaluates test results and takes appropriate corrective actions if the statistical process control criteria are not met. The FSIS auditors confirmed that SENACSA has established process control criteria for generic *E. coli* that are consistent with those listed in 9 CFR 310.25(a) in order to verify process control on beef carcasses.

The microbiological control program requires the implementation of an official government sampling and testing program for *Salmonella* on beef carcasses at pre-chill and post-chill to ensure that raw beef products are produced safely and that pathogen levels are reduced or eliminated during slaughter and processing operations. Moreover, the program describes the performance standard criteria for the evaluation of *Salmonella* results for cattle carcasses collected at both the pre-chill and post-chill sample locations.

The FSIS auditors confirmed through observation and record review that DIGELAB personnel follow the VIDAS Up (as validated) to screen for *Salmonella* and the ISO 6579 method for isolation and confirmation to test pre-chill carcass samples.

Regarding the *Salmonella* performance standard at pre-chill, the FSIS auditors confirmed that the Chief VI prepares a *Salmonella* sampling annual plan and submits the plan to DIGELAB for approval. The plan must establish a sampling frequency of two sampling events per month, each event consisting of a five-sample set from one production day. In addition, the program describes the performance standard criteria for the evaluation of *Salmonella* results for cattle carcasses (including cows/bulls and steers/heifers) collected at the post-chill sample location. The performance standards for *Salmonella* at post-chill is verified through the collection of 58 consecutive daily samples in which no more than two positive samples are allowed for cows/bulls, and 82 consecutive daily samples in which no more than one positive sample is

allowed for steers/heifers. After interviewing GIP at the establishments, the FSIS auditors found the following noncompliance regarding the execution of the microbiological control program:

- Government inspection personnel were not collecting *Salmonella* samples on chilled carcasses as specified in SENACSA's Microbiological Control Program.

The microbiological control programs identify STEC (O157:H7, O26, O45, O103, O111, O121, and O145) as adulterants in beef trimmings. The FSIS auditors verified that GIP collect official government samples for STEC testing of raw beef trim once per month while the establishments collect for STEC testing five raw beef trim samples per month. SENACSA requires that establishments take corrective actions when there is a STEC positive, from either establishment testing or official government testing. If an establishment sample test is positive for STEC, the establishment must inform GIP and implement corrective actions.

The document Official Procedures for the Collection and Submission of Samples for the Determination of *E. coli* O157:H7 and Non-O157 outlines the procedures for the official government verification sampling of raw beef trimmings. The FSIS auditors observed the N60 sample collection at one establishment and confirmed that GIP aseptically collected the 60 pieces from the surface and the total weight of the sample was not less than 375g, as required by SENACSA.

The FSIS auditors visited DIGELAB, the government microbiological laboratory and confirmed that DIGELAB implements the Bio-Rad iQ Check STEC screening test for detection of virulence genes (*stx*, *eae*) and subsequent detection of serogroups O157, O26, O45, O103, O111, O121, and O145. Screen positives are confirmed using the FSIS method Microbiology Laboratory Guidebook (MLG) 5C, including using the Bio-Rad iQ Check STEC. The FSIS auditors found the following noncompliance regarding DIGELAB's management of the N60 samples:

- DIGELAB personnel were not analyzing all 60 trim pieces of the N60 sample submitted to the laboratory when the sample portion collected is greater than the size of the prescribed laboratory test portion.

The FSIS auditors verified that Paraguay's food safety inspection system maintains the legal authority to regulate, plan, and execute activities of the inspection system aimed at controlling the presence of microbiological pathogens in raw beef products to be exported to the United States, and that those beef products are unadulterated, safe, and wholesome in accordance with FSIS requirements. The nature of the findings related to this component indicates the need for SENACSA to strengthen its oversight of the microbiological testing programs.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held November 17, 2021 by videoconference with SENACSA officials. At this meeting, the FSIS auditors presented the following preliminary findings from the audit.

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- SENACSA did not implement its enforcement program at an establishment failing to take required corrective actions including reassessing the adequacy of its HACCP plan or making changes to its production process to address repeated positive Shiga toxin-producing *Escherichia coli* (STEC) samples.
- SENACSA did not implement its requirement that would ensure that livestock carcasses and parts subjected to routine chemical residue testing and production lots subjected to official STEC sampling be precluded from export to the United States until receipt of acceptable testing results, should Paraguay become eligible to export raw intact beef products to the United States.
- SENACSA did not ensure that laboratories conducting official government analyses of microbiological and chemical residue samples report the results to SENACSA officials in a timely manner.
- SENACSA did not ensure that its official microbiology laboratory (General Directorate of Laboratories - DIGELAB) personnel calibrate the equipment at the frequency required by the laboratory's written quality assurance program.

GOVERNMENT HACCP SYSTEM

- Government inspection personnel did not ensure that the HACCP plans' design at establishments complied with SENACSA's requirements for HACCP plan content.
- Government inspection personnel did not ensure that establishments' implementation of their HACCP plans complied with SENACSA's requirements for HACCP plan execution.
- Government inspection personnel did not ensure that establishments' HACCP records complied with SENACSA's requirements for HACCP recordkeeping.
- Government inspection personnel did not ensure that establishments' hazard analyses, flow charts, and supporting documentation complied with SENACSA's requirements.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- DIGELAB personnel were not analyzing all 60 trim pieces of the N60 sample submitted to the laboratory when the sample portion collected is greater than the size of the prescribed laboratory test portion.
- Government inspection personnel were not collecting *Salmonella* samples from chilled beef carcasses as specified in SENACSA's Microbiological Control Program.

The findings related to government oversight, government HACCP system and government microbiological testing programs will require SENACSA to submit revised procedures and laboratory methods for equivalence review before FSIS can allow the import of raw intact beef products. As part of the equivalence review process, FSIS will consider whether an additional on-site audit is necessary in order to verify the CCA's ability to implement the revised procedures and methods once they are submitted.

An exit meeting was held November 17, 2021, by videoconference with SENACSA. During the exit meeting, SENACSA committed to addressing the findings as presented. FSIS will evaluate the adequacy of SENACSA's proposed corrective actions once received and base future equivalence verification activities on the information provided. FSIS requests a written response within 60 calendar days of the date of the audit report.

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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Coop. Mult. Neuland Ltda. Frigorífico Neuland Ruta Transchaco Km 28,5 Villa Hayes, Paraguay	11/09/2021	1	Paraguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
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	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		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.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.	X	44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		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.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		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	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance	X		

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals, subprimals, trimmings

60. Observation of the Establishment

During the audit of the establishment, government inspection personnel (GIP) did not identify the following noncompliances:

10. *Implementation of Sanitation SOPs, including monitoring of implementation*
- The saw used to split carcasses was not being adequately cleaned between carcasses

15. *Contents of the HACCP lists the food safety hazards, critical control points, procedures, corrective actions*
- HACCP plan does not identify verification frequency for CCP1

16. *Records documenting implementation and monitoring of the HACCP plan*
- Incorrect monitoring record referenced in HACCP plan for CCP2

17. *The HACCP plan is signed and dated by the responsible establishment individual*
- HACCP plan was not signed

19. *Verification and validation of the HACCP plan*
- CCP1 verification does not include direct observation of monitoring
- Validation data does not state the percentage of lactic acid that was used to make the preparations
- The establishment's lactic acid program includes temperatures up to 55°C but the validation only included temps up to 30.4°C.

20. *Corrective actions written in HACCP plan*
- Corrective actions are not performed for every deviation of CCP1
- Corrective actions for CCP2 does identify the cause of the deviation

22. *Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences*
- CCP1 monitoring records did not include the time or initial for each event

32. *Salmonella Sampling*
- GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/09/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Matadero Frigorífico Frigomerc S.A Capitán Lombardo y Calle Corta Barrio Tablada Nueva Asunción, Paraguay	11/05/2021	2	Paraguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals, subprimals, beef trimmings

60. Observation of the Establishment

During the audit of the establishment, the government inspection personnel (GIP) did not identify the following noncompliances:

22. *Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences*

- CCP1 monitoring records did not include the time or initial for each event
- CCP1 verification records did not include initial for each event
- Five monitoring events for CCP1 were not recorded on 09/03/21

30. *Salmonella sampling*

- GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/05/2021

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Matadero Frigorífico San Antonio "FRISA S.A." Av. San Antonio y Cadete de Boquerón San Antonio, Paraguay	11/04/2021	3	Paraguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
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	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	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.	X	44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		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.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		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	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records	X	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance	X		

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals, subprimals, beef trimmings

60. Observation of the Establishment

During the audit of the establishment, the government inspection personnel (GIP) did not identify the following noncompliances:

14. *Developed and implemented a written HACCP plan*
- Flow chart includes multiple directions for processing products but does not define which products should go in which direction of processing

15. *Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions*
- HACCP plan did not list the monitoring frequency for CCP2

17. *The HACCP plan is signed and dated by the responsible establishment individual*
- HACCP plan was not signed

22. *Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences*
- CCP1 monitoring records did not include the time or initial for each event

29. *Records*
- Establishment's graphs of generic *E. coli* results were missing data points, the upper limit varied month to month, and the markings for the acceptability levels were not defined
- Establishment's sample results from two pieces of equipment that was sampled on 03/02/21 during pre-operations were missing from the records

32. *Salmonella Sampling*
- GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/04/2021

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorífico Frigochorti Neudorf, Loma Plata Boquerón	11/04/2021	9	Paraguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
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	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		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.	X	44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		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.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		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	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance	X		

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals, subprimals, beef trimmings

60. Observation of the Establishment

During the audit of the establishment, government inspection personnel (GIP) did not identify the following noncompliances:

7. *Written SSOP program*

- The corrective actions listed in the establishment's SSOP did not include all three requirements of 9 CFR 416.15b

16. *Records Documenting implementation and monitoring of HACCP plan*

- The HACCP monitoring records for the zero tolerance for fecal material, milk and ingesta CCP (Slaughter HACCP plan) and the metal detection CCP (Deboning HACCP plan) monitoring records did not include a recording of direct observation and record review.

19. *Verification and validation of HACCP Plan*

- The establishment’s ongoing verification activities listed in the Slaughter and Deboning HACCP plans did not include:
  (a) direct observation of the monitoring activity and frequency and
  (b) review of records and frequency (for both HACCP plans)
  (c) calibration of the process monitoring device (Deboning HACCP plan only).

20. *Corrective actions written in HACCP plan*

- The establishment's corrective actions listed in both the Slaughter and Deboning HACCP plans for a deviation covered by a critical limit did not include all four requirements of 9 CFR 417.3b

22. *HACCP Records*

- The HACCP monitoring records did not include record review and direct observation under ongoing verification

32. *Salmonella sampling*

- GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA’s Microbiological Control Program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/04/2021

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Cooperativa Colonizadora Multiact. Ferheim Ltda. "Frigorífico Frigochaco" Limpio, Paraguay	11/10/2021	10	Paraguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals and subprimals

60. Observation of the Establishment

During the audit of the establishment, the government inspection personnel (GIP) did not identify the following noncompliances:

14. *Developed and implemented a written HACCP plan*
- Establishment did not have support for their decision for monitoring frequency for CCP2A
- Establishment's supporting documentation for product temperatures did not support the decision for the critical limits for CCP2A
- Flow chart includes multiple directions for processing products but does not define which products should go in which direction of processing
- Processing steps in flow chart have different names from the processing steps in the Hazard Analysis

15. *Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions*
- HACCP plan for CCP1 does not include verification of monitoring records
- HACCP plan does not identify monitoring frequency for CCP2A
- HACCP plan for CCP2A does not accurately state verification frequency
- The HACCP plan does not include calibration of process monitoring equipment
- HACCP plan does not identify verification of monitoring records for CCP2B

16. *Records documenting implementation and monitoring of the HACCP plan*
- Incorrect monitoring record referenced in HACCP plan for CCP1
- Verification record not referenced in HACCP plan for CCP2A

17. *The HACCP plan is signed and dated by the responsible establishment individual*
- HACCP plan was not signed

20. *Corrective actions written in HACCP plan*
- Corrective actions for CCP2B does identify the cause of the deviation

21. *Reassessment of adequacy of HACCP plan*
- SENACSA did not implement its enforcement program, which requires establishments to take effective corrective actions and preventive measures, at an establishment with positive STEC samples. The establishment did not reassess its HACCP plan or make changes to its production process to address the repeated product adulteration. On 2/05/21, 3/29/21 and 4/20/21, GIP collected STEC samples as part of the official microbiology testing program. The first two samples were confirmed positive for *E. coli O26* while the third one was presumptive positive for the same SETC serogroup (until August 21, the official laboratory did not have a STEC confirmatory method; therefore, all presumptive positive samples were considered as positive at that time). GIP have not verified that the establishment take corrective actions that met all requirements of 9 CFR 413 including a reassessment of the adequacy HACCP plan (the HACCP plan was last reassessed in October 2020).

22. *Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences*
- CCP1 and CCP2A verification records do not include the time for each event
- CCP1 monitoring records did not include the time or initial for each event

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/10/2021

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorífico FrigoNorte Callejón 1111 Camino a Fortuna Guazú Pedro Juan Caballero	11/09/2021	15	Paraguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
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	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	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	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		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	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance	X		

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals, subprimals, beef trimmings

60. Observation of the Establishment

During the audit of the establishment, government inspection personnel (GIP) did not identify the following noncompliances:

14. *Development and Implementation of a Written HACCP Plan*
- The establishment accepts returned products; however, the establishment did not address returned products in the flow chart and hazard analysis.

15. *Content of HACCP plan (listing of food safety hazards)*
- The establishment did not identify and address *E. coli O157* and non-O157 STECs as a food safety hazard in the hazard analysis of the slaughter HACCP plan.

16. *Records documenting implementation and monitoring of HACCP plan*
- The CCP daily monitoring records did not include a recording of direct observation of monitoring activities and the time the event occurred.

19. *Verification and validation of HACCP plan*
- The establishment's ongoing verification activities listed in the Slaughter/Deboning HACCP plan did not include direct observation of the monitoring activity as well as calibration of the process monitoring device and their frequencies.

32. *Salmonella sampling*
- GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/09/2021

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorífico Guaraní S.A.C.I. Av. Sta. Teresa y Chaco Boreal Fernando de la Mora, Paraguay	11/08/2021	17	Paraguay
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals, subprimals, beef trimmings

60. Observation of the Establishment

During the audit of the establishment, the government inspection personnel (GIP) did not identify the following noncompliances:

15. *Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions*

- The corrective actions listed in the HACCP plan does not include identifying the cause of the deviation or preventative measures
- The HACCP plan does not include calibration of process monitoring equipment

19. *Verification and validation of HACCP plan*

- Verification of CCP 1, zero-tolerance for fecal, ingesta, and milk occurs after the carcass wash

22. *Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences*

- CCP1 monitoring records did not include the time or initial for each event
- Verification of CCP1 monitoring records is not recorded

29. *Generic E. coli Records*

- The acceptability levels were not defined on the graphs of generic *E. coli* sample results.

32. *Salmonella Sampling*

- GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/08/2021

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Beef Paraguay S.A. Calle José Batista Sobrinho - Belén Concepción	11/08/2021	23	Paraguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals, subprimals, beef trimmings

60. Observation of the Establishment

During the audit of the establishment, government inspection personnel (GIP) did not identify the following noncompliances:

7. *Written SSOP program*

- The corrective actions listed in the SSOP program does not include all three the requirements of 9 CFR 416.15b

32. *Salmonella sampling*

- GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/08/2021

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Frigorífico Concepción S. A. Km 6,5 Camino Aeropuerto Concepción	11/05/2021	38	Paraguay
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Primals, subprimals, beef trimmings

60. Observation of the Establishment

During the audit of the establishment, government inspection personnel (GIP) did not identify the following noncompliances:

19. *Verification and validation of HACCP plan*
- The establishment's ongoing verification activities listed in the Slaughter and Deboning HACCP Plans did not include direct observation of the monitoring activity and frequency as well as review of records and frequency (for both HACCP plans).
- The Deboning HACCP plan did not list calibration of the process monitoring device and frequency as an ongoing verification activity.

32. *Salmonella sampling*
- GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.

39. *Establishment construction and maintenance*
- Rust buildup was observed on numerous overhead structures in the slaughter room.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/05/2021

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

TYMBA RESÃIHA IPORÃMBYRÃ
Tetã Rembiapo
Servicio Nacional de
CALIDAD Y SALUD ANIMAL

TETÃ REKUÁI
GOBIERNO NACIONAL

Paraguay de la gente

San Lorenzo, March 15 , 2022

N.P. Nº 86 .-

Mrs
MICHELLE CATLIN, PhD
International Coordination Executive
Office of International Coordination (OIC)
Food Safety and Inspection Service
United States Department of Agriculture
Present:

I am pleased to address you, on the occasion of referring to the note dated February 15, 2022, by which you submit the draft of the final report of the audit of the meat inspection system of Paraguay, carried out by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), which took place from November 1 to 17, 2021, in a hybrid, remote and on-site way.

In this regard, I comply with submitting in attachment to this note, the comments and corrective actions to the findings of the audit, which was carried out on one hundred percent (100%) of the beef slaughter and processing establishments potentially authorized for export to the United States.

The Annexes are in the following link:

http://documentos.senacsa.gov.py/alfresco/webdav/Sitios/presidencia/documentLibrary/Auditoria%20EEUU

username: fsis
password: audit.2022

Without further ado, and awaiting a prompt response, which allows for the long-awaited objective of opening the market to export Paraguayan meat to the United States, I take this opportunity to greet you with the expressions of my most distinguished consideration.

DR. JOSÉ CARLOS MARTIN C.
President

TYMBA RESÃIHA IPORÃMBYRÃ
Tetã Rembiapo
Servicio Nacional de
CALIDAD Y SALUD ANIMAL

TETÃ REKUÁI
GOBIERNO NACIONAL

Paraguay de la gente

San Lorenzo, 15 de marzo de 2022

N.P. Nº 86 .-

Señora
MICHELLE CATLIN, PhD
Ejecutiva de Coordinación Internacional
Oficina de Coordinación Internacional (OIC)
Servicio de Inspección y Seguridad Alimentaria
Departamento de Agricultura de los Estados Unidos
Presente:

Tengo el agrado de dirigirme a usted, en ocasión de hacer referencia a la nota de fecha 15 de febrero de 2022, por la cual eleva el borrador del reporte final de la auditoría del sistema de inspección de carne del Paraguay, realizada por el Servicio de Inspección y Seguridad Alimentaria (FSIS) del Departamento de Agricultura (USDA) de los Estados Unidos de América, que se llevó a cabo los días 1 al 17 de noviembre de 2021, en forma híbrida, remota e in situ.

Al respecto, cumplo en remitir en adjunto a la presente nota, los comentarios y las acciones correctivas a los hallazgos de la auditoría, que fuera practicada al cien por ciento (100%) de las plantas frigoríficas potencialmente habilitadas para la exportación a los Estados Unidos.

Los Anexos se encuentran en el siguiente link:

http://documentos.senacsa.gov.py/alfresco/webdav/Sitios/presidencia/documentLibrary/Auditoria%20EEUU

usuario: fsis
contraseña: audit.2022

Sin otro particular, y aguardando una pronta respuesta, que permita el tan anhelado objetivo de la apertura del mercado para exportar carne paraguaya a los Estados Unidos, hago propicia la ocasión para saludarla con las expresiones de mi consideración más distinguida.

DR. JOSÉ CARLOS MARTIN C.
Presidente

COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)	
SENACSA did not implement its enforcement program at an establishment failing to take required corrective actions including reassessing the adequacy of its HACCP plan or making changes to its production process after repeated positive STEC samples.	SENACSA, through DIGECIPOA as CCA, updated and shared with government inspection personnel the compliance programs to ensure that all measures are taken to guarantee that the products to be exported to the US are not adulterated. The resolutions that regulate said programs are attached. - **SENACSA Resolution No. 30/2022** "Sanitary hygiene requirements in establishments slaughtering, preparing and/or processing food of animal origin" effective from January 13, 2022. **ANNEX 1** - **SENACSA Resolution No. 31/2022** "BPM approval procedure – POES and recognition of HACCP. MIVO-FOR 16. Rev. 04" effective date from January 13, 2022. **ANNEX 2** - **SENACSA Resolution No. 32/2022** "Critical control point (CCP) verification procedure and form. Rev.04" with effective date from January 13, 2022. **ANNEX 3**
SENACSA did not implement its requirement that would ensure that livestock carcasses and parts subjected to routine chemical residue testing and production lots subjected to official STEC sampling would be precluded from export to the United States until receipt of acceptable testing results, should Paraguay become eligible to export raw intact beef products to the United States.	**SENACSA Resolution No. 1522/2021** "General Requirements for the export of beef to the United States of America" effective as of November 2, 2021, establishes in section 5.4 "Of the products", subsection d: The products resulting from cattle sampled within the framework of the microbiological verification and veterinary drug residue control program will be retained until the results are obtained

Carlos Martín C.
Presidente del SENACSA

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	it was shared with government inspection personnel and implemented immediately to guarantee that the products will not be exported to the US pending acceptable test results, should Paraguay be eligible to export beef products to the US. **ANNEX 4**
SENACSA did not ensure that DIGELAB personnel calibrate the laboratory equipment at the frequency required by the laboratory's written quality assurance program.	SENACSA has a cooperation framework agreement between the NATIONAL INSTITUTE OF STANDARDIZATION TECHNOLOGY AND METROLOGY (INTN), in the field of metrology which, in the third clause of activities and commitments, includes performing the calibration of instruments and laboratory equipment owned by SENACSA, according to the list of instruments previously provided to the metrology organization, in each case. **ANNEX 9** SENACSA has an Annual Calibration Plan and a specific RG-53 record where the periodicity of equipment maintenance and calibration is specified. The equipment is currently fully calibrated. Accreditation of the STEC technique by the ONA: The audit of the ONA (National Accreditation Body of Paraguay) for the accreditation of the microbiological analysis technique of STEC and SALMONELLA was carried out on March 8, 9, 10 and 11, without finding no finding, consequently, the technique is accredited by the aforementioned quality body. This process was carried out within the framework of the NP ISO/IEC 17025:2018. "General requirements for the competence of testing and calibration laboratories". The ACCREDITATION CERTIFICATE is in the process of being prepared by the ONA. **ANNEX 10**

SENACSA PRESIDENCIA
Dr. [illegible] Martin C.
Presidente del SENACSA

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	The Salmonella spp proficiency certificate is attached as an annex as well as the Listeria monocytogenes certificate from SENAI, Brazil, recently carried out with satisfactory results. **ANNEX 11** In addition, from the financial resources area of SENACSA, the amounts allocated for MAINTENANCE AND MINOR REPAIRS are contemplated in the PGN (General Expenditure Budget of the Nation, established by National Law 6873 and regulated by Decree 6581), of the year 2022, which is in force, in subgroup 240, Object of Expenditure 246, which allocates sufficient funds for the financial coverage of maintenance and calibration of laboratory equipment. The Calibration Plan is formulated in the first quarter of each year, according to the needs of each team, in compliance with the requirements of the Quality Management Plan. **ANNEXES 12 AND 13.**

SENACSA PRESIDENCIA

José Carlos Martin C.
Presidente del SENACSA

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL

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SENACSA did not ensure that laboratories conducting official government analyses of microbiological and chemical residue samples report the results to SENACSA officials in a timely manner.	Resolution No. 1585 of December 13, 2021 has been promulgated. "BY WHICH THE IMPLEMENTATION OF THE IMMEDIATE COMMUNICATION SYSTEM IS AUTHORIZED VIA EMAIL OF THE RESULTS OF LABORATORY DIAGNOSIS FROM THE PRIVATE SUBCONTRACTED LABORATORIES TO THE GENERAL DIRECTORATE OF LABORATORIES-DIGELAB- AND THE GENERAL DIRECTORATE OF QUALITY AND SAFETY OF PRODUCTS OF ANIMAL ORIGIN- DIGECIPOA- OF THE INSTITUTION." Institutionally, this procedure is already operational. **ANNEX 7** Additionally, the LIMS (Laboratory Information Management System Software) computer program for laboratories is in an advanced stage of implementation, in which total priority has been given to the microbiology and residues sectors. This will allow the results reports to be available to all users immediately, once the analysis of the samples has been completed, assuring the service the immediate online reception of the information, for timely decision-making. **LIMS-IDB-SENACSA Project – Act No. 6521(03/26/2020) ANNEX 8** The system will allow the computerized processing of sample results sent to SENACSA laboratories by internal and external users, providing the data and analytical tools for the immediate preparation of an extensive list of reports required by the authorities, both to inform buying markets and for making decisions affecting livestock production.

SENACSA PRESIDENCIA

José Carlos Martin C.
Presidente del SENACSA

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL

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COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM	
However, during the record review of the audited establishments' HACCP systems, the FSIS auditors found multiple HACCP non compliances and concluded that: a. Government inspection personnel did not ensure that the HACCP plans' design at establishments complied with SENACSA's requirements for HACCP plan content.	SENACSA, through DIGECIPOA as CCA, updated and shared with government inspection personnel Resolution No. 30/2022 "Sanitary hygiene requirements in establishments slaughtering, preparing and/or processing food of animal origin", it establishes in sections **5. Application, 6. HACCP Plan**, respectively, the points that must be described in the content of the HACCP Plan. To ensure compliance with its design, government inspection personnel record the evaluation of the HACCP Plan in the **Evaluation Form** contained in SENACSA Resolution No. 31/2022 "BPM approval procedure – POES and recognition of HACCP. MIVO-FOR 16. Rev. 04". The **Evaluation Form** contemplates in point E. **Review of the Plan** the following items: - Identification of CCPs - Hazard Description - Establishment of Critical Limits - Monitoring procedure: WHAT, HOW, FREQUENCY, WHO, WHERE - HACCP Records - Date - Signature

José Carlos Martin C.
Presidente del SENACSA

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL
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b. Government inspection personnel did not ensure that establishments' implementation of their HACCP plans complied with SENACSA's requirements for HACCP plan execution.	SENACSA, through DIGECIPOA as CCA, updated and shared with government inspection personnel Resolution No. 30/2022 "Sanitary hygiene requirements in establishments slaughtering, preparing and/or processing food of animal origin", which establishes the requirements that must be verified to ensure the correct implementation of the establishment's HACCP Plan. To ensure its satisfactory implementation, the government inspection staff records the evaluation of the HACCP Plan in the Evaluation Form contained in SENACSA Resolution No. 31/2022 "BPM approval procedure – POES and recognition of HACCP. MIVO-FOR 16. Rev. 04" and performs the verifications as established in SENACSA Resolution No. 32/2022 "Procedure and verification form for critical control points (CCP). Rev.04". Likewise, DIGECIPOA issued the **Circular No. 1/2022 ANNEX 5** which establishes the obligation for all export establishments to submit to SENACSA the Initial Validation of the HACCP Plan.
c. Government inspection personnel did not ensure that establishments' HACCP records complied with SENACSA's requirements for HACCP recordkeeping.	The government inspection personnel received the update of **SENACSA Resolution No. 32/2022** "Procedure and verification form for critical control points (CCP). Rev.04", it establishes the requirements that must be verified to guarantee that the records associated with HACCP meet all the established requirements.

SENACSA PRESIDENCIA
Dr. José Carlos Martín C.
Presidente del SENACSA

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d. Government inspection personnel did not ensure that establishments' Hazard analyses, flow charts, and supporting documentation complied with SENACSA's requirements.	The government inspection staff received the update of **SENACSA Resolution No. 31/2022** "Approval procedure for BPM – POES and recognition of HACCP. MIVO-FOR 16. Rev. 04", it establishes the points that must be verified to guarantee compliance with the requirements in terms of hazard analysis, flow diagrams and supporting documentation complies with what is required by SENACSA.

SENACSA PRESIDENCIA

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Presidente del SENACSA

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL

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COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	
Government inspection personnel were not collecting *Salmonella* samples on chilled carcasses as specified in SENACSA's Microbiological Control Program.	Government inspection personnel received **SENACSA Resolution No. 1396/2021 ANNEX 6** "Mandatory implementation of the official Salmonella spp. in carcasses after cooling, in establishments authorized to export beef to the United States of America" in force since November 8, 2021 to ensure the taking of samples according to the provisions of Point 7.4 of the Salmonella spp. in channels after cooling.
DIGELAB personnel were not analyzing all 60 trim pieces of the N60 sample submitted to the laboratory when the sample portion collected is greater than the size of the prescribed laboratory test portion.	Modifications have been made to the sample processing method. In PE-CA-51 (modified on November 2, 2021) it is established that the samples must have 325 grams. If this weight is exceeded, by more than 63 grams, this portion is analyzed as a sub-sample of the same batch. If it does not exceed 63 grams, it is processed as a single sample. The reagents and culture media will be calculated in both cases, in order to adjust them to the number of samples and sub-samples that are generated from the batch in question, maintaining the 1:4 ratio. The procedure PE/CA-51 Detection, isolation and confirmation of STEC E. coli producing Shiga Toxin automated system iQ Check® Real Time PCR was updated according to what was written in the MLG 5C.01. Detection, Isolation, and Identification of Top Seven Shiga Toxin-Producing Escherichia coli (STEC) from Meat Products and Carcass and Environmental Sponges from FSIS USA. The modification was carried out immediately by those responsible for the Microbiology area. Attached is Procedure PE/CA-51 Detection, isolation and confirmation of STEC E. coli that produce Shiga Toxin iQ Check® Real Time PCR automated system with version 3.0 in force.

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	since 11/02/2021 in which the reference: Sampling according to N60 (MLG 5C.01 Sample Preparation and Primary Enrichment. With these adjustments, all portions of samples that arrive at the laboratory are analyzed. **ANNEX 14** At the same time, the IDB-SENACSA Project Law No. 6521 (03/26/2020) has managed, through international public bidding, the hiring of an international consultant on food microbiology, in order to strengthen the operational levels of food processing. STEC samples, in products destined for export to the United States. The respective contract is in the process of collecting documents and their subsequent signature by the parties (contractor-contractor). **ANNEX 15** SENACSA will also soon participate in the EA.MIC.044 "Aptitude Tests" for the detection of E. Coli O157:H7 and STEC, (stx/eae genes) in meat products, organized by LATU (Uruguayan Technological Laboratory) that is accredited by the OUA (Uruguayan Accreditation Body) according to the ISO/IEC 17043 standard as a provider of microbiological aptitude tests. **ANNEXES 16 AND 17**

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ADITIONAL COMMENTS	
As a SENACSA-appointed veterinary professional, the VI works under the supervision of the Chief VI. The VAs are not appointed but hired by and paid by the national government to perform post-mortem inspection on all carcasses and parts. VAs may also assist the Deputy Chief VI during ante-mortem inspection; comply with the directives of the Chief VI, Deputy Chief VI and VIs; notify the veterinary staff of any unfamiliar signs of disease or injuries; assist the veterinary staff in official verification activities; inform the Chief VI or Deputy Chief VI of any abnormality in terms of infrastructure, sanitary condition of the animals and/or carcasses; and perform administrative functions, as needed. The FSIS auditors verified through interviews, observation of their activities, and document review that GIP will be directly responsible for ensuring that FSIS requirements are implemented daily at all establishments that intend to produce products for export to the United States.	Regarding this point, we clarify the following: The National Animal Health and Quality Service (SENACSA) has permanent and contracted officials on its staff. In the cases of permanent officials, they are included in the Personnel Annex of the General Budget of the Nation for each Fiscal Year. In the case of the Contracted, they perform functions permanently, and have Contracts in force from January 1 to December 31 of each fiscal year, according to the General Budget of the Nation. These officials receive their monthly salary, as well as the complementary allowances corresponding to each position, and what is established by Resolution issued by the Highest Institutional Authority. It is worth mentioning that the official, whether permanent or contracted, submits the Affidavit of Assets and Income, to the Comptroller General of the Republic, in accordance with current regulations. And everything perceived by officials; Whether permanent or contracted, it is published monthly on the Institutional Web page http://www.senacsa.gov.py/index.php/institucional/transparencia/ley-5189, in accordance with the provisions of Law 5189/14 "WHICH ESTABLISHES THE OBLIGATION OF THE PROVISION OF INFORMATION ON THE USE OF PUBLIC RESOURCES ON REMUNERATION AND OTHER REMUNERATION ASSIGNED TO THE PUBLIC SERVANT OF THE REPUBLIC OF PARAGUAY". **(REFERENCE: SRT 2019 QUESTION #5 – DATED JULY 1, 2020)**

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ESTABLECIMIENTO N°1 NEULAND	
10. *Implementation of Sanitation SOPs, including monitoring of implementation.* The saw used to split carcasses was not being adequately cleaned between carcasses	Government inspection personnel immediately notified the establishment of the SSOP deviation. The establishment analyzed the causes of the deviation and immediately carried out corrective actions that included cleaning and sterilizing the equipment to restore hygienic conditions. Preventive actions were also applied, reviewing and adjusting the equipment's cleaning and sterilization system.
15 . *Contents of the HACCP lists the food safety hazards, critical control points, procedures, corrective actions.* HACCP plan does not identify verification frequency for CCP1	The establishment updated the version of the HACCP Plan and included the frequency with which the control of the CCP is carried out 1. The government inspection personnel verify the update of the HACCP Plan.
16 . *Records documenting implementation and monitoring of the HACCP plan.* Incorrect monitoring record referenced in HACCP plan for CCP2	The record related to PPC2 is added within the HACCP plan in the updated version. Government inspection personnel verify the update of the HACCP Plan.
17 .*The HACCP plan is signed and dated by the responsible establishment individual.* HACCP plan was not signed	The HACCP plan was signed by the person responsible for the establishment. The government inspection staff verifies the signature of the HACCP Plan.

SENACSA PRESIDENCIA
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19. Verification and validation of the HACCP plan a. CCP1 verification does not include direct observation of monitoring b. Validation data does not state the percentage of lactic acid that was used to make the preparations. The establishment's lactic acid program includes temperatures up to 55°C but the validation only included temps up to 30.4°C.	Direct observation during verification of monitoring of CCP 1 is included in the HACCP plan in the updated version. Government Inspection Personnel verify the inclusion of direct observation in the CCP verification. Validations of the lactic acid solution are performed at different temperatures and percentages. The Government Inspection Personnel check validation documents. Validations of the lactic acid solution are performed at different temperatures. The Government Inspection Personnel verifies the validation documents.
20. Corrective actions written in HACCP plan a. Corrective actions are not performed for every deviation of CCP1 b. Corrective actions for CCP2 does not identify the cause of the deviation	The establishment updates the HACCP Plan and records the corrective actions for each CCP 1 deviation; government inspection personnel verify the update of CCP records. The establishment updates the HACCP Plan and establishes the identification of the cause of deviation for CCP2; government inspection personnel verify the update of the HACCP Plan.
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. CCP1 monitoring records did not include the time or initial for each event.	SENACSA initiated the equivalence request process for CCP monitoring records as an **Individual Sanitary Measure (ISM)** to the **International Equivalence Staff (IES).**

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32. *Salmonella Sampling* GIP was not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.	SENACSA Resolution No. 1396 came into effect on 11-08-2021. The Official Veterinary Inspection of the NEULAND Cold Storage Establishment No. 1 complied with said resolution by putting into practice the official taking of samples for Salmonella analysis after cooling on 09-11-2021.

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ESTABLECIMIENTO N°2 FRIGOMERC	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. - CCP1 monitoring records did not include the time or initial for each event. - CCP1 verification records did not include initial for each event. - Five monitoring events for CCP1 were not recorded on 09/03/21	SENACSA initiated the equivalence request process for CCP monitoring records as an **Individual Sanitary Measure (ISM)** to the **International Equivalence Staff (IES).** The establishment proceeded to update the PCC1 verification record format, including the item for the time of each event. Government inspection personnel check the record. The establishment proceeded to retrain the CCP monitors and Quality Supervisor on the correct completion of the registry. Government inspection personnel check supporting retraining records and PCC records.
30. Salmonella sampling GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.	SENACSA Resolution No. 1396 came into effect on 11-08-2021. The Official Veterinary Inspection of Establishment No. 2 FRIGOMERC complied with said resolution and proceeded to take official samples for analysis of Salmonella in carcasses after cooling.

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ESTABLECIMIENTO N°3 SAN ANTONIO	
14. Developed and implemented a written HACCP plan. Flow chart includes multiple directions for processing products but does not define which products should going which direction of processing.	The establishment updated the HACCP Plan flow chart to include detail of the product lines that follow each processing direction. Government inspection personnel verify the HACCP Plan flowcharts.
15. *Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.* HACCP plan did not list the monitoring frequency for CCP2	The establishment updated the HACCP Plan and included the monitoring frequency of the CCP 2. Government inspection personnel verify the update of the HACCP Plan.
17. The HACCP plan is signed and dated by the responsible establishment individual. HACCP plan was not signed	The HACCP plan was signed by the person responsible for the establishment. The government inspection staff verified the signature of the HACCP Plan.
22. *Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.* CCP1 monitoring records did not include the time or initial for each event.	SENACSA initiated the equivalence request process for CCP monitoring records as an **Individual Sanitary Measure (ISM)** al **International Equivalence Staff (IES).**

SENACSA PRESIDENCIA

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29. Records • Establishment's graphs of generic *E. coli* results were missing data points, the upper limit varied month to month, and the markings for the acceptability levels were not defined. • Establishment's sample results from two pieces of equipment that was sampled on 03/02/21 during pre-operations were missing from the records	The establishment updated the format of the generic E. coli results graphs, aggregated all data, and defined and identified the upper limit set. Government Inspection Personnel verified the updated charts.The establishment issued a correction in the report, detailing the results of the surfaces sampled on 02/03/2021. Government inspection staff verified updated report.
32 . Salmonella Sampling GIP was not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.	SENACSA Resolution No. 1396 came into effect on 11-08-2021. The Official Veterinary Inspection of Establishment No. 3 San Antonio complied with said resolution and proceeded to take official samples for analysis of Salmonella in carcasses after cooling.

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ESTABLECIMIENTO N°9 FRIGOCHORTI	
7. Written SSOP program The corrective actions listed in the establishment's SSOP did not include all three requirements of 9 CFR416.15b	The establishment updated the SSOP and included the corrective actions according to the requirements of the updates of the Resolutions referring to "Sanitary hygiene requirements in establishments slaughtering, preparing and/or processing food of animal origin." The Government Inspection Personnel verifies the updated version.
16. Records Documenting implementation and monitoring of HACCP plan. The HACCP monitoring records for the zero tolerance for fecal material, milk and intake CCP (Slaughter HACCP plan) and the metal detection CCP (Deboning HACCP plan) monitoring records did not include a record of direct observation and record review.	The establishment updated the version of the HACCP Plans and included the items of direct observation and review of the registry of the monitoring sheets of the zero tolerance CCPs for feces, intake and milk (CCP 1) and metal detection (CCP 6). Government inspection staff verifies the updated version.
19.Verification and validation of HACCP Plan The establishment's ongoing verification activities listed in the Slaughter and Deboning HACCP plans did not include: a- direct observation of the monitoring activity and frequency and b- review of records and frequency (for both HACCP plans) c- calibration of the process monitoring device (Deboning HACCP plan only).	The establishment updated the version of the HACCP Plans and included the items of direct observation, record review and equipment calibration, with their respective frequencies in the verification activities. The Government Inspection Personnel verifies the updated version.

SENACSA PRESIDENCIA

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20 . *Corrective actions written in HACCP plan* The establishment's corrective actions listed in both the Slaughter and Deboning HACCP plans for a deviation covered by a critical limit did not include all four requirements of 9 CFR 417.3b	The establishment updated the version of the HACCP Plans and included the four requirements for corrective actions for a critical limit deviation. The Government Inspection Personnel verifies the updated version.
22. *HACCP Records* The HACCP monitoring records did not include record review and direct observation under ongoing verification	The government inspection personnel received the update of SENACSA Resolution No. 32/2022 "Procedure and verification form for critical control points (CCP). Rev.04", it includes the review of records and direct observation of CCP under continuous verification.
32. *Salmonella sampling* GIP was not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.	SENACSA Resolution No. 1396 came into effect on 11-08-2021. The Official Veterinary Inspection of Establishment No. 9 FRIGOCHORTI received the update of said resolution and it was included in the sampling plan for Salmonella of beef carcasses refrigerated for at least 12 hours.

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ESTABLECIMIENTO N°10 FRIGOCHACO	
14. Developed and implemented a written HACCP plan - Establishment did not have support for their decision for monitoring frequency for CCP2A. - Establishment's supporting documentation for product temperatures did not support the decision for the critical limits for CCP2A. - Flow chart includes multiple directions for processing products but does not define which products should go in which direction of processing. - Processing steps in flow chart have different names from the processing steps in the Hazard Analysis	- The establishment updated the version of the HACCP Plans and, through the risk analysis carried out, determined that the PCC2A is of medium risk, for which it will be monitored by means of a Control Point (PC). - The establishment updated the version of the HACCP Plans and, through the risk analysis carried out, determined that the PCC2A is of medium risk, for which it will be monitored by means of a Control Point (PC). - The establishment updated the HACCP Plan flow chart to include detail of the product lines that follow each processing direction. Government inspection personnel verify the HACCP Plan flowcharts. - The establishment updated the HACCP Plan flowchart by unifying flowchart terms and processing steps in the hazard analysis. Government inspection personnel verify the flowcharts and hazard analysis of the HACCP Plan.

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15.Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions - HACCP plan for CCP1 does not include verification of monitoring records - HACCP plan does not identify monitoring frequency for CCP2A - HACCP plan for CCP2A does not accurately state verification frequency - The HACCP plan does not include calibration of process monitoring equipment - HACCP plan does not identify verification of monitoring records for CCP2B	- Establishment updated version of HACCP Plans and included verification of CCP 1 monitoring record. Government Inspection Personnel verifies updated version. - The establishment updated the version of the HACCP Plans and, through the risk analysis carried out, determined that the PCC2A is of medium risk, for which it will be monitored by means of a Control Point (CP). - The establishment updated the version of the HACCP Plans and, through the risk analysis carried out, determined that the PCC2A is of medium risk, for which it will be monitored by means of a Control Point (CP). - The establishment updated the version of the HACCP Plans and included the calibration of equipment for process monitoring. The Government Inspection Personnel verifies the updated version. - The establishment updated the version of the HACCP Plans and included verification of monitoring records for PCC2B. The Government Inspection Personnel verifies the updated version.

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16.Records documenting implementation and monitoring of the HACCP plan Incorrect monitoring record referenced in HACCP plan for CCP1 Verification record not referenced in HACCP plan for CCP2A	- The establishment updated the version of the HACCP Plans and corrected the name of the record for CCP1 in relation to the plan. The Government Inspection Personnel verifies the updated version. - The establishment updated the version of the HACCP Plans and referenced the registry for CCP2A verification. The Government Inspection Personnel verifies the updated version.
17.The HACCP plan is signed and dated by the responsible establishment individual HACCP plan was not signed	The establishment updated the version of the HACCP Plans, registering the signature of the person in charge of the establishment and the date of the update. The Government Inspection Personnel verifies the updated version.
20. Corrective actions written in HACCP plan. Corrective actions for CCP2B does identify the cause of the deviation	The establishment updated the version of the HACCP Plans and included the identification of the cause of the deviation in the corrective actions. The Government Inspection Personnel verifies the updated version.
21. .*Reassessment of adequacy of HACCP plan* / SENACSA did not implement its enforcement program, which requires establishments to take effective corrective actions and preventive measures, at an establishment with positive STEC samples. The establishment did not reassess its HACCP plan or make changes to its production process to address the repeated product adulteration. On 2/05/21, 3/29/21 and	SENACSA, through DIGECIPOA as CCA, updated and shared with the government inspection personnel of establishment No. 10 FRIGOCHACO the compliance programs to ensure that all measures are taken to guarantee that the products to be exported to the US are not adulterated. The resolutions that regulate said programs are attached.

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4/20/21, GIP collected STEC samples as part of the official microbiology testing program. The first two samples were confirmed positive for *E. coli O26* while the third one was presumptive positive for the same SETC serogroup (until August 21, the official laboratory did not have a STEC confirmatory method; therefore, all presumptive positive samples were considered as positive at that time). GIP have not verified that the establishment take corrective actions that met all requirements of 9 CFR 413 including a reassessment of the adequacy HACCP plan (the HACCP plan was last reassessed in October 2020).	- SENACSA Resolution No. 30/2022 "Sanitary hygiene requirements in establishments slaughtering, preparing and/or processing food of animal origin" effective from January 13, 2022. - SENACSA Resolution No. 31/2022 "BPM approval procedure – POES and recognition of HACCP. MIVO-FOR 16. Rev. 04" effective date from January 13, 2022 - SENACSA Resolution No. 32/2022 "Critical control point (CCP) verification procedure and form. Rev.04", with effective date from January 13, 2022. With these updates, the government inspection personnel must necessarily indicate a **REEVALUATION** of the establishment's HACCP plan and apply the established measures to it in case of repetitive deviations.
22.Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. CCP1 and CCP2A verification records do not include the time for each event. CCP1 monitoring records did not include the time or initial for each event	The establishment updated the version of the HACCP Plans and included the time for each event during verification. The Government Inspection Personnel verifies the updated version. - SENACSA started the equivalence request process for CCP monitoring records as an **Individual Sanitary Measure (ISM) al International Equivalence Staff (IES)**

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ESTABLECIMIENTO N°15 FRIGONORTE	
14. Development and Implementation of a Written HACCP Plan. The establishment accepts returned products; however, the establishment did not address returned products in the flow chart and hazard analysis.	The establishment updated the version of the HACCP Plans and included the return of products in the flow diagram and hazard analysis. The Government Inspection Personnel verifies the updated version.
14. Content of HACCP plan (listing of food safety hazards) - The establishment did not identify and address *E. coli O157* and non-O157 STECs as a food safety hazard in the hazard analysis of the slaughter HACCP plan.	The establishment updated the version of the HACCP Plans and included E. coli O157 and non-O157 STECs as a food safety hazard. The Government Inspection Personnel verifies the updated version.
16 .*Records documenting implementation and monitoring of HACCP plan.* The CCP daily monitoring records did not include a recording of direct observation of monitoring activities and the time the event occurred.	The establishment updated the version of the HACCP Plans and expanded and included the description of the methodology to be used in direct observation and the time of each event. The Government Inspection Personnel verifies the updated version.
19.Verification and validation of HACCP plan. The establishment's ongoing verification activities listed in the Slaughter/Deboning HACCP plan did not include direct observation of the monitoring activity as well as calibration of the process monitoring device and their frequencies.	The establishment updated the version of the HACCP Plans and included the direct observation of the monitoring and calibration activity of the process monitoring device and its frequencies in the CCP verification. The Government Inspection Personnel verifies the updated version.

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Presidente del SENACSA

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL

CIENCIAS VETERINARIAS N° 265 CASI RUTA MCAL. ESTIGARRIBIA KM 10,5
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32 . *Salmonella sampling* GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.	SENACSA Resolution No. 1396 came into effect on 11-08-2021. The Official Veterinary Inspection of Establishment No. 15 FRIGONORTE received the update of said resolution and it was included in the sampling plan for Salmonella of beef carcasses refrigerated for at least 12 hours.

Dr. José Carlos Martin C.
Presidente del SENACSA

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ESTABLECIMIENTO N°17 GUARANÍ	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions - The corrective actions listed in the HACCP plan does not include identifying the cause of the deviation or preventative measures - The HACCP plan does not include calibration of process monitoring equipment	- The establishment updated the version of the HACCP Plans and included the identification of causes and preventive measures. The Government Inspection Personnel verifies the updated version. - The establishment updated the version of the HACCP Plans and included the calibration of the process monitoring equipment. The Government Inspection Personnel verifies the updated version.
19 . Verification and validation of HACCP plan Verification of CCP 1, zero-tolerance for fecal, intake, and milk occurs after the carcass wash	- The establishment updated the version of the HACCP Plans, modified the verification point to the point located immediately after monitoring the CCP 1 and before washing the carcasses. The Government Inspection Personnel verifies the updated version.
22 . Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences - CCP1 monitoring records did not include the time or initial for each event - Verification of CCP1 monitoring records is not recorded	- SENACSA started the equivalence request process for CCP monitoring records as an **Individual Sanitary Measure (ISM) al International Equivalence Staff (IES).** - The establishment updated the version of the HACCP Plans and included the verification of the CCP1 monitoring records with the signature and date of the person responsible for the verification. Government inspection staff verifies the updated version.

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29 . Generic E. Coli Records 30 . The acceptability levels were not defined on the graphs of generic *E. coli* sample results.	- The establishment updated the format of the generic E. coli results graphs, establishing the levels of acceptability. The Government Inspection Personnel verifies the updated version.
32 . Salmonella Sampling GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.	- SENACSA Resolution No. 1396 came into effect on 11-08-2021. The Official Veterinary Inspection of Establishment No. 17 GUARANI complied with said resolution and proceeded to take official samples for analysis of Salmonella in carcasses after cooling.

SENACSA PRESIDENCIA

Presidente del SENACSA

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL

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ESTABLECIMIENTO N°23 BELÉN	
7 . *Written SSOP program* The corrective actions listed in the SSOP program does not include all three the requirements of 9 CFR416.15b	The establishment updated the SSOP and included the corrective actions according to the requirements of the updates of the Resolutions referring to "Sanitary hygiene requirements in establishments slaughtering, preparing and/or processing food of animal origin." The Government Inspection Personnel verifies the updated version.
32 . *Salmonella sampling* GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.	SENACSA Resolution No. 1396 came into effect on 11-08-2021. The Official Veterinary Inspection of Establishment No. 23 BELÉN complied with said resolution and proceeded to take official samples for analysis of Salmonella in carcasses after cooling.

SENACSA PRESIDENCIA

Dr. José Carlos Martín
Presidente del SENACSA

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL

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ESTABLECIMIENTO N°38 CONCEPCIÓN	
19 . Verification and validation of HACCP plan - The establishment's ongoing verification activities listed in the Slaughter and Deboning HACCP Plans did not include direct observation of the monitoring activity and frequency as well as review of records and frequency (for both HACCP plans). - The Deboning HACCP plan did not list calibration of the process monitoring device and frequency as an ongoing verification activity.	- The establishment updated the version of the HACCP Plans and included the items of direct observation and review of records, with their respective frequencies in the verification activities. The Government Inspection Personnel verifies the updated version. - The establishment updated the version of the HACCP Plans and included the calibration of the process monitoring device. The Government Inspection Personnel verifies the updated version.
32. Salmonella sampling - GIP were not collecting *Salmonella* samples from beef carcasses that have been chilled for at least 12 hours at the frequency of one sample per day until a set is completed, as required by the CCA's Microbiological Control Program.	SENACSA Resolution No. 1396 came into effect on 11-08-2021. The Official Veterinary Inspection of Establishment No. 38 CONCEPCIÓN complied with said resolution and proceeded to take official samples for analysis of Salmonella in carcasses after cooling.
39 . Establishment construction and maintenance - Rust buildup was observed on numerous overhead structures in the slaughter room.	Government inspection personnel immediately reported the finding. The establishment applied corrective measures that included cleaning and maintenance of the structures in the slaughter room. Government inspection personnel verified corrective and preventive actions.

Dr. José Carlos Martin C.
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Servicio Nacional de Calidad y Salud Animal	PLAN DE ACCIÓN ESTABLECIMIENTO FRIGORIFICO	MIVO – FOR 13-01 Ed: 10/06/2008 Rev. 04

ESTABLECIMIENTO NOMBRE y Nº: FRIGOCHACO N° 10 Nº DE NOTIFICACION: 11626

NC.	OBS.	Descripción del Plan	Fecha estimada de conclusión	Verificación I.V.O				
Ítem Nº	Ítem Nº			Eficaz	No Eficaz	Firma	Fecha	Hora
	21. SENACSA no implemento su programa de cumplimiento , que requieren que los establecimientos tomen acciones correctivas y preventivas efectivas, en un establecimiento con pruebas de STECs positivas el establecimiento no volvió a evaluar su plan HACCPni realizo cambios en el proceso de producción para abordar la adulteración repetida del producto.	El establecimiento cumplirá con lo establecido en las resoluciones SENACSA N° 30/2022- SENACSA N° y 31/2022 así como punto 9.1.5.2 del programa de Control Microbiológico del SENACSA Se emitió un informe de investigación por presencia de STEC en Trimming que describe los hallazgos encontrados de las verificaciones y sus recomendaciones correspondientes Reunión del equipo de Haccp para revisión del informe técnico de investigación por presencia de STEC en Trimming. Se instruye al personal en el correcto lavado y desinfección de las herramientas de trabajo entra cada canal en palya de faena Se instruye sobre la correcta operatoria de aserrado de pecho así como la esterilización de la sierra de pecho	12-04-2022	✓		#	12-04-22	14:10
Acción/es preventiva/s: - Asegurar que se cumplan estrictamente todos los puntos establecidos por el Programa de Control Microbiológico del SENACSA								

Observaciones: Se adjuntan el acta N° 56/2022 del equipo de HACCP, El Informe de investigación por presencia de STEC en Trimmig, informe de seguimiento STEC, fotos de la retroalimentación al personal de Playa, y de cambios en la infraestructura de playa de faena

Fecha Recepción I.V.O 12-04-22

Korni Pauls
Gerente de Planta
FRIGOCHACO

Responsable del Establecimiento
Firma y Sello

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL
Calidad e Inocuidad de Productos de Origen Animal
Insp. Veterinaria
EST. Nº 10

I.V.O
Firma y Sello

Dr. Félix Helman
Jefe Inspección Veterinaria
Est. Nº 10

SENACSA
Dra. Claudia Silva Quevedo
Coordinadora de Establecimientos de Exportación
Coordinación de Establecimientos de Exportación
Firma y Sello

Elaborado: Coordinación de Establecimiento de Exportación.	Revisado: Dirección de Mataderos y Frigoríficos	Aprobado por: Dirección General

Servicio Nacional de Calidad y Salud Animal	PLAN DE ACCIÓN ESTABLECIMIENTO FRIGORIFICO	MIVO – FOR 13-01 Ed: 10/06/2008 Rev. 04

ESTABLECIMIENTO NOMBRE y Nº: FRIGOCHACO N° 10 Nº DE NOTIFICACION: 11626

NC.	OBS.	Descripción del Plan	Fecha estimada de conclusión	Verificación I.V.O				
Ítem Nº	Ítem Nº			Eficaz	No Eficaz	Firma	Fecha	Hora
	21. SENACSA no implemento su programa de cumplimiento , que requieren que los establecimientos tomen acciones correctivas y preventivas efectivas, en un establecimiento con pruebas de STECs positivas el establecimiento no volvió a evaluar su plan HACCPni realizo cambios en el proceso de producción para abordar la adulteración repetida del producto.	Incluir al monitoreo del ambiente en el sector de lavado de reses para determinar presencia de gérmenes en el aerosol generado por el lavado de ½ canales Concienciar al personal de su responsabilidad del correcto Procedimiento Operativo Estandarizado y no solo cuando se le controla Utilizar dos cuchillos de colores diferentes en el eviscerado Instruir al personal sobre el correcto procedimiento para la enucleación y ligadura de recto Cambiar a un tamaño mayor la bolsa para la ligadura de recto Instruir al personal de ingreso de cuartos sobre la utilización en forma exclusiva de ganchos Se agrego una verificación adicional semanal de los	12-04-2022	✓		✓	12-04-22	14:10
Acción/es preventiva/s: - Asegurar que se cumplan estrictamente todos los puntos establecidos por el Programa de Control Microbiológico del SENACSA								

Observaciones: Se adjuntan el acta N° 56/2022 del equipo de HACCP, El Informe de investigación por presencia de STEC en Trimmig, informe de seguimiento STEC, fotos de la retroalimentación al personal de Playa, y de cambios en la infraestructura de playa de faena

Fecha Recepción I.V.O 12-04-22

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Coordinación de Establecimientos de Exportación
Firma y Sello

Elaborado: Coordinación de Establecimiento de Exportación.	Revisado: Dirección de Mataderos y Frigoríficos	Aprobado por: Dirección General

Servicio Nacional de Calidad y Salud Animal	PLAN DE ACCIÓN ESTABLECIMIENTO FRIGORIFICO	MIVO – FOR 13-01 Ed: 10/06/2008 Rev. 04

ESTABLECIMIENTO NOMBRE y Nº: FRIGOCHACO N° 10 Nº DE NOTIFICACION: 11626

NC.	OBS.	Descripción del Plan	Fecha estimada de conclusión	Verificación I.V.O				
Ítem Nº	Ítem Nº			Eficaz	No Eficaz	Firma	Fecha	Hora
	21. SENACSA no implemento su programa de cumplimiento , que requieren que los establecimientos tomen acciones correctivas y preventivas efectivas, en un establecimiento con pruebas de STECs positivas el establecimiento no volvió a evaluar su plan HACCPni realizo cambios en el proceso de producción para abordar la adulteración repetida del producto.	Procedimientos Operativos Estandarizados además de los controles ordinarios Minimizar la utilización de manos para el prolijado de cortes en despostada Retroalimentación al personal de playa en tiempo real de hallazgos por medio de una pantalla gigante, de las correcciones realizadas en el prolijado final Cambios en infraestructura (prolongación del palco de evisceración) a fin de que facilite el desplazamiento del operario Cambio de dirección de los forzadores ubicados en el sector de desollados de cuero a fin de que el posible arrastre del viento no contribuya a la contaminación de las canales Se procedió a la revisión de los manuales de BPM y SSOP y HACCP	12-04-2022	✓		#	12-04-22	14:10
Acción/es preventiva/s: - Asegurar que se cumplan estrictamente todos los puntos establecidos por el Programa de Control Microbiológico del SENACSA								

Observaciones: Se adjuntan el acta N° 56/2022 del equipo de HACCP, El Informe de investigación por presencia de STEC en Trimmig, informe de seguimiento STEC, fotos de la retroalimentación al personal de Playa, y de cambios en la infraestructura de playa de faena

Fecha Recepción I.V.O 12-04-22

Korni Pauls
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SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL – Calidad e Inocuidad de Productos de Origen Animal – Insp. Veterinaria – EST. Nº 10

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SENACSA – Calidad e Inocuidad de Productos de Origen Animal – Coordinación de Establecimientos de Exportación

Dra. Claudia Silva Quevedo
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Coordinación de Establecimientos de Exportación
Firma y Sello

Elaborado:	Revisado:	Aprobado por:
Coordinación de Establecimiento de Exportación.	Dirección de Mataderos y Frigoríficos	Dirección General

Servicio Nacional de Calidad y Salud Animal	PLAN DE ACCIÓN I.V.O	MIVO – FOR 13-02 Ed: 10.06.08 *Rev. 03*

ESTABLECIMIENTO, NOMBRE y Nº: FRIGORIFICO FRIGOCHACO S.A – EST N° 10 FECHA: 26-02-2022

NC. Ítem Nº	OBS. Ítem Nº		Fecha estimada de conclusión
		El SENACSA a través de la DIGECIPOA como CCA actualizó y socializó con el personal de inspección gubernamental los programas de cumplimientos para asegurar que sean tomadas todas las medidas que garanticen que los productos a ser exportados a los EEUU no se encuentren adulterados. Se anexan copias de los registros de capacitación atravez de los cuales fueron socializadas las siguientes resoluciones con el equipo de la Inspección Veterinaria Oficial. - Resolución SENACSA N° 30/2022 "Requisitos higiénicos sanitarios en establecimientos faenadores, elaboradores y/o procesadores de alimentos de origen animal" - Resolución SENACSA N° 31/2022 "Procedimiento de aprobación de BPM – POES y reconocimiento de HACCP. MIVO-FOR 16. Rev. 04" - Resolución SENACSA N° 32/2022 "Procedimiento y formulario de verificación de puntos críticos de control (PCC). Rev.04"	26-02-2022
Observación:			

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