United States Department of Agriculture

DEC 0 1 2022

Food Safety and Inspection Service

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

Dr. José Carlos Martin
President
Servicio Nacional de Calidad y Salud Animal (SENACSA)
Avda. Ciencias Veterinarias No. 265
San Lorenzo, Paraguay

Dear Dr. Martin,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a reinstatement of equivalence verification audit of Paraguay's meat food safety and inspection system July 11–22, 2022. Enclosed is a copy of the final audit report. The comments received from the Government of Paraguay are included as an attachment to the report.

For any questions regarding this audit report, please contact the Office of International Coordination by e-mail at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL FOLLOWUP REPORT OF AN AUDIT CONDUCTED OF

PARAGUAY

JULY 11–22, 2022

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

RAW INTACT BEEF PRODUCTS

INTENDED FOR EXPORT TO THE UNITED STATES OF AMERICA

November 29, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a targeted onsite reinstatement-of-equivalence verification audit of Paraguay conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) July 11–22, 2022. The purpose of the audit was to verify the implementation of the Central Competent Authority's (CCA) corrective actions in response to FSIS' November 1–17, 2021, audit findings, and verify Paraguay's food safety system governing raw intact beef products 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 targeted followup audit focused on three system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (4) Government Hazard Analysis and Critical Control Point (HACCP) System; and (6) Government Microbiological Testing Programs. The FSIS auditors verified the implementation of corrective actions to the following findings identified during the FSIS audit in 2021:

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

- The CCA 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.
- The CCA 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.
- The CCA did not ensure that laboratories conducting official government analyses of microbiological and chemical residue samples reported the results to the CCA officials in a timely manner.
- The CCA did not ensure that personnel from the General Directorate of Laboratories calibrated 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 the CCA's requirements for HACCP plan content.
- Government inspection personnel did not ensure that establishments' implementation of their HACCP plans complied with the CCA's requirements for HACCP plan execution.
- Government inspection personnel did not ensure that establishments' HACCP records complied with the CCA's requirements for HACCP recordkeeping.
- Government inspection personnel did not ensure that establishments' hazard analyses, flow charts, and supporting documentation complied with the CCA's requirements.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- General Directorate of Laboratories personnel were not analyzing all 60 trim pieces of the N60 sample submitted to the laboratory when the sample portion collected was 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 the CCA's Microbiological Control Program.

The FSIS audit confirmed that the CCA has fully implemented the corrective actions submitted to FSIS to address the prior audit findings within the three equivalence components.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a targeted onsite audit of Paraguay's food safety system from July 11–22, 2022. The audit began with an entrance meeting held July 11, 2022, in Asunción, Paraguay, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA)–Servicio Nacional de Calidad y Salud Animal (SENACSA). Representatives from SENACSA accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference on July 22, 2022.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a targeted, onsite, reinstatement-of-equivalence verification audit. The audit objective was to verify the implementation and effectiveness of SENACSA's corrective actions in response to the systemic findings identified during the FSIS audit conducted on November 1–17, 2021, and that Paraguay's food safety system governing raw intact beef products is functioning in a manner equivalent to that of the United States, ensuring products produced are safe, wholesome, unadulterated, and correctly labeled and packaged.

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

Prior to the targeted followup audit, FSIS reviewed and analyzed Paraguay's responses and supporting documentation related to the audit findings identified during the FSIS audit in 2021. During this targeted followup audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify implementation of SENACSA's corrective actions. Determinations concerning program effectiveness focused on performance with the following three equivalence components with systemic audit findings identified in the prior FSIS audit: Government Oversight (e.g., Organization and Administration); Government Hazard Analysis and Critical Control Point (HACCP) System; and Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at SENACSA's headquarters and five local inspection offices within the establishments. The FSIS auditors evaluated the implementation and efficacy of the national system of inspection, verification, and enforcement documented in the country's Self-Reporting Tool responses and supporting documentation.

A sample of five slaughter and processing establishments was selected from a total of nine slaughter and processing establishments that have requested certification from SENACSA to export raw intact beef products to the United States.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• SENACSA headquarters, Asunción
Beef slaughter and processing establishments		5	• Establishment No. 1, Frigorífico Neuland, Villa Hayes

		• Establishment No. 3, Frigorífico San Antonio, San Antonio • Establishment No. 9, Frigorífico Frigochorti, Loma Plata • Establishment No. 10, Frigorífico Frigochaco, Limpio • Establishment No. 17, Frigorífico Guaraní, S.A.C.I., Fernando de la Mora

FSIS performed the audit to verify that the food safety 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 Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR 301 to the end).

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

III. BACKGROUND

The FSIS reinstatement-of-equivalence verification audit conducted from November 1–17, 2021, identified the following systemic findings:

Summary of Systemic Findings from the 2021 FSIS Audit of Paraguay
Component 1: 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 reported the results to the CCA officials in a timely manner. • SENACSA did not ensure that personnel from the General Directorate of Laboratories (Dirección General de Laboratorios (DIGELAB)) calibrated the equipment at the frequency required by the laboratory's written quality assurance program.
Component 4: 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.
Component 6: 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 was 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.

During the targeted followup audit, the FSIS auditors verified through interviews, review of records, and observations that the corrective actions for the systemic findings identified during the previous FSIS audit in 2021 were implemented and effective.

The most recent FSIS final audit report for Paraguay's food safety system is available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

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

The first of three equivalence components the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The FSIS auditors verified the implementation and effectiveness of SENACSA's corrective actions submitted in response to the following systemic findings identified during the FSIS audit conducted in 2021:

- 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 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 reported the results to SENACSA officials in a timely manner.
- SENACSA did not ensure that personnel from DIGELAB calibrated the equipment at the frequency required by the laboratory's written quality assurance program.

Verification Results: Enforcement of Required HACCP Reassessments

In response to the 2021 FSIS audit, SENACSA issued and enforced Resolution No. 30/2022, which describes the requirements for initial validation of the HACCP system and requirements for reassessment of the HACCP plan. HACCP plans must be reassessed at least once a year and whenever any changes occur that may affect the hazard analysis or alter the HACCP plan such as unforeseen hazards. The establishment must make a record of each reassessment and document the reasons for any changes to the HACCP plan based on the reassessment. The General Directorate of Quality and Safety of Products of Animal Origin (Dirección General de Calidad e Inocuidad de Productos de Origen Animal (DIGECIPOA)) issued Circular No. 1/2022 on January 31, 2022, which required establishments that intend to export to the United States to carry out and submit to SENACSA their initial validation data documentation for their current HACCP system.

Additionally, SENACSA issued and enforced Resolution No. 31/2022, which updates the procedure for approval of establishments' Good Manufacturing Practices (GMP) programs and Sanitation Standard Operating Procedures (Sanitation SOPs) programs and the procedure for recognition of establishments' HACCP systems. This new resolution requires establishments to submit their GMP programs and Sanitation SOP programs to SENACSA for review and approval and submit their HACCP systems to SENACSA for review and recognition. The process of approval and recognition is subject to official verification at two levels. First level verification is by the official veterinary inspection team (Inspección Veterinaria Oficial (IVO)) which has 30 calendar days to evaluate the programs. The IVO team evaluation consists of the following two components: verification that the procedures described in the manuals comply with SENACSA's guidelines and verification that the establishment is implementing their procedures as described. Upon satisfactory review by the IVO team, the programs are submitted to the DIGECIPOA for the second level verification. Resolution No. 31/2022 also implements changes to the evaluation form used by the IVO team for evaluation of the establishment's HACCP system. The new evaluation form adds the requirement for the IVO team to verify initial validation data and reassessment of the HACCP plan. Additionally, the new evaluation form was expanded to provide specific verification points under each topic.

During the visit to the five beef slaughter and processing establishments, the FSIS auditors confirmed that each IVO team verified the establishments had performed initial validation of their HACCP systems and performed reassessments of their HACCP plans as required. The FSIS auditors verified the IVO teams were utilizing the updated evaluation forms when performing the first level verification of the establishments' HACCP plans and were submitting them to DIGECIPOA for the second level verification.

Verification Results: Implementation of Requirement to Ensure that Livestock Carcasses and Parts subjected to Routine Chemical Residue Testing be Precluded from Export to the United States Pending Acceptable Test Results

SENACSA issued and enforced Resolution No. 1135, which requires products resulting from cattle sampled in the framework of the residue control program to be retained until results are obtained.

The FSIS auditors verified the IVO team at all five beef slaughter and processing establishments visited were requiring deboned products from carcasses subject to routine chemical residue testing to be held by the establishment until the receipt of results. The FSIS auditors reviewed examples of noncompliant results and verified the product was held by the establishment pending results and the products were either condemned or sent to less restrictive markets. The FSIS auditors also reviewed notifications by the chief IVO to the establishments when chemical residue test results exceeded levels for specific markets.

Verification Results: Reporting of Government Microbiological and Chemical Residue Results in a Timely Manner

DIGELAB has implemented the MAS LABS laboratory information management system under a pilot program that will run alongside the current program that requires results to be provided in hard copy. MAS LABS allows the reports of results from DIGELAB to be available to all users immediately after completion of the analyses. DIGELAB currently performs all government microbiological analyses as well as testing for heavy metals and sulfonamides in samples collected at establishments that intend to export to the United States.

The FSIS auditors verified the IVO teams were receiving results from government microbiological testing and heavy metal and sulfonamides testing electronically via the MAS LABS system as well as receiving hard copy results.

SENACSA issued and enforced Resolution No. 1585, which requires subcontracted laboratories that analyze government microbiological and chemical residue testing to provide results electronically to the DIGELAB and DIGECIPOA. A hard copy of the results must also be provided to DIGELAB. On June 13, 2022, SENACSA requested subcontracted laboratories that test official samples collected under the national residue program to take part in the pilot program for implementation of MAS LABS.

The pilot program for implementation of MAS LABS at the subcontracted laboratories was in the initial phase during the FSIS followup audit. The subcontracted laboratories were in the process of training their staff on the MAS LABS system. Since the subcontracted laboratories had not begun to distribute chemical residue results electronically via the MAS LABS system, the FSIS auditors were unable to verify this aspect of the corrective actions.

Verification Results: Calibration of DIGELAB Equipment and Instruments

DIGELAB developed an annual equipment calibration plan, which is required to be periodically reviewed and verified by an assigned employee. SENACSA requires all laboratory equipment to be calibrated by laboratories accredited to the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:2017 standards, General Requirements for the Competence of Testing and Calibration Laboratories, by the national accreditation body (Organismo Nacional de Acreditación (ONA)). Additionally, DIGELAB is in the process of incorporating equipment calibration and stock management of reagents into the MAS LABS system. The FSIS auditors verified through records review that all laboratory

equipment and instruments are currently calibrated according to laboratory procedures and ISO standards.

Additionally, in conjunction with corrective actions implemented to address the audit finding in component six related to N60 trim testing for STEC, laboratory personnel participated in training at DIGELAB on the detection, isolation, and confirmation of STEC provided by instructors from a United States educational institution. Further, the laboratory personnel participated in external training by the manufacturer of the equipment. SENACSA also hired a consultant for six months to help strengthen DIGELAB's microbiological analytical capabilities. As a result, DIGELAB also added a STEC method to its scope of accreditation on May 12, 2022, and laboratory personnel participated in proficiency testing for detection of STEC.

The FSIS auditors reviewed DIGELAB's new procedure for detection of STEC in N60 trim samples and verified that the procedure is consistent with FSIS' Microbiology Laboratory Guidebook (MLG) Chapter 5C. The FSIS auditors also reviewed attendance documentation for the internal training as well as certificates of participation from the external trainings. Finally, the FSIS auditors reviewed the results of the proficiency testing in March 2022 for the detection of *Escherichia coli* O157:H7 and STEC genes (*stx*/*eae*) and verified DIGELAB received acceptable results. No concerns were identified by the FSIS auditors.

Lastly, in conjunction with the review of corrective actions implemented by DIGELAB to address another finding in component six, the FSIS auditors verified that the laboratory's analytical method for detection of *Salmonella* was added to DIGELAB's scope of accreditation from ONA on May 12, 2022.

Conclusion

The FSIS auditors confirmed that SENACSA has implemented the corrective actions submitted to FSIS to address the 2021 audit findings related to this component. This included the development and enforcement of new requirements related to initial validation of HACCP systems and reassessment of HACCP plans. SENACSA has implemented their requirement that carcasses and parts subject to routine chemical residue testing be precluded from being eligible to export to the United States until receipt of acceptable results. DIGELAB has implemented the MAS LABS system, which allows them to provide results electronically for microbiological analyses and testing for heavy metals and sulfonamides residues. The subcontracted chemical residue testing laboratories are in the process of implementing the MAS LABS system so that all results from chemical residue testing will be provided electronically. DIGELAB also implemented a new system for monitoring the calibration of laboratory equipment, including assigning personnel to periodically review and verify calibration is being performed according to the schedule. Lastly, DIGELAB implemented training and proficiency testing for a revised analytical method for detection of STEC in beef trimmings and added analytical methods for detection of STEC in beef trimmings and for detection of *Salmonella* in beef carcass samples to its scope of accreditation.

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)

This component was not assessed during the followup audit because FSIS identified no systemic audit findings during the November 2021 reinstatement-of-equivalence audit.

VI. COMPONENT THREE: GOVERNMENT SANITATION

This component was not assessed during the followup audit because FSIS identified no systemic audit findings during the November 2021 reinstatement-of-equivalence audit.

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

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

The FSIS auditors verified the implementation and effectiveness of SENACSA's corrective actions submitted in response to the following findings identified during the FSIS audit conducted in 2021:

- 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 the SENACSA's requirements.

Verification Results: HACCP Plan Content

In response to the 2021 FSIS audit, SENACSA issued and enforced Resolution No. 30/2022, which specifies that the HACCP plan should contain ongoing verification activities and corrective and preventative actions to be taken when there is a deviation from a critical limit. It also requires that the HACCP plan be dated and signed by the appropriate establishment person.

SENACSA issued and enforced Resolution No. 31/2022, which implements changes to the evaluation form used by the IVO team for evaluation of the establishment's HACCP plan content. The new evaluation form was expanded to provide additional points for verification of the establishment's HACCP plan content.

The FSIS auditors reviewed the HACCP plans at the five beef slaughter and processing establishments included in the audit. The FSIS auditors verified the HACCP plans contained corrective and preventative actions to be taken when there is a deviation from a critical limit. The

FSIS auditors also verified the HACCP plans had been signed and dated by the appropriate establishment employee. The FSIS auditors verified the HACCP plans contained ongoing verification activities, except the HACCP plan at one establishment did not state the frequency for verification activities and the HACCP plan at a second establishment did not include procedures and frequency for the calibration of process monitoring equipment. Other than those isolated deficiencies, the FSIS auditors verified the HACCP plans contained the content required by SENACSA.

Verification Results: HACCP Plan Implementation

Resolution No. 32/2022 requires the IVO team to verify the implementation of the establishment's HACCP plan by performing daily on-site observations and record review at the critical control points (CCPs) to verify the establishment personnel are performing tasks specified in the HACCP plan.

The FSIS auditors verified HACCP plan implementation through record review at all establishments included in the audit. The FSIS auditors found that one establishment did not identify the cause of the deviation as part of their corrective actions. Other than that isolated deficiency, the FSIS auditors verified the establishments are implementing their HACCP plans as described and the IVO teams are performing onsite observations and record reviews of the CCPs.

Verification Results: HACCP Records

Resolution No. 32/2022 requires the IVO team to perform weekly verification of the HACCP records for the previous week to ensure they comply with SENACSA's HACCP recordkeeping requirements. DIGECIPOA issued Circular No. 3/2022 on June 29, 2022, which required establishments intending to export to the United States to comply with FSIS regulatory requirements consistent with 9 CFR 417.5(b) that require establishment employees to sign, date, and authenticate each record maintained as part of the HACCP plan (i.e., monitoring activities, verification activities, and corrective actions).

The FSIS auditors reviewed HACCP monitoring, verification, and corrective action records at all the visited establishments. The establishments implemented electronic recordkeeping for their zero tolerance CCPs. The FSIS auditors verified the establishments implemented appropriate controls to ensure the integrity of the electronic data and signatures. The records of verification of monitoring at two establishments did not include the time the event occurred. Other than those isolated deficiencies, the FSIS auditors verified the HACCP records complied with SENACSA's HACCP recordkeeping requirements and that the IVO teams performed weekly record verification activities according to established procedures.

Verification Results: Requirements for Hazard Analyses, Flow Charts, and Supporting Documentation

In response to the 2021 FSIS audit, SENACSA issued and enforced Resolution No. 30/2022, which requires establishments to ensure their flow charts accurately reflect their manufacturing stages and correspond with the steps contained in the hazard analyses. Additionally, SENACSA

issued and enforced Resolution No. 31/2022, which updates the procedure for recognition of establishments' HACCP systems for establishments eligible for export. This resolution requires establishments eligible for export to submit their HACCP systems to SENACSA for review and recognition.

The FSIS auditors reviewed the hazard analyses, flow charts, and supporting documentation at the establishments included in the audit scope. The FSIS auditors verified the steps in the flow charts were consistent with the steps in the hazard analyses. One establishment performed a risk assessment to support changing a CCP to a control point. The measurements employed during the risk assessment did not accurately reflect the concept under evaluation; therefore, impacting the validity of the conclusion based on the risk assessment. Other than that isolated deficiency, the FSIS auditors verified the hazard analyses, flow charts, and supporting documentation complied with SENACSA's requirements.

Conclusion

The FSIS auditors confirmed that SENACSA has implemented the corrective actions submitted to FSIS to address the 2021 audit findings related to this component. This included the development and enforcement of new resolutions to ensure that the establishments' HACCP systems are designed and implemented according to SENACSA's requirements and guidance to the IVO teams to help them verify the design and implementation of the establishments' HACCP systems.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

This component was not assessed during the followup audit because FSIS identified no systemic audit findings during the November 2021 reinstatement-of-equivalence audit.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last of three equivalence components the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety system is to implement certain sampling and testing programs to ensure that beef products prepared for export to the United States are safe and wholesome.

The FSIS auditors verified the implementation and effectiveness of SENACSA's corrective actions submitted in response to the following findings identified during the FSIS audit conducted in 2021:

- DIGELAB personnel were not analyzing all 60 trim pieces of the N60 sample submitted to the laboratory when the sample portion collected was 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.

Verification Results: N60 Trim Sample Analyses Procedure

DIGELAB modified its N60 trim sample collection and analytical testing methodology on November 2, 2021. The changes align the sample preparation and enrichment of N60 trim samples with the MLG Chapter 5C to ensure that all 60 pieces of trim are analyzed when a sample is collected. Additional information regarding laboratory training and proficiency testing is discussed in component one of this report.

Verification Results: Official *Salmonella* Testing of Post-Chill Beef Carcasses

SENACSA issued and enforced Resolution No. 1396, which requires sample collection and testing for *Salmonella* of post-chill beef carcasses at establishments that intend to export to the United States.

The FSIS auditors verified that official *Salmonella* sampling of post-chill carcasses was being conducted at all establishments included in the audit. The FSIS auditors observed *Salmonella* sampling at two of the audited establishments. At one establishment, the sample collector did not follow SENACSA's procedure for sponging the carcass, which requires 10 swipes vertically, 10 swipes horizontally, and 10 swipes diagonally. The observed sample collector only performed 10 vertical swipes and 10 horizontal swipes. Additionally, the sample collector did not follow appropriate aseptic techniques when donning gloves, which introduces the potential for contamination of the gloves that may affect the outcome of the analytical result for the sample. The FSIS auditors reviewed the post-chill *Salmonella* results for cows/bulls and steers/heifers at all establishments included in the audit. All results reviewed were acceptable. Other than the isolated deficiencies, the FSIS auditors verified *Salmonella* sampling of post-chill carcasses was being conducted at all establishments included in the audit in accordance with SENACSA's procedures.

Conclusion

The FSIS auditors confirmed that SENACSA has implemented the corrective actions submitted to FSIS to address the 2021 audit findings related to this component. This included testing of the entire N60 trim sample for STEC and implementation of official sampling and testing for *Salmonella* on post-chill beef carcasses.

X. CONCLUSIONS AND NEXT STEPS

A remote exit meeting was held July 22, 2022, with representatives from SENACSA. At this meeting, the FSIS auditors presented the observations from the targeted followup audit. An analysis of the observations within the three equivalence components did not result in systemic deficiencies or represent an immediate threat to public health.

The FSIS auditors verified the implementation of corrective actions to the following aspects of the food safety system:

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 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 reported the results to the SENACSA officials in a timely manner.
- SENACSA did not ensure that personnel from DIGELAB calibrated 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 was 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 the CCA's Microbiological Control Program.

The FSIS auditors confirmed that SENACSA has implemented the corrective actions submitted to FSIS to address the prior audit findings within all three equivalence components.

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	7/18/2022	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.		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.		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.		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. Official *Salmonella* sampling	X
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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

60. Observation of the Establishment

During the audit of the establishment, the IVO team did not identify the following noncompliances:

57. *Official Salmonella sampling*

The sample collector did not follow SENACSA's procedure for sponging the carcass, which requires 10 swipes vertically, 10 swipes horizontally, and 10 swipes diagonally. The observed sample collector only performed 10 vertical swipes and 10 horizontal swipes. Additionally, the sample collector did not follow appropriate aseptic techniques when donning gloves, which introduces the potential for contamination of the gloves that may affect the outcome of the analytical result for the sample.

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	7/12/2022	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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
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, subprimals, beef trimmings

60. Observation of the Establishment

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/21/2019

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
Frigorífico Frigochorti Neudorf, Loma Plata Boquerón	7/15/2022	9	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.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
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 IVO team did not identify the following noncompliance:

19. Verification and validation of HACCP Plan

- The establishment's ongoing verification activities listed in the Deboning HACCP plan did not include all calibrations of process monitoring instruments

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

61. NAME OF AUDITOR

62. AUDITOR SIGNATURE AND DATE

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	7/13/2022	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	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.		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.	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.		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			

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

60. Observation of the Establishment

During the audit of the establishment, the IVO team did not identify the following noncompliances:

14. Developed and implemented a written HACCP plan

- The establishment performed a risk assessment to support changing a critical control point (CCP) to a control point. The measurements employed during the risk assessment did not accurately reflect the concept under evaluation; therefore, impacting the validity of the conclusion based on the risk assessment.

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

- HACCP plan for CCP1 and CCP2 do not state frequency of verification of monitoring records

20. *Corrective actions written in HACCP plan*

- Corrective actions for CCP2 do not identify the cause of the deviation

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/21/2019

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
Frigorífico Guaraní Av. Sta. Teresa y Chaco Boreal Fernando de la Mora, Paraguay	7/14/2022	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	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 .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
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		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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

60. Observation of the Establishment

During the audit of the establishment, the IVO team 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*

- Verification of monitoring records for critical control point (CCP) 1 and CCP2 do not include time of specific even occurrences
- Verification of monitoring records for CCP1 and CCP2 do not contain the signature or initial of the employee making the entry
- Verification of monitoring records for CCP1 does not include all results, only non-compliant results

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	11/21/2019

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, November 2, 2022

N.P. N° 470 .-

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

Dear Madam,

I have the pleasure to address you, on behalf of the National Service of Quality and Animal Health (SENACSA) of the Republic of Paraguay, to present my respects and to extend my sincere appreciation for your letter dated 12th October 2022, enclosing the copy of the final-report draft on the specific on-site verification audit, carried out from 11th to the 22nd of July 2022; referring the meat products and food safety inspection system of Paraguay, for the restatement of the equivalence and by which is requested the provision of comments on the audit report.

In this regard, the action plan carried out to address the audit findings is attached, for your consideration and for all pertinent purposes.

Thanking you for your polite attention to this letter, kindly accept the assurance of my highest consideration.

DR. JOSÉ CARLOS MARTIN C.
President

CCA's response to the draft final audit report

SERVICIO NACIONAL DE CALIDAD Y SALUD ANIMAL
CIENCIAS VETERINARIAS N° 265 CASI RUTA MCAL. ESTIGARRIBIA KM 10,5
Casilla de Correo: CAPY – 1101 – 1110 CAMPUS UNA - 2169
SAN LORENZO – PARAGUAY
Teléfonos: + 595 21 574501 / +595 21 501374 / +595 21 505727 / +595 21 576435 / +595 21 507862
Fax: +595 21 574501 / +595 21 507863

ESTABLISHMENT N°1 NEULAND	
60. Observation of the establishment During the audit, the IVO team did not identify the following non-conformities: 57.- Official sampling for *Salmonella* The person in charge of collecting the samples did not follow the procedure established by SENACSA for sponging the carcass, which requires 10 vertical sweeps, 10 horizontal sweeps and 10 diagonal sweeps. The person in charge of collecting the samples who was observed only made 10 vertical and 10 horizontal passes. In addition, the sample collector did not follow proper aseptic techniques when putting on the gloves, which introduces the possibility of glove contamination that may affect the result of the sample analysis.	SENACSA, through the Competent Central Authority (CCA) of the General Directorate for Quality and Safety of Products of Animal Origin (DIGECIPOA), conducted feedback training on the "*Salmonella* spp Program in carcasses after cooling". The activity was carried out on August 12, 2022 through the Webex platform. Government Inspection Personnel (GIP) participated in the activity, including an evaluation at the en., in reference to the following topics developed: - Responsible for sample collection - Sampling procedure - Sample selection criteria - Sampling supplies - Sampling areas - Aseptic placement technique of sterile gloves - Sampling frequency - Refrigeration and transport - Microbiological criteria - Record of results - Notification of the IVO

	On October 13, 2022, the CCA and the Government Inspection Personnel participated in a training activity on "Validation of interventions, STECS, sponge sampling and N60", carried out remotely with external technicians representing laboratory supplies. After the FSIS audit, the Government Inspection Personnel of Establishment No. 1 NEULAND, conducted feedback training in the "*Salmonella* spp Program in carcasses after cooling" to the members of the Official Veterinary Inspection team, on date July 20, 2022, including the development of topics related to the program. The effectiveness of the measures taken has been verified in Establishment No. 1 NEULAND during the supervision of the Official Veterinary Inspection, carried out by the designated technical team ANNEX 1

Dr. José Carlos Martin C.
Presidente del SENACSA

ESTABLISHMENT N° 9 FRIGOCHORTI	
60. Observation of the establishment : During the audit of the establishment, the IVO team did not identify the following non-conformities. 19. HACCP Plan Verification and Validation The establishment's ongoing verification activities listed in the deboning HACCP plan did not include all calibrations of process monitoring instruments.	The CCA, through the Government Inspection Personnel of Establishment No. 9 FRIGOCHORTI, verified the inclusion of all the calibrations of the process monitoring instruments in the deboning HACCP plan. In addition, the ACC verified the effectiveness of the measures taken through documentary review. ANNEX 2

Dr. José Carlos Martin C.
Presidente del SENACSA

ESTABLISHMENT N°10 FRIGOCHACO	
60. Observation of the establishment: During the audit of the establishment, the IVO team did not identify the following non-conformities: 14. Develop and implement a written HACCP plan: The establishment performed a risk assessment to support the change from a critical control point (CCP) to a control point. The measurements used during the risk assessment did not accurately reflect the assessed concept; therefore, they affected the validity of the conclusion based on the risk assessment. 15. HACCP content lists food safety hazards, critical control points, critical limits, procedures, corrective measures. The HACCP plan for CCP1 and CCP2 does not indicate the frequency of verification of control records. 20. Corrective actions written in the HACCP plan	The CCA, through the Government Inspection Personnel of Establishment No. 10 FRIGOCHACO, verified that the measurements used by the establishment accurately reflect the evaluated concept and thus the conclusion is totally valid. The Government Inspection Personnel specifically verified that the conforming results of the statistical study of the temperature of the deboning room versus the temperature of the cuts have been taken into account; of the microbiological tests carried out on 03/29/22 and 03/30/22 and of the results of sampling carried out according to the internal laboratory plan, as well as the documentary review of the CCP2A for the whole year 2021. In all the cases have obtained results within the range and compliant. No deviations have been observed during the monitoring or verification of the CCP2A, giving the risk analysis of the HACCP Plan revision 08, at this point of the process (stage 31) the risk due to biological hazards is of "medium" severity and taking into account as justification for the preventive measures adopted, together with the answers to the questions in the decision tree, the CCP becomes a Control Point.

SENACSA
Dr. José Carlos Martín
Presidente del SENACSA

The corrective actions for CCP2 do not identify the cause of the deviation.	Also, the Government Inspection Personnel verified that the conforming of the statistical study of the temperature of the Maturation Chamber versus the temperature of the offal product hada been taken into account; the microbiological tests carried out on 03/29/22 and the results of sampling carried out according to the internal laboratory plan, as well as the documentary review of the CC3PA for the whole year 2021, have had results within the range and in compliance. No deviations have been observed during monitoring or verification of CCP3A. Also, the risk analysis of the HACCP plan revision 08, shows that at this point in the process (stage 50) the risk for biological hazards is of "medium" severity and taking into account as justification the preventive measures adopted, together with the responses to questions of the decision tree, the CCP becomes a Control Point. In addition, the CCA verified the effectiveness of the measures taken through documentary review. ANNEX 3

Dr. José Carlos Martin C.
Presidente del SENACSA

ESTABLISHMENT N°17 GUARANÍ	
60. Observation of the establishment During the audit of the establishment, the IVO team did not identify the following non-conformities: 22. Records documenting the HACCP plan, monitoring of critical control points, dates and times of occurrence of specific events. - The verification of monitoring records for critical control points (CCP) 1 and 2 does not include the time of specific events. - The verification of the control records for CCP1 and CCP2 do not contain the signature or the initial of the person in charge of carrying out the data upload. - The verification of the control records for CCP1 does not include all the results, only the non-compliant results.	The CCA through the Government Inspection Personnel of Establishment No. 17 GUARANI verified that the establishment has included in the verification record of CCP1 and CCP2 the start and end time of the verification operation. With respect to the critical control point monitoring records, the GIP verified that the verification record for CCP1 and CCP2 included the signature or initial of the person responsible for carrying out the verification operation for each event recorded. In reference to the verification of the CCP1 control records, GIP verified that the establishment has included in the CCP1 verification record the qualification of each recorded event. The effectiveness of the measures taken has been verified in Establishment No. 17 GUARANI during the supervision of the Official Veterinary Inspection, carried out by the designated technical team. ANNEX 4