USDA

United States Department of Agriculture

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Food Safety and
Inspection Service

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General Directorate for Medicines, Food and Health Products (DIGEMAPS)
Ministry of Public Health (MSP)
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Dear Dr. Santoni,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a reinstatement equivalence verification audit of Dominican Republic's meat inspection system from September 13 to September 23, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of Dominican Republic are included as an attachment to the report.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

THE DOMINICAN REPUBLIC

SEPTEMBER 13–23, 2021

EVALUATING THE FOOD SAFETY INSPECTION SYSTEMS GOVERNING

RAW INTACT BEEF PRODUCTS INTENDED FOR EXPORT TO

THE UNITED STATES OF AMERICA

March 18, 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 conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from September 13–23, 2021. FSIS previously found the country's inspection system for meat products to be equivalent to FSIS' inspection system; however, the country withdrew its eligibility to export meat products to the United States in 1999.

Due to the global COVID-19 pandemic the audit was conducted following an audit process which included both remote and onsite audit activities. The purpose of the audit was to verify that the Dominican Republic'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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors concluded that the Dominican Republic's inspection system for raw intact beef is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Central Competent Authority (CCA) has required establishments that will be certified as eligible to export products to the United States to implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, the CCA has implemented chemical residue and microbiological testing programs to verify its food safety inspection system.

An exit meeting was held on September 23, 2021, by videoconference with the CCA. At this meeting, the FSIS auditors presented the preliminary findings from the audit including the following laboratory related findings:

GOVERNMENT OVERSIGHT (e.g., Organization and Administration)

- The CCA did not ensure that two of the three audited laboratories fully comply with certain general quality assurance and control criteria provided in the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025. The FSIS auditors identified findings related to sample receipt and storage, implementation of internal quality control procedures, use of assays to ensure the quality of results, and traceability of test results.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will assess the adequacy of the CCA's corrective actions and determine whether those proposed corrective actions satisfy FSIS' equivalence requirements.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of the Dominican Republic's food safety inspection system from September 13–23, 2021. The audit began with an entrance meeting held on September 13, 2021, with representatives from the Central Competent Authority (CCA) – Food and Beverage Risk Control Department (Food Department-FD). Representatives from FD accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a reinstatement of equivalence verification audit. The audit objective was to verify that the Dominican Republic's 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 USDA's Animal and Plant Health Inspection Service (APHIS) currently recognizes the Dominican Republic as free of foot-and-mouth disease (FMD) and undetermined risk for bovine spongiform encephalopathy (BSE).

Prior to the onsite reinstatement of equivalence verification audit, FSIS reviewed and analyzed the Dominican Republic's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether the Dominican Republic'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 auditor reviewed administrative functions at FD headquarters and three local inspection offices within the establishments. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as documented in their SRT and supporting documentation.

The FSIS auditor audited three beef slaughter and processing establishments that have requested certification from the FD to export raw intact beef to the United States. During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS

auditor assessed the FD'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) Part 327.2.

The FSIS auditors visited two government laboratories (one microbiology and one chemical residue) and one private laboratory (microbiology) to verify their ability to provide adequate technical support to the food safety inspection system.

Audit Scope		#	Locations
Competent Authority	Central	1	• FD headquarters, Santo Domingo
Laboratories		3	• Laboratorio Veterinario Central (LAVECEN) – national government laboratory for chemical residue testing, Santo Domingo • Instituto de Innovación en Biotecnología e Industria (IIBI) – national government laboratory for microbiology testing, San Geronimo • Laboratorio Agroempresarial Dominicano (LAD) – private laboratory for microbiology testing, Santo Domingo
Beef slaughter and processing establishments		3	• Establishment No. C1- 002, Suplidora de Carnes A&B/Carretera Yamasa, Sierra Prieta, municipio de Santo Domingo Norte • Establishment No. C1- 005, Agrocarne/Carretera La Romana-Guaymate, Km 101/2 Batey Higueral, provincia La Romana • Establishment No. C1- 007, Mercarne, SRL/Cancino adentro, Santo Domingo Este

FSIS performed the audit to verify that the Dominican Republic's 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. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of the Dominican Republic'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

The Dominican Republic had previously been eligible to export meat products to the United States. However, in 1999, the Dominican Republic withdrew its eligibility to export meat products to the United States because the inspection system had not yet implemented requirements to be equivalent under the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (PR/HACCP) final rule published by FSIS on July 25, 1996.

On December 3, 2013, the Dominican Republic requested that FSIS reactivate the reinstatement equivalence process for meat products. On May 15, 2017, the Dominican Republic submitted responses and supporting documents as part of its SRT. On November 5, 2019, FSIS completed its review of the Dominican Republic's SRT responses and the corresponding supporting documentation and reached a tentative determination that the Dominican Republic's documented food safety inspection system is equivalent to FSIS' inspection system.

On March 2, 2020, FSIS sent a letter to the Dominican Republic informing them of FSIS' intention to reinstate equivalence of their raw intact beef products. The letter also proposed that FSIS would conduct an onsite audit from March 30 to April 8, 2020, to verify that all aspects of the Dominican Republic's food safety inspection system is being implemented as documented in the SRT and is equivalent to FSIS' inspection system. However, due to foreign travel restrictions associated with the global COVID-19 pandemic, FSIS had to postpone the 2020 scheduled onsite audit.

FSIS' final audit report for the Dominican Republic's food safety inspection system will be available on the FSIS website at: www.fsis.usda.gov/inspection/import-export/international-reports/foreign-audit-reports.

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

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

FD is the Dominican Republic's CCA responsible for the implementation of their national meat inspection system and all activities related to the export of meat products to the United States. FD is an agency within the General Directorate of Drugs, Food and Sanitary Products (Dirección General de Medicamentos, Alimentos y Productos Sanitarios – DIGEMAPS) under the Ministry of Public Health (Ministerio de Salud Pública – MSP). The Dominican Republic's Law No. 42–01 indicates that MSP is responsible for regulating and controlling imported and domestically produced food marketed in the country to ensure it is wholesome and of good quality.

DIGEMAPS is the authority responsible for enforcing the law and sanitary regulations, as well as coordinating the functions of different departments including FD. FD is responsible for official control of slaughter and processing establishments, including those facilities that will be certified as eligible to export to the United States.

The Dominican Republic's meat inspection system is organized on two levels: central and establishment. At the central level, FD's headquarters provides direct supervision over establishments that will be certified as eligible to export to the United States in accordance with national legislation and FSIS import requirements. At the establishment level, Official Veterinary Doctors (MVOs) are responsible for performing inspection and verification procedures as well as supervision of Official Inspection Assistants (AIOs) who assist the MVOs in conducting inspection activities. The FSIS auditors verified through interviews and record reviews that all inspection personnel are permanent government employees who are hired and paid by the national government in accordance with the document titled Contract Registry of the Office of the Comptroller General of the Dominican Republic (Registro de Contrato de la Contraloría General de la República Dominicana).

The FSIS auditors confirmed that inspection personnel possessed the appropriate educational credentials, training, and experience to carry out their inspection tasks. All MVOs possess a Doctor of Veterinary Medicine degree. The minimum educational qualification for AIOs is a high school diploma. All new employees must take an introductory training course (three days for MVOs and two days for AIOs), attend a three-month field training, and pass an evaluation exam as a condition of employment. In addition, FD conducts ongoing (annual) training sessions for MVOs and AIOs to ensure that they have the appropriate training to conduct inspection activities.

The FSIS auditor verified that FD has a mechanism in place to conduct, at a minimum, two performance appraisals for each inspector per year to assess their knowledge, skills, and abilities. Each performance appraisal includes interviews, review of inspection-generated records, and direct observation of inspection personnel while conducting their assigned inspection activities in the following areas: ante-mortem inspection; post-mortem inspection; humane handling; verification of Sanitation Standard Operating Procedures (Sanitation SOPs) and Sanitation Performance Standards (SPS); HACCP verification; economic adulteration and verification of labeling; sampling methodology; export certificates; complete separation of authorized establishments; and official control over the condemned materials.

The Dominican Republic's Regulation No. 329–11 describes FD's authority and responsibility to require corrective measures in establishments and to take enforcement actions as appropriate when an establishment does not meet the importing country's or the Dominican Republic's regulatory requirements. The enforcement strategies include closure of the establishment, suspension of inspection, or partial withdrawal of inspection. At the establishment level, regulatory control actions that may be taken by inspection personnel include detaining products, rejecting equipment or facilities, or stopping or slowing the line speed. The FSIS auditor verified through interviews and record reviews that FD has provided instructions to its inspection personnel to document any noncompliance findings on a Noncompliance Record (NR). The FSIS

auditor reviewed NRs for the three audited establishments. The FSIS auditor verified that inspection personnel had identified and documented noncompliance findings in NRs in accordance with FD's requirements. Inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's preventive and corrective actions.

Within its SRT submission, FD has provided a regulatory definition for adulterated and misbranded products with specific instructions to the inspection personnel to control and prevent movement of these products in commerce. These definitions describe food safety and misbranding criteria, including production under unhygienic conditions of any food that contains any poisonous or deleterious substance, which may render it injurious to health, including those that have levels of chemical residues exceeding specific limits.

FD's legal authority and responsibility to ensure that adulterated or misbranded product is not prepared for export to the United States is granted in Articles 9 and 199 of Regulation No. 329–11; Articles 109 and 130 of the Law No. 42–01, and Chapter II of the Procedure for Adulterated Products and their Disposal (DIGEMAPS-AL-DE-024), which provide regulatory definitions consistent with FSIS import requirements. FD verifies that each establishment that will be certified as eligible to export to the United States follows the regulatory requirements. FD also requires that each establishment maintains recall procedures in accordance with its official procedure, Recall of Meat and Poultry Products (Retiro de Productos de Carnes y Aves-DIGEMAPS-AL-DE-022), which is consistent with 9 CFR Parts 418.2–418.4. The FSIS auditor noted that each audited establishment maintained these procedures, as well as records sufficient to conduct traceback activities if adulterated product were produced or exported.

The Dominican Republic's Regulation No. 329–11 and its associated procedural articles provide mandatory requirements applicable in all meat producing establishments, including those that will be certified as eligible to export to the United States, to ensure uniform implementation and enforcement of the laws and regulations governing meat inspection. Article 9 of Regulation No. 329– 1 prescribes that each establishment authorized and approved for export must meet importing country regulatory requirements. Title IX, Articles 157–170 of Regulation No. 329 – 11 and the procedure titled Requirements for the Approval of Establishments that Slaughter and Process Animals (DIGEMAPS-AL-FO-005) describe an establishment's approval process which includes inspection personnel's evaluation of establishment written programs and onsite audits to determine their compliance with the following FD requirements:

- Establishment has a written sanitation program that complies with Article 145 of Regulation No. 329–11 and consistent with 9 CFR Part 416;
- Establishment's facility structure and maintenance complies with the official requirement according to Title IV of Regulation No. 329–11 and consistent with 9 CFR Part 416;
- Establishment has a written recall procedure consistent with 9 CFR Part 418.2;
- Establishment has a hazard analysis and a written HACCP plan for products intended to be exported to the United States in accordance with Title VIII of Regulation No. 329–11 and consistent with 9 CFR Part 417;
- Establishment has a written program of statistical process control using quantitative testing of generic *E. coli* consistent with 9 CFR Part 310.25; and

- Establishment has implemented all aspects of FSIS import requirements for the product to be exported to the United States.

FD has the authority to approve or reject an establishment for certification based on the outcome of the record reviews and onsite inspection verification of compliance with FSIS requirements. Article 167 of Regulation No. 329–11 describes the circumstances for revoking the approval of an establishment that no longer meets the requirements in Regulation No. 329–11.

The FSIS auditor confirmed that FD only intends to export raw intact beef from livestock slaughtered in establishments within the country that will be certified by FD as eligible to export products to the United States. The FSIS auditor noted that FD has requirements in place, including Title XI (Articles 181–200) and Title XXI (Articles 308 and 311) of Regulation No. 329–11, that describe the export certification requirements that are to be met prior to issuance of an export certificate by inspection personnel. The FD's procedure titled Label Verification for Meat and Poultry Products (DIGEMAPS-AL-DE-028) indicates that inspection personnel must verify that the shipment containers, immediate packaging, and protective covers comply with the labeling and branding requirements described in the regulations.

MSP has the legal authority and responsibility to approve or disapprove laboratories conducting analytical testing of products intended for export to the United States. The FSIS auditors visited one chemical residue and two microbiology laboratories: Laboratorio Veterinario Central (LAVECEN), Instituto de Innovación en Biotecnología e Industria (IIBI), and Laboratorio Agroempresarial Dominicano (LAD). The FSIS auditors audit scope in each laboratory included sample receipt, timely analysis, analytical methodologies, analytical controls, analyst qualifications, proficiency testing, and recording and reporting of results. The FSIS auditors noted that the laboratory audit team from the Public Health National Laboratory conducts annual audits of both domestic laboratories and a contracted foreign laboratory in Honduras as part of government oversight functions over laboratories that perform analyses of official government sampling and testing programs for meat products intended for export to the United States. The FSIS auditors verified that annual audits and related follow-up audits have been conducted in accordance with MSP requirements.

LAVECEN is a government laboratory that is not yet accredited in accordance with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025. Therefore, it is not approved to perform analyses for official government chemical residue or official government microbiological testing programs. Currently, the only functions of LAVECEN are to receive, store, safeguard, and ship the chemical residue samples to the designated laboratory in Honduras (Laboratorio Nacional de Análisis de Residuos-LANAR). The FSIS auditors reviewed the laboratory procedures from sample receipt to sample repackaging and shipment to LANAR and did not identify any concerns.

IIBI is a government laboratory that conducts analytical testing on both the inspection personnel's *Salmonella* verification samples and the establishments' generic *E. coli* monitoring samples. IIBI is ISO/IEC 17025 accredited by the Costa Rican accreditation body (Ente Costarricense de Acreditación-ECA). IIBI uses the Food and Drug Administration's

Bacteriological Analytical Manual (BAM-8) for *Salmonella* and the Association of Official Analytical Chemists 991.14 for generic *E. coli* testing. The FSIS auditors reviewed sample flow and documentation from sample receipt to reporting results for generic *E. coli* and *Salmonella*. IIBI provided proper training for laboratory analysts performing the methods along with annual proficiency samples. Most of the process and techniques were acceptable; however, the FSIS auditors identified the following findings:

- FD did not ensure that the laboratory implements technical requirements in accordance with ISO/IEC 17025 standards, including:
    - For use of appropriate assays to assure the quality of the results: the FSIS auditors identified that IIBI laboratory technicians used pH strips with increments that were not sensitive enough to properly confirm and adjust the pH when preparing enrichment broth for the *Salmonella* method.
    - For implementation of internal quality control parameters, including positive and negative assay controls: the FSIS auditors identified that a positive control is not being used throughout the *Salmonella* method. Positive and negative controls must be included for each step of analysis from the beginning to the end of the method.
    - For traceability of test results: the FSIS auditors identified that IIBI laboratory technicians did not properly record start and stop times for incubation steps in the *Salmonella* and generic *E. coli* methods. Additionally, while a control is used during generic *E. coli* testing, the result for the control is not recorded.

LAD is a private laboratory which conducts analytical testing on both government official verification testing and establishment monitoring sampling for STEC (O157:H7, O26, O45, O103, O111, O121, and O145). LAD is ISO/IEC 17025 accredited by the Dominican Accreditation Organization (Organismo Dominicano de Acreditación-ODAC). LAD uses method PS-O157H7-LAD for STEC testing. The FSIS auditors reviewed laboratory procedures and analysis from sample receipt to reporting results for STEC samples. Most of the process and techniques were acceptable; however, the FSIS auditors identified the following findings:

- FD did not ensure that the laboratory implements technical requirements in accordance with ISO/IEC 17025 standards, including:
    - For sample receipt and storage prior to analyses at the laboratory: the FSIS auditors identified that during sample receipt at LAD, there were several samples accepted and analyzed outside of the laboratory's 23-hour collect-to-receipt requirement.
    - For use of appropriate assays to assure the quality of the results: the FSIS auditors identified that the LAD laboratory method for STEC does not specify the time and temperature required for the enrichment step in accordance with the validated method.
    - For implementation of internal quality control parameters, including positive and negative assay controls: the FSIS auditors identified that a positive control is not being used with each batch of samples analyzed for STEC at LAD. Positive and negative controls must be included for every batch of STEC samples.

- For traceability of test results: the FSIS auditors identified that LAD laboratory technicians did not properly record start and stop times for incubation steps in the STEC method.

FSIS analysis and onsite audit verification activities indicate that FD's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement for the core regulatory requirements for this component, except for the laboratory findings described above with regard to sample receipt and storage prior to analysis, use of assays appropriate to assure the quality of the results of the method, implementation of internal quality control parameters, and traceability of results.

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. FSIS requires that the foreign country's inspection system provides for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and part; 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 auditor confirmed that in-plant inspection personnel are required to conduct humane handling and slaughter procedures daily in accordance with Titles XIII and XIV of the Regulation No. 329–11. This includes verification of proper repair and maintenance of holding pens and alleyways, proper handling of livestock prior to slaughter, and evaluation of the proper stunning and sticking procedures in accordance with FD requirements. The FSIS auditor's review of records, including in-plant inspection verification of humane handling and slaughter and periodic supervisory review records, in conjunction with FSIS observation of humane handling and slaughter practices did not identify any concerns.

The FSIS auditor confirmed that in-plant inspection personnel are required to conduct ante-mortem inspection in accordance with Title XV of the Regulation No. 329–11. The FSIS auditor observed that in-plant inspection personnel conduct ante-mortem inspection on the day of slaughter by: (1) reviewing required documentation accompanying the livestock to ensure that all information (number of animals, origin of the lots, etc.) is accurately documented in ante-mortem records, and (2) observing all animals at rest and in motion from both sides in designated holding pens to determine whether they are fit for slaughter. The FSIS auditor observed that all animals have access to water in all holding pens, and feed is available if animals are held longer than 24 hours. The FSIS auditor confirmed that each audited slaughter establishment provides a separate holding pen designated for observation and further examination of suspect animals. Regulation No. 329–11 provides instructions for handling of suspect animals including identification of reportable and condemnable disease conditions. Article 251 of Regulation No. 329–11 states that

inspection personnel shall immediately dispose of non-ambulatory animals and determine whether to collect and submit brain samples when an animal shows signs of central nervous system disorders during ante-mortem inspection. Article 130 of the Law No. 42–01 describes the requirement for the disposition and condemnation of animals including dead, dying, diseased, or disabled condemned that are not allowed to be used to manufacture meat for export to the United States. Chapter III of the Procedure for Adulterated Products and their Disposal (DIGEMAPS-AL-DE-024) states that condemned products must remain under the custody of official inspection personnel until they are sent to the digestor at the end of the day. MVOs are responsible for verifying the disposal of condemned livestock and that establishments maintain required records. The FSIS auditor's review of records, including ante-mortem inspection reports and periodic supervisory review records, in conjunction with FSIS observation of ante-mortem inspection activities did not identify any concerns.

The FSIS auditor confirmed that in-plant inspection personnel are required to conduct post-mortem inspection in accordance with Title XV of the Regulation No. 329–11. The FSIS auditor observed that in-plant AIOs conduct post-mortem inspection of every carcass immediately after slaughter. This included proper presentation, identification, examination, and disposition of each carcass and accompanying viscera. FD provides adequate staffing at three audited beef slaughter and processing establishments to ensure continuous inspection coverage during slaughter operations, and at least once per shift during processing operations. The inspection team at the audited establishments consists of one MVO as Chief of Inspection, one MVO, and four AIOs who conduct post-mortem inspection activities at the head, viscera, and carcass inspection stations. The FSIS auditor correlated the number of inspection personnel who conduct post-mortem inspection examination in each audited establishment with the maximum slaughter rate and concluded that FD has provided enough inspection personnel for the existing production volume and slaughter line speed.

The FSIS auditor observed the performance of in-plant inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes are made in accordance with FD's requirements. The FSIS auditor's review of records (including in-plant inspection post-mortem disposition reports and periodic supervisory review records), in conjunction with FSIS observation of post-mortem inspection activities by AIOs did not identify any concerns.

Requirements for complete separation of establishments that will be certified as eligible to export product to the United States from other facilities are outlined in FD's Requirements for the Approval of Establishments that Slaughter and Process Animals (DIGEMAPS-AL-FO-005). FD requires establishments to maintain the identity of products and to control and segregate ineligible products from eligible products for export to the United States. The FSIS auditor was informed that the audited beef slaughter and processing establishments processed raw meat products only from livestock that were slaughtered on-premises and do not receive any raw meat from outside sources. The FSIS auditor confirmed that inspection personnel have established procedures for complete separation of eligible products intended for export to the United States from ineligible products by space or time in the coolers and freezers. The FSIS auditor's review of records (including in-plant inspection verification records and periodic supervisory review

records), in conjunction with FSIS observation of designated areas in the coolers and freezers did not identify any concerns.

The labeling requirements for raw intact beef eligible for export to the United States are described in the procedure titled Label Verification of Meat and Poultry Products (Verificación de Etiqueta en Productos de Carnes y Aves de Corral-DIGEMAPS-AL-DE-028). The FSIS auditor was informed that in-plant inspection personnel are to conduct labeling verification activities before every shipment destined for export to the United States to ensure that the information on the product labels is complete, accurate, and meets FSIS labeling requirements. In addition, FD requires species verification testing by inspection personnel prior to every shipment destined for export to the United States.

FD ensures that its raw intact beef products intended for export to the United States are not subject to animal health restrictions by regularly consulting the APHIS regional office located in Santo Domingo and reviewing relevant sections of the APHIS website. The FSIS auditor was informed that the Dominican Republic has an Early Warning System in place that collects immediate notifications of animal health events. This module establishes a permanent communication system between the regional and central government levels. In the event an alert is received on suspicion of an exotic disease (foot and mouth disease, African swine fever, etc.), the Surveillance Division is to immediately notify the authorities of the MSP. The relevant information will be disseminated to inspection personnel assigned to establishments through written publications, e-mails, classroom training, and supervisory visits.

Article 282 of Regulation No. 329–11 identifies the following materials as SRMs: 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 wings of the sacrum) and dorsal root ganglia of cattle thirty months of age and older, and the tonsils and the distal portion of the ileum for all cattle. FD's Verification Instructions Related to Specified Risk Materials in Cattle of All Ages (GA-CPC-08) provides instruction to its inspection personnel concerning removal, segregation, and disposal of SRMs. The FSIS auditor visually verified the proper removal of SRMs and their storage in designated containers identified with the Spanish acronyms for SRM or BSE to prevent cross-contamination with other products. The audited establishments did not use any device that injects air into the cranium of cattle. Establishments that used a penetrating device to stun the animals sealed the stunning hole in the frontal bone with a plug to prevent leakage of brain to surrounding tissues. Establishment employees responsible to remove SRMs are required to wash and sanitize their hands and equipment after each carcass. FD requires that all SRMs must be disposed of through rendering, incineration, or burial in an approved landfill. The FSIS auditor's review of records (including in-plant inspection verification records concerning removal, segregation, and disposal of SRM), in conjunction with the auditor's observation of removal and segregation of SRMs, did not identify any concerns.

The control of condemned materials is accomplished through the application of Chapter III, Number 3 of the Procedure for Adulterated Products and their Disposal (DIGEMAPS-AL-DE-024) that states condemned products must remain under the custody of the official inspection personnel until they are sent to the digestor at the end of the day. The FSIS auditor observed the

disposal process of condemned and inedible materials at each audited establishment including: (1) appropriate identification of inedible or condemned materials; (2) segregation in specially marked or otherwise secure containers; and (3) documentation of final disposal of these materials at rendering facilities. The FSIS auditor did not identify any concerns.

The Veterinary Doctor National Supervisor in Charge (Médico Veterinario Supervisor Nacional a Cargo-MVSN) is responsible for conducting the periodic (monthly) supervisory reviews. During these reviews, the MVSN verifies the proper implementation of regulatory requirements cited in Regulation No. 329–11, including: ante-mortem inspection; humane handling and slaughter requirements; post-mortem inspection; *Salmonella,* generic *E. coli,* and STEC sample collection; economic and labeling procedures; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities, including the critical control point (CCP) verification in the beef slaughter and processing establishments. These reviews are recorded on a standard form that includes a follow-up section regarding the previous supervisory review findings. The MVSN also conducts performance evaluation of inspection personnel with a minimum frequency of two performance evaluations per year. These evaluations consist of onsite observations of in-plant inspection personnel to assess their knowledge, skills, and abilities in conducting their assigned inspection verification activities. The FSIS auditor's review of periodic supervisory reviews and performance evaluation reports did not identify any concerns.

FSIS analysis and onsite audit verification activities indicate that FD has the legal authority and responsibility to establish regulatory controls to operate its inspection system.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

The FSIS auditor verified that FD requires establishments eligible to export to the United States to develop and implement written sanitary programs that prevent direct product contamination and function in a manner that prevent the creation of insanitary conditions by complying with the requirements of Articles 17–106 and 145–147 of Regulation No. 329–11 that are consistent with 9 CFR Part 416 requirements.

The FSIS auditor verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or creation of insanitary condition. Each audited establishment's sanitation SOPs included maintenance and improvement of sanitary conditions through ongoing evaluation of the establishment's hygienic practices. The FSIS auditor confirmed that in-plant inspection personnel conduct daily verification procedures in accordance with the Official Verification Activities in Authorized Establishments (Tareas Oficiales de Verificación en Establecimientos Autorizados-GA-CPC-03). Inspection verification activities

consist of a combination of document reviews, observations, and hands-on inspection verification.

The FSIS auditor observed in-plant inspection personnel conduct pre-operational sanitation verification inspection in one of the audited establishments. The verification inspection was performed after the establishment had conducted its pre-operational sanitation procedures and determined that the facility was ready for production. The in-plant inspection personnel conduct pre-operational sanitation verification in accordance with Articles 145–147 and 171 of Regulation No. 329–11.

The FSIS auditor observed in-plant inspection personnel perform operational sanitation verification at all audited establishments. The FSIS auditor confirmed that the inspection verification activities included direct observation of operations and review of establishment records. The FSIS auditor reviewed the establishments' sanitation monitoring and corrective action records, in addition to inspection records documenting in-plant inspection verification results, noncompliances, and monthly supervisory reviews. The inspection records showed that in-plant inspection personnel have identified and documented sanitation findings in their daily verification records in accordance with Chapter VI, Section I of the procedure titled Verifying an Establishment's Food Safety System (GA-CPC-09).

FD requires sanitary dressing of livestock throughout the slaughter process in accordance with Title XIV, Articles 217 and 222–225 of Regulation No. 329–11. The audited slaughter establishments have implemented monitoring procedures to prevent potential carcass contamination. These included sanitary practices to prevent potential carcass contamination during hide removal, direct contact between carcasses during dressing procedures, and carcass contamination with gastrointestinal contents during evisceration, including tying the bung and esophagus. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the sanitation SOPs and any corrective actions taken. Establishment personnel responsible for the implementation and monitoring of the sanitation SOPs correctly authenticated these records with initials or signatures and the date.

FSIS analysis and onsite audit verification activities indicate that FD requires establishments to develop, implement, and maintain sanitation programs that are consistent with criteria established for this component. The FSIS auditor identified isolated noncompliances related to the inspection verification of sanitation requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

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

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

The FSIS auditor verified that FD requires establishments that will be certified to export to the United States to develop, implement, and maintain a HACCP system in accordance with Articles 143–156 and 171 of Regulation No. 329–11 that is consistent with 9 CFR Part 417 requirements. The FSIS auditor verified that each audited establishment's HACCP programs include written hazard analysis, flow charts, and HACCP plans to identify, evaluate, and prevent or control food safety hazards in their production processes. The HACCP plans included activities designed to validate adequacy of controls, to conduct monitoring and verification procedures, and to document the results of monitoring and verification activities, as well as implementation of corrective actions in response to deviations from CCP critical limits.

The in-plant inspection personnel conduct daily or weekly verification activities in accordance with the Official Verification Activities in Authorized Establishments (Tareas Oficiales de Verificación en Establecimientos Autorizados-GA-CPC-03). Inspection verification methodology includes such activities as evaluating the establishment's written HACCP programs and observing establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. Inspection verification activities also include direct observation of monitoring of establishment employees, hands-on verification, and review of establishment records, with the results of verification being entered in the associated inspection records.

The FSIS auditor conducted an onsite observation and review of establishment records for all CCPs, including zero tolerance (control of fecal material, ingesta, and milk contamination) and antimicrobial intervention CCPs. At each audited slaughter establishment, the FSIS auditor observed the establishment personnel conducting hands-on HACCP monitoring and verification activities for zero tolerance and antimicrobial intervention CCPs. The FSIS auditor also reviewed establishment records for monitoring, verification, corrective actions, and validation, as well as inspection verification records for all CCPs. The FSIS auditor verified that audited establishments took appropriate corrective actions in response to any critical limit deviations.

The procedure titled Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations (DIGEMAPS-AL-DE-010) describes the inspection procedures for hands-on verification of livestock carcasses for visible fecal material, ingesta, and milk. The inspection verification is conducted based on the number of animals slaughtered: two carcasses are selected if 100 animals or less are slaughtered, and four carcasses are selected if 101 to 250 animals are slaughtered. The FSIS auditor confirmed that the physical location of the zero tolerance CCP verification for both the establishment personnel and in-plant inspection personnel is before the final carcass wash in all audited slaughter establishments.

The FSIS auditor confirmed that the audited beef slaughter and processing establishments that will be certified as eligible to export to the United States had addressed contamination of beef carcasses with STEC as a hazard reasonably likely to occur in their HACCP system. This included the use of a validated intervention (organic acid spray) and a zero tolerance CCP for the presence of fecal material, ingesta, and milk. In addition, each establishment had controls in place to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens. Furthermore, the audited establishments have implemented microbiological sampling and testing programs for carcasses (generic *E. coli*) and beef trimmings (STEC) to

support their hazard analysis. Through interviews and document review, the FSIS auditor identified no concerns with establishment microbiological sampling programs or inspection verification procedures related to the implementation of those programs.

FSIS analysis and onsite audit verification activities indicate that FD requires establishments to develop, implement, and maintain a HACCP system that is consistent with criteria established for this component. The FSIS auditor identified isolated noncompliances related to the inspection verification of HACCP record-keeping requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Title XIX of Regulation No. 329–11 describes the FD authority to develop a national residue control program (NCRP), which must be reviewed annually and contains the previous year's residue test results. The implementation and maintenance of the NRCP is carried out by the central office of MSP and the sampling is performed by the government inspection personnel assigned to the establishments. The MSP sets criteria for modifying the plan, which include historical data, number of establishments, new chemicals of concern, toxicity, and withdrawal times. The NRCP provides the lists of chemical residue compounds, number of samples, targeted matrix (tissues), and amounts of tissues to be collected for each analysis. All substances to be analyzed under NRCP must comply with the Maximum Residue Limit (MRL) of that substance in the tissue being analyzed. Additionally, the NCRP indicates that the MRLs are set to be consistent with Title 21 of CFR for tolerance values set by the U.S. Food and Drug Administration and the Title 40 of CFR for tolerance values set by the U.S. Environmental Protection Agency.

FD is responsible for preparing the sample collection schedules and determining the number of random samples to be collected for specific matrices within a defined period in each establishment. The FSIS auditors verified through records review, interviews, and observation that trained in-plant inspection personnel collect, prepare, and send sealed samples to LAVECEN in accordance with FD instructions. Currently, LAVECEN is not accredited to conduct analytical testing on chemical residue samples; therefore, as the designated laboratory, it is responsible to collect all chemical residue samples within the country and ship them under seal to LANAR in Honduras.

The FSIS auditor verified that in-plant inspection personnel were retaining carcasses and offals sampled for chemical residues until acceptable laboratory results were received, as required by Section II, Part B (2) of the 2018 NRCP. When violative chemical residue results are detected,

FD formally notifies the establishment's management of the violative results, determines the disposition of the retained product, and conducts additional chemical residue sampling on all animals that come from the same origin.

The FSIS auditor review of the chemical residue sampling records maintained at the inspection offices of the audited slaughter establishments indicated that the 2021 sampling program was being implemented as scheduled. The MVSN also ensures that MVOs comply with NRCP procedures and sampling timeframes during monthly supervisory reviews.

FD has adopted a hold and test procedure within its NRCP to ensure that no sampled carcass is exported to the United States until acceptable results are obtained. The FSIS auditor observed the veterinary retained cage and associated verification records to confirm that FD's test and hold policy was being implemented as designed. No concerns arose from these observations and reviews.

FSIS analysis and onsite audit verification activities indicate that FD is implementing the NRCP as intended.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth equivalence component that 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 auditor verified the Dominican Republic's microbiological sampling and testing programs through direct observation, document review, and interviews of FD's personnel at the local inspection offices within the audited slaughter and processing establishments, as well as of microbiological laboratory personnel.

FD's Resolution No. 24–97 requires establishments to implement sampling and testing programs for generic *E. coli* to verify process control during bovine slaughter and carcass dressing. In addition, Chapter II of the National Pathogen Control Program (Programa Nacional de Control de Patógenos (GA-CPC-10)) states that establishments are required to develop written generic *E. coli* programs consistent with requirements stipulated in 9 CFR Part 310.25(a). Furthermore, the procedure titled *Escherichia coli* Analysis for the Verification of Process Control at Establishments that Slaughter Cattle and Hogs (Análisis de la *Escherichia Coli* para la Verificación del Proceso de Control de los Establecimientos que Sacrifican Ganado y Cerdos-DE-CPC-07), requires that establishments develop written sampling procedures for generic *E. coli*, identify the employees responsible for sample collection, set the required frequency (one sample per 300 carcasses), identify the locations of sampling (three-site sponge sample from the flank, brisket, and rump for a total of 300 cm^2), and identify how randomness is achieved as well as measures to ensure sample integrity.

The FSIS auditor verified through observations, interviews, and records review that generic *E. coli* sampling and testing programs are conducted by establishment personnel at all three audited establishments. The FSIS auditor confirmed that MVOs and MVSN (during monthly supervisory reviews) verify that slaughter establishments comply with FD's regulatory requirements regarding generic *E. coli* sampling and testing of chilled bovine carcasses, including sampling frequency, technique, and methodology; maintaining records of analytical results; and sampling requirements. The FSIS auditor's review of establishments and inspection records identified no concerns.

FD implements a *Salmonella* official sampling and testing program for chilled beef carcasses that is consistent with the FSIS *Salmonella* performance standards in 9 CFR Part 310.25(b). Chapter III of GA-CPC-10 provides instructions to inspection personnel on official *Salmonella* sampling techniques and methodology. This includes collection of 100 cm^2 sponge samples from the flank, rump, and brisket (for a total of 300 cm^2) of chilled carcasses for *Salmonella* testing. The in-plant inspection personnel are required to collect one sample on each production day. FD's *Salmonella* performance standards consist of a random collection of 58 consecutive samples from slaughtered and chilled cow and bull carcasses, for which no more than two positive samples are permitted. *Salmonella* samples are sealed by inspection personnel prior to submission to IIBI. If the established set of samples of the year is completed satisfactorily, another set is scheduled for the next year. If the number of positive samples exceeds the permitted standard consistent with the provisions of Table 2 (*Salmonella* Performance Standard) of 9 CFR Part 310.25 (b), then the establishment must take immediate corrective actions, after which FD schedules follow-up samples in accordance with Chapter VI of GA-CPC-10.

The FSIS auditor verified through observations, interviews, and records review that in-plant inspection personnel were collecting one sample on each production day, thus meeting FD's sampling and testing techniques and methodology. The FSIS auditor's review of inspection records (including laboratory *Salmonella* testing results) identified no concerns.

FD has identified *E. coli* O157:H7 and non-O157 STEC serogroups O26, O45, O103, O111, O121, and O145 in all raw non-intact beef and raw intact beef intended for use in raw non-intact products as adulterants. In-plant inspection personnel conduct N60 official verification sampling of beef trimmings with a minimum of two samples per month (based on current production volume in accordance with Chapter IV of GA-CPC-10). The MVSN also verifies the sampling methodology and testing results as part of his monthly supervisory review activities. The in-plant inspection personnel conduct daily and weekly HACCP verification activities, through direct observation and records review, to verify that establishments are implementing their written STEC programs in accordance with Articles 143–156 and 171 of Regulation No. 329–11 and the adopted HACCP regulatory requirements consistent with 9 CFR Part 417. In addition, FD requires establishments to conduct routine sampling of beef manufacturing trimmings in accordance with N60 methodology.

The FSIS auditor verified the N60 sample collection techniques and methodology in three audited establishments by observing responsible establishments' employees and in-plant inspection personnel collecting STEC samples. This included aseptic random collection of 60 slices of a specified dimension (1 inch x 3 inches x 1/8 inch) from the exterior surface of beef

manufacturing trimmings to achieve the desired sample size (325 grams). Both the establishments' monitoring samples and the inspection personnel's verification samples are sent under secure seal to LAD as the only designated laboratory that analyzes samples using LAD internal method PS-O157H7-LAD for STEC testing. STEC testing results are submitted to the Chief of the Veterinary Service at the central level and to the assigned MVO at the local level. FD considers the screening result as the confirmed and final result since LAD does not perform any confirmatory analyses for STEC testing. The FSIS auditor confirmed that FD requires a test and hold policy for the sampled lot tested for STEC through either the establishment's self-monitoring or the official government verification sampling programs.

FD provides enforcement strategies in Chapter IV, Section IX of GA-CPC-10 to address disposition of affected products and actions to be taken when STEC positive test results are found in either the establishment's self-monitoring or official government verification testing programs. The enforcement strategies may include issuing of a noncompliance report, conducting HACCP verification activities, verifying the proper implementation of the establishment's corrective actions, or conducting follow-up sampling activities.

FSIS analysis and onsite audit verification activities indicate that FD is implementing its microbiological sampling and testing programs as documented through their SRT submission.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on September 23, 2021, by videoconference with FD. At this meeting, the FSIS auditors presented the preliminary findings from the audit including the following laboratory related findings:

GOVERNMENT OVERSIGHT (e.g., Organization and Administration)

- FD did not ensure that two of the three audited laboratories fully comply with certain general quality assurance and control criteria provided in ISO/IEC Guide 17025. The FSIS auditors identified findings related to sample receipt and storage, implementation of internal quality control procedures, use of assays to ensure the quality of results, and traceability of test results.

During the audit exit meeting, FD committed to address the preliminary findings as presented. FSIS will assess the adequacy of FD's corrective actions and determine whether those proposed corrective actions satisfy FSIS' equivalence requirements.

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
Suplidora de Carnes A&B/Carretera de Yamasa-Sierra Prieta, municipio de Santo Domingo Norte	09/17/2021	C1-002	Dominican Republic
	5. NAME OF AUDITOR(S) 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		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	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
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. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Name:	Suplidora de Carnes A&B/Carretera de Yamasa-Sierra Prieta, municipio de Santo Domingo Norte
Audit Date:	09/17/2021
Species:	Bovine
Establishment Operations:	Slaughter and Processing (cutting)
Prepared Products:	Raw Intact beef products: Cuts, Primals/Subprimals, Other Intact (Boneless Meat), and Boneless Manufacturing Trimmings

60. Observation of the Establishment

38 - The FSIS auditor observed deteriorated seals under two exterior shipping doors that did not provide a tight seal when the doors were closed. This could create insanitary condition and facilitate the entrance of vermin to the production areas.
39 - The FSIS auditor observed several rusted areas on the overhead structures above exposed products in the production areas. The auditor did not observe any direct products contamination. However, this condition may create an insanitary condition.
41 - The FSIS auditor observed beaded condensate on the overhead structures above exposed products in the beef carcass coolers. The auditors did not observe any direct product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
OIEA International Audit Staff (IAS)	09/17/2021

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
Agrocarne/Carrete La Tomana-Guaymate, Km 101/2 Batey Higueral, provincia La Romana	09/20/2021	C1-005	Dominican Republic
	5. NAME OF AUDITOR(S) 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.	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.	
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	X
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. Monthly Review	
58.	
59.	

Establishment Name:	Agrocarne/Carrete La Tomana-Guaymate, Km 101/2 Batey Higueral, provincia La Romana
Audit Date:	09/20/2021
Species:	Bovine – Swine (slaughters swine only on Fridays)
Establishment Operations:	Slaughter and Processing (cutting)
Prepared Products:	Raw Intact beef products: Cuts, Primals/Subprimals, Other Intact (Boneless Meat), and Boneless Manufacturing Trimmings

60. Observation of the Establishment

15 - The establishment's HACCP plan did not address its return product procedures in its hazard analysis or flow chart.
16 - The establishment's HACCP verification records did not include the results of the verification activities.
41 -The FSIS auditor observed beaded condensate on the overhead structures above exposed products in the beef carcass cooler. The auditor did not observe any direct product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
OEA International Audit Staff (IAS)	09/20/2021

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
Mercarne,SRL/Cancino adentro, Santo Domingo Este	09/16/2021	C1-007	Dominican Republic
	5. NAME OF AUDITOR(S)		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.	X
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	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. Monthly Review	
58.	
59.	

Establishment Name:	Mercarne,SRL/Cancino adentro, Santo Domingo Este
Audit Date:	09/16/2021
Species:	Bovine
Establishment Operations:	Slaughter and Processing (cutting)
Prepared Products:	Raw Intact beef products: Cuts, Primals/Subprimals, Other Intact (Boneless Meat), and Boneless Manufacturing Trimmings

60. Observation of the Establishment

15 - The establishment's HACCP plan did not address its return product procedures in its hazard analysis or flow chart.
16 - The establishment's HACCP verification records did not include the dates of the verification activities.
39 - The FSIS auditor observed exposed insulation materials on the overhead structures above products in the beef carcass coolers. The auditor did not observe any direct product contamination.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
OIEA International Audit Staff (IAS)	09/16/2021

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

GOBIERNO DE LA
REPÚBLICA DOMINICANA
SALUD PÚBLICA

digemaps

Santo Domingo, D. N.
March 11, 2022.

Mrs
Michelle Catlin, PhD
International Executive Coordinator
Office of International Coordination
United States Department of Agriculture
Food Safety and Inspection Service (FSIS)
Washington, DC.

Distinguished Mrs. Catlin:

After extending a cordial greeting, I am writing to thank you for submitting the draft final report of the audit conducted by the Food Safety Inspection Service (FSIS) of the United States Department of Agriculture to the Dominican meat inspection system on September 13 to 20, 2021.

It is noteworthy that we have implemented all the corrective actions considering the findings found by the FSIS audit team, and we attach to this communication the actions taken in the different components of our inspection system, this, in order to continue with the reinstatement process and start exports raw intact beef from Dominican Republic to US.

Likewise, we express that we agree with what is described in this draft of the final audit report.

Sincerely,

JAIME RAFAEL SANTONI HERNANDEZ

Jaime Rafael Santoni Hernández, MSP
Jefe de los Servicios Veterinarios
Dirección General de Medicamentos, Alimentos y Productos Sanitarios

GOBIERNO DE LA REPÚBLICA DOMINICANA SALUD PÚBLICA	**Verification form of official findings / observations**	digemaps

Establishment: Suplidora de Carnes A&B No. C1-002 Date: September 17, 2021.

Supervision findings dated: September 17, 2021 (FSIS audit).

No[1].	Finding / observation[2]	No compliance number[3]	Corrective action[4]	Preventive measures[5]	Correction date[6]	Official verification date[7]	The corrective and preventive actions of the establishment comply[8] (YES or NO)	Official verification (signature and stamp)[9]
1	Beaded condensate on the overhead structures above exposed products in beef carcass coolers. No product contamination. Root cause: Involuntary neglect by the technician of the refrigeration machine room when the system was in a manual defrost. Also, lack of installation of a plastic curtain at the exit of the rail to the dispatch room to minimize entry of warm air. Condensate was also present in # 1 cooler, which was empty at the time.	48-SPS	Condensate was eliminated using the roller mop tool. In addition, quality control increased the number of staff for greater coverage in the area to control condensate. This same procedure was followed in the other coolers prior to the transfer of the present carcasses.	Automatic controllers and timers with equal cycle time were installed in all units under an electronic control system with the necessary functions to prevent the units from reaching a freezing point and meeting the parameters of temperature required by the HACCP plan. Plastic curtain was installed as a barrier to the inlet and outlet of the carcass cooler rail to prevent the entry of warm air coming from viscera dispatch area. Installation (2) of industrial fans, additional in each carcass cooler to increase and reinforce the air flow that allows mitigate the creation of condensate.	October 15, 2021	November 12, 2021	YES	MINISTERIO DE SALUD PÚBLICA DIGEMAPS Departamento de Alimentos Unidad de Carnes

2	Rusted areas on the overhead structures above exposed products in the production areas. No product contamination. Root cause. Current roof covering based on galvanized metal sheets favored the presence of rust in some sections as an effect of the humid environment in the production areas.	**49-SPS**	Deep cleaning was scheduled to suppress the presence of rust using acid-based product and restore sanitary condition in ceilings surface.	1. Coordinated with the Maintenance Manager to perform surface sanitization on the roof sheets of production area. 2. The surface was cleaned and an acid product was applied to reduce the presence of rust. 3. The surface was dried and a curing treatment based on epoxy resin was applied, which stands out for its resistance to corrosive substances and does not give off any type of odor. 4. The Maintenance Manager was instructed to comply with the frequency established in the preventive maintenance program.	September 21, 2021	September 27, 2021	**YES**	MINISTERIO DE SALUD PÚBLICA DIGEMAPS Departamento de Alimentos

3	Deteriorated seals under two exterior shipping doors did not provide a tight seal when the doors were closed. This condition facilitates the entrance of vermin to the production areas. Root cause: The floor level in the dispatch bay was uneven, which did not allow a tight seal to be achieved when the doors were closed.	**50-SPS**	Floor maintenance was performed and an industrial epoxy-based product was applied to correct openings by leveling the floor in the cargo bays.	1, A meeting was held with the participation of the general management and maintenance and it is required to ensure the necessary conditions so that the doors seal with a high degree of hermeticism in all the loading bays and access doors to the areas related to offices and processes for prevent the risk of pest entering the process room. 2, Compliance with the preventive maintenance program related to the physical conditions of the establishment is demanded.	November 11, 2021	November 12, 2021	**YES**	MINISTERIO DE SALUD PÚBLICA DIGEMAPS Departamento de Alimentos Unidad de Carnes

MINISTERIO DE SALUD PÚBLICA DIGEMAPS Departamento de Alimentos Unidad de Carnes República Dominicana

SUPLIDORA DE CARNES A & B Carretera Yamasá Km. 26, Sierra Prieta A&B RNC 1 02535-9 Tel.809-620-8585 Santo Domingo, R.D.

Signature and stamp of the establishment

Name and signature of the CVO

¿ Attached to this form is some supporting document (for example: photos, forms, procedures)? YES ■ NO □

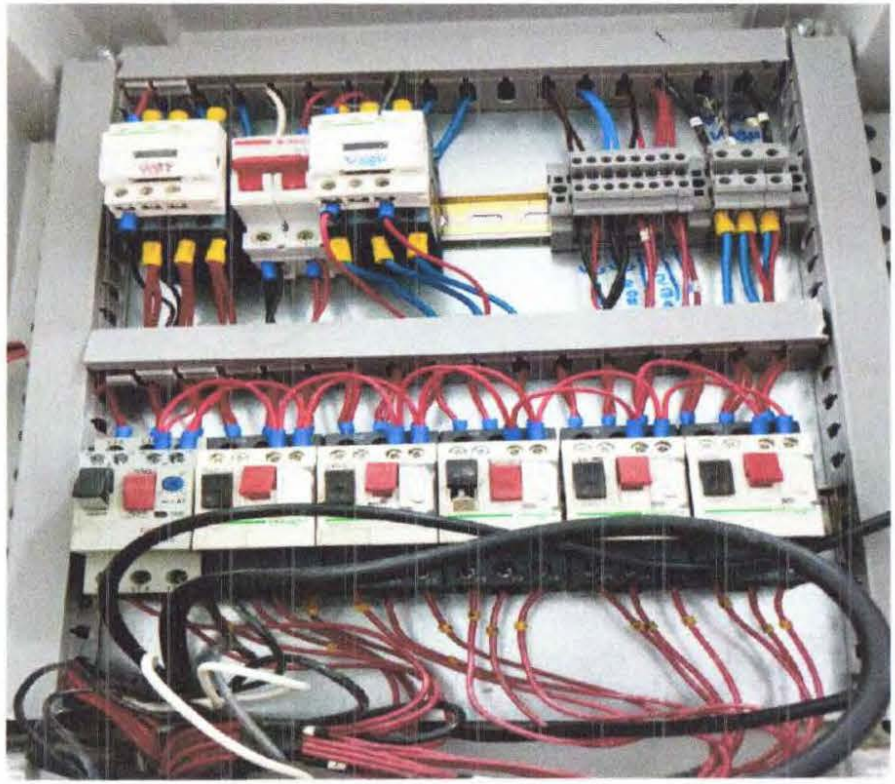
Instructions for filling:

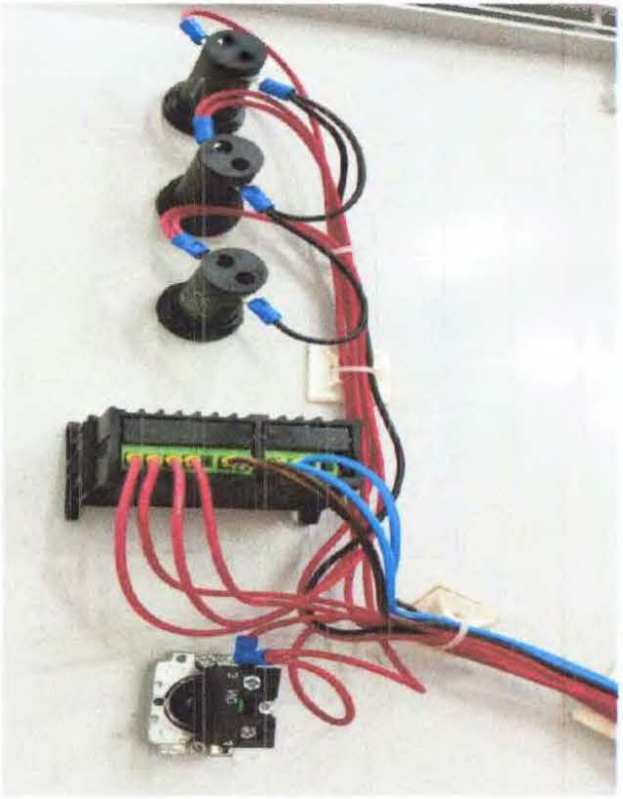
[1]You must enter the sequence number of the finding (1,2,3, etc).
[2]You must place the finding that was found. You will place the area where the find was found and then detail what was found.
[3]Sequential number of non-compliance raising based on the finding by the Official Veterinary Inspector, national supervisor or foreign auditor.
[4]The establishment must respond to this box with "immediate corrective action" to correct the non-compliance including the correct disposal of the prod
[5]The establishment must answer this box with "planned future action" to avoid recurrence.
[6]The establishment must answer this box with the date the correction was made.
[7]The Official Inspector Veterinary Doctor must answer this box with the date on which he/she verified the correction carried out by the establishment.
[8]The Official Veterinary Inspector Doctor must answer this box with the answer "YES" for cases in which the correction carried out by the establishme adequate and "NO" if the correction carried out by the establishment is not adequate.
[9]The Official Inspector Veterinary Doctor must place his signature and official seal in this box.

NOTE: Both, the CVO and the Official Inspector Veterinary Doctor must sign each sheet issued, staple them to the corresponding supervision forms and l a copy of said document in the official offices.

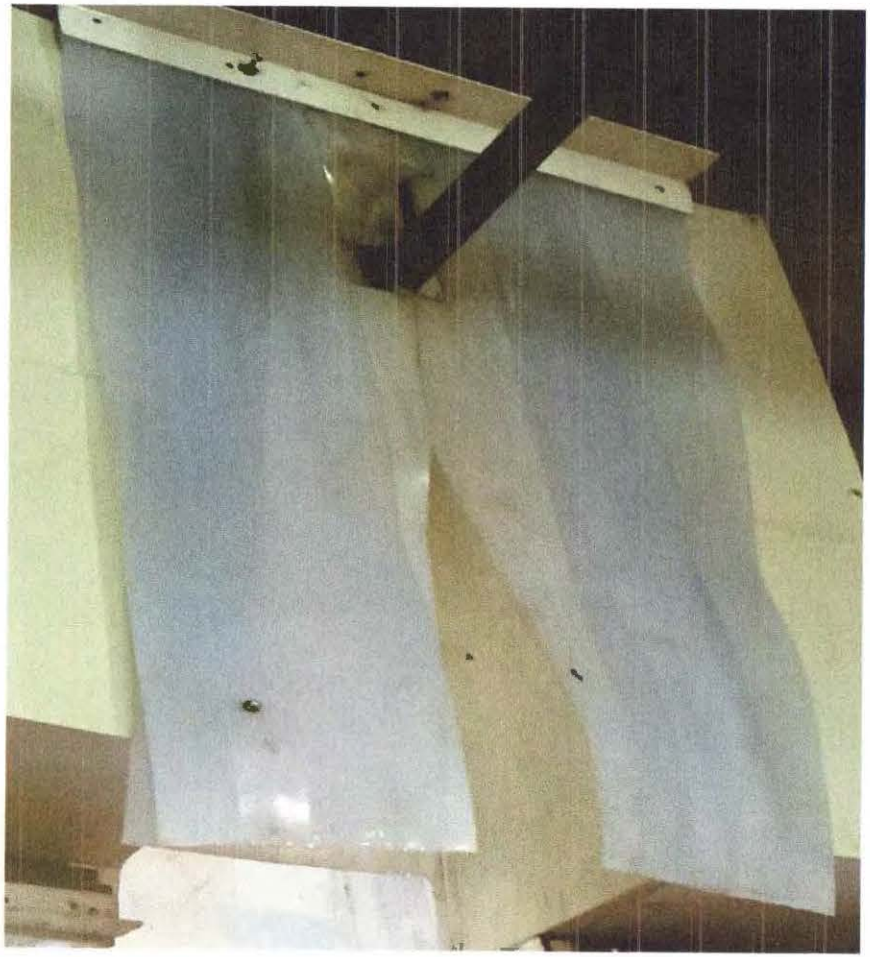
MINISTERIO DE SALUD PÚBLICA DIGEMAPS Departamento de Alimentos Unidad de Carnes República Dominicana

AUTOMATIC CONTROLLERS AND TIMERS

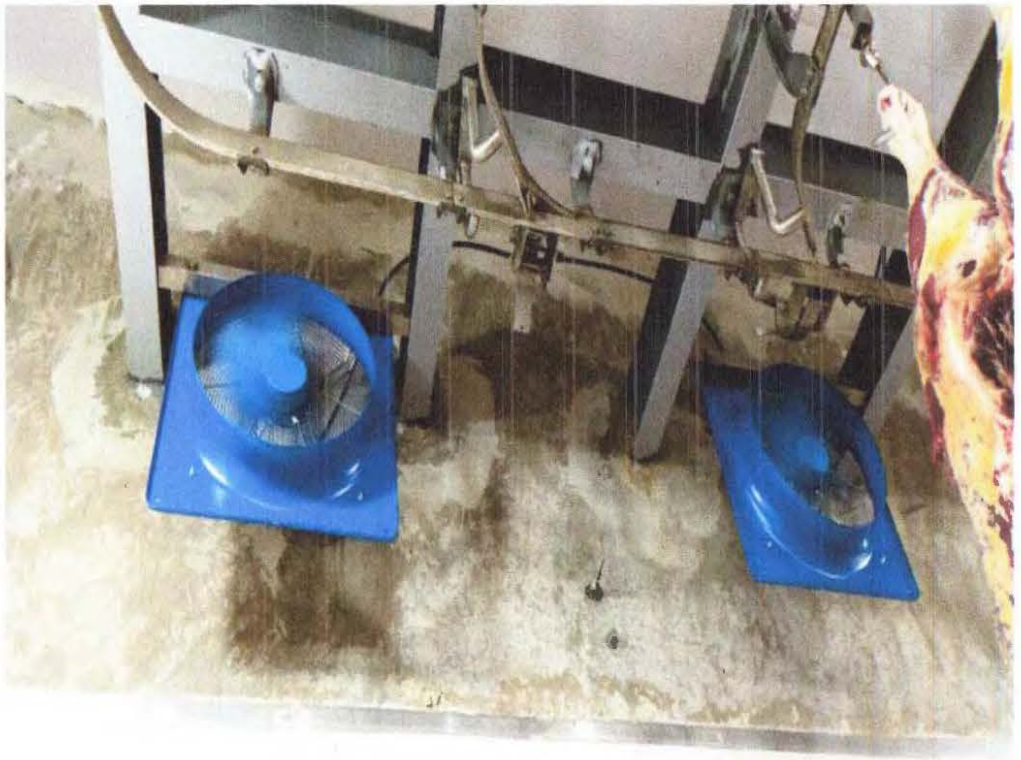




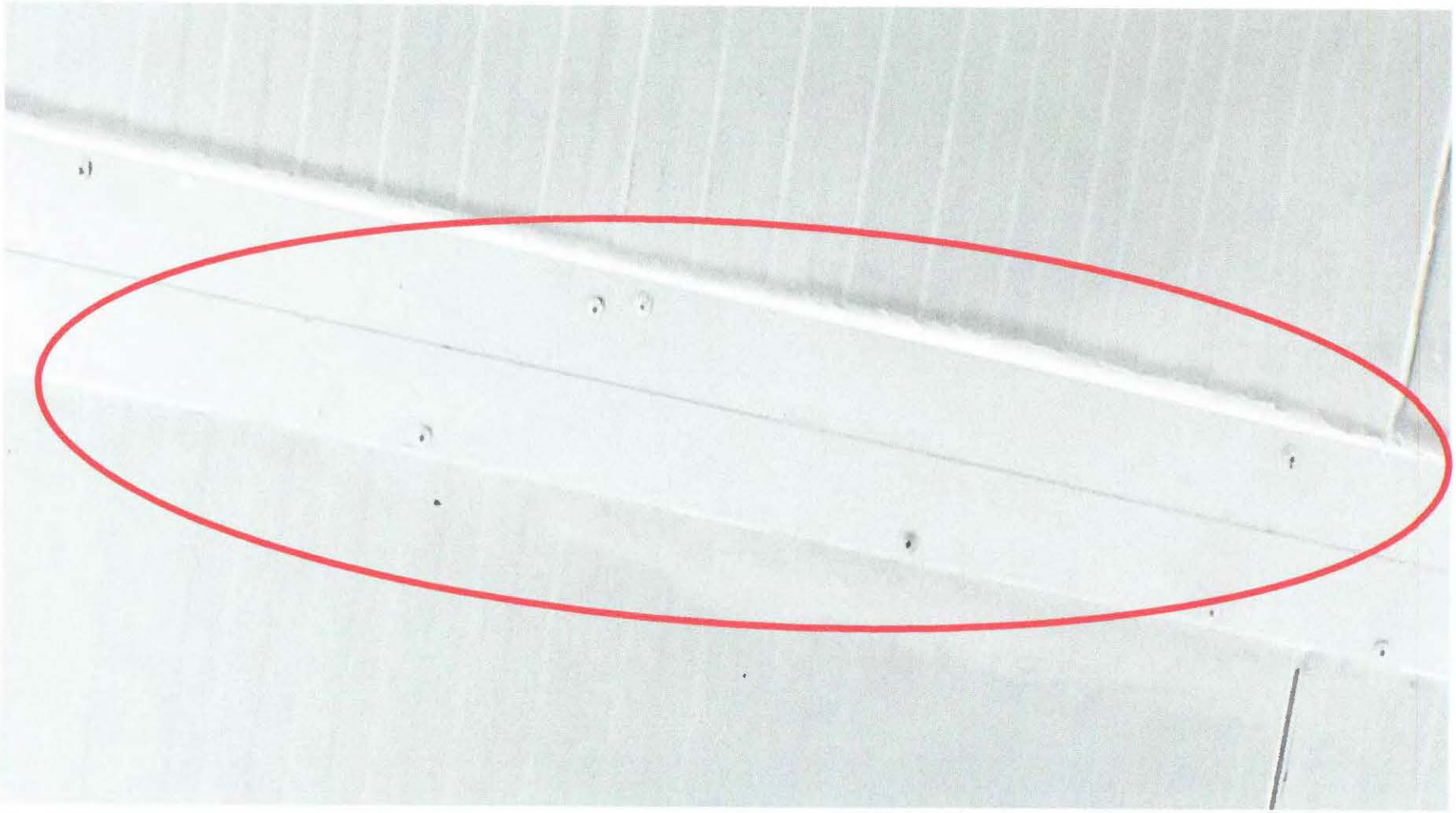
PLASTIC CURTAIN



INDUSTRIAL FANS



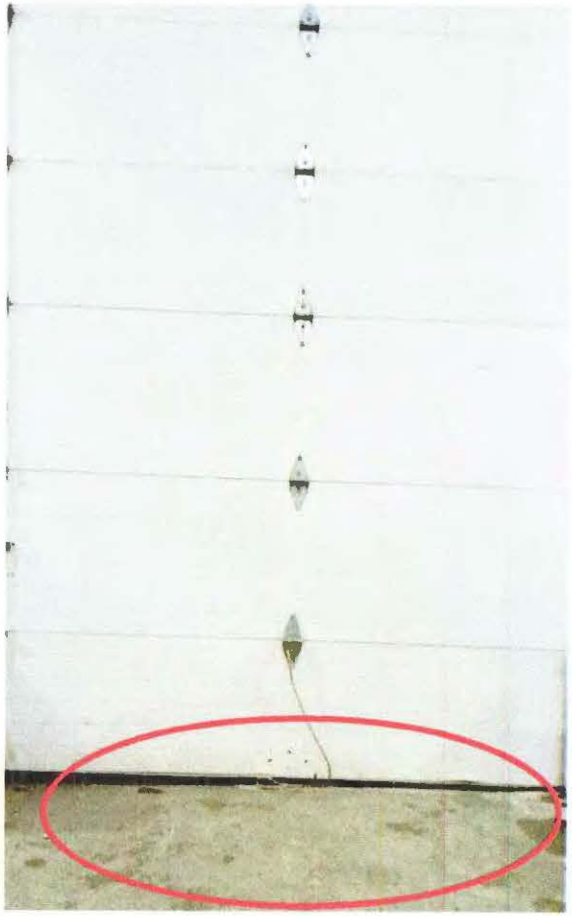
CURING TREATMENT BASED ON EPOXY RESIN WAS APPLIED IN THE PRODUCTION AREAS.



Floor maintenance was performed in the shipping doors area (dispatch area)

Shipping door # 1

Shipping door # 2



Shipping door # 3

GOBIERNO DE LA REPÚBLICA DOMINICANA SALUD PÚBLICA	**Verification form of official findings / observations**	digemaps

Establishment: Agrocarne No. C1-005 Date: September 20, 2021.

Supervision findings dated: September 20, 2021 (FSIS audit) .

No[1].	Finding / observation[2]	No compliance number [3]	Corrective action[4]	Preventive measures[5]	Correction date [6]	Official verification date [7]	The corrective and preventive actions of the establishment comply [8] (YES or NO)	Official verification (signature and stamp)[9]
1	The establishment's HACCP verification records did not include the results of the verification activities.	05-HACCP	1. A check box was added to the forms where the result of the verification activity will be marked, that is, compliant or non-compliant.	The correct filling of the documents will be verified in internal audits.	September 21, 2021	September 21, 2021	YES	
2	The establishment's HACCP plan did not address its return product procedures in its hazard analysis or flow chart.	07-HACCP	1. The hazard analysis and the flow chart were modified and the return of the returned product was added in the Dispatch area where the steps to follow at the time of receipt of the returned product are established. 2. Train inspection personnel on changes made to hazard analysis.	At the time of the reviews of the hazard analysis and the flow diagram, it will be verified that the return of the returned product is contemplated. In the Internal audits, it will be checked that this step is being fulfilled.	September 29, 2021	September 29, 2021	YES	

aded condensate on e overhead structures ove exposed products in ef carcass coolers (Beef ller).	**43-SPS**	The surface was dried immediately and the product was checked, no affected product was found. This action was verified by the official team of the Ministry of Public Health. It was determined that there were different climate temperatures inside the beef carcass cooler (inside it was 0 ° C and at the top of the cooler it was 30 ° C). See attached image	In order to reduce temperature differences and prevent condensation, three (3) fans were placed in the spaces between the evaporators. In addition, two layers of elastomeric paint were placed. This paint helps reflect the heat that the outside of the roof receives. To ensure that if at any point water droplets formed somewhere on the ceiling, sponge moisture removers were purchased to absorb the droplets without spillage.	October 10, 2021	October 13, 2021	**YES**	

CENTRAL ROMANA CORP
División Agrocarne

Signature and stamp of the establishment

Dr. Saira R. Santos

Name and signature of the CVO

¿ Attached to this form is some supporting document (for example: photos, forms, procedures)? YES ■ NO ☐

for filling:

nter the sequence number of the finding (1,2,3, etc).
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number of non-compliance raising based on the finding by the Official Veterinary Inspector, national supervisor or foreign auditor.
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Inspector Veterinary Doctor must answer this box with the date on which he/she verified the correction carried out by the establishm
Veterinary Inspector Doctor must answer this box with the answer "YES" for cases in which the correction carried out by the esta
d "NO" if the correction carried out by the establishment is not adequate.
Inspector Veterinary Doctor must place his signature and official seal in this box.

the CVO and the Official Inspector Veterinary Doctor must sign each sheet issued, staple them to the corresponding supervision form
document in the official offices.

GOBIERNO DE LA REPÚBLICA DOMINICANA SALUD PÚBLICA	**Verification form of official findings / observations**	digemaps

Establishment: Mercarne, SRL No. C1-007 Date: September 16, 2021.

Supervision findings dated: September 16, 2021 (FSIS audit).

No[1].	Finding / observation[2]	No compliance number[3]	Corrective action[4]	Preventive measures[5]	Correction date[6]	Official verification date[7]	The corrective and preventive actions of the establishment comply[8] (YES or NO)	Official verification (signature and stamp)[9]
1	The establishment's HACCP verification records did not include the dates of the verification activities.	04-HACCP	Detected nonconformity, a meeting with the HACCP team was coordinated. At said meeting, the measure was taken to update the verification forms for CCP 1 and 2 and a box was added to place the date of the verification activity.	Adequacy of the document control procedure where it is specified that the CCP verification records must be given the date on which the verification was executed.	September 17, 2021	September 17, 2021	YES	
2	The establishment's HACCP plan did not address its return product procedures in its hazard analysis or flow chart.	08-HACCP	Detected nonconformity, a meeting with the HACCP team was coordinated. At said meeting, the measure was taken to update the hazard analysis and the flow chart in order to include the "return product" step.	A reassesment of the hazard analysis and flow chart was performed to include the "return product" step. A product return procedure was created where the activities to be carried out in case the customer rejects a product are stipulated. This procedure also includes the protocol	September 27, 2021	September 27, 2021	YES	

				for accepting a return product at the establishment.				
3	Exposed insulation materials on the overhead structures above products in the beef carcass coolers.	**45-SPS**	Once the non-conformity was detected, the carcasses that were in the coolers were removed and the maintenance personnel were contacted, who immediately began to remove all the polyurethane and correct all the structural deficiencies. See attached image	Feedback with the maintenance personnel where they were informed of the importance of preventive maintenance and that the coolers must be designed in such a way that they are easy to clean and the safety of the exposed product is not compromised.	September 28, 2021	September 28, 2021	**YES**	

MINISTERIO DE SALUD PÚBLICA DIGEMAPS Departamento de Alimentos Unidad de Carnes República Dominicana

Margarita De Los Santos Adon

Signature and stamp of the establishment

MERCARNE, S.R.L. Santo Domingo, REP. DOM.

Dr. Jose R. Santos

Name and signature of the CVO

MINISTERIO DE SALUD PÚBLICA DIGEMAPS Departamento de Alimentos Unidad de Carnes República Dominicana

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GOBIERNO DE LA
REPÚBLICA DOMINICANA
SALUD PÚBLICA

Viceministerio de Garantía de la Calidad
Laboratorio Nacional de Salud Pública Dr. Defilló

TECHNICAL ASSESSMENT OF IIBI LABORATORY CORRECTION FOLLOW-UP DURING THE FSIS VISIT (SEPTEMBER 14, 2021)

FSIS OBSERVATIONS	IIBI RESPONSES	EVIDENCE
Salmonella method: 1) For use of appropriate assays to assure the quality of the results: the FSIS auditors identified that IIBI laboratory technicians used pH strips with increments that were not sensitive enough to properly confirm and adjust the pH when preparing enrichment broth for the *Salmonella* method.	The pH tapes with the required characteristics were purchased.	[redacted]
Salmonella method: 2) For implementation of internal quality control parameters, including positive and negative assay controls: the FSIS auditors identified that a positive control is not being used throughout the *Salmonella* method. Positive and negative controls must be included for each step of analysis from the beginning to the end of the method.	The use of positive controls has been implemented from the first stage in the tests for the determination of salmonella in export samples.	
3) Salmonella: the FSIS auditors identified that IIBI laboratory technicians did not properly record start and stop times for incubation steps in the *Salmonella* methods.	The Salmonella spp log was checked where the start and stop times for incubation steps will be recorded, at the entrance of each stage of the method, date and time of departure.	See in annex: Log sheet copies (Analysis Control Register, Data, Calculations and Results. Exclusive for Salmonella spp - FSIS Equivalence Program)
4) Generic *E. coli* method (traceability of test results): a) The FSIS auditors identified that IIBI laboratory technicians did not properly record start and stop times for incubation steps in the generic *E. coli* methods. b) Additionally, while a control is used during generic *E. coli* testing, the result for the control is not recorded.	Since October 5, 2021, the positive control count and the start and stop times for incubation steps has been recorded in the log (Analysis Control Register, Data, Calculations and Results).	See in annex: Log sheet copies (Analysis Control Register, Data, Calculations and Results. Exclusive for E. coli - FSIS Equivalence Program)

TECHNICAL ASSESSMENT OF JAD / LAD LABORATORY CORRECTION FOLLOW-UP DURING THE FSIS VISIT (SEPTEMBER 15, 2021)

FSIS OBSERVATIONS	LAD RESPONSES	EVIDENCE
1) For traceability of test results: the FSIS auditors identified that LAD laboratory technicians did not properly record start and stop times for incubation steps in the STEC method.	A form has been implemented to record the date and time of the daily incubation of the samples, in addition to the corresponding incubator and the date and time of the reading of the results;	FO-INCUBACION-LAD-001 See annex form
2) For implementation of internal quality control parameters, including positive and negative assay controls: the FSIS auditors identified that a positive control is not being used with each batch of samples analyzed for STEC at LAD. Positive and negative controls must be included for every batch of STEC samples.	The use of positive and negative controls for the PCR test of export meats has been implemented. Positive Control strain of E. coli O157: H7 ATCC 43888 and Negative Control strain of Salmonella spp. ATCC 35640.	[redacted]
3) For sample receipt and storage prior to analyses at the laboratory: the FSIS auditors identified that during sample receipt at LAD, there were several samples accepted and analyzed outside of the laboratory's 23-hour collect-to-receipt requirement.	The internal arrangement of the 23 hours was modified and changes were made in FO-SAMPLES-LAD-002	Point 6 was eliminated from the internal sample entry control. Form FO-SAMPLES-LAD-002 was modified In column 3 in the condition of the sample it says: these samples must be received no later than 12 M and delivered to the microbiology laboratory no later than 1:00 pm See Annex
4) For use of appropriate assays to assure the quality of the results: the FSIS auditors identified that the LAD laboratory method for STEC does not specify the time and temperature required for the enrichment step in accordance with the validated method.	The procedure code PT-O157H7-LAD entitled Detection of Escherichia coli O157:H7 and STEC in Food already includes the time and temperature required for the enrichment step.	On page 4 in the last paragraph, the time and temperature required for the enrichment step is specified (see paragraph underlined in pink). See Annex