



United States Department of Agriculture

Food Safety and
Inspection Service

December 10, 2023

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Dear Dr. Santoni,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of the Dominican Republic's meat inspection system May 22–31, 2023. Enclosed is a copy of the final audit report. The comments received from the Government of the Dominican Republic are included as an attachment to the report.

The Dominican Republic's actions in response to the FSIS audit findings will guide the scope and frequency of future equivalence verification activities. For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic email at InternationalCoordination@usda.gov.

Sincerely,

**MICHELLE
CATLIN**

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Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF
DOMINICAN REPUBLIC
MAY 22–31, 2023

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
RAW BEEF PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

December 5, 2023

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

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of the Dominican Republic conducted by the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) May 22–31, 2023. The purpose of the audit was to verify whether the Dominican Republic’s food safety inspection system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. The Dominican Republic currently exports raw intact beef products to the United States.

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

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

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

- The Dominican Republic’s Central Competent Authority—General Directorate of Drugs, Food and Sanitary Products (Dirección General de Medicamentos, Alimentos y Productos Sanitarios (DIGEMAPS))—did not ensure documentation of positive and negative controls used throughout the analysis of official beef samples for Shiga toxin-producing *Escherichia coli* (STEC) at one microbiological laboratory.

GOVERNMENT SANITATION

- DIGEMAPS did not ensure the condition of the overhead structures and equipment were adequately maintained to prevent contamination of product and food contact surfaces.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- DIGEMAPS did not ensure the microbiological laboratory performing analyses for STEC on official samples of raw beef trimmings complied with the official method submitted through Self-Reporting Tool responses and supporting documentation.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of the Dominican Republic’s food safety inspection system May 22–31, 2023. The audit began with an entrance meeting May 22, 2023, in Santo Domingo, Dominican Republic, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA)—General Directorate of Drugs, Food and Sanitary Products (Dirección General de Medicamentos, Alimentos y Productos Sanitarios (DIGEMAPS)). Representatives from DIGEMAPS accompanied the FSIS auditor throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference May 31, 2023.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products¹
Raw - Intact	Raw Intact Beef	Beef – All products eligible except cheek meat; head meat; heart meat; and weasand meat

The USDA’s Animal and Plant Health Inspection Service (APHIS) recognizes the Dominican Republic as free of foot-and-mouth disease and undetermined risk for bovine spongiform encephalopathy.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Dominican Republic’s Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to verify whether the Dominican Republic’s food safety inspection system governing beef is being implemented as documented in the country’s SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS since the Dominican Republic became eligible to export raw beef products to the United States, in addition to information obtained directly from DIGEMAPS through the SRT.

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

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 DIGEMAPS headquarters and two 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 the country’s SRT responses and supporting documentation.

Both beef slaughter and processing establishments certified to export to the United States were selected for the audit. These establishments produce and export raw intact beef products 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 DIGEMAPS’ ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2.

The FSIS auditor also visited one government and one third-party (private) laboratory conducting microbiological testing to verify that these laboratories can provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> DIGEMAPS, Santo Domingo
Laboratories		2	<ul style="list-style-type: none"> Instituto de Innovación en Biotecnología e Industria (IIBI) (government) (microbiological), San Gerónimo Laboratorio Agroempresarial Dominicano (LAD) (private, third-party) (microbiological), Santo Domingo
Beef slaughter and processing establishments		2	<ul style="list-style-type: none"> Establishment No. C1-002, Suplidora de Carnes A&B, Santo Domingo Oeste Establishment No. C1-007, Mercarne SRL, Santo Domingo Este

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

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of the Dominican Republic’s inspection system for beef products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization’s Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From May 4, 2022, to January 31, 2023, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 44,620 pounds of beef products from the Dominican Republic. This included 44,620 pounds of raw intact beef products exported by the Dominican Republic to the United States. Of these amounts, additional types of inspection were performed on 44,570 pounds of raw intact beef. These additional types of inspection included physical examination, chemical residue analysis, and testing for microbiological pathogens (e.g., Shiga toxin-producing *Escherichia coli* (STEC) including serogroups O157, O26, O45, O103, O111, O121, and O145). As a result of this additional testing, no products were rejected during FSIS reinspection.

The previous FSIS audit in 2021 identified the following findings:

Summary of Findings from the 2021 FSIS Audit of the Dominican Republic
Component 1: Government Oversight (e.g., Organization and Administration)
<ul style="list-style-type: none"> • The CCA did not ensure that two of the three audited laboratories fully complied 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.

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

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

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

The first equivalence component the FSIS auditor 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.

DIGEMAPS, under the authority of the Ministry of Public Health and Social Assistance (currently known as the Ministry of Public Health - Ministerio de Salud Pública (MSP)) was established by Decree No. 82-15. DIGEMAPS is the CCA responsible for regulation, control, inspection, and surveillance of food and food production processes. The Food Department (Departamento de Alimentos) of DIGEMAPS is responsible for official control of meat slaughter and processing establishments. Within the Food Department, the Meat and Meat Products Unit, led by the National Supervisory Veterinarian in Charge (Médico Veterinario Supervisor Nacional a Cargo [MVSN]), coordinates the inspection services of the authorized meat slaughter and processing establishments.

The Dominican Republic's meat inspection system is organized on two levels: central and local (establishment). The central level provides direct supervision over establishments certified for export to the United States, in accordance with national legislation and FSIS import requirements. At each establishment, there are two official veterinary medical inspectors (Médico Veterinario Inspector Oficial (MVIO)). The MVSN directly supervises the MVIOs. The MVIOs are responsible for performing inspection and verification procedures. The head MVIO is responsible for supervision of the inspection personnel (Personal de Inspección (PI)) that assist the MVIOs in conducting inspection activities.

Regulation No. 329-11 describes DIGEMAP's regulatory 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 government inspection personnel include detaining products, rejecting equipment or facilities, or stopping or slowing the line. The FSIS auditor verified through interviews and record reviews that DIGEMAPS has provided instructions to government inspection personnel to document any noncompliance findings on a noncompliance record (Registro de No Cumplimiento (NC)). The FSIS auditor reviewed NCs at the audited establishments and verified that government inspection personnel had identified and documented noncompliances related to HACCP, sanitation performance standards (SPS), and sanitation standard operating procedures (Sanitation SOP). Government inspection personnel closed the NCs after verifying the adequacy and effectiveness of the establishment's preventive and corrective actions.

The Dominican Republic solely exports raw beef products to the United States from animals born and raised in the Dominican Republic. The MVSN conducts periodic audits to determine whether establishments are complying with the requirements to maintain a tracking system with information from the livestock producer to the final distributor. The FSIS auditor verified the MVSN annually reviews the establishment's traceability program and the simulation program for animal traceability.

Regulation No. 329-11 describes the export certification requirements that are to be met prior to the issuance of export certificates by government inspection personnel. DIGEMAPS' export certification process is designed to ensure that beef products intended for export to the United States are not adulterated or misbranded and that only eligible raw beef products are certified for export to the United States. DIGEMAPS requires that FSIS be notified via e-mail within 24 hours of becoming aware that adulterated product has been shipped to the United States. DIGEMAPS also requires that each establishment prepare and maintain written recall procedures and records sufficient to conduct traceback activities if adulterated product were produced or exported. The FSIS auditor verified that establishments maintain recall procedures as required by DIGEMAPS. Pre-shipment review is performed for every shipment and includes review of HACCP records, the establishment's pre-shipment review, and results of microbiological and chemical residue testing. Physical inspection of each shipment includes verifying accuracy of labels, condition of boxes, product temperature, and condition of the cargo shipping container. The MVIOs and PI are both involved with performing pre-shipment reviews; however, only MVIO's are authorized to issue export certificates. The export certificate is printed and one of the MVIOs applies the DIGEMAPS stamp and a wet signature. The completed export certificate is then sent to the central office for review and signature. The MVIOs are responsible for securing the DIGEMAPS stamp in the government office. The FSIS auditor reviewed export certificates, associated documents, and the documentation of the export verification task, and verified that the MVIOs and PI are performing export certification procedures sufficient to ensure FSIS import requirements are met prior to certifying product for export to the United States.

DIGEMAPS headquarters disseminates information about FSIS import requirements to the in-plant government inspection personnel through written publications, email, classroom training, and supervisory visits. The FSIS auditor reviewed examples of disseminated information from the MVSN to the MVIOs regarding the Dominican Republic's reinstated equivalence and the 2021 FSIS audit findings as documented in the final audit report.

DIGEMAPS has mandatory requirements for all meat producing establishments, including those 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. Approval will only be granted after evaluation of the establishment's written programs and an onsite audit. Establishments interested in exporting to the United States must implement all aspects of FSIS import requirements before they can be added to the certified list of establishments. There have not been any establishments certified or decertified for export to the United States since the previous FSIS audit in 2021.

The MVSN conducts monthly supervisory visits to the establishments certified to export to the United States. The supervisory visits include evaluation of the establishment's HACCP system, Sanitation SOP, SPS program, results of generic *Escherichia coli* (*E. coli*) and STEC testing, labeling, and other inspection requirements. The FSIS auditor reviewed documentation of supervisory visits to the establishments certified to export to the United States and verified the reviews are performed at the required frequency and include the required elements.

Official personnel at the central and local levels of the food safety inspection system are public employees. Salaries of the government inspection personnel are paid directly by MSP. The FSIS auditor reviewed earning statements for an MVIO and PI and verified payment by MSP.

DIGEMAPS provides adequate staffing at the beef slaughter and processing establishments to ensure inspection coverage during all slaughter operations, and at least once per shift during processing operations. Government inspection personnel submit planned leave requests to the MVSN who oversees staffing. The head veterinarian notifies the MVSN of any unscheduled absences. The MVSN is responsible for ensuring there are enough qualified government inspection personnel to provide continuous inspection coverage during slaughter. The FSIS auditor reviewed staffing records from the establishments certified to export to the United States and verified they had the required government inspection personnel to provide continuous inspection during slaughter.

The FSIS auditor confirmed that government inspection personnel possessed the appropriate educational credentials, training, and experience to carry out their inspection tasks. All MVIOs possess a doctor of veterinary medicine degree. The minimum educational qualification for PI is a high school diploma. All new employees must take an introductory training course, attend three-month field training, and pass an evaluation exam as a condition of employment. DIGEMAPS also conducts ongoing (annual) training for MVIOs and PI to ensure that they have the appropriate training to conduct inspection activities. The FSIS auditor reviewed records associated with ongoing training in 2023 that covered regulatory requirements of HACCP, Sanitation SOPs, SPS, labeling, and export certificates. The FSIS auditor verified the MVIOs at the establishments certified to export to the United States attended and verified that information regarding FSIS import requirements was covered during that training.

MSP has the legal authority and responsibility to approve and remove the approval of laboratories conducting analytical testing of products intended for export to the United States. FSIS audited two microbiology laboratories: Instituto de Innovación en Biotecnología e Industria (IIBI) and Laboratorio Agroempresarial Dominicano (LAD). FSIS' 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 Laboratorio Nacional de Salud Pública Dr. Defilló (Dr. Defilló National Public Health Laboratory) conducts annual audits of the domestic laboratories and the third-party (foreign) laboratory in Honduras (Laboratorio Nacional de Análisis de Residuos (LANAR)) 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 auditor verified that annual audits and related follow-up audits have been conducted in accordance with MSP requirements.

IIBI is a government laboratory that conducts analytical testing on official *Salmonella* carcass samples. IIBI is ISO/IEC 17025-accredited by the Costa Rican accreditation body (Ente Costarricense de Acreditación (ECA)). ECA audits some aspects of the laboratory annually, but all aspects are covered over a four-year period. In 2021, ECA evaluated the *Salmonella* procedure at the laboratory. The FSIS auditor reviewed the 2021 ECA audit report and verified the laboratory addressed the audit findings. Although the laboratory does not participate in

proficiency testing for *Salmonella* on beef carcass samples due to the challenge of locating organizations that provide this proficiency test for sponge samples, the analysts are required to be trained and have a certification of competency for the methods of analysis they perform. The official *Salmonella* samples arrive at the laboratory in a cooler with security tape and a lock if delivered by a non-government official. If the sample arrives and the container is not secured or it does not comply with the acceptability criteria, the sample is rejected, and the laboratory notifies the MVSN of the rejected sample. The FSIS auditor reviewed paperwork associated with a *Salmonella* sample that was rejected. The laboratory followed their rejection protocol, and the FSIS auditor verified the MVSN was notified and reacted appropriately. The results from official *Salmonella* samples are provided to the MVSN, the head veterinarian, and the establishment. The FSIS auditor reviewed laboratory procedures and analysis from sample receipt to reporting of results for *Salmonella* samples and did not identify any concerns.

LAD is a third-party (private) laboratory that conducts analytical testing for official verification samples of beef trimmings for STEC serogroups O157, O26, O45, O103, O111, O121, and O145. LAD is ISO/IEC 17025-accredited by the Dominican Accreditation Organization (Organismo Dominicano de Acreditación (ODAC)). ODAC conducts annual audits that include all aspects of the laboratory. The FSIS auditor reviewed the 2022 ODAC audit report and verified the laboratory addressed the audit findings. The FSIS auditor verified the laboratory analysts conducting STEC testing received initial training and ongoing training, most recently in 2023, on the STEC method implemented by the laboratory. The laboratory participates in annual proficiency testing for STEC. The FSIS auditor reviewed the results from 2022 proficiency testing, and they were satisfactory. The official STEC samples arrive at the laboratory in a cooler with security tape and a lock if delivered by a non-government official. If the sample arrives and the container is not secured or it does not comply with the acceptability criteria, the sample is rejected, and the laboratory notifies the MVSN and head veterinarian of the rejected sample. The FSIS auditor reviewed paperwork associated with a rejected STEC sample. The laboratory followed their rejection protocol, and the FSIS auditor verified that the MVSN and head veterinarian were notified and reacted appropriately. The results from official STEC samples are provided to the MVSN, the head veterinarian, and the establishment. The FSIS auditor 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 auditor identified the following findings:

- DIGEMAPS did not ensure documentation of positive and negative controls used throughout the analysis of official beef samples for STEC at one microbiological laboratory.

FSIS onsite audit verification activities indicate that DIGEMAPS' 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 finding described above regarding inadequate recordkeeping.

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 auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of all animals; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

DIGEMAPS requires government inspection personnel to conduct humane handling and slaughter verification tasks in accordance with Titles XIII and XIV of the Regulation No. 329-11. The verifications are categorized under nine humane handling verification tasks, which are to be performed each week and at least one verification task is to be performed each day. The FSIS auditor confirmed that government inspection personnel are conducting at least one humane handling and slaughter verification task each day. These verification tasks include 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 DIGEMAPS requirements. 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 verified that government inspection personnel are identifying and documenting NCs related to humane handling and slaughter and requiring the establishment to perform corrective actions.

The FSIS auditor confirmed that government inspection personnel are required to conduct ante-mortem inspection on every animal in accordance with Title XV of the Regulation No. 329-11. The FSIS auditor observed that government inspection personnel conduct ante-mortem inspection on the day of slaughter as described in the Ante-Mortem Inspection of Livestock (PR-CPC-04) by: (1) reviewing required documentation accompanying the livestock to ensure that all information, such as number of animals and origin of the lots, is accurately documented on 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 confirmed that each audited slaughter establishment provides a separate holding pen designated for observation and further examination of suspect animals. Article 130 of Law No. 42-01 describes the requirements 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. The FSIS auditor verified through interviews and record reviews that government inspection personnel condemn non-ambulatory/disabled animals. Condemned products must remain under the custody of the government inspection personnel until they are sent to the digester at the end of the day. MVIOs 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 government inspection personnel are required to conduct post-mortem inspection in accordance with Title XVI of the Regulation No. 329-11. The FSIS auditor verified that the inspection procedures for every livestock carcass, head, and viscera included proper incision, observation, and palpation of required organs and lymph nodes. The FSIS auditor also verified proper presentation and identification of each carcass, head, and accompanying viscera. The inspection team at the audited establishments consists of two MVIOs and four PI. Three PI conduct post-mortem inspection activities at the head, viscera, and carcass inspection stations and one inspector performs off-line verification activities. The FSIS auditor correlated the number of government inspection personnel who conduct post-mortem inspection examination in each audited establishment with the maximum slaughter rate and concluded that DIGEMAPS has provided enough inspection personnel for the existing production volume and slaughter line speed to be consistent with FSIS' maximum slaughter rates and inspection staffing standards. The FSIS auditor's review of records (including post-mortem disposition reports and periodic supervisory review records), in conjunction with FSIS observation of post-mortem inspection activities conducted by the PI, did not identify any concerns.

Performance reviews of the MVIOs are conducted twice a year by the MVSN. The MVIOs are evaluated on how they perform inspection tasks on ante-mortem; post-mortem; humane handling and slaughter; SPS; Sanitation SOPs; HACCP; *Salmonella* and STEC sampling; evaluation of generic *E. coli* data; zero tolerance for feces, ingesta, and milk; sanitary dressing; chemical residue sampling; export certification; label verification; document organization; and ethics. The first annual review covers all the evaluation criteria. The second review is designated for follow up. The MVIOs conduct performance reviews of the PI twice a year. The performance reviews for the PI cover the same evaluation criteria except for issuing export certificates. The FSIS auditor reviewed employee performance reviews and verified they are being conducted at the required frequency, cover the required evaluation criteria, and address unsatisfactory performance.

DIGEMAPS 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 confirmed that government 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.

Government inspection personnel conduct labeling verification activities before every shipment destined for export to the United States to ensure that information on the product labels is complete, accurate, and meets FSIS labeling requirements. The FSIS auditor verified that government inspection personnel are reviewing labels as part of pre-shipment review. The FSIS auditor verified that information pertaining to FSIS labeling requirements was included in the ongoing annual training sessions for MVIOs and PI. In addition, DIGEMAPS requires species verification testing by government inspection personnel prior to every shipment destined for export to the United States. The FSIS auditor verified species testing is being conducted at the required frequency.

DIGEMAPS 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. New information is disseminated to government 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), the dorsal root ganglia of cattle thirty months of age and older, and the tonsils and the distal portion of the ileum for all cattle. 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 matter to surrounding tissues. Establishment employees responsible for removing SRMs are required to sanitize equipment after each carcass. DIGEMAPS requires that all SRMs be disposed of through rendering, incineration, or burial in an approved landfill. Government inspection personnel verify the proper removal, segregation, and disposal of SRMs once a week in accordance with the Verification Instructions Related to Specified Risk Materials in Cattle of All Ages (GA-CPC-08). The FSIS auditor visually verified the proper removal of SRMs and their storage in identified containers to prevent cross-contamination with other products and verified government inspection personnel performed the SRM verification task at the required frequency.

Condemned products must remain under the custody of the government inspection personnel until they are sent to the digester at the end of the day. The FSIS auditor observed appropriate identification and segregation of inedible or condemned materials and documentation of final disposal of these materials at rendering facilities. The FSIS auditor did not identify any concerns.

FSIS onsite audit verification activities indicate that DIGEMAPS 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 the CCA 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.

DIGEMAPS requires establishments eligible to export to the United States to implement sanitary dressing and process control procedures to prevent potential contamination of carcasses in accordance with Title XIV, Articles 217 and 222–225 of Regulation No. 329-11. The FSIS auditor reviewed sanitary dressing and process control procedures at the audited establishments and verified they developed measures to prevent contamination throughout the slaughter process. The FSIS auditor verified that government inspection personnel are performing sanitary dressing verification tasks once a week.

The Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Cattle Slaughter Operations (PR-CPC-02) describes the inspection procedures for hands-on verification of livestock carcasses for visible fecal material, ingesta, and milk before the final wash. The number of randomly selected carcasses examined per shift is based on slaughter volume. The FSIS auditor verified that government inspection personnel are performing and documenting zero tolerance verification tasks daily on the required number of carcasses.

DIGEMAPS requires government inspection personnel to verify that establishments maintain sanitary conditions through various SPS tasks. SPS-01 task is for verification of pest control, and it is performed once a week. SPS-04 task is for verification of sanitary conditions related to construction, lighting, ventilation, plumbing and sewage, water potability, lavatories and dressing rooms, equipment and utensils, and employee hygiene. Government inspection personnel verify one SPS-04 activity daily and ensure all areas covered by this task are verified over time. AE-01 task for verification of sanitary conditions of the outside premises is performed once every two weeks. The FSIS auditor verified that government inspection personnel are performing SPS verification tasks at the required frequency and verifying all activities over time. The FSIS auditor reviewed documented NCs and verified that government inspection personnel are identifying and documenting SPS noncompliance. During the establishment visits, the FSIS auditor observed water dripping from the ceilings in multiple departments in both audited establishments. In one establishment, the FSIS auditor observed water dripping onto exposed product and food contact surfaces in the deboning department. The FSIS auditor also observed water spraying off an air conditioning hose onto carcasses in the carcass cooler. Government inspection personnel took immediate regulatory control actions involving retention of product and rejection of equipment in the situations where product and food contact surface contamination from dripping or spraying water was observed. As a result, the FSIS auditor identified the following finding:

- DIGEMAPS did not ensure the condition of the overhead structures and equipment were adequately maintained to prevent contamination of product and food contact surfaces.

Prior to the end of the audit, DIGEMAPS made the decision to stop issuing export certificates for products originating from both eligible facilities until corrective actions were implemented to correct the deficiencies identified during this audit. DIGEMAPS requires establishments to maintain written Sanitation SOPs to prevent direct product contamination or creation of insanitary conditions. 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 reviewed the establishments' Sanitation SOPs and associated documents and verified that the establishments are documenting Sanitation SOP monitoring and corrective actions when deviations are identified. The FSIS auditor confirmed that government inspection personnel conduct daily Sanitation SOP verification procedures. Verification activities consist of a combination of document reviews, observations, and hands-on inspection verification.

The FSIS auditor observed government inspection personnel conducting pre-operational Sanitation SOP verification in accordance with Articles 145–147 and 171 of Regulation No. 329-11. The verification was performed after the establishment had conducted its pre-operational

sanitation procedures and determined that the facility was ready for production. The government inspection personnel identified noncompliances and verified corrective actions prior to releasing the department to begin operations.

The FSIS auditor verified that government inspection personnel are verifying Sanitation SOPs before and during operations at the required frequency. The FSIS auditor reviewed NCs and verified that government inspection personnel are identifying and documenting noncompliances related to Sanitation SOPs.

FSIS onsite audit verification activities indicate that DIGEMAPS requires establishments to develop, implement, and maintain sanitation programs that are consistent with criteria established for this component, except for the sanitation finding described above regarding maintenance of overhead structures and equipment. The FSIS auditor also identified isolated noncompliances related to sanitation which 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 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 DIGEMAPS requires establishments certified to export to the United States to develop, implement, and maintain HACCP systems in accordance with Articles 143–156 and 171 of Regulation No. 329-11 that are consistent with 9 CFR Part 417 requirements. The FSIS auditor verified that each audited establishment's HACCP system included hazard analyses, flow charts, and HACCP plans that identify, evaluate, and prevent or control food safety hazards in their production processes. DIGEMAPS requires establishments' HACCP plans to include activities designed to validate adequacy of controls, monitoring, and verification procedures; records for documenting results of monitoring and verification activities; and corrective actions in response to deviations from critical limits. The FSIS auditor reviewed required documentation associated with HACCP systems at each audited establishment. The FSIS auditor conducted onsite observations of critical control point (CCP) monitoring and reviewed records associated with the establishments' design and implementation of their HACCP systems, including their hazard analyses, flow charts, CCPs, critical limits, monitoring procedures and frequencies, initial validation, ongoing verification, reassessment, records, and pre-shipment reviews. The FSIS auditor verified that audited establishments took appropriate corrective actions in response to any critical limit deviations.

The government inspection personnel perform weekly verification which includes 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. The FSIS auditor verified that government

inspection personnel are performing HACCP verification tasks at the required frequency and are identifying and documenting noncompliances.

The FSIS auditor confirmed that the audited beef slaughter and processing establishments 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 onsite audit verification activities indicate that DIGEMAPS 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 plan content. 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 the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

The Dominican Republic tests for chemical residues through routine surveillance sampling under the national program of chemical residues (NPCR) (Programa Nacional de Residuos Químicos) and suspicious (targeted) sampling when the MVIO suspects that an animal presented for slaughter may contain a violative level of one or more chemical residues or when the producer is included on the suspect list. For suspicious (targeted) sampling, government inspection personnel perform a kidney inhibition swab test. If the kidney inhibition swab test is positive, the government inspection personnel retain the carcasses and parts and submit kidney and muscle tissues to the laboratory for further analysis. The NPCR specifies the analytes included in the testing program, the method of analysis to be used, the matrix to be collected, the maximum residue level (MRL), compounds of interest, compound substance class, criteria used to determine sampling numbers, and the total number of samples to be collected and tested. The implementation and maintenance of the NPCR is carried out by the central office of MSP and the sampling is performed by the government inspection personnel assigned to the establishments. MSP sets criteria evaluated for modifying the plan, which includes historical data, number of establishments, new chemicals of concern, toxicity, and withdrawal times. The NPCR indicates that the MRL are set to be consistent with 21 CFR Part 556 for veterinary drug tolerance values

set by the U.S. Food and Drug Administration and 40 CFR Part 180 for pesticide tolerance values set by the U.S. Environmental Protection Agency.

DIGEMAPS 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 auditor verified through record reviews, interviews, and observation that government inspection personnel collect, prepare, and send sealed samples to the Laboratorio Veterinario Central (LAVECEN) in accordance with DIGEMAPS procedures. LAVECEN is responsible for collecting all chemical residue samples within the Dominican Republic and shipping them under seal to LANAR in Honduras.

The FSIS auditor review of the chemical residue sampling records maintained at the inspection offices of the audited slaughter establishments indicated that the 2023 national sampling program was being implemented as scheduled. The MVSN also ensures that MVIOs comply with NPCR procedures and sampling timeframes during monthly supervisory reviews.

DIGEMAPS requires that carcasses and parts eligible for export to the United States, sampled for chemical residues through the NPCR, be retained until acceptable results are received. The FSIS auditor observed the veterinarian-retained cages and associated verification records to confirm that DIGEMAPS' test and hold policy was being implemented as designed. No concerns arose from these observations and reviews.

When violative chemical residues are detected, either through routine or suspicious (targeted) sampling, DIGEMAPS formally notifies the establishment's management of the violative results, determines the disposition of the retained product, and the producer is added to the suspect list managed by MSP. The MVIO performing ante-mortem inspection is responsible for reviewing the suspect list every day. Every lot from a producer on the suspect list is sampled for chemical residues and held pending acceptable results. The producer is removed from the suspect list after one year of compliant results. The FSIS auditor reviewed procedures taken when a sample exceeded established tolerances and verified the producer was added to the suspect list and lots from that producer were sampled and held pending acceptable results.

There have not been any POE violations related to this component since the previous FSIS audit in 2021. FSIS onsite audit verification activities indicate that DIGEMAPS continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in beef products intended for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

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 (GA-CPC-10) states that establishments are required to develop written generic *E. coli* programs consistent with requirements stipulated in 9 CFR 310.25(a). Government inspection personnel perform generic *E. coli* verification once a month. Government inspection personnel observe the establishment collecting samples, review and analyze generic *E. coli* data to evaluate the effectiveness of the establishment's food safety controls, and verify the establishment uses the results to identify times when the slaughter process is out of control and take steps to re-establish control. The FSIS auditor reviewed the generic *E. coli* results at the audited establishments and verified the establishments had developed criteria that indicate when the process is out of control. The FSIS auditor verified the establishments implement testing as required by DIGEMAPS and react when process control deviations are detected. The FSIS auditor also verified that government inspection personnel are performing generic *E. coli* verification at the required frequency.

DIGEMAPS implements an official *Salmonella* sampling and testing program for chilled beef carcasses that is consistent with the FSIS *Salmonella* performance standards in 9 CFR 310.25(b). Government inspection personnel are responsible for collecting a sponge sample from the flank, rump, and brisket on chilled carcasses for *Salmonella* testing. The samples are submitted to IIBI for analytical testing using the Food and Drug Administration's Bacteriological Analytical Manual (BAM-8) for detection of *Salmonella* with modifications. The primary classes of cattle slaughtered at certified establishments are cows and bulls. Government inspection personnel collect one sample on each production day until all samples in the set have been collected. If the established set of samples for the year is completed satisfactorily, another set is scheduled for the next year. If the number of positive samples exceeds the permitted standard, then the establishment must take immediate corrective actions, after which DIGEMAPS schedules follow-up samples. The FSIS auditor observed *Salmonella* sampling on carcasses at the audited establishments and did not have any concerns. The FSIS auditor also reviewed *Salmonella* results and verified that government inspection personnel were collecting samples at the required frequency and monitoring for compliance with the *Salmonella* performance standards.

DIGEMAPS considers STEC, (including serogroups O157, O26, O45, O103, O111, O121, and O145), in raw intact beef to be adulterants consistent with FSIS' definition of adulteration. Government inspection personnel are responsible for performing N60 sampling of beef trimmings according to the establishment's production volume. In addition, DIGEMAPS requires establishments to conduct routine sampling of beef trimmings in accordance with N60 sampling methodology. The FSIS auditor observed STEC sampling at the audited establishments and verified that government inspection personnel performed the sampling in accordance with established N60 sampling methodology. The FSIS auditor also reviewed sample results and verified that government inspection personnel are collecting samples at the required frequency. The FSIS auditor confirmed that DIGEMAPS requires that the sampled lot tested for STEC through either the establishment's self-monitoring or the official government verification sampling program be held pending receipt of acceptable results.

DIGEMAPS indicated to FSIS through SRT responses and supporting documentation that laboratories conducting testing for STEC would be implementing the FSIS Microbiology

Laboratory Guidebook (MLG) methods for enrichment of samples being tested for both *E. coli* O157:H7 and for non-O157 STEC (including serogroups O26, O45, O103, O111, O121, and O145). Following enrichment, the samples would be screened for *E. coli* O157:H7 using the Association of Official Analytical Chemists Performance-Tested Method (AOAC-PTM) #031002 and for non-O157 using the AOAC-PTM method #091301. The FSIS auditor verified the laboratory analyzes the entire sample for STECs. However, the FSIS auditor determined the laboratory implemented enrichment procedures were not consistent with the FSIS MLG method for detection of STEC, and the incubation temperatures were not consistent with the validated AOAC-PTM #091301 method.

- DIGEMAPS did not ensure the microbiological laboratory performing analyses for STEC on official samples of raw beef trimmings complied with the official method submitted through SRT responses and supporting documentation.

DIGEMAPS provides enforcement strategies 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 a noncompliance report, conducting HACCP verification activities, verifying the proper implementation of the establishment's corrective actions, or conducting follow-up sampling activities. The FSIS auditor reviewed documents associated with a positive STEC sample and verified the government inspection personnel issued an NC, verified corrective actions, and performed 16 follow-up samples to verify efficacy of corrective actions.

There have been no POE violations related to this component since the previous FSIS audit in 2021. FSIS onsite audit verification activities indicate that DIGEMAPS maintains overall authority to implement an official microbiological sampling program organized and administered by the national government to verify that beef products intended for export to the United States are unadulterated, safe, and wholesome. However, the FSIS auditors identified a finding related to the laboratory implementation of the STEC method, which deviated from the method indicated as the official method by DIGEMAPS.

X. CONCLUSIONS AND NEXT STEPS

A remote exit meeting was held May 31, 2023, with DIGEMAPS officials. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

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

- DIGEMAPS did not ensure documentation of positive and negative controls used throughout the analysis of official beef samples for STEC at one microbiological laboratory.

GOVERNMENT SANITATION

- DIGEMAPS did not ensure the condition of the overhead structures and equipment were adequately maintained to prevent contamination of product and food contact surfaces.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- DIGEMAPS did not ensure the microbiological laboratory performing analyses for STEC on official samples of raw beef trimmings complied with the official method submitted through SRT responses and supporting documentation.

During the exit meeting, DIGEMAPS committed to address the preliminary finding as presented. FSIS will evaluate the adequacy of DIGEMAPS' documentation of proposed corrective actions once received and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Suplidora de Carnes A&B Km. 26 Carretera Yamasa Sierra Prieta municipio de Santo Domingo Oeste Dominican Republic	2. AUDIT DATE 5/25/23	3. ESTABLISHMENT NO. C1-002	4. NAME OF COUNTRY Dominican Republic
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Raw-intact products

60. Observation of the Establishment

During the audit of the establishment, the FSIS auditor observed the following noncompliances:

15. HACCP plan for CCP1 for zero tolerance of fecal, ingesta, and milk does not state the verification procedures for direct observation of monitoring, it only states the frequency of weekly.

15. HACCP plans do not state the procedure or frequency for verification of monitoring records.

39. Water dripping from the ceiling in multiple areas of the establishment during heavy rainfall. No droplets were observed falling onto product or food contact surfaces.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

5/25/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Mercame, SRL Calle 3 antigua Camino de la Barca Cancino adentro Santo Domingo Dominican Republic	2. AUDIT DATE 5/26/23	3. ESTABLISHMENT NO. C1-007	4. NAME OF COUNTRY Dominican Republic
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	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	
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.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and processing
Prepared Products:	Raw-intact products

60. Observation of the Establishment

During the audit of the establishment, the FSIS auditor observed the following noncompliances:

10/39. Water dripping from the ceiling in multiple areas of the establishment during heavy rainfall. Water dripping on product being processed in the deboning area and the product was then placed in a bin with other products. Water dripping onto food contact surfaces in the deboning area. The CCA notified the establishment of the observed noncompliances and verified corrective actions were implemented.

10/39. Liquid dripping off a hose connected to the air conditioning unit in one of the carcass coolers. The liquid was seen dropping on multiple carcasses. The CCA notified the establishment of the observed noncompliances and verified corrective actions were implemented.

38. Multiple flying insects in the slaughter department before and during operations.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

5/26/2023

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

Santo Domingo, D.N.
October 27, 2023

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 you in order to send you the corrections made by the authorized establishments Suplidora de Carnes, No. C1-002, Mercarne, SRL, No. C1-007 and the authorized laboratory JAD/LAD, this, as a result of the findings found during the ongoing audit of the meat inspection system for intact raw beef from the Dominican Republic [REDACTED] from May 22 to 31 on behalf of the Food Safety Inspection Service (FSIS) of the United States Department of Agriculture.

Likewise, we want to detail the following actions taken by this inspection system to ensure that the corrective actions and preventive measures implemented will be effective over time;

Equivalence component(s): (1) Government Oversight (e.g., Organization and Administration) and (6) Government Microbiological Testing Programs:

- 1) The Food Department has decided to strengthen operational and technical capacity in terms of laboratory audits and other related aspects, therefore, the frequency of monitoring visits will be greater in a calendar year, thus determining that, before the end of this year 2023 we will be visiting the local authorized laboratories every two (2) months to verify compliance with the requirements of the ISO 17025 Standard and those of FSIS. Specifically, on October 19 of this year, our technical team visited the JAD/LAD laboratory to verify firsthand that they are complying with the corrective actions carried out by said laboratory as a result of the FSIS audit.

- 2) Follow-up visits to authorized laboratories may include one or more visit topics so that our audit team can ensure first-hand that the audited component is in compliance with all established requirements. Topics to be evaluated include, but are not limited to;
 - Periodic visits to the sample reception area during the execution of the activities related to it, in order to verify first-hand that each laboratory is complying with the established requirements.
 - Periodic visits to verify whether the laboratories are being consistent in the implementation of corrective actions according to previous findings found by consultants, FSIS auditors and by our audit team.
 - Exhaustive review of the reports of the accrediting entities (annual evaluations) and the corrective actions issued by the different laboratories, this, to determine compliance and the non-existence of possible trends.

Equivalence component(s): (3) Government Sanitation:

- 1) To verify the compliance of both authorized establishments with respect to the FSIS findings, official verifications (tasks) were carried out in a targeted manner in each one, as well as support from the national supervisor to verify by direct observation (DO) and review of records (RR) in applicable cases corrections. Specifically, we did the following official verifications:
 - **Establishment No. C1-007:** on October 23 of this year, our veterinarian in charge carried out official verification tasks code POES-02 and POES-03 and confirmed that the procedure of the establishment code **MC-PR-Mant-011** it is being implemented as described. Likewise, the supervision activities in the month of October were focused on verifying by DO and RR that the corrective and preventive actions offered by the establishment to the findings of the FSIS audit (non-compliance number 30-SPS and 35-SPS) were consistent to close these non-compliances.

- **Establishment No. C1-007:** a review of the evaluation of trends was carried out regarding the **pest control component (specifically, the presence of flying insects both pre- and operational in the slaughter room)** and we were able to conclude that, the trend reports from June to September do not present non-compliance associated with said component, thus determining that the preventive measures implemented by said establishment were effective.
 - **Establishment No. C1-002:** on October 24 of this year, our veterinarian in charge carried out official verification tasks code SPS-C and SPS-V and confirmed that NO water dripping from the ceiling was observed (specifically in the deboning room) falling on the product or surfaces in contact with food. Likewise, the supervision activities in the month of October were focused on verifying by OD and RR that the corrective and preventive actions offered by the establishment to the findings of the FSIS audit (non-compliance number 03-HACCP, 04-HACCP and 29 -SPS) were consistent to close these non-compliances.
- 2) As a monitoring method, from our central office, we will be assigned directed tasks to the official personnel assigned in both authorized establishments (for example: construction verifications, ventilation, review of written programs, review of records, among others) to verify for different forms (DO, RR or combined) that said establishments continue to comply with the corrective and preventive actions presented.

Mrs. Catlin, taking into consideration what is specified in this communication in addition to the reports of the actions taken, we understand that the regulatory control action (SUSPEND THE SIGNING OF MEAT EXPORT CERTIFICATES TO THE UNITED STATES OF NORTH AMERICA (USA)) on May 31 can be discarded and authorized establishments can begin producing lots for the North American market starting October 30 of the current year.

Please inform us of the next steps to execute in relation to this process.

Sincerely,

**Jaime
Santoni**

Firmado digitalmente por Jaime Santoni
Nombre de reconocimiento (DN):
cn=Jaime Santoni, o=privada,
ou=privada, email=jrsh7@hotmail.com,
c=ES
Fecha: 2023.10.27 21:50:56 -04'00'

Jaime Rafael Santoni Hernández, MSP

Jefe de los Servicios Veterinarios

Dirección General de Medicamentos, Alimentos y Productos Sanitarios