



United States Department of Agriculture

Food Safety and
Inspection Service

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Dr. Albertine Shilongo
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Directorate of Veterinary Services
Ministry of Agriculture, Water and Forestry
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Dear Dr. Shilongo,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Namibia's inspection system from September 23 through September 27, 2019. Enclosed is a copy of the final audit report. The comments received from the Government of Namibia are included as an attachment to the report.

Should you have any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at InternationalCoordination@usda.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michelle Catlin".

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN THE
REPUBLIC OF NAMIBIA
SEPTEMBER 23 - 27, 2019

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

February 11, 2020

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from September 23 - 27, 2019. The purpose of the audit was to determine whether the Republic of Namibia's (Namibia) food safety inspection system governing raw beef remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Namibia currently exports only raw intact beef 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.

The FSIS auditor identified the following findings:

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

- Government inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate. This is inconsistent with the Central Competent Authority's (CCA's) requirements to hold product pending negative residue results, as prescribed in *Circular V5/2018, Post-Mortem Livestock Inspection*.
- The CCA is not following *Quality Management Standard Operating Procedure 17 Sample Receiving and Handling Procedure*, which prescribes laboratory rejection of government verification samples submitted with inadequate information.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The Central Veterinary Laboratory (CVL) is not analyzing the entirety of the N60 sample for *Escherichia coli* (*E. coli*) O157:H7 and non-O157 Shiga toxin-producing *E. coli* (STEC) during screening of official testing.
- The CVL is not following its validated method for sample preparation and enrichment for *E. coli* O157:H7 and non-O157 STEC official testing.

During the audit exit meeting on September 27, 2019, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the Republic of Namibia’s (Namibia) food safety system from September 23 through September 27, 2019. The audit began with an entrance meeting held on September 23, 2019, in Windhoek, Namibia, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA), the Directorate of Veterinary Services (DVS). During the audit exit meeting on September 27, 2019, the CCA committed to address the preliminary findings as presented. Representatives from the CCA accompanied the FSIS auditor throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing raw intact beef remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Namibia is eligible to export the following category of products to the United States:

Process Category	Product Category	Eligible Products¹
Raw - Intact	Raw intact beef	Carcass (including carcass halves or quarters); cuts; edible offal; other intact; primals and subprimals.

The USDA’s Animal and Plant Health Inspection Service (APHIS) recognizes Namibia as negligible risk for bovine spongiform encephalopathy, and free of foot-and-mouth disease (FMD); however, the importation of meat and other animal products from the region south of the Veterinary Cordon Fence² into the United States is subject to restrictions specified in Title 9 of the United States Code of Federal Regulations (CFR) 94.11.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g.,

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

² The Veterinary Cordon Fence (VCF) is a pest-exclusion barrier that bisects the country from east to west, separating northern Namibia from the central and southern parts of the country ([Food and Agriculture Organization, page 16](#)) where commercial farms are located that produce livestock as the source for meat products exported to the United States.

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.

Administrative functions were reviewed at CCA headquarters and one local inspection office within the establishment. 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 intended.

The audit included a visit to the sole establishment certified to export to the United States, a beef slaughter establishment that produces and exports raw intact beef to the United States.

During the establishment visit, 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 CCA’s ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

Additionally, one government microbiological and chemical residue laboratory was audited to verify its ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits	#	Locations
Central Competent Authority	1	• DVS, Windhoek
Laboratory	1	• Central Veterinary Laboratory (CVL), government microbiological and chemical residue testing laboratory, Windhoek
Beef slaughter and processing establishment	1	• Establishment No. NA22, Meatco Windhoek, Windhoek

FSIS performed the audit to verify the food safety inspection system met 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.] 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Namibia’s inspection system for raw 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 1, 2016 through April 30, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 165 pounds of raw intact beef exported by Namibia to the United States. FSIS also performed reinspection on 78 pounds at POE for additional types of inspection, including testing for chemical residues and microbiological pathogens (Shiga toxin-producing *Escherichia coli* [STEC] O157:H7, O26, O45, O103, O111, O121, and O145), for which no products were rejected for issues related to public health.

The previous audit in 2017 did not identify any systemic findings.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Namibia's SRT responses and supporting documentation. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to determine whether Namibia's food safety inspection system governing meat is being implemented as documented in the country's SRT responses and supporting documentation.

The FSIS final audit reports for Namibia's food safety inspection system are available on the FSIS website at: <https://www.fsis.usda.gov/foreign-audit-reports>.

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

The first of six equivalence components 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.

The national government of Namibia organizes and manages the food safety system governing meat products. The CCA is the DVS, a Directorate under the Ministry of Agriculture, Water and Forestry, which has the responsibility for developing and implementing Namibian policy in the fields of food safety and animal health and welfare under the authority of the *Animal Health Act*. The DVS is headed by the Chief Veterinary Officer (CVO) and consists of four divisions that are each headed by a Deputy CVO: the Veterinary Public Health Division; the Animal Disease Control Division; the Epidemiology, Training, Import and Export Control Division; and the Diagnostic Services and Research Division. The FSIS auditor verified that there have not been any changes in the DVS organizational structure since the last FSIS audit.

The Veterinary Public Health Division is responsible for the coordination of inspection in meat establishments and ensuring compliance with requirements of trading partners. At the headquarters level, the Veterinary Public Health Division consists of the Deputy Chief Veterinary Officer and Chief Veterinarian who oversees government inspection staff. The government inspection staff assigned to the slaughter and processing establishment certified to export to the United States is headed by a State Veterinarian (SV), who supervises Veterinary

Hygiene Inspectors (VHIs) and Veterinary Hygiene Inspector Assistants (VHIAs). The FSIS auditor verified through document review that all inspection staff are employees of the Namibian government who are paid from the national budget.

The Animal Disease Control Division is responsible for the planning and implementation of control and eradication programs for animal diseases and enforcing animal health legislation. The Epidemiology, Training, Import and Export Control Division is responsible for overseeing the Namibia Livestock Identification and Traceability System (NamLITS), training, and ensuring import and export requirements are met. The Diagnostic Services and Research Division oversees the CVL, which is responsible for microbiological and residue testing. The FSIS auditor verified the process for establishment certification as defined in *Circular V18/2015, Updated Veterinary Services Requirements for Approval, Registration, and Listing and Regulatory Actions/Measures Following Failures with Regulatory Compliance*.

An establishment intending to export to the United States must first send a letter of intent to the DVS, which then sends the required circulars that must be adhered to in order to meet Namibia's requirements for eligible establishments. The establishment must then develop a plan defining how these requirements will be met, which the inspection staff must then verify and subsequently submit to the DVS headquarters. The DVS headquarters will then conduct an audit of the establishment and proceed with approval or require additional audits prior to approval if requirements are not met.

The FSIS auditor verified that there have not been any recalls at the establishment eligible to export to the United States since the last FSIS audit. In the event adulterated or misbranded products were shipped to the United States, the DVS would inform FSIS of the implicated product through the CVO. Additionally, the DVS requires establishments to maintain and implement a recall plan.

The FSIS auditor verified that there have not been any enforcement measures at the establishment eligible to export to the United States since the last FSIS audit. The CCA's enforcement action process is defined in *Circular V18/2015*. If inspection personnel find that an establishment's failure to meet requirements warrants decertification, the DVS headquarters will send a team for evaluation. If the DVS headquarters personnel confirm the assessment from inspection personnel, the establishment will be decertified, and FSIS will be immediately informed.

The FSIS auditor reviewed government inspection records including noncompliance reports at the establishment certified to export to the United States. The FSIS auditor verified that inspection personnel are documenting noncompliance and requiring corrective actions to be implemented and documented in writing from the establishment. Corrective actions and preventative measures are required immediately for imminent threats to public health then verified by inspection personnel once implemented.

Inspection personnel verify export requirements for each shipment of product prior to signing export certificates through a review of inspection records, HACCP and sanitation records, and microbiological test results in addition to verifying that APHIS requirements are met through

animal tracking information for each animal. The FSIS auditor verified that security of export stamps and certificates is maintained by keeping them in a locked inspection office when not in use. The FSIS auditor's review of records and discussion with the DVS headquarters and the SV indicated that inspection personnel routinely confirm acceptable test results of official microbiological sampling (i.e., "hold and test") prior to certifying product for export to the United States; this was not the case for official chemical residue testing conducted as part of Namibia's national residue monitoring program. This resulted in the following finding:

- Government inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate. This is inconsistent with the CCA's requirements to hold product pending negative residue results, as prescribed in *Circular V5/2018, Post-Mortem Livestock Inspection*.

The FSIS auditor verified that the establishment certified to export to the United States does not use any source material from any other establishments or countries. The traceability of the cattle slaughtered is verified by inspection personnel when certifying products for export to ensure compliance with APHIS requirements.

The FSIS auditor verified that the slaughter establishment maintained continuous staffing during slaughter operations through a review of inspection records and observation of staffing for post-mortem inspection. The establishment operates a single shift. Relief staffing schedules are maintained by supervisory personnel for all inspection staff in the event of any planned or unplanned absences.

The FSIS auditor reviewed the hiring process of government inspection personnel and verified that SVs are required to hold a Doctor of Veterinary Medicine degree in order to qualify for their positions. When new government inspection personnel are hired, they are required to undergo training which includes both classroom training and on-the-job training and covers all relevant circulars to the establishment they are assigned. Refresher training is also held at least once per year. The FSIS auditor verified that the last training occurred in June and July of 2019 and covered sanitation performance standards (SPS), sanitation standard operating procedures (SSOPs), HACCP principles, *Salmonella*, generic *E. coli*, *E. coli* O157:H7 and STEC sampling, ante-mortem and post-mortem inspection, specified risk material (SRM) removal, and documenting noncompliance.

The FSIS auditor verified that information regarding FSIS requirements is conveyed to inspection personnel and establishments certified to export to the United States through the issuance of circulars. Additionally, DVS monitors the FSIS website for policy changes that would warrant the issuance of a circular. When a new circular is issued, the DVS holds a training session for inspection personnel to ensure their understanding of updated policies.

The CVL organized within the DVS is the primary laboratory that conducts microbiological and chemical analysis as well as diagnostics of animal diseases. The CCA conducts annual audits of the CVL. The FSIS auditor reviewed the most recent DVS audit of the CVL and verified that when deficiencies were identified the CVL implemented corrective actions and subsequently

verified that those corrective actions were adequate. The CVL is accredited by the South African Development Community Accreditation Service (SADCAS) according to International Organization for Standardization (ISO) 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*, standards. The FSIS auditor verified that the current accreditation certificate was dated March 20, 2018, and expires on March 19, 2023, and that the SADCAS conducts annual audits of the CVL. The FSIS auditor reviewed the most recent audits of the CVL and verified that audits and accreditation covered methods used on products eligible for export to United States, and when deficiencies were found, corrective actions were taken and subsequently verified.

The CVL subcontracts chemical residue analysis to an Italian laboratory, and maintains oversight over this laboratory through annual audits, which are conducted as on-site audits every two years, and as desk audits when not on-site. The FSIS auditor verified that the CCA conducted audits of the subcontracted laboratory at the prescribed frequency and has the authority to approve and disapprove laboratories that are used to analyze official samples of products that are destined for the United States.

The CVL conducts proficiency testing in methods that are used to analyze official samples at least once per year. The FSIS auditor verified that proficiency testing conducted by the SADCAS covers the methods used by laboratory personnel to analyze official samples of products that are destined for the United States and found no concerns.

The CCA maintains Quality Management Standard Operating Procedures (QUA SOPs) to ensure quality management in sample handling, sample security, and adherence with ISO 17025 standards at the CVL. However, the FSIS auditor identified the following finding:

- The CCA is not following *QUA SOP 17, Sample Receiving and Handling Procedure*, that prescribes laboratory rejection of government verification samples submitted with inadequate information. The FSIS auditor identified an official sample that was submitted with a form that did not include the production lot number or species, and yet the CVL accepted and analyzed the sample for *E. coli* O157:H7 and non-O157 STEC.

The audit verified that Namibia's meat inspection system is organized and administered by the national government. The FSIS auditor also verified that the DVS inspection officials are assigned to enforce the laws and regulations governing meat. However, at the time of the audit, the DVS was unable to demonstrate confirmation of acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing the export certificate, or adequate government oversight of sample traceability.

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 of six equivalence components 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 animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations, and periodic supervisory visits to official establishments.

The FSIS auditor verified that SVs perform humane handling verification activities daily, in accordance with *Circular V3/2018, USDA-FSIS Regulatory Requirements: DVS Veterinary Public Health Verification Activities of an Establishment's Food Safety System*, which implements requirements consistent with 9 CFR Part 313. SVs verify truck unloading, water and feed availability, handling of suspect and disabled livestock, handling during livestock movement, electric prod/alternative object use, observations for slips and falls, stunning effectiveness, and checks for conscious animals on the rail.

Ante-mortem inspection of livestock is conducted on the day of slaughter by the SV, as per *Circular V17/2008, Ante-mortem Inspection Guidelines*. The FSIS auditor verified that ante-mortem inspection is performed on all livestock at rest and in motion to determine whether animals are fit for slaughter, and the SV identifies and segregates livestock with disease conditions. The FSIS auditor verified that the establishment certified to export to the United States maintained a suspect pen for the purpose of segregating suspect animals. The SV reviews incoming documentation associated with each animal to verify that they are properly identified and that they originate only from Namibia, from areas that are located south of the Veterinary Cordon Fence, per APHIS requirements. The DVS also maintains an electronic system, NamLITS, which documents the traceability of animals through their radio-frequency identification tags to ensure that they do not originate from FMD-affected areas. The FSIS auditor reviewed records associated with ante-mortem inspection and verified that the SV conducted ante-mortem procedures in compliance with Namibia's guidelines.

The FSIS auditor verified that post-mortem inspection procedures were conducted in accordance with *Circular V5/2018*, through observation of VHIs and VHAs and through a review of post-mortem inspection records. The FSIS auditor observed and verified proper presentation, identification, examination, and disposition of carcasses and parts are being implemented during post-mortem inspection. VHAs are inspecting heads, viscera, and carcasses through incision, palpation, and observation, and inspecting every carcass for contamination with fecal material, ingesta, or milk contamination. The establishment has a mechanism in place to divert carcasses from the slaughter line for further disposition if pathology or the need for trimming is identified. The FSIS auditor verified that the CCA maintains line speed requirements and that the line speed at the time of the audit was appropriate for the staffing of VHAs as observed.

The FSIS auditor verified that VHIs confirm the removal of SRM daily, in compliance with *Circular V14/2013, Standard Operating Procedures for Verification Activities Pertaining to Specified Risk Material (SRM) Removal, Segregation, and Disposition*. Condemned materials are disposed of in designed containers that are clearly marked as "inedible". The FSIS auditor confirmed that verification of handling of condemned animals and parts and inedible products by the SV or a VHI is conducted daily.

The FSIS auditor verified that the CCA conducts supervisory review visits once per quarter in accordance with *Circular V7/2018, In-Plant Performance System Assessment Sheet (Assessment of Official Controls) - Procedures on How to Conduct the In-Plant Performance Assessment/Supervisory Assessment*, to evaluate the performance of government inspection personnel. Government inspection personnel are evaluated on humane handling, ante-mortem and post-mortem inspection; microbiological and residue sample collection, verification of humane handling, SRM controls, condemned materials, HACCP, SSOPs, and SPS. In addition, a Chief Veterinarian from headquarters conducts annual audits of export establishments and verifies compliance with Namibian requirements for export to the United States. Supervisory reviews are conducted of SVs by a Chief Veterinarian from headquarters and of VHIs and VHAs by the SV. The FSIS auditor reviewed the most recent audit report and verified that corrective actions were taken and confirmed when deficiencies were identified.

Establishments certified to export to the United States are required to maintain identity of products, and to control and segregate product destined for the United States from other products. VHIs verify compliance with labeling requirements in accordance with *Circular V8/2018, USDA-FSIS Regulatory Requirements: Labeling of Meat Products Exported to the United States Market*, on a daily basis and additionally for each shipment of product destined for export to the United States. The FSIS auditor verified that labeling requirements were met and that this was verified daily by VHIs or the SV. The CCA has the ability to conduct species testing if warranted; however, the establishment certified as eligible to export raw beef products to the United States handles only raw beef products.

With the exception of the isolated finding listed in Appendix A, the FSIS auditor concluded that Namibia's food safety inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components the FSIS auditor reviewed was Government Sanitation. The food safety inspection system is to require that each official establishment to develop, implement, and maintain written SSOPs to prevent direct product contamination or insanitary conditions.

The FSIS auditor verified that the CCA requires establishments certified to export to the United States to develop, implement, and maintain SSOPs to prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions. Procedures must be developed to address sanitary dressing requirements, facility construction and maintenance, equipment maintenance, and pest control consistent with FSIS regulations.

Sanitary dressing verification is conducted by VHIs, in accordance with *Circular V16/2013, Verifying Sanitary Dressing and Process Control Procedures by Off-line DVS Inspection Personnel (VHI) in Slaughter Operations of Cattle of any Age*. VHIs observe sanitary dressing procedures daily at multiple points in the slaughter process where contamination is likely to occur.

The FSIS auditor verified that VHIs conduct a review of SPS on a daily basis, by observing areas of the establishment and through a records review. VHIs monitor the establishment for condensation control, chemical use and storage, employee hygiene, water potability, pest control, outside premises, and lighting. The FSIS auditor verified that this was conducted daily, as prescribed in *Circular V3/2018* which provides guidelines consistent with 9 CFR Part 416 requirements.

The FSIS auditor observed a VHI performing pre-operational and operational SSOP verification at the establishment certified to export to the United States and found no concerns. VHIs conduct pre-operational and operational sanitation verification daily, consisting of both direct observation and a records review, and document their results on their daily verification records. When deficiencies are identified, the VHIs have the authority to restrict an area from operating and to require immediate corrective actions when deficiencies are identified involving direct product contamination or product contact surfaces. The FSIS auditor reviewed records and verified that such deficiencies were identified, documented as noncompliance, corrected by the establishment, and verified by VHIs.

With the exception of the isolated finding listed on the establishment checklist attached to this report (Appendix A), the analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs and that the CCA continues to maintain requirements.

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

The fourth of six equivalence components that the FSIS auditor reviewed was Government HACCP System. The food safety inspection system requires that each official establishment develop, implement, and maintain a HACCP system.

The FSIS auditor verified that the CCA requires establishments certified to export to the United States to develop, implement, and maintain a HACCP system. The CCA has the authority to take enforcement measures in the event that an establishment does not implement a HACCP system. The FSIS auditor verified that VHIs confirm HACCP activities on a daily basis in accordance with *Circular V3/2018* which implements requirements consistent with 9 CFR Part 417. The CCA's guidance listed in *Reference Guide to Establishment and Inspector Daily Responsibilities (Pre-Requisite Programmes/SPS, Sanitation, Food Safety)* outlines the daily HACCP verification activities required to be conducted, including observation of monitoring and verification, verification of corrective actions, and review of pre-shipment records. VHIs also review basic HACCP requirements (hazard analysis, flowchart, HACCP plans) initially and when modified. The FSIS auditor verified through direct observation and records review that a VHI conducts zero tolerance verification for fecal material, ingesta, and milk contamination daily prior to the final wash and reviewed associated records documenting government verification for zero tolerance.

The FSIS auditor reviewed documents and records to assess the establishment's HACCP monitoring and verification activities, and the DVS' implementation of regulatory enforcement.

The review of documents showed that the establishment maintained a written hazard analysis for each step in the slaughter process, flow chart, and HACCP plan. The FSIS auditor verified that the HACCP plan addressed hazards identified as reasonably likely to occur, critical limits, monitoring frequency corrective actions, and verification procedures. The HACCP plan included a critical control point for the monitoring of zero tolerance for fecal material, milk, and ingesta contamination, which was located prior to the final lactic acid wash. The FSIS auditor verified that the HACCP records include a pre-shipment review to confirm that all HACCP requirements are met prior to export and HACCP corrective action records in response to deviations from a critical limit.

The FSIS auditor's analysis and on-site verification activities indicate that the CCA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs for each processing category. FSIS determined that the HACCP program as described is consistent with criteria established for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components 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 by government inspection personnel of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS' residue experts reviewed the Residue Annual Monitoring Plan 2019, associated methods of analysis, and additional SRT responses outlining the structure of Namibia's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

The Residue Annual Monitoring Plan is developed by the CVL under the authority of the *Prevention of Undesirable Residues in Meat Act* and distributed to the SV assigned to the establishment. Government inspection personnel are responsible for carrying out the sampling plan. The DVS headquarters ensures that sampling is carried out according to the prescribed plan during quarterly supervisory reviews. If violative residues are identified, the SV will ensure appropriate disposition of product, (i.e., verifying condemnation). The FSIS auditor verified through a review of documentation that no residue samples have exceeded Namibia's or FSIS' tolerances in Namibia's Residue Annual Monitoring Plan 2018 and 2019, to date. The FSIS auditor verified Namibia's adherence to the 2019 monitoring plan. The CCA receives laboratory results for official government chemical residue testing directly from the CVL in a timely manner, assesses the data, and takes actions in accordance with the procedures described in their official government chemical residue control program.

The FSIS auditor reviewed the routine and targeted residue sampling procedures and associated records and verified that samples are collected by VHIs in accordance with the *National Residue Program Monitoring Guidelines*. If the SV identifies animals suspected of residues on ante-

mortem inspection, those animals are segregated, slaughtered last, and sampled for residues once slaughtered. VHAs may also identify carcasses upon post-mortem inspection that warrant targeted residue sampling, which are then retained and sampled. Residue results are reported to the SV, who is responsible for ensuring proper disposition in the case of residue violations. Samples are delivered directly to the CVL by DVS personnel, and samples are sent for confirmation when warranted. Traceability information is collected on the sampled animal for both routine and targeted residue sampling; however, product is not held pending the results of routine residue testing.

Except for the finding listed in Component One pertaining to the CCA's verification of chemical residue test results prior to export certification, the FSIS auditor's analysis and on-site audit verification indicated that the CCA continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components 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 products prepared for export to the United States are safe and wholesome.

Circular V18/2007, USDA-FSIS Regulatory Requirements: Contamination with Microorganisms; Process Control Verification and Testing; Pathogen Reduction Standards, implements generic *E. coli* testing requirements consistent with 9 CFR Part 310.25 that VHIs are to verify. The FSIS auditor observed generic *E. coli* sampling by the establishment and verified that VHIs are observing sample collection and reviewing the establishment's test results for generic *E. coli* sampling. The VHIs are verifying that generic *E. coli* testing is performed at the required frequency of one test per 300 carcasses and that the establishment is using statistical process control to evaluate results.

The FSIS auditor observed a VHI performing sample collection for official *Salmonella* sampling and verified that sampling procedures were consistent with *Circular V19/2008, USDA-FSIS Regulatory Requirements: Pathogen Reduction Performance Standards in Red Meat Establishments: Salmonella spp.* Samples are sent directly to the CVL and results are received and reviewed by the SV. The SV evaluates results to verify process control and ensure that corrective actions are taken by the establishment when performance criteria are not met. Negative test results are required by the DVS prior to shipping product to the United States. The FSIS auditor reviewed the records documenting sample collection and results. During the audit of the CVL, the FSIS auditor verified that the laboratory is using BAX® *BIO SOP 03* for *Salmonella* screening, and *FHG SOP 04* for *Salmonella* confirmation, which is an ISO 6579, *Microbiology of the Food Chain – Horizontal Method for the Detection, Enumeration and Serotyping of Salmonella*, validated method.

The FSIS auditor verified that official government sampling for *E. coli* O157:H7 and non-O157 STEC is done by VHIs, according to instructions in *Circular V24/2015, Namibia's Verification Sampling and Testing Program for Shiga Toxin Producing Escherichia coli (E. coli O157:H7*

and non-O157 STECs), which is consistent with FSIS' N60 sampling methodology. The CVL is performing confirmation for non-O157 STEC using the *BIO SOP 15 BAX E. coli non-O157 Screening and Typing*, and considering product that screens positive for *E. coli* O157:H7 to be positive using *BIO SOP 32 BAX E. coli O157:H7 Detection for United States Market*. The FSIS auditor verified that the SV receives laboratory results for *E. coli* O157:H7 and non-O157 STEC testing in raw beef products directly from the laboratory in a timely manner, assesses the results, and ensures proper disposition of product. The DVS headquarters reviews these test results and provides oversight on a quarterly basis during supervisory reviews. Government inspection personnel will not certify products for export until negative results for *E. coli* O157:H7 and non-O157 STEC testing are received from establishment and DVS testing. The FSIS auditor identified the following findings at the CVL:

- The CVL is not analyzing the entirety of the N60 sample for *E. coli* O157:H7 and non-O157 STEC during screening of official testing. The laboratory is analyzing less than 325 grams for its test portion.
- The CVL is not following its validated method for sample preparation and enrichment for *E. coli* O157:H7 and non-O157 STEC. The laboratory is using MP ® media at a 1:4 dilution, which is inconsistent with the BAX ® method for non-O157:H7 or O157 screening.

The establishment is sampling each lot of product for *E. coli* O157:H7 and non-O157 STECs, and is using a lotting system that ensures microbiological independence between each lot. The FSIS auditor reviewed testing results and verified that the DVS is reviewing results for each shipment of product destined for the United States. Product is held while it is being tested and VHIs or SVs are reviewing results on a weekly basis to ensure that their testing program supports decisions made by the establishment within their HACCP system.

There have not been any POE violations related to this component since the last FSIS audit. The FSIS auditor found that Namibia's meat inspection system has a microbiological testing program organized and administered by the national government, and that the DVS has implemented the necessary sampling and testing programs to verify the effectiveness of its system. While Namibia's program includes microbiological sampling requirements that are equivalent to United States standards, the FSIS auditor identified deficiencies related to microbiological testing practices that could potentially impact the accuracy of results.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on September 27, 2019, in Windhoek, Namibia, with the CCA. At this meeting, the FSIS auditor 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 auditor identified the following findings:

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

- Government inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical residue testing prior to signing

the export certificate. This is inconsistent with the CCA's requirements to hold product pending negative residue results, as prescribed in *Circular V5/2018*.

- The CCA is not following *QUA SOP 17* which prescribes laboratory rejection of government verification samples submitted with inadequate information.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The CVL is not analyzing the entirety of the N60 sample for *E. coli* O157:H7 and non-O157 STEC during screening of official testing.
- The CVL is not following its validated method for sample preparation and enrichment for *E. coli* O157:H7 and non-O157 STEC official testing.

During the audit exit meeting on September 27, 2019, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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 Meatco Windhoek Sheffield Rd. PO Box 2166 Windhoek, Namibia	2. AUDIT DATE 09/24/2019	3. ESTABLISHMENT NO. NA 22	4. NAME OF COUNTRY Namibia
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		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	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Other	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

10. A hose attached to the splitting saw was contacting the inedible trough, and subsequently contacting edible exposed carcasses. The carcasses were not used for United States production.
55. A carcass was observed entering the final wash after post-mortem inspection with significant bruising remaining on the ribs. In discussion with inspection personnel, the carcass had been retained, and the retain tag had been removed by the establishment, allowing it to reenter production without further inspection. The carcass was diverted for the domestic market.
57. Official *Salmonella* sampling collected by government inspection is utilizing gauze pads, instead of sponges, as prescribed by Circular 19/2008.

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

ACTION PLAN FOR 2019 FSIS AUDIT FINDINGS

Equivalence components	Findings	Corrective Action	Target Date to Complete
<p>1. Government oversight</p>	<p>1.1 The CCA allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from CCA's routine chemical residue program. This is not consistent with the CCA's requirements to hold product pending negative residue results, as prescribed in Circular V5/2018.</p>	<ul style="list-style-type: none"> • Circular V5/2018 has been reviewed and replaced with Circular V3/2020. The new Circular V3/2020, Appendix 4 includes the hold and test requirement for livestock carcasses and their parts selected for residue testing under the official chemical residues testing programme. • The State Veterinarian/Veterinarian-in-charge will not issue an export certificate for product intended for export to the United States for meat products produced from carcasses that were held and tested before acceptable results are obtained from such carcasses. 	<p>Completed</p>

	1.2 The CCA is not following Quality Management Standard Operating Procedure 17 Sample Receiving and Handling Procedure, which prescribes laboratory rejection of government verification samples submitted with inadequate information.	<ul style="list-style-type: none"> • CCA has re-trained staff members at CVL on Quality Management Standard Operating Procedure 17 Sample Receiving and Handling Procedure, which prescribes laboratory rejection of government verification samples submitted with inadequate information. • Samples with inadequate information are rejected. • A State Veterinarian has been assigned on a full time basis to be in charge of the sample receiving area. 	Completed
2. Government Microbiological Testing Programs	2.1 The Central Veterinary Laboratory (CVL) is not analyzing the entirety of the N60 sample for <i>Escherichia coli</i> (<i>E. coli</i>) O157:H7 and non-O157 Shiga toxin-producing <i>E. coli</i> (STEC) during screening of official testing.	<ul style="list-style-type: none"> • CVL has implemented testing the entirety of the N60 sample for <i>Escherichia coli</i> (<i>E. coli</i>) O157:H7 and non-O157 Shiga toxin-producing <i>E. coli</i> (STEC) during screening of official testing. 	Completed
	2.2 The CVL is not following its validated method for sample preparation and enrichment for <i>E. coli</i> O157:H7 and non-O157 STEC official testing.	<ul style="list-style-type: none"> • For enrichment of Raw beef trim CVL has adopted the manufacturer's recommended and validated dilution factors of 1:4 for TSB media or 1:5 for MP media. Both media are used at CVL depending on availability. 	Completed
	2.3 Official <i>Salmonella</i> sampling collected by government inspection is utilizing gauze pads, instead of sponges, as prescribed by Circular 19/2008.	<ul style="list-style-type: none"> • Official <i>Salmonella</i> sampling by government inspection will start utilizing sponges instead of gauze pads as prescribed in Circular V19/2008. 	April 2020