Food Safety and Inspection Service

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

Dr. Milton A. F. Maseke Chief Veterinary Officer Directorate of Veterinary Services Ministry of Agriculture, Water and Forestry P/Bag 12022 Windhoek, Namibia

Dear Dr. Maseke,

The FSIS onsite audit conducted from September 11 through September 15, 2017, supports that Namibia's inspection system continues to remain equivalent to that of the United States. 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.

If you have any questions, please feel free to contact Kristen Hendricks, in the Office of International Coordination by email at <u>Kristen.hendricks@fsis.usda.gov</u> or by telephone at (202) 708-9550.

Sincerely,

Todd Furey

Acting International Coordination Executive

Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

REPUBLIC OF NAMIBIA

September 11 - 15, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

March 14, 2018 Food Safety and Inspection Service United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 11–15, 2017. The purpose of the audit was to determine whether the Republic of Namibia's (Namibia) 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 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor concluded that Namibia's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has implemented sanitary operating procedures and a HACCP system to ensure controls of the meat inspection system. In addition, the CCA has implemented a microbiological and chemical residue testing programs that are organized and administered by the national to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY	1
III.	BACKGROUND	2
IV.	COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)	3
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)	6
VI.	COMPONENT THREE: GOVERNMENT SANITATION	8
VII.	COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND	
	CRITICAL CONTROL POINTS (HACCP) SYSTEM	9
VIII.	COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	10
IX.	COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	11
X.	CONCLUSIONS AND NEXT STEPS	13
APPI	ENDICES	14
Ap	ppendix A: Individual Foreign Establishment Audit Checklist	
Ar	opendix B: Foreign Country Response to Draft Final Audit Report (Once available)	

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Namibia's food safety system from September 11-15, 2017. The audit began with an entrance meeting held on September 11, 2017, in Windhoek, Namibia with the participation of representatives from the Central Competent Authority (CCA), the Directorate of Veterinary Services (DVS) and the FSIS auditor.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing raw intact beef maintains equivalence 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 raw intact beef products to the United States.

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) 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). In addition, the FSIS auditor conducted an onsite verification of the CCA's corrective actions in response to the audit findings reported during the previous FSIS initial equivalence audit in 2013 and the follow-up audit in 2014. The FSIS auditor verified that the CCA is effectively maintaining its proposed corrective actions.

Representatives from the CCA and local government inspection office accompanied the FSIS auditor throughout the entire audit. 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative functions at the CCA headquarters and local government inspection office located within the establishment. The FSIS auditor evaluated the implementation of control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

FSIS audited the one certified establishment currently eligible to export raw intact beef products 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 threaten food safety. The FSIS auditor examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

The FSIS auditor also visited the Central Veterinary Laboratory (CVL), a government laboratory conducting microbiological and chemical residue analyses to verify its ability to provide adequate technical support to the inspection system and assess the CCA's oversight of laboratory functions.

Competent Authority Visits			Locations		
Central Competent Authority	Headquarters	1	CCA – DVS, Windhoek		
Laboratory			CVL, WindhoekMicrobiological DivisionChemical Residue Division		
Meat slaughter establishment			Establishment NA22, Meats, Windhoek		

The audit was undertaken 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, et seq.); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR §327).

The audit standards applied during the review of Namibia's raw intact beef inspection system 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 Sanitary/Phytosanitary Agreement.

III. BACKGROUND

Namibia is eligible to export raw intact beef products to the United States. USDA's Animal and Plant Health Inspection Service (APHIS), which regulates the importation of animals and animal products into the United States, considers Namibia as negligible risk for Bovine Spongiform Encephalopathy (BSE). Namibia is considered free of Foot and Mouth Disease and Rinderpest by APHIS, excluding the region north of the Veterinary Cordon Fence. Namibia must comply with 9 CFR § 94.11, restrictions on importation of meat and other animal products from specified regions

On July 13, 2016, Namibia was listed in the United States Code of Federal Regulations as eligible to export meat products to the United States. At the time of the audit, Namibia has not shipped any meat products to the United States.

The final audit reports for Namibia's food safety inspection system will be posted on the FSIS Web site at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditor reviewed was Government Oversight. The national government of the foreign country must design and administer an inspection system with standards equivalent to those of the United States.

The evaluation of all the components included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT. The FSIS onsite audit component included record reviews, interviews, and observations made by the FSIS auditor. The audited facilities included a local government inspection office, one government laboratory, and one establishment currently certified as eligible to export to the United States.

The CCA of Namibia is the Directorate of Veterinary Services (DVS), which is under the purview of the Ministry of Agriculture Water and Forestry (MAWF). MAWF has given DVS the responsibility to ensure that raw intact beef products from the establishment certified to export to the United States are not adulterated or misbranded. The primary laws for regulating meat inspection in Namibia are the *Meat Safety Act*, 2000 (Act No. 40 of 2000), Red Meat Regulations, No. 1072, September 2004, and the Promulgation of Prevention of Undesirable Residues Meat Act 21 of 1991. The CCA implements controls to ensure the safety of meat products for human consumption and to establish sanitary controls in the slaughter establishment. DVS has a command structure that includes the Chief Veterinary Officer (CVO) assisted by four deputy CVOs: the Division of Veterinary Public Health (DVPH), the Division of Animal Disease Control (DADC), the Division of Epidemiology, Import, Export, and Training, and the Division of Diagnostic Services and Research.

The CCA is responsible for verifying the implementation of regulatory requirements pertaining to the production of raw intact beef products destined for export to the United States. The CCA's meat inspection system has two levels: central and establishment. At the central level, the DVS's headquarters is located in Windhoek and it provides direct supervisory authority over the establishment that is certified to export to the United States in accordance with national legislation and adopted FSIS' import requirements. At the establishment level, the inspection personnel conduct inspection verification tasks, including sampling in accordance with the CCA's prescribed frequency; document enforcement actions; assess the effectiveness of the establishment's corrective action plans submitted in response to identified noncompliance; and communicate inspection personnel's verification task results through the chain of command.

The CCA also has the responsibility to take enforcement actions in accordance with the *Meat Safety Act*. The FSIS auditor reviewed documented enforcement actions at the CCA's headquarters and the audited establishment. This included review of inspection-generated noncompliance reports and follow up enforcement actions. A review of the inspection-generated records did not raise any concerns regarding the enforcement of the inspection requirements or proper implementation of the establishment's corrective actions in accordance with the CCA's requirements.

The FSIS auditor verified that all CCA inspection personnel are full time government-paid employees. The *Public Service Act No. 13 of 1995* provides for staffing establishment operations with government inspection personnel. The CCA provides relief inspectors when regular inspectors are absent. The central government of Namibia funds DVS, which is responsible for carrying out the inspection program. The document review at the CCA headquarters and local inspection office, located within the audited establishment, showed that the CCA requires the presence of the inspection personnel during all hours of operations in the slaughter establishment that is certified to export to the United States.

The *Public Service Act No. 13 of 1995* stipulates that the inspection personnel are the official employees of the national government. The national government of Namibia, through the Ministry of Finance, pays the inspection personnel. The FSIS auditor reviewed payroll documents from the Ministry of Finance and individual pay stubs during the audit and verified that DVS employees receive payment from the Namibian government.

The FSIS auditor interviewed the Head Veterinarian, conducted direct observations of inspection activities within the establishment, and reviewed daily government inspection records. The auditor verified that the CCA has provided the required government inspection personnel to conduct inspection activities including ante-mortem inspection of all animals prior to slaughter and carcass-by-carcass post-mortem inspection for all operating shifts.

The establishment has a staff comprised of a Veterinarian In-Charge (VIC), a Chief Veterinary Hygiene Inspector (CVHI), and several Veterinary Hygiene Inspectors (VHIs) and Veterinary Hygiene Inspection Assistants (VHIAs). The VIC is the overall supervisor at the establishment responsible for implementation of policies, legal requirements, exports, and ante-mortem and post-mortem inspection including animal welfare. The role of the CVHI and VHIs are to monitor and check for compliance with hygiene and food safety management system requirements (e.g., pest control, sanitation, personnel hygiene, sampling for microbiological residue, and BSE analysis), monitoring adherence to good manufacturing practices (GMPs) during slaughter, and deboning, as well as supervise post-mortem inspection and deboning activities. The VHIAs ensure that meat from animals is free from disease, is wholesome, and is of no risk to human health by carrying out post-mortem inspection of carcasses, offal, and organs.

The FSIS auditor reviewed initial employment and ongoing training records at the CCA headquarters and establishment. The auditor identified that all official veterinarians have veterinary medical degrees from an accredited university. In addition, the veterinarians must register and pass a competency test administered by Namibia's veterinary association every year. The VHI and VHIA must have at least diploma degrees in public health. The CCA's government inspection and laboratory personnel receive extensive training prior to assignment to an establishment. All newly employed inspection staff (including veterinarians) undergo one month of on-the-job training in addition to the CCA's educational requirements. During the audit, no concerns arose with the initial employment requirements, initial training, or ongoing training of employees.

The FSIS auditor reviewed how the CCA disseminates materials at headquarters to the certified establishment and found no concerns. The FSIS auditor verified that the CCA issues instructions associated with implementing and verifying relevant Namibian laws and regulations through circulars. In some cases, the CCA instructs government inspection personnel to share circulars with the certified establishment. The auditor also observed that the CCA has a procedure in place to disseminate inspection materials including FSIS requirements and laboratory documents to inspection and CVL, respectively. In addition, Namibia has an official Website to convey inspection information to their inspection personnel.

The FSIS auditor noted that Circular V19/2015, *Special brand: Imported Cattle and Slaughter at Export Abattoirs*, outlines the establishment is required to have a written procedure for trace back and recall. The CCA will provide notification to the United States for any exported products affected by a recall. The FSIS auditor confirmed that the inspection personnel review and verify the implementation of this requirement at the United States-certified establishment in accordance with the CCA's requirements. The FSIS auditor verified through document reviews and interviews that the establishment only slaughters cattle that were born and raised in Namibia south of the Veterinary Cordon Fence. In addition, the establishment is not receiving any raw materials from any other establishment for further processing.

The FSIS auditor reviewed and verified the process of certification of the establishment to export to the United States. The auditor verified that the CCA has the authority to de-list an establishment that fails to meet regulatory requirements or if the establishment cannot ensure it will resolve deficiencies outlined as noncompliance issues. Prior to becoming initially certified, the establishment must provide all required documentation to include sanitation controls, Sanitation Standard Operating Procedures (SSOP), HACCP system, product sampling programs, animal acceptance criteria, slaughtering/humane handling procedures, product recall/traceability system, pest controls, all food safety programs, and specific export requirements. Prior to granting final approval for certification, the CCA conducts a series of onsite verification audits.

The FSIS auditor verified that the CCA conducts annual certification audits of the certified establishment. The FSIS auditor verified that the CCA reviews the required documents submitted by the exporting establishment, conducts an onsite audit of the establishment, and evaluates the establishment's ability to meet the CCA's regulatory requirements prior to granting renewal of certification to export meat products to the United States. No concerns arose regarding the CCA's implementation of this process.

The CVL is the national government reference laboratory for the testing of official verification samples collected from products that are destined for export to the United States. The CVL, which is under the authority of MAWF, analyzes all government verification and certified establishment samples. The FSIS auditor noted the CCA provides administrative and technical support to the CVL. Furthermore, the FSIS auditor observed inspection (sampling) and laboratory personnel (testing) while they were conducting their assigned activities. The CCA utilizes Istituto Zooprofilattico Sperimentale of Abruzzo and Molise (IZSAM), an Italian laboratory, for some of the chemical residue testing. IZSAM is International Standards Organization (ISO) 17025 certified and as Namibia's internal laboratory auditing body conducts audits of the laboratory. No concerns arose as a result of these reviews or observations.

The FSIS auditor reviewed the CCA's oversight activities including the CCA's audit reports for laboratories. The auditor observed that Namibia's laboratory quality management system is based on the ISO 17025 accreditation standards. It consists of a quality system, quality manual (proficiency test), document control, internal audit, management review, corrective and preventive actions, personnel, equipment, reagents, reference materials and supplies, test method, sample testing, measurement traceability, data management, and instrumentation. The laboratory personnel apply the quality manual to ensure accuracy and consistency in conducting test methods.

The FSIS auditor verified that the laboratory quality management system carries out annual proficiency testing of its laboratory. The laboratory maintained training and equipment calibration records supporting that each technician had been qualified for their assigned duties. The FSIS auditor also verified that the CCA's reviews of intra-lab and inter-lab proficiency testing ensure that each analyst possesses the required competencies necessary to conduct the analyses. The Southern African Development Community Accreditation Service and the South African National Accreditation System accredited Namibia's government laboratory in accordance with ISO 17025 accreditation standards in February 2013. No concerns arose as the result of these reviews.

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 that 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 carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment daily inspection.

The FSIS auditor verified that in-plant inspection personnel are required to conduct ante-mortem inspection in accordance with the CCA's requirements. The VIC, with the assistance of the VHI, conducts ante-mortem inspection on the day of slaughter by observing all animals at rest and in motion from both sides in designated holding pens. Inspection personnel document the results of ante-mortem inspection daily. The FSIS auditor noted that the audited slaughter establishment provides a holding pen designated for observation and further examination of suspect animals.

The CCA has provided instructions describing disease conditions warranting condemnation of animals at ante-mortem inspection. The VICs identify and condemn any animal that shows signs of central nervous system disorders, including non-ambulatory cattle during the ante-mortem inspection. The CCA mandates that inspection personnel collect required tissue samples from any animal with signs of neurological disorders, document their ante-mortem observations on suspect animals, and dispose of the entire carcass of these animals in accordance with the CCA's requirements. The FSIS auditor reviewed inspection records and observed execution of ante-

mortem procedures that demonstrate proper implementation of the CCA's requirements. No concerns arose as a result of these reviews and observations.

The FSIS auditor also observed implementation of the humane handling programs at the audited beef slaughter establishment. This included the inspection personnel's hands-on verification of the maintenance and conditions of the holding pens, movement of animals, and proper stunning of animals. Additionally, the FSIS auditor reviewed the inspection-generated humane handling verification records documenting the results of their verification activities. The FSIS auditor did not identify any areas of concern during the review of records and direct observations.

The FSIS auditor verified that in-plant inspection personnel perform post-mortem inspection at the time of slaughter in accordance with the CCA's requirements. Inspection personnel are required to document post-mortem inspection results, including any retained or condemned carcasses. The FSIS auditor observed the implementation of the CCA's requirements by inspection personnel during post-mortem inspection presentation, identification, examination, and disposition of beef carcasses and parts. The FSIS auditor also observed the performance of in-plant inspection personnel examining the heads, viscera, and carcasses to assess whether the proper incision, observation, and palpation of required organs and lymph nodes is conducted in accordance with the CCA's requirements.

The FSIS auditor verified that inspection personnel are conducting carcass-by-carcass post-mortem inspection examination on the final rail prior to the carcass wash during all slaughter operations to ensure carcasses are free from pathological conditions or any contamination prior to applying the mark of inspection. Additionally, the FSIS auditor noted that the government requires re-inspection by a VHI or the VIC for any carcasses or parts railed out during the slaughter process.

The CCA requires that facilities and equipment be constructed in a manner that prevents direct product contamination or creation of insanitary conditions; maintained in good condition; installed in such a way that product does not come into direct contact with the floor or walls; and constructed with materials that facilitate thorough cleaning and disinfection. The FSIS auditor verified that the CCA provides inspection instructions to its personnel to verify the establishment's requirements during in-plant inspection verification of pre-operational and operations sanitary inspection.

The FSIS auditor noted that the audited beef slaughter establishment considered all slaughtered cattle as older than 30 months in their operations. The CCA defines specified risk materials (SRMs) as the skull, brain, eyes, and spinal cord of animals aged over 12 months. This includes the vertebral column (excluding the vertebrae of the tail), the spinous and transverse process of the cervical, thoracic, and lumbar vertebrae, and the median sacral crest and wings of the sacrum (including the dorsal root ganglia) of animals aged over 24 months. It also includes the tonsils, intestines from the duodenum to the rectum, and the mesentery of animals of all ages.

The FSIS auditor observed the implementation of SRM removal and disposal during the slaughter operation. The CCA's document, PROC-016-COMN, *Handling Specified Risk Materials*, provides instructions to the establishment for the identification, removal, segregation,

and disposal of SRMs. Circular V14/2013, outlines the inspections verification procedures for SRM controls. The FSIS auditor reviewed inspection verification records and the establishment's monitoring records concerning control and disposal of SRMs. The auditor also observed that the establishment uses dedicated equipment for removal of SRMs and ensures the safeguarding of inedible of materials. No issues were observed regarding the implementation of SRM controls at the establishment.

The CCA requires the establishment segregates and stores inedible products in a separate area from edible products. In addition, containers used for collecting inedible products must be marked and distinguished from other containers. The FSIS auditor noted that the inspection personnel have the authority and responsibility to ensure inedible products are denatured and disposed of in accordance with the CCA's regulatory requirements. The FSIS auditor reviewed both inspection and establishment generated records, and observed the disposal process of condemned and inedible materials at the audited establishment and found no concerns.

The CCA's meat inspection system has regulatory framework to implement the CCA's regulatory requirements for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions.

The FSIS auditor verified that the CCA requires the establishment to meet Namibian regulatory requirements equivalent to 9 CFR §416. The establishment's sanitary procedures must include the required frequency and a list of the establishment's personnel accountable for conducting sanitary procedures. The establishment is required to take necessary measures to prevent direct product contamination or creation of insanitary conditions. The CCA also provides instructions to the inspection personnel for verifying that the establishment has adequately implemented SSOP and sanitation performance standards (SPS), including records review and how to conduct direct observation verifications.

The FSIS auditor reviewed records related to the design and implementation of sanitation programs in the audited establishment. The FSIS auditor verified the implementation of preoperational inspection verification was adequate by observing in-plant inspection personnel conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and determined that the establishment was ready for the in-plant inspector's pre-operational sanitation verification inspection. Inspection personnel conduct and document pre-operational sanitation verification activities daily and in accordance with the CCA's established procedures.

The FSIS auditor observed in-plant inspection to verify the establishment's operational sanitation procedures and compared their overall sanitary conditions to the inspection documentation.

Observations included inspection personnel activities directly observing establishment operations and reviewing the establishment's operational sanitation records. The FSIS auditor noted that the CCA requires the certified establishment to develop and implement a sanitary dressing program of livestock at the slaughter establishment. As a result, the audited slaughter establishment has implemented daily sanitary dressing procedures to prevent potential carcass contamination for each step throughout the process. These included sanitary procedures to prevent carcass contamination during hide removal; direct contact between carcasses; and carcass contamination with gastrointestinal contents during evisceration.

The FSIS auditor's observations and record reviews of the establishment's sanitation monitoring and corrective action records, and in-plant inspection verification results did not raise any concerns. The CCA's meat inspection system continues to maintain regulatory requirements that meet the core requirements for this component.

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

The fourth of six equivalence components that the FSIS auditor reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP plan.

The FSIS auditor verified that the CCA requires the establishment to develop, implement, and maintain a HACCP system. The FSIS auditor noted that the United States-certified establishment is required to meet all regulatory requirements under 9 CFR §417. This includes a flow diagram, hazard analysis, HACCP plan for hazards identified as likely to occur, monitoring and verification activities, corrective action, reassessment, validation, and recordkeeping requirements supporting the implementation of the HACCP system. In addition, the establishment's documents must support the decisions made in the hazard analysis and HACCP plan. This supporting documentation includes the validation of the HACCP system. The CCA provides instructions to inspection personnel for verifying the establishment has developed and implemented a HACCP system. The FSIS auditor noted that in addition to daily HACCP verification activities the CCA also audits the establishment's HACCP system annually and prior to granting United States certification.

The FSIS auditor visited the beef slaughter establishment to determine whether the CCA maintained adequate government oversight for the implementation of HACCP requirements. In addition, FSIS assessed the adequacy of HACCP program verification activities conducted by inspection personnel and establishment employees at the audited establishment.

The FSIS auditor verified that the CCA does not allow the exportation of head meat, cheek meat, weasand meat, heart meat, and partially defatted meat fatty tissue to the United States. The CCA mandates that certified establishments that intend to export to the United States implement control measures, including sanitary dressing procedure, to prevent adulteration of raw non-intact beef with Shiga-toxin producing *Escherichia coli* (STEC) (adulterant non-O157 STEC and E. coli O157:H7). In addition, the certified establishment shall develop sampling and testing program for beef trimmings and primal cuts for non-intact use and analyze samples for STEC.

Inspection personnel verify daily that the certified establishment complies with their STEC programs by reviewing their HACCP system (including HACCP plans, prerequisite programs, or SSOPs) to address STECs. Circular V24/2015, STEC Verification Program, states that STECs are an adulterant for raw beef products intended for non-intact use, and requires the establishment to identify STECs as a biological hazard and have at least one Critical Control Point (CCP). The FSIS auditor reviewed the HACCP plan and conducted direct observation of the implementation of the CCP and did not have any concerns with the STEC controls at the establishment.

The FSIS auditor noted that the audited beef slaughter establishment has elected to conduct 100 percent monitoring of beef carcasses for the zero tolerance CCP for presence of fecal matter, ingesta, and milk. The FSIS review of the establishment's monitoring and corrective actions records in response to the few observed deviations from the zero tolerance critical limit showed that the establishment took appropriate corrective actions addressing all four parts of the corrective action regulation. The FSIS auditor also reviewed the inspection verification records and observed the in-plant inspection personnel's hands-on verification activities for the CCPs and antimicrobial intervention. The FSIS auditor noted that inspection personnel conduct daily verification of the CCPs through records review and direct observation in accordance with the CCA's requirements. The physical zero tolerance CCP monitoring and verification location for both the establishment's employees and in-plant inspection personnel is before the final wash in the beef slaughter establishment.

The FSIS auditor concluded the CCA's meat inspection system continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The inspection system is to present a chemical residue control program, organized and administered by the national government, which includes random sampling 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.

The CCA maintains the legislative authority and implements a national residue control program through *Prevention of Undesirable Residues in Meat Act*, No 21 of 1991 and corresponding regulations. The Act provides for control over certain products administered to animals that may cause undesirable residue in meat and meat products; further regulation of the slaughtering of animals and the marketing of meat and meat products; and for incidental matters. The national residue plan is utilized to prevent and control the presence of residues of veterinary drugs and contaminants in the tissues of animals slaughtered for meat and meat products for human consumption.

Circular V48/1990, instructs government inspection personnel to begin monitoring distributors of veterinary medicine, private practitioners, areas of environmental pollution, and feedlots for misuse of chemicals. Circular V10/2014, *Field Procedures in Dealing with Residue Violations*,

provides guidance to all government inspection personnel when suspected cases of repeat violations of the Act No. 21 of 1991 have been reported from the CVL or the exporting establishment. The FSIS auditor reviewed the national drug residue plan that outlines the frequency and type of testing done by the CVL. At the establishment the FSIS auditor reviewed the sampling plan for the establishment and concluded the testing frequency is currently up to date.

The CCA provides instructions to inspection personnel assigned in the slaughter establishment for random selection of animals, tissue sample collection, proper handling of samples, and secure transportation of samples to the designated laboratories. At the establishment level, the VICs are responsible for ensuring the proper implementation of the program in accordance with the CCA's requirements. The FSIS auditor's review of the inspection documentation in the audited beef slaughter establishment indicated that in-plant inspection personnel have collected the required residue samples in accordance with the CCA's prescribed sample collection schedule.

The CVL is the official government laboratory for chemical residue analysis and it utilizes IZSAM, an approved private laboratory, for some of the chemical residue testing. The laboratories are ISO 17025 accredited and receive annual internal audits performed by the CVL. The FSIS auditor interviewed the CVL analysts to assess their technical competency, training, and knowledge of the analytical methods used to detect chemical residues. The FSIS auditor examined the laboratory quality management system documents; sample handling and frequencies; timely analyses; data reporting; tissue matrices for analysis; equipment operation and printouts; minimum detection levels; recovery frequency; percent recoveries; and corrective action. The FSIS auditor noted that the CVL maintains a web-based system to ensure accurate tracking and reporting of all samples received. The FSIS auditor's review of the laboratory analyst technical competency, training, and analysis used to detect chemical residues did not identify any areas of concern.

The CCA's meat inspection system has regulatory requirements for a chemical residue testing program that is organized and administered by the national government. No concerns arose during the audit with the chemical residue laboratory.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence component that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome.

The CCA requires the establishment to design and implement a sampling and testing program to verify sanitary dressing process control. The United States-certified establishment must comply with requirements consistent with 9 CFR §310.25(a). The FSIS auditor reviewed the establishment's written generic *Escherichia coli* (*E. coli*) sampling and testing programs as well as the records of analytical testing results. Government inspection personnel are required to review the certified establishment's *E. coli* test results. If the certified establishment receives

repeated results that demonstrate loss of process control, and the corrective actions have not been effective in bringing the process back into compliance, inspection personnel are to conduct an investigation and notify their supervisors. The FSIS auditor reviewed the *E. coli* sample results and discussed the government verification activities at the establishment without any concerns with the sampling program or government verification activities.

The CCA implements a national microbiological sampling program to monitor *Salmonella* prevalence. Circular V19/2008 adopts FSIS' pathogen reduction performance standards for *Salmonella* for raw meat as stated in 9 CFR §310.25(b). The FSIS auditor observed that the inplant inspection personnel's *Salmonella* sample collection methodology was in accordance with the CCA's requirements. The FSIS auditor verified that the CCA provides instructions to its inspection personnel to verify the establishment's corrective measures when the establishment does not meet the performance standards. The instructions included requiring the establishment to re-evaluate sanitary dressing procedures and implement additional follow-up sampling.

The CCA requires that the United States-certified establishment implement a sampling program for STEC (*E. coli* O157:H7, O26, O45, O103, O111, O121, and O145) based on N60 methodology for each lot of products. In addition, the establishment is required to have procedures in place to hold the product pending test results. Products subject to sampling are beef trim, chucks, blades, and whole muscle beef products (excluding heart, head, and cheek meat) intended for non-intact use. Currently, the establishment does not ship head meat, cheek meat, weasand meat, heart meat, and partially defatted meat fatty tissue to the United States. The FSIS auditor verified that the CCA has implemented official verification sampling (weekly) for STECs as part of its oversight verification activity. Furthermore, the FSIS auditor verified the government implemented intensified sampling whenever tests results from the establishment or government samples are presumptive positive for STECs. The FSIS auditor noted that Namibia currently does not test out presumptive positive results and considers them as positive test results.

The FSIS auditor observed the inspection personnel's implementation of N60 sampling methodology when collecting official verification samples of beef trimmings, reviewed inspection-generated verification sampling records, and interviewed the VIC regarding the government STEC verification sampling program. The in-plant inspection personnel were taking samples at the designated frequencies in accordance with the CCA's requirements. The FSIS auditor noted that the CCA was currently in the intensified verification process and testing each lot daily. No concerns arose as the results of this verification activity.

The FSIS auditor observed and verified at the CVL sample receipt and handling procedures, testing methodology, timely analysis of samples, data reporting, equipment operation, technical training, and intra-lab competencies. In addition, the FSIS auditor reviewed the most recent ISO accreditation audit reports. The FSIS auditor noted that the CVL also performs its internal audits according to the Quality Assurance Manual. The FSIS auditor's observation of the laboratory processes and review of the laboratory documents including the annual audit reports and corresponding follow-up reports found no concerns with the CCA's documentation of its laboratory oversight activity.

The FSIS auditor concluded that the CCA's meat inspection system has a microbiological testing program that is organized and administered by the national government and that the CCA has implemented sampling and testing programs to verify its system.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on September 15, 2017, in Windhoek, Namibia, with the CCA. The FSIS auditor concluded that Namibia's meat inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has implemented sanitary operating procedures and a HACCP system to ensure controls of the meat inspection system. In addition, the CCA has implemented a microbiological and chemical residue testing programs that are organized and administered by the national to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Meatco NA22	9/12/17		3. ESTABLISHMENT NO. 4. NAME OF COUNTRY NA22 Namibia 6. TYPE OF AUDIT			
Windhoek, Namibia						
5. AUDIT		AFF		6. TYPE OF AUDIT		
OIEA In			al Audit Staff (IAS)	X ON-SITE AUDIT DOCUMENT		
		compl	mpliance with requirements. Use O if not applicable.			
Part A - Sanitation Standard Operating Procedures (SSOP)	Audit Results	Part D - Continued			
Basic Requirements 7. Written SSOP			Economic Sampling 33. Scheduled Sample			
Records documenting implementation.			'			
Signed and dated SSOP, by on-site or overall authority.			34. Species Testing			
Sanitation Standard Operating Procedures (SSOP))		35. Residue			
Ongoing Requirements			Part E - Other Requirements			
10. Implementation of SSOP's, including monitoring of impleme	ntation.		36. Export			
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import			
 Corrective action when the SSOPs have failed to prevent di product contamination or adulteration. 	irect		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			
Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective are	ctions		42. Plumbing and Sewage			
16. Records documenting implementation and monitoring of the			43. Water Supply			
HACCP plan. 17. The HACCP plan is signed and dated by the responsible			44. Dressing Rooms/Lavatories			
establishment individual.			45. Equipment and Utensils			
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			46. Sanitary Operations			
18. Monitoring of HACCP plan.			47. Employee Hygiene			
19. Verification and validation of HACCP plan.			48. Condemned Product Control			
20. Corrective action written in HACCP plan.						
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements			
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 Covera	ge		
23. Labeling - Product Standards			51. Enforcement			
24. Labeling - Net Weights			52. Humane Handling			
25. General Labeling						
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	oisture)		53. Animal Identification			
Part D - Sampling Generic <i>E. coli</i> Testing			54. Ante Mortem Inspection			
27. Written Procedures			55. Post Mortem Inspection			
28. Sample Collection/Analysis			Port C. Other Beau	latory Oversight Requirement	anta	
29. Records			Fait G - Other Regu	latory Oversight Requirem	ents	
Salmonella Performance Standards - Basic Requirements			56. European Community Di	rectives	0	
30. Corrective Actions			57. Monthly Review			
31. Reassessment			58.			
32. Written Assurance			59.			

FSIS 5000-6 (04/04/2002)							
FSIS 5000-6 (04/04/2002) 60. Observation of the Establishment							
61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT						
OIEA International Audit Staff (IAS)	9/12/2017						

Appendix B: Foreign Country Response to Draft Final Audit Report



REPUBLIC OF NAMIBIA

MINISTRY OF AGRICULTURE, WATER AND FORESTRY

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Reference:

V13/P

Chief Veterinary Officer

Private Bag 12022

Ausspanplatz, Windhoek

Namibia

20 February 2018

Mary H. Stanley
Acting International Coordination Executive
Office of International Coordination
Food Safety Inspection Service
1400 Independence Avenue, SW.
Washington, D.C.
20250
United States of America

Dear Mary Stanley,

RE: RESPONSE TO THE FSIS AUDIT FINDINGS, SEPTEMBER 2017

We thank you for the audit report and we would like to respond as follows:

1. On Page 4, Paragraph 5, Sentence 3, stated that the veterinarians must register and pass a competency test administered by Namibia's veterinary association every year.

Clarification: All Veterinarians intending to practice in Namibia are required to be registered with the Namibian Veterinary Council as per the Veterinary and Para-Veterinary Professions Act, No. 1 of 2013. Veterinarians that graduate from universities not accredited by the Namibian Veterinary Council and intend to practice in Namibia are required to write and pass

an examination set by the Namibian Veterinary Council and not by the Namibian Veterinary Association. The above-mentioned Act also stipulates that all registered Veterinarians are required to undergo Continuing Professional Development (CPD) to maintain their registration. The Veterinary Association of Namibia amongst other institutions facilitates CPDs during its annual Veterinary Congress.

2. On Page 4, Paragraph 5, Sentence 4, states that The VHI and VHIA must have at least diploma degrees in public health.

Clarification: The VHI must have at least diploma degree in public health or equivalent whereas the VHIA must have a grade 12 qualification as well as a certificate in meat inspection after a 6 months in-service training.

3. On Page 6, Paragraph 4, Sentence 2, states that the VIC, with the assistance of the VHI, conducts ante-mortem inspection on the day of slaughter by observing all animals at rest and in motion from both sides in designated holding pens.

Clarification: The VIC conducts ante-mortem inspection on all animals within 24 hours of slaughter. If for some reason animals have not been slaughtered within that period, they are to be re-inspected prior to slaughter.

Besides the above mentioned comments, DVS is in agreement with the rest of the content in the draft audit report.

Veterinary Services

Frivate Bag 12022

Sincerely,

2018 -02- 2 0

Dr. A.F. Maseke

Chief Veterinary Officer

Directorate of Veterinary Services