USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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

Dr. Adrianatus Maseke
Chief Veterinary Officer
Ministry of Agriculture, Water and Forestry
2nd Floor, Directorate of Veterinary Services
Government Office Park
Luther Street
Windhoek, Namibia

MAR 2 6 2015

Dear Dr. Maseke:

Enclosed is a copy of the final audit report that describes the outcome of two initial equivalence on-site audits of Namibia's meat inspection system conducted by FSIS from January 28 to February 1, 2013, and August 13 to 21, 2014. Your comment is included as an attachment in the final audit report.

If you have any questions, please contact Mr. AJ Ogundipe by telephone at 202.205.3819, by facsimile at 202.720.6050 or by electronic mail at aj.ogundipe@fsis.usda.gov or internationalequivalence@fsis.usda.gov

Sincerely,

for Gregory J. Buckhoum, DVM
Andreas Keller, Director
International Equivalence Staff
Office of International Affairs

Enclosures

FINAL REPORTS OF INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDITS

CONDUCTED IN

NAMIBIA

JANUARY 28 to FEBRUARY 1, 2013

AND

AUGUST 13 TO 21, 2014

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
THE PRODUCTION OF MEAT (SLAUGHTER AND PROCESSING)
PRODUCTS INTENDED FOR EXPORT TO THE
UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

In 2002 and again in 2005 Namibia contacted the United States (U.S.) and expressed an interest in gaining equivalence in order to export meat (beef) products to the U.S. In 2006, Namibia submitted a complete initial equivalence package of the documents necessary for FSIS to begin an evaluation of the Namibian meat inspection system was provided.

This audit report describes the outcome of two initial equivalence on-site audits of Namibia's meat inspection system conducted by FSIS from January 28 to February 1, 2013, and August 13 to 21, 2014. The objective of the two follow-up audits was to determine whether Namibia has implemented an equivalent meat inspection system to that of U.S. with the ability to produce meat products that are safe, wholesome, unadulterated, and properly labeled. These audits were also critical to inform an Agency decision concerning whether to proceed to the next step in the initial equivalence process and initiate rulemaking to propose to add Namibia to the list of countries eligible to export meat products to the U.S. The 2013 and 2014 follow up audits were necessary to assess the effectiveness of the implementation of corrective action plans proffered by Namibia in response to the 2009 and 2013 on-site audit findings. The 2014 audit also assessed the effectiveness of the implementation of Namibia's sampling and testing program for Shiga toxin-producing *E.coli* (STEC), which Namibia implemented in response to FSIS' recommendation to implement such a program for an equivalent microbiological sampling program.

In 2013, FSIS conducted an initial equivalence follow-up on-site audit of Namibia's meat inspection system and verified that the CCA had satisfactorily implemented the corrective action plans proffered in response to the 2009 on-site audit. In the 2013, FSIS audit identified new findings in four equivalence components: Government Oversight, Statutory Authority and Food Safety Regulations, Sanitation, and Chemical Residue Testing Programs. In response to the audit findings, the CCA implemented immediate corrective actions and submitted a corrective action plan on how it would incorporate the actions it took during the audit into its food safety system. FSIS reviewed Namibia's corrective action plan and concluded that Namibia had satisfactorily addressed 2013 audit findings. FSIS conducted the 2014 audit to verify whether Namibia had effectively implemented those corrective actions.

Based on the 2014 follow-up on-site audit, FSIS has concluded that Namibia has fully implemented the corrective action plan that it had submitted in response to the 2013 audit, and FSIS did not find any systemic problems during the audit. Furthermore, the audit indicated that Namibia has implemented a STEC sampling and testing program that meets FSIS' equivalence criteria. Therefore, FSIS determined that the CCA has adequately addressed all previous audits findings and met FSIS equivalence criteria related to all six components.

FSIS had conducted a thorough document review to evaluate the laws, regulations, and other documentation used by Namibia to execute its meat inspection program prior to any of the on-site audits. Through the document review, FSIS determined that the meat inspection laws and regulations are equivalent to FSIS's requirements.

Together, the results of document reviews and on-site audits provide a basis for FSIS to conclude that Namibia has implemented an equivalent meat inspection system to the FSIS system. Therefore,

FSIS intends to move forward with the proposed rule to add Namibia to the list of countries in the codified in the *Code of Federal Regulations* as eligible to export meat products to the U.S.

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority
CCP	Critical Control Point
CVL	Central Veterinary Laboratory
CVO	Chief Veterinary Officer
DVS	Directorate of Veterinary Services
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
IPPS	In Plant Performance System Assessment Sheet
ISO17025QM	ISO 17025 Quality Manual for the CVL
NR	Non-compliance Record
NRP	National Residue Program
SOP	Standard Operating Procedure
SRM	Specified Risk Material
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
STEC	Shiga Toxin–Producing *Escherichia coli*

1. INTRODUCTION

FSIS conducted two initial equivalence follow-up on-site audits of Namibia's meat inspection system from January 28 to February 1, 2013 and August 13 to 21, 2014. The 2013 and 2014 audits were necessary to verify that Namibia had effectively implemented its corrective action plans proffered in response to the 2009 and 2013 on-site audit findings. The 2014 audit also assessed the effectiveness of the implementation of Namibia's Shiga toxin-producing *E.coli* (STEC) sampling and testing program. These follow-up audits began with meetings with the Ambassador, United States (U.S.) Embassy, Namibia, and with entrance meetings held on January 28, 2013, and August 13, 2014, in Windhoek, Namibia with representatives from the Central Competent Authority (CCA) – the Ministry of Agriculture, Water and Forestry, Directorate of Veterinary Services (DVS), and a representative from the U.S. Embassy in Namibia. The FSIS auditor was accompanied throughout the audit by representatives from the DVS.

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of the two follow-up audits was to determine whether Namibia has implemented an equivalent meat inspection system to that of the U.S., with the ability to produce meat products that are safe, wholesome, unadulterated, and properly labeled. Before conducting these audits, the auditor reviewed the proffered corrective action plan and supporting documents provided by the CCA in response to the previous audit findings. These documents included descriptions of the new control measures and procedures adopted by Namibia's meat inspection system. The audits focused on the CCA's performance in addressing six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems (HACCP), (5) Chemical Residue Programs, and (6) Microbiological Testing Programs.

The audits were conducted through interviews, observations, and record reviews at the CCA headquarters, one slaughter and processing establishment that intends to export beef product to the U.S., and the government's Central Veterinary Laboratory (CVL).

In response to previous audit findings, the FSIS auditor conducted a thorough review of those management control systems that ensure that the national inspection system, verification, and enforcement strategies are implemented as intended at the CCA headquarters in Windhoek. The auditor paid particular attention to the extent to which industry and government interact to control public health hazards and meet the equivalence standards and other FSIS import requirements. The auditor also assessed the CCA's training strategy to verify the competency of (1) Namibia's in-plant inspection personnel for implementing Namibia's inspection procedures, and (2) laboratory analysts for implementing laboratory quality system in accordance with Namibia's *ISO 17025 Quality Manual for CV Laboratory* (*ISO 17025QM*).

At this time, only one establishment intends to export product to the U.S., so that establishment was the focus of the audit. The establishment intends to export to the U.S. raw beef chuck, blade, and beef manufacturing trimmings. At this establishment, the auditor interviewed Namibia's inspection personnel and reviewed inspection verification records to verify whether information collected at the headquarters regarding competency of Namibia's inspection personnel in implementing

verification inspection activities is in accordance with Namibia's inspection procedures. The auditor also assessed the effectiveness of establishment's sanitary dressing procedures, how Namibia's in-plant inspection personnel verified whether sanitary dressing procedures met requirements, and how inspection personnel enforce compliance with requirements to prevent carcass contamination during the slaughter process. Because of the 2013 audit finding regarding Specified Risk Material (SRM), the auditor assessed how Namibia's in-plant inspection personnel verified whether establishments have implemented required SRM control measures.

The FSIS auditor audited one government laboratory, CVL, to verify whether the CCA provides adequate laboratory oversight and technical support to the laboratory. The auditor assessed how Namibia implemented its (1) random sampling collection procedures for collecting beef tissues for residue sampling and testing, and (2) enforcement strategy for samples that contain detectable residues above allowable levels. The auditor interviewed laboratory analysts and reviewed laboratory implementation records to assess (1) the effectiveness of the implementation of laboratory chain-of-custody procedure for securing, storing, and maintaining integrity of samples, and (2) the ability of the laboratory analysts to effectively implement an equivalent laboratory testing method for analyzing beef samples for STEC (Bax Non O157 STEC Screening and Typing). Further discussion of the laboratory audit can be found in Sections 9 and 10.

AUDIT SCOPE SUMMARY			
		2014 Audit	2013 Audit
		8/13 to 8/21, 2014	1/28 to 2/1, 2013
Sector Audited			
	Headquarters	1	1
	Local Inspection Office	1	1
Laboratories Audited			
	Central Veterinary Laboratory	1	1
Establishments Audited			
	Slaughter/processing	1	1

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

The audits were critical to inform an Agency decision regarding whether to proceed to the next step in the initial equivalence process and initiate rulemaking to propose to add Namibia to the list of countries eligible to export meat products to the U.S. To further that goal, FSIS performed the audits determine whether the country has requirements equivalent to the specific provisions of U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- Meat Inspection Regulations (9 CFR Part 301 *et seq.*)
- Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7)

Namibia has adopted ante-mortem inspection, post-mortem inspection, pathogen reduction, HACCP, and sanitation standard operating procedures (SSOP) requirements consistent with FSIS regulations.

4. BACKGROUND

In 2002 and again in 2005 Namibia contacted FSIS and expressed an interest in securing initial equivalence in order to be able to export raw beef products to the U.S. In 2006, Namibia submitted documents necessary for FSIS to begin an evaluation of the Namibian meat inspection system.

From September 25 to October 11, 2006, FSIS conducted an initial equivalence on-site audit of Namibia's meat inspection system and identified systemic deficiencies within six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Chemical Residues, and (6) Microbiological Testing Programs. From September 2 to 9, 2009, FSIS conducted a second initial equivalence on-site audit of Namibia's meat inspection system to determine whether Namibia had satisfactorily implemented all the laws, regulations, and other issuances that FSIS found to be equivalent during the document analysis, and whether the findings of the previous audit had been addressed. During the 2009 on-site audit, FSIS verified that Namibia had implemented the corrective actions that it had proffered in response to the 2006 on-site audit findings. However, during the 2009 audit, FSIS identified systemic findings in the following equivalence components:

- *Government Oversight*: The CCA did not provide adequate control over the implementation of inspection procedures and laboratory quality systems, and it did not have a strategy to provide relief staff assignments for planned and unplanned absences of field inspection personnel.

- *Statutory Authority and Food Safety Regulations*: The CCA was unable to demonstrate that it had adequate and effective periodic supervisory reviews. The CCA failed to: (1) assign qualified inspection personnel at the supervisory level or staff from headquarters to conduct supervisory reviews; (2) conduct follow-up reviews and close out the findings that were identified; and (3) clearly identify the scope of establishment's review and how inspection personnel verify compliance with regulatory requirements.

- *Sanitation*: The CCA did not ensure that inspection program personnel effectively verified whether the establishment had implemented sanitation programs. As a result, the sanitation programs employed by the establishment were not effectively implemented, as designed, to prevent the risk of direct contamination or adulteration of exposed products.

- *HACCP Systems:* The CCA did not ensure that inspection program personnel verified whether the establishment had effectively implemented HACCP plans. As a result, the HACCP plans employed by the establishment were not effectively implemented, as designed, to prevent food safety hazards.

- *Chemical Residue Programs*: The CCA was unable to demonstrate how it assessed its residue plan results, including statistical calculations. *Namibia's National Residue Program*

(NRP) did not have (1) sampling plan procedures for collecting and testing meat samples for residues, and (2) strategies for a random selection of meat tissue samples and for the enforcement of repeat residue violators.

Following the 2009 on-site audit, Namibia developed and provided corrective action plans addressing the findings that were identified during the 2009 on-site audit. The CCA provided responses and supporting documentation; including laws, regulations, and new procedures and guidelines (directives) to address systemic findings and to ensure that its compliance requirements are consistent with FSIS's requirements. FSIS conducted a document analysis of Namibia's corrective action plan and concluded that Namibia had satisfactorily addressed all the 2009 audit findings. FSIS determined that the implementation of the proffered corrective action plan needed to be verified through a follow-up on-site audit of Namibia's meat inspection system.

From January 28 to February 1, 2013, FSIS conducted a follow-up on-site audit of Namibia's meat inspection system to verify whether the corrective action plan proffered by the CCA in response to the 2009 on-site audit had been satisfactorily implemented. The 2013 audit revealed that Namibia had fully implemented the corrective action plan that it had submitted in response to the 2009 audit. The 2013 audit did not identify systemic deficiencies that would adversely impact the ability of Namibia's meat inspection system to ensure food safety. Nonetheless, the 2013 audit identified new findings in four equivalence components: Government Oversight, Statutory Authority and Food Safety Regulations, Sanitation, and Chemical Residue Testing Programs. During the audit, the CCA implemented immediate corrective actions to address some findings. In addition to the actions taken during the audit, Namibia submitted a corrective action plan on how it would incorporate the actions it took during the audit into its food safety system. FSIS reviewed this corrective action plan and concluded that Namibia had satisfactorily addressed the findings of 2013 audit. However, FSIS determined that it needed to verify that Namibia had effectively implemented the proffered corrective action plan through another follow-up on-site audit of Namibia's meat inspection system.

Therefore, from August 13 to 21, 2014, FSIS conducted another follow-up on-site audit of Namibia's meat inspection system. This report is summary of that audit and its findings, as well as the 2013 audit findings.

5. GOVERNMENT OVERSIGHT

The first of the six equivalence components reviewed by FSIS auditor was Government Oversight. This component addresses the requirement for the foreign inspection system to be organized and administered by the national government and to employ standards equivalent to those of the federal system of meat inspection in the U.S. This component also addresses the requirement for the foreign laboratory system to comply with the general criteria for testing laboratories provided in ISO/IEC Guide 17025. The laboratories must establish quality control procedures and ensure that these procedures are followed.

2013 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:

The 2009 audit revealed that Namibia had fully implemented the corrective action plan that it had submitted in response to the 2006 audit. Nonetheless, the 2009 audit identified a new systemic finding in this equivalence component:

- *Government Oversight*: The CCA did not provide adequate control over the implementation of inspection procedures and laboratory quality systems, and it did not have a strategy to provide relief staff assignments for planned and unplanned absences of field inspection personnel.

Following the 2009 on-site audit, Namibia developed and submitted a corrective action plan and documentation addressing the finding that was identified in this component. The documentation included inspection and laboratory procedures: (1) *Standard Operating Procedure* (*SOP*) for providing relief inspection personnel, (2) *Circular V20/2008*, *Inspectors' verification activities of establishments' food safety system (sanitation, HACCP, PR), September 2008*, (3) *Circular V12/*2009, *Inspection system recording and monitoring enforcement action (Sanitation, HACCP, PR)*, and (4) *ISO 17025 Quality Manual for CV Laboratory* (*ISO 17025QM)*. FSIS reviewed this corrective action plan and concluded that Namibia had satisfactorily addressed the findings of the 2009 audit in this component.

During the 2013 on-site audit, the auditor assessed the CCA's performance in this component by verifying how the corrective action plan and documentation were being implemented at the government headquarters, local inspection office, establishment, and the CVL, the government laboratory.

At the government headquarters, the auditor reviewed the implementation of the *Public Service Act No 13, 1995* and *SOP* for providing relief staff assignments. While the *Public Service Act No 13, 1995* provides the legal basis for staffing establishment operations with government inspection personnel, including providing a relief inspector when the regular inspector is absent, the *SOP* is the CCA's procedure to implement this legislation. The CCA identified three qualified and competent inspection personnel (veterinary medical officers) in its *SOP* to relieve regular inspection personnel if they are absent. The CCA stated that it has implemented this procedure on two occasions (on November 27 and 28, 2011) when the regular veterinarian-in-charge was absent. A review of inspection records at the establishment showed that the regular veterinarian in charge was absent on November 27 and 28, 2011, and a relief veterinarian was assigned to the establishment according to the CCA's *SOP*. According to records reviewed by the auditor, the CCA had implemented its policy and procedure for providing relief staff assignment in accordance with the *SOP*.

The auditor visited headquarters and the local inspection office to assess the CCA's implementation strategy for its inspection procedures, *Circulars V20/2008* and *V12/2009*, by reviewing communication and training records. Based on the review of official records and the CCA's response at the headquarters and local inspection offices, FSIS found that *Circulars V20/2008 and V12/2009* were properly disseminated from the CCA headquarters to all inspection personnel by e-mail, Intranet, or SharePoint®. Namibia has an official website to convey inspection information to its inspection personnel. However, the CCA was unable to provide any record to demonstrate that

the inspection personnel at the local establishment had been trained on how to implement *Circulars V20/2008* and *V12/2009*.

At the establishment, the auditor reviewed inspection records and observed how inspection personnel document inspection activities and noncompliance findings. The review showed that the inspection personnel at the establishment were not documenting the inspection activities in accordance with *Circular V20/2008, Annex I A, Inspector's verification activities form*, and *Annex VII, SOP on completing a non-compliance record form*. The inspection personnel were documenting both inspection activities and non-compliance findings on a Inspection Verification Activities Sheet instead of using a separate non-compliance record (NR) form to document non-compliance findings.

Regarding the adequate control over the implementation of laboratory quality systems, the auditor visited the CVL, the government laboratory, to assess the implementation strategy for *ISO 17025QM*. The auditor reviewed the following records: analyst training records, calibration records, equipment maintenance records, intra-laboratory performance checks, Standard Operating Procedures (SOP), laboratory test methods, reporting test results, periodic internal audit report, and corrective action form. In addition, the auditor observed and interviewed laboratory analysts to verify how they are applying protocols specified in *ISO 17025QM* to conduct FSIS test methods.

The review indicated that the CCA had implemented all the corrective action plans related to laboratory quality systems and followed *ISO 17025QM* to meet the general criteria for testing laboratories provided in ISO/IEC Guide 17025. The CCA conducted annual internal audits of the activities at the laboratory to ensure that testing protocols meet the general criteria provided in ISO/IEC Guide 17025. The laboratory analysts conducted FSIS test methods in accordance with the guidelines specified in *ISO 17025QM*. The auditor also noted that the CVL, the government laboratory, was undergoing a laboratory accreditation process.

Although the CCA had implemented all corrective action plans related to this component, as noted above, FSIS found problems associated with this component during the 2013 audit.

- *Government Oversight*: The CCA was unable to provide any record to demonstrate that the inspection personnel at the local establishment had been trained on how to implement its inspection procedure, *Circulars V20/2008* and *V12/2009*. In addition, the inspection personnel at the establishment were not documenting the inspection activities in accordance with *Circular V20/2008, Annex I A, Inspector's verification activities form*, and *Annex VII, SOP on completing a non-compliance record form* and were including non-compliance findings on the Inspection Verification Activities Sheet instead of using a separate non-compliance record (NR) form to document non-compliance findings.

<u>2014 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:</u>

Following the 2013 on-site audit, Namibia developed and submitted corrective action plans and documentation addressing the findings that were identified in this component. The documentation included: (1) *Circular V20/2008, Inspectors' verification activities of establishments' food safety system (sanitation, HACCP, PR), September 2008*, (2) *Inspector Daily Verification Activities*, (3) *In*

plant supervisory assessment sheet (December 16, 2013, and March 27, 2014), (4) *Training agenda/program- FSIS regulatory compliance and STEC sampling testing program*, and (5) *VPH Attendance Training records*. FSIS reviewed this corrective action plan and concluded that Namibia had satisfactorily addressed the findings of the 2013 audit in this component. During the 2014 on-site audit, the auditor assessed the CCA's performance on this component by verifying whether the corrective action plan was being implemented at the government headquarters, local inspection office, establishment, and the CVL, as documented to FSIS.

At the government headquarters, the auditor assessed the CCA's training strategy and reviewed these implementation records: (1) *Training Assessment for VPH*, (2) *Training Verification Form*, (3) *VPH Attendance Training,* and (4) *In plant performance system assessment sheet* to verify the competency of Namibia's in-plant inspection personnel for implementing Namibian inspection procedures. A review of the implementation records revealed that the CCA tracked the effectiveness and progress of its training procedures, assessed the competence level of all inspection personnel, and implemented procedures if needed to retrain Namibia's in-plant inspection personnel in areas of underperformance. According to the records, the CCA had implemented an effective training strategy to enhance the competency of Namibia's inspection personnel for implementing Namibia inspection procedures.

At the establishment, the auditor interviewed four of Namibia's inspectors to verify that Namibia's inspection personnel were performing verification activities in accordance with Namibia's inspection procedures. The auditor also reviewed *Inspector Daily Verification Activities* records and corresponding NRs to assess whether Namibia's inspection personnel were correctly documenting inspection activities, evaluating the appropriateness of establishment corrective actions, and linking deficiencies identified in NRs in accordance with Namibian inspection procedures. In addition, the auditor interviewed four out of eight of Namibia's on-line inspectors and observed how they performed post-mortem inspection to verify whether they effectively perform post-mortem inspection. The auditor's assessment showed that Namibia's in-plant inspection personnel effectively implemented Namibia inspection procedures. Namibia's in-plant inspection personnel were also correctly documenting inspection activities, evaluating appropriateness of establishment corrective actions, and linking deficiencies identified in NRs in accordance with Namibia inspection procedures. The assessment of the four on-line official inspection personnel also revealed that they effectively performed post-mortem inspection.

At the laboratory, the auditor noted that the CVL, the government laboratory, had been accredited in accordance with recognized international standard ISO/IEC 17025 on February 28, 2013. According to the certificate of accreditation, "The CVL facilities demonstrate technical competency for operating laboratory quality management system." The certificate of accreditation will expire on February 27, 2018. The auditor interviewed laboratory analysts to verify and correlate information collected at the headquarters regarding the CCA's training strategy and the competency of laboratory analysts. The auditor also reviewed training records to verify whether laboratory analysts had been trained in applying protocols specified in *ISO/IEC 17025* to conduct FSIS test methods, including Bax Non O157 STEC Screening and Typing for STEC samples.

The records showed that the CCA had implemented the training protocol and tracked the effectiveness and progress of its training procedures as specified in its laboratory quality systems, *ISO/IEC 17025*. The CCA conducted annual internal audits of the activities at the laboratory to

ensure that testing protocols meet the criteria in its ISO/IEC 17025. The laboratory analysts conducted FSIS test methods in accordance with the guidelines specified in *ISO/IES 17025*.

FSIS found that the CCA had implemented corrective actions related to this component and did not find any problems associated with this component during the audit. The CCA has administrative controls to support the inspection system. Therefore, FSIS concludes that Namibia's inspection system meets the equivalence criteria for this component.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework utilized by the CCA to maintain procedures and requirements equivalent to FSIS' procedures and requirements related to ante-mortem inspection; humane handling of livestock; post-mortem inspection of carcasses and parts; requirements concerning condemned materials; requirements concerning establishments construction, facilities, and equipment; daily inspection; direct and continuous official supervision of slaughter activities; and periodic supervisory visits to official establishments to ensure implementation of equivalent measures to those governing the meat inspection system as organized and maintained in the U.S.

2013 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:

The 2009 audit revealed that Namibia had fully implemented the corrective action plan that it had submitted in response to the 2006 audit by incorporating the plan in its inspection system. However, the 2009 audit identified a new systemic finding in this equivalence component:

- *Statutory Authority and Food Safety Regulations*: The CCA was unable to demonstrate that it had adequate and effective periodic supervisory reviews. The CCA failed to: (1) assign qualified inspection personnel at the supervisory level or staff from headquarters to conduct supervisory reviews; (2) conduct follow-up reviews and close out the findings that were identified; and (3) clearly identify the scope of establishment's review and how inspection personnel verify compliance of regulatory requirements.

Following the 2009 on-site audit, Namibia developed and submitted a corrective action plan and documentation addressing the finding that was identified in this component. The documentation included: (1) *Internal Audit Procedure* (periodic supervisory review), and (2) *In Plant Performance System Assessment Sheet* (*IPPS*). FSIS reviewed this corrective action plan and concluded that Namibia had satisfactorily addressed the findings of the 2009 audit in this component.

During the 2013 on-site audit, the auditor assessed the CCA's performance in this component by verifying how corrective action plans were being implemented and documented at the government headquarters and the establishment.

While the CCA developed and implemented *IPPS* to document the job performance of inspection personnel, the *Internal Audit Procedure* is used to meet the periodic supervisory visit requirement. During the audit of the government headquarters, the auditor assessed the CCA's implementation

strategy for *Internal Audit Procedure* and *IPPS* by reviewing internal audit reports and *IPPS* records and interviewing the CCA officials to determine: (a) who was conducting supervisory reviews; (b) how the CCA was reporting and providing feedback and recommendations of supervisory review findings; (c) the scope of the internal audit; and (d) whether follow up reviews and close out the findings were being conducted.

The auditor's found that the CCA's staff from the headquarters: (a) conducted supervisory reviews; (b) provided feedback and recommendations to inspection personnel and establishment management; (c) clearly identified the scope of the establishment's review and how inspection personnel verified compliance of regulatory requirements within the scope of the internal audits, and (d) conducted follow up reviews to assess corrective actions and close-out the findings, if warranted. In addition, the CCA demonstrated how it documented inspection personnel job performance using IPPS and provided examples. The records showed that the CCA had implemented its policy and procedure regarding supervisory visits and it had adequate and effective periodic supervisory reviews.

At the establishment, the auditor interviewed Namibia's inspection personnel to verify and correlate information collected at the headquarters regarding CCA's policy on supervisory reviews. The auditor also reviewed copies of supervisory reviews at the establishments and corresponding *Inspection Verification Activities Sheet* to assess whether Namibia's inspection personnel were documenting deficiencies identified during supervisory reviews and evaluating the appropriateness of establishment corrective actions. The auditor's assessment showed that Namibia's in-plant inspection personnel were correctly documenting noncompliances identified during supervisory reviews and evaluating the appropriateness of establishment corrective actions.

Although the CCA had implemented all corrective action plans related to this component, one finding associated with this component was detected during the 2013 audit of the establishment.

- *Statutory Authority and Food Safety Regulations*: The CCA was unable to demonstrate that it had adequate records to verify that establishments met SRM requirements, to enforce SRM requirements, and to prevent potential SRM contamination from cattle 30 months of age or older. During the on-site audit, the auditors observed leakage of SRM (brain tissue) from the opening of the knock-hole after the head skinning operation during dressing procedures at the kill floor. The establishment presented its SRM program, including the records. According to Section 5 of the establishment's SRM program, "The Abattoir - Superintendent must ensure that all appropriate Specified Risk Materials are removed completely from the carcass as soon as practicable after slaughter and <u>before</u> the carcass is presented for post-mortem health inspection and marking....." The auditor did not observe any product contaminated by SRM.

<u>2014 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:</u>

Following the 2013 on-site audit, Namibia developed and submitted a corrective action plan and documentation addressing the finding that was identified in this component. The documentation included: (1) *Circular V20/2008, Inspectors' verification activities of establishments' food safety system (sanitation, HACCP, PR), September 2008*, (2) *Circular V14/2013, Standard Operating*

Procedures (SOP) for Verification Activities pertaining to Specified Risk Material (SRM) removal, segregation, and disposition (3) *Inspector Daily Verification Activities*, (4) *Reference guide to establishment and inspector daily responsibilities...*, (5) *Establishment 22 procedure for handling Specific Risk Material, Rev 3, October 2012*, (6) *Records of SRM condemned carcasses, January 4 and 9, 2013.* FSIS reviewed this corrective action plan and concluded that Namibia had satisfactorily addressed the findings of the 2013 audit in this component.

During the 2014 on-site audit, the auditor assessed the CCA's performance on this component by verifying whether corrective action plans were being implemented and documented at the establishment. The auditor also assessed the effectiveness of the establishment's sanitary dressing procedures, and how Namibia's in-plant inspection personnel verified sanitary dressing procedures and enforced compliance with sanitary dressing requirements to prevent contamination of carcasses during the slaughter process in accordance with Namibia's STEC sampling and testing program. The auditor observed slaughter operations by critically assessing these processes: stunning, head removal, tail removal, anus removal, leg removal, skinning, evisceration of gastrointestinal tract, splitting of exposed carcass in half, and SRM removal. The purpose was to assess (1) the effectiveness of establishment's sanitary dressing procedures, and (2) how Namibia's in-plant inspection personnel verified sanitary dressing procedures and enforced compliance to prevent carcass contamination during slaughter operation. Because of the 2013 audit finding regarding SRM, the auditor assessed how Namibia in-plant inspection personnel verified whether the establishment was effectively implementing its proposed corrective actions for the stunning process to prevent leakage of SRM (brain tissue) from the opening of the knock-hole.

During the audit, the auditor observed that Namibia's in-plant inspection personnel identified smears of fecal material on exposed carcasses around the anus area after the anus removal step during the establishment's sanitary dressing procedure. Namibia's in-plant inspection personnel took regulatory enforcement action by stopping the line and notifying the establishment supervisor. The establishment trimmed the contaminated surface, and Namibia's in-plant inspection personnel verified and accepted the establishment's immediate corrective actions. Namibia's inspector informed the auditor that he would document the finding on a NR.

The auditor's assessment revealed that Namibia's in-plant inspection personnel was effectively implementing Namibia's STEC sampling and testing program, *Circular V15/2013,* by verifying the effectiveness of the establishment's sanitary dressing procedures and enforcing compliance to prevent carcass contamination during the slaughter process.

The auditor did not observe any new finding during the SRM removal and stunning of the head steps. The auditor's assessment showed that Namibia's in-plant inspection personnel verified that the establishment's corrective actions were effective in preventing leakage of SRM (brain tissue) from the opening of the knock-hole, and thus the 2013 audit finding regarding SRM (brain tissue) from the opening of knock-hole had been resolved. In addition, the CCA provided a letter to the auditor notifying FSIS that head meat would not be exported to the U.S. if equivalence is granted.

The corrective action plans proffered by the CCA regarding the 2013 SRM finding and verification of the establishment's sanitary dressing procedures outlined in Namibia's STEC program, *Circular V15/2013*, were effectively implemented. The CCA has the legal authority and the regulatory

framework to impose control measures equivalent to FSIS' requirements. Therefore, FSIS concluded that Namibia's inspection system meets the equivalence criteria for this component.

7. SANITATION

The third of the six equivalence components that FSIS auditor reviewed was Sanitation. To be equivalent to FSIS's inspection system, the inspection system must maintain sanitation operation requirements, require the sanitary handling of products, and require the development and implementation of sanitation standard operating procedures (SSOPs). Namibia's meat inspection system requires that each official establishment meet requirements consistent with FSIS' regulatory requirements for sanitation in 9 CFR 416. The review and analysis of the relevant regulations, circulars, verification procedures, inspection records, and other relevant documents found that Namibia's sanitation requirement meets criteria for this component.

2013 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:

The 2009 audit revealed that Namibia had fully implemented the corrective action plan in response to the 2006 audit by incorporating the plan in its inspection system. Nonetheless, the 2009 audit identified a new systemic finding in this equivalence component:

- *Sanitation*: The CCA did not provide effective oversight over the implementation of sanitation programs. As a result, the sanitation programs employed by the establishment were not effectively implemented, as designed, to prevent the risk of direct contamination or adulteration of exposed products.

Following the 2009 on-site audit, Namibia developed and submitted a corrective action plan and documentation addressing the finding that was identified in this component. The CCA issued *new Circulars V20/2008* and *V12/*2009 (instructions) to its field inspection personnel on how to verify compliance with sanitation requirements. These circulars are based on FSIS Directive 5000.1. The CCA also revised its inspection schedule and non-compliance report. In addition, the CCA submitted establishment corrective actions and a *Planned Improvement Program* (*PIP*), including a target date for completion. FSIS conducted a document analysis and concluded that the documents submitted by the CCA satisfactorily addressed the findings of the 2009 on-site audit.

During the 2013 on-site audit, the auditor assessed the CCA's performance on this component by verifying whether corrective action plans were being implemented at the establishment. The auditor interviewed Namibia's inspection personnel and reviewed sanitation inspection records to verify and correlate information collected at the headquarters regarding the CCA's issuance: *Circulars V20/2008* and *V12/*2009. The auditor assessed (1) the sanitary condition of the establishment during pre-operation and operation, and (2) how Namibia's in-plant inspection personnel conducted verification inspection activities during pre-operation and operation, determined compliance, and enforced regulatory requirements in accordance with Namibia's *circular V20/2008*. Although the assessment showed that Namibia had fully implemented the corrective action plan that it had submitted in response to the 2009 audit, a new finding was identified during the 2013 audit of the establishment:

- *Sanitation*: The CCA did not effectively implement its requirements for sanitation performance standards (SPS) contained in *Circular V20/2008, September 2008, Annex1A (Inspector's verification activities form)* and *Annex II (Sanitation Performance Standard (SPS)/Pre-requisite Programs)*. This circular outlines how the inspection personnel should implement verification and enforcement procedures for sanitation performance standards. 90 days of inspection verification records showed that the CCA did not identify and document findings related to facility maintenance such as rust, corrosion, beaded condensate, cracks, and holes that were easily observed by the auditors. In addition, the CCA did not identify that the height of the fixed metal stand was not sufficient to enable establishment employees to properly observe the hind quarter of beef carcasses for fecal material, ingesta, and milk. This situation may affect monitoring and verification of CCP 1 (zero tolerance) results and compliance with critical limits. The auditor did not observe any fecal material, ingesta, and milk contamination on the carcasses.

2014 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:

Following the 2013 on-site audit, Namibia developed and submitted a corrective action plan to address the finding that was identified in this component. The documentation included: (1) *Circular V20/2008, Inspectors' verification activities of establishments' food safety system (sanitation, HACCP, PR), September 2008*, (2) *Inspector Daily Verification Activities*, (3) *Reference guide to establishment and inspector daily responsibilities...*, (4) *Training agenda/program- FSIS regulatory compliance*, (5) *VPH Attendance Training records*, and (6) *In-plant Supervisory Assessment Sheet (December 16, 2013, and March 27, 2014)*. FSIS conducted a document analysis and concluded the documents submitted by the CCA satisfactorily addressed the findings of the 2013 on-site audit.

The auditor assessed the effectiveness of the implementation of the corrective action plan and documentation proffered by Namibia in response to the 2013 audit findings at the establishment. The auditor reviewed and analyzed sanitation verification records contained in the *Inspector Daily Verification Activities* and corresponding *Noncompliance Record* (NR). The verification records revealed that 180 sanitation inspection activities were performed by Namibia's in-plant inspection personnel and two deficiencies regarding sanitation performance standards were documented in NRs. During the establishment operations, the auditor assessed (1) the sanitary condition of the establishment, and (2) how Namibia's in-plant inspection personnel conducted verification inspection activities, determined compliance, and enforced regulatory requirements in accordance with Namibia's *circular V20/2008*. The auditor correlated sanitation inspection verification records with the oversight of inspection activities of the CCA to verify sanitation requirements and the ability of the establishment to consistently prevent the risk of direct contamination or adulteration of exposed products.

The assessment revealed that (1) Namibia's in-plant inspection personnel were verifying whether the establishment met sanitation requirements and enforcing regulatory requirements in accordance with Namibia's *Circular V20/2008*, and (2) the corrective action plan proffered by the CCA regarding the 2013 audit finding was effectively implemented by the establishment and verified by the CCA. Therefore, the audit did not reveal any finding associated with this component during the 2014 audit.

In conclusion, the CCA has taken measures to ensure that the establishment implemented effective SSOPs and other sanitation procedures that prevent direct contamination and adulteration of meat products destined for the U.S. export. The measures employed by the CCA were found to be equivalent to those in the U.S. meat inspection system. Therefore, it was determined that Namibia's meat inspection system meets the equivalence criteria for the Sanitation component.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS (HACCP)

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. This component addresses the inspection system's ability to ensure that each official establishment develops, implements, and maintains an effective HACCP system. Namibia's meat inspection system requires that each official establishment meet all the HACCP requirements by adopting regulatory requirements for HACCP consistent with those in 9 CFR 417. The review and analysis of the relevant regulations, circulars, verification procedures, inspection records, and other relevant documents indicated that Namibia's HACCP requirement meets HACCP criteria for this component.

2013 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:

The 2009 audit revealed that Namibia had fully implemented the corrective action plan that it had submitted in response to the 2006 audit. Nonetheless, the 2009 audit identified a new systemic finding for this equivalence component:

- *HACCP Systems:* The CCA did not provide effective oversight with respect to the implementation of HACCP plans. As a result, the HACCP plans employed by the establishment were not effectively implemented, as designed, to prevent food safety hazards.

Namibia responded by submitting a written corrective action plan and documentation. The CCA issued *Circulars V20/2008* and *V12/*2009 (instructions) to its field inspection personnel on how to verify compliance with food safety regulatory requirements (HACCP). These circulars are based on FSIS Directive 5000.1. The CCA also revised its inspection schedule and non-compliance reports. In addition, the CCA submitted to FSIS records to show how it verified the establishment's implementation of a corrective action plan. Through the document analysis, FSIS concluded that the documentation submitted by the CCA for this component satisfactorily addressed the findings of the 2009 on-site audit.

During the 2013 on-site audit, FSIS audited the one establishment that intends to export meat products to the U.S. to verify whether the CCA implemented corrective actions. The auditor reviewed HACCP records maintained by local inspection offices to verify how the inspection personnel were implementing the following sections of *Circular V20/2008:*Hazard Analysis and Critical Control Point (HACCP), 9 CFR 417; inspector daily responsibilities for verifying HACCP; plant responsibilities for complying with HACCP; Rules of Practice, 9 CFR 500 (Enforcement); and Noncompliance Records. Specifically, the auditors conducted on-site observation and record review to determine how inspection personnel applied *Circular V20/2008, section 2, Annexes IA & B, V, VI,* and *IX* to verify the adequacy of the HACCP plans and initiate enforcement action when

appropriate. In accordance with *Circular V20/2008, Annex 1A, Inspector Verification Activities,* the inspection personnel conducted on-going verification of establishment compliance with HACCP requirements, documented noncompliance, and initiated enforcement actions when appropriate. Namibia inspection program personnel also verified that the establishment conducted monitoring and verification of the CCP, implemented corrective actions if critical control limits are not met, and reassessed HACCP plans in accordance with its HACCP plan.

The auditor did not detect any HACCP finding during the 2013 on-site audit. The final assessment indicated that the CCA has a system in place to verify and enforce HACCP requirements. The CCA has demonstrated process control for the HACCP equivalence component; therefore, FSIS concluded that Namibia's inspection system meets the requirements for this component.

2014 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:

Although the auditor did not detect any HACCP findings during the 2013 on-site audit, the auditor assessed the effectiveness of the implementation of recent changes made to the HACCP documentation submitted by the CCA after the document review process. The CCA revised these documents: (1) *Circular V20/2008, Inspectors' verification activities of establishments' food safety system (sanitation, HACCP, PR), September 2008*, (2) *Inspector Daily Verification Activities*, and (3) *Reference guide to establishment and inspector daily responsibilities.* Through the document analysis, FSIS concluded that these documents satisfactorily met the criteria of this component.

During the 2013 on-site audit, FSIS audited the one establishment intending to export meat products to the U.S. to determine whether the CCA was implementing HACCP regulatory requirements. The auditor reviewed and analyzed HACCP verification records contained in *Inspector Daily Verification Activities* and corresponding *Noncompliance Records* (NR). The records revealed that 120 HACCP inspection activities were performed by Namibia's in-plant inspection personnel and three HACCP deficiencies were documented in NRs. During establishment operation, the auditor observed how (1) the establishment was conducting monitoring and verification of the two Critical Control Points in its HACCP plan, and (2) Namibia's in-plant inspection personnel verified HACCP requirements, determined compliance, and enforced regulatory requirements in accordance with Namibia's *Circular V20/2008*. The auditor correlated HACCP inspection verification records with the oversight of inspection activities of the CCA to verify the adequacy of the establishment's HACCP system and the establishment's ability to consistently prevent food safety hazards through effective HACCP implementation. The auditor's assessment showed that (1) the establishment was conducting monitoring and verification procedures in accordance with its HACCP plan, and (2) Namibia's in-plant inspection personnel were verifying the establishment's compliance with HACCP requirements and enforcing regulatory HACCP requirements in accordance with Namibia's *Circular V20/2008*.

The auditor did not detect any HACCP finding during the 2014 on-site audit. The final assessment indicated that the CCA has a system in place to verify and enforce HACCP requirements. The CCA has demonstrated process control for the HACCP equivalence component. Therefore, FSIS concluded that Namibia's inspection system meets the requirements for this component.

9. CHEMICAL RESIDUE PROGRAMS

The fifth of the six equivalence components the FSIS auditor reviewed was Chemical Residues. The inspection system is required to have a chemical residue control program that is organized and administered by the national government. The residue control program includes random sampling of muscle, internal organs, and fat of carcasses for chemical residues identified by either the exporting country's meat inspection authorities or by FSIS as potential contaminants. The program must include an effective enforcement action that addresses handling and disposition of contaminated product and measures to deter repeat violators.

2013 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:

The 2009 audit revealed that Namibia had fully implemented the corrective action plan that it had submitted in response to the 2006 audit. Nonetheless, the 2009 audit identified a new systemic finding in this equivalence component:

- *Chemical Residue Programs*: The CCA was unable to demonstrate how it assessed its residue plan results. *Namibia's National Residue Program (NRP)* did not have (1) sampling plan procedures for collecting and testing meat samples for residues, and (2) strategies for a random selection of meat samples and for the enforcement of residue violators.

The auditor discussed the findings with the CCA during the 2009 on-site audit and informed representatives of the CCA that they needed to assess these findings and submit corrective action plan, including a systematic solution to prevent recurrence of 2009 findings. The CCA responded by submitting a corrective action plan and supporting documentation. The CCA revised and submitted a new *NRP* that contains information on its implementation strategy, monitoring, laboratory analysis, and reporting of residue testing results, as well as an enforcement strategy for residue violators. The program includes export-based sampling, random selection of samples, and procedure for sample collection, transmission of samples results, surveillance, and enforcement. In addition, the CCA submitted records to show how it (1) assessed residue plan results, and (2) implemented procedures for the sampling plan, including the random selection of residue samples and enforcement strategies for repeat residue violators in accordance with their *NRP*. Through document analysis, FSIS concluded that the CCA satisfactorily addressed the findings identified in the 2009 on-site audit before conducting the 2013 on-site audit. During the 2013 on-site audit, an assessment of the CCA's ability to implement its corrective action plan for the 2009 on-site audit findings and its residue control program was conducted through on-site visits to the government laboratory and establishment.

At the government laboratory, the CCA presented and discussed how the new *NRP* was developed, and the data was computed and analyzed. The auditor reviewed the 2010 and 2011 residue plans, the sampling plans, and enforcement records. The records indicated that the CCA compiled the results of residue plans from the previous year sampling plans and revised its residue plans to include statistical calculations. Also, the CCA included samples of animals to be tested for residues in its new *NRP*. In case of a violative sample result, the CCA implemented an enforcement strategy that includes documenting noncompliance, investigating the cause of the violation, collecting

additional samples, and retaining the affected products, if available. The investigation will determine the type of enforcement action taken against the violator in accordance with the *NRP*.

FSIS audited the only establishment that intends to export meat products to the United States to assess the CCA's ability to implement and enforce the requirements of the Chemical Residue Control Program at the establishment level. The auditor reviewed inspection procedures for collecting samples in abattoirs, and the inspection records that were maintained by the local inspection office. Also, the auditors observed how inspection personnel used Namibian legislation and official instructions to verify whether the establishment met requirements related to residues. The auditor observed that inspection personnel were following sampling protocols in accordance with the *NRP*. The protocols included sampling location, sampling size and site, and the delivery of residue samples to laboratories. Laboratory personnel report test results to DVS at the headquarters.

Although the deficiency identified for this component during the 2009 on-site audit had been corrected, the auditors noted a new finding in the 2013 audit:

> The CCA was unable to demonstrate that it had implemented the following sections of its *National Residue Program*: (1) criminal and civil sections of its enforcement strategy for repeat/multiple violators, and (2) random selection of residue samples.

2014 INITIAL EQUIVALENCE FOLLOW-UP ON-SITE AUDIT:

Following the 2013 on-site audit, the CCA developed and submitted a corrective action plan and documentation addressing the finding that was identified for this component. FSIS reviewed these documents: (1) *Procedures for Sample Collection under the Veterinary Drug Residue Monitoring*, (2) *Random Sampling Procedure for the Collection of Residue Samples in the Bovine Slaughterhouse,* and (3) *Measures on to proceed in establishments that intend to export to the U.S. and have multiple residue violations*. FSIS reviewed the corrective action plan and concluded that Namibia had satisfactorily addressed the findings of the 2013 audit before conducting the 2014 on-site audit. During the 2014 on-site audit, FSIS verified that the CCA had effectively implemented its corrective action plan to address the 2013 on-site audit finding.

At the government headquarters, the auditor reviewed the implementation of the *Promulgation of Prevention of Undesirable Residues Meat Act 21 of 1991e Act No 13, 1995*. While the *Promulgation of Prevention of Undesirable Residues Meat Act 21 of 1991* provides Namibia legal authority to take enforcement actions, including criminal and civil sanctions against repeat/multiple residue violators, the *National Residue Program (NRP)* specifies an enforcement strategy to implement the criminal/civil sections of this legislation. The *Promulgation of Prevention of Undesirable Residues Meat Act 21 of 1991* stipulates that repeat/multiple violators would be penalized for a fine up to 8,000 Namibian dollars or an imprisonment period not to exceed two years. The CCA stated that it did not have records to demonstrate that it had implemented its criminal and civil sections of its enforcement strategy for repeat/multiple violators because residue violations that occurred over the past years did not meet the threshold for criminal/civil prosecution. All the residue violations were instead handled through administrative enforcement actions specified in the (1) *NRP*, (2) *Field Procedures in Dealing with Residue Violations*, and (3) *Measures on to proceed in establishments that intend to export to the U.S. and have multiple residue violations*.

The auditor assessed the CCA's implementation strategy as reflected in the following documents: (1) *NRP*, (2) *Measures on to proceed in establishments that intend to export to the U.S. and have multiple residue violations*, (3) *Field Procedures in Dealing with Residue Violations*, (4) Procedures *for Sample Collection under the Veterinary Drug Residue Monitoring*, (5) *Random Sampling Procedure for the Collection of Residue Samples in the Bovine Slaughterhouse*. The CCA responded to the auditor's questions and provided implementation records to support its responses. Enforcement records showed that when the CCA at the headquarters received violative sample results, the CCA initiated enforcement in accordance with the *Field Procedures in Dealing with Residue Violations* and the *Measures on to proceed in establishments that intend to export to the U.S. and have multiple residue violations*. The CCA documented noncompliance, required the establishment to implement immediate and preventive corrective action including reassessing the adequacy of its HACCP plan, investigated the cause of the violation, collected additional samples, and retained the affected products. The CCA required the establishment to identify, segregate, dispose, and exclude from commerce meat and meat products with violative residue levels.

At the government laboratory, the CCA presented and discussed the electronic system in place to communicate residue sample results to the CCA's headquarters, Namibian inspection personnel, and the establishment. The record showed that laboratory analysts documented the following information in the *Reporting of Confirmed Non-Compliant Results of Chemical Residue Analysis*: inspector name, date sample received, matrix (liver, muscle, fat, and urine), residue violative sample result, and date notified the CCA, inspector, and establishment. The auditor noted that the CVL, the government laboratory, was accredited in accordance with recognized international standard ISO/IEC 17025 on February 28, 2013.

Regarding random selection of residue samples, the auditor visited the establishment to assess its implementation of (1) *Procedures for Sample Collection under the Veterinary Drug Residue Monitoring*, and (2) *Random Sampling Procedure for the Collection of Residue Samples in the Bovine Slaughterhouse*. The auditor interviewed four Namibia's inspection personnel and reviewed 60 days of *Veterinarian Verification Activities Schedules* for residue sampling to assess whether Namibia's inspection personnel were correctly documenting residue sampling collection. To follow-up on and confirm information collected during records review, the auditor also asked Namibia's in-plant inspection personnel to demonstrate how they select and document random residue samples in accordance with the *Random Sampling Procedure for the Collection of Residue Samples in the Bovine Slaughterhouse.*

The auditor's assessment indicated that Namibia's in-plant inspection personnel were correctly collecting and documenting residue samples in accordance with (1) *Procedures for Sample Collection under the Veterinary Drug Residue Monitoring*, and (2) *Random Sampling Procedure for the Collection of Residue Samples in the Bovine Slaughterhouse*. Namibia's in-plant inspection personnel documented the following information in *Veterinarian Verification Activities Schedules*, *Laboratory Form*, and *Inspection Record Book*: inspector name, date sample collected, matrix (liver, muscle, or fat), sample condition (fresh or frozen), date sample sent to the laboratory, residue sample result, and inspectors' actions. The auditor also observed that Namibia's in-plant inspection personnel satisfactorily performed all the inspection tasks related to sampling collection procedures: randomly collecting residue samples (metrics), handling of residue samples, documenting residue samples in *Inspector Daily Verification Activities*. The corrective action plan

proffered by the CCA had been effectively implemented. The CCA had an effective strategy for implementing: (1) *Procedures for Sample Collection under the Veterinary Drug Residue Monitoring*, (2) *Random Sampling Procedure for the Collection of Residue Samples in the Bovine Slaughterhouse, and (3) Measures on to proceed in establishments that intend to export to the U.S. and have multiple residue violations*. The auditor did not observe any new findings in this component during the audit.

In conclusion, analysis of all the audit observations, records, documents, and findings indicated that the CCA effectively implemented a national residue control program for its meat inspection system. Namibia's inspection system had effective laboratory support (accredited laboratory) to conduct laboratory analysis in accordance with the SOP and recognized international standard (ISO/IEC 17025). Therefore, FSIS determined that Namibia's meat inspection system meets the equivalence criteria for the Chemical Residue Programs component.

10. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was the CCA's Microbiological Testing Program. The inspection system must implement sampling and testing programs to ensure that meat products produced for export to the United States are safe, wholesome and unadulterated. As part of document review process, a comprehensive review and analysis of all relevant legislation, regulations, and microbiological testing programs supporting this component had been conducted and determined by FSIS to be equivalent. The 2014 audit assessed the effectiveness of the implementation of Namibia's sampling and testing program for Shiga toxin-producing *E.coli* (STEC).

2014 INITIAL EQUIVALENCE ON-SITE AUDIT:

Following FSIS' implementation of sampling and testing of manufacturing trim for both *Escherichia coli* O157:H7 (*E. coli* O157:H7) and six other serogroups of Shiga toxin-producing *E.coli* (STEC), O26, O45, O103, O111, O121, and O145 in 2012, FSIS notified Namibia via letter and the Self Reporting Tool (SRT) that the CCA needed to submit complete responses to SRT questions, and supporting documents to demonstrate how the CCA will implement equivalent sampling and testing procedures in its meat inspection system. Namibia responded to the SRT questions and provided supporting documentation on its STEC sampling and testing program, *Circular V15/2013*. FSIS reviewed the submitted information and concluded that Namibia's STEC program, as expressed in *Circular V15/2013,* met the Agency's STEC criteria. However, FSIS determined that it needed to verify that Namibia had effectively implemented its STEC program as documented to FSIS in the SRT through an on-site audit. During the 2014 on-site audit, FSIS verified whether the country had implemented the program through on-site visits to the government laboratory and establishment.

At the government laboratory, the CCA presented and discussed how its *Laboratory Information Management System*, (electronic data records) tracks microbiological laboratory information such as sample receipt date, sample condition, sample species, sample test conducted, name of the analyst, test method used, date test completed, result of the analysis, date validated by the supervisor, date reported to the CCA, Veterinarian in-charge, and the establishment, and remarks. They also presented and discussed *Laboratory Sampling and Handling Procedure*, an instruction to the analyst

on how laboratory samples are handled (from receiving to reporting sample result). The auditor reviewed data and records generated from the *Laboratory Information Management System* and *Laboratory Sampling, Handling Procedure*, and *Standard Operating Procedure for Bax Non O157 STEC Screening and Typing*. Regarding the competency of laboratory analysts, the auditor reviewed training records and data generated from *Demonstration of Competency (Technical)* and asked laboratory analysts to demonstrate how they analyze and document STEC samples in accordance with the *Standard Operating Procedure for Bax Non O157 STEC Screening and Typing*. The data and records revealed that the CCA had effective laboratory technical support including laboratory chain-of-custody for securing, storing, documenting, and maintaining the integrity of samples to perform Bax Non O157 STEC Screening and Typing, laboratory testing method for STEC.

At the establishment, the auditor interviewed four Namibia's inspection personnel and reviewed 60 days of *Inspector Daily Verification Activities* and corresponding NR to assess whether Namibia's inspection personnel were correctly implementing Namibia's STEC program, *Circular V15/2013*. In addition, the auditor reviewed April to June, 2014, STEC verification sample results. The CCA sampled and tested the following beef products for STEC: head meat, cheek meat, chuck and blade, and beef trimmings. Records for 2014 showed the following STEC test results: (1) head meat tested positive in April and May, (2) cheek meat tested positive in April, May, and June, (3) chuck and blade beef tested negative in April, May, and June, and (4) beef trimmings tested negative in April, May, and June. According to Namibia's STEC program, *Circular V15/2013, section 3, Test and Hold procedure*, the establishment is required to hold related production lots until STEC results are received. Inspection records showed that the CCA initiated enforcement in accordance with Namibia's STEC program, *Circular V15/2013, section 3, Action taken by DVS in response to establishment or government positive test results* for positive STEC results. The establishment identified, segregated, disposed, and excluded from export market meat and meat products with positive STEC results. The CCA documented noncompliance and required the establishment to implement immediate and preventive corrective action including reassessing the adequacy of its HACCP plan and sanitary dressing process control procedure. The CCA stated that the establishment intends to export the following beef products to the U.S. if equivalence is granted: chuck, blade, and trimmings. Head and cheek meat will not be offered for U.S. export. The CCA submitted a letter to the auditor to confirm this intention.

The auditor's assessment showed that the CCA had an effective strategy for implementing Namibia's STEC sampling and testing program, *Circular V15/2013*, *Namibian Shiga Toxin Producing Escherichia Coli (E.coli O157:H7 and non-O157 STECs) Verification and Testing Program, March 31, 2014* in its inspection system. The CCA has regulatory requirements including sampling and enforcement strategies for the microbiological testing programs. The CCA was found to be capable of designing, coordinating, and reporting microbiological testing programs and their respective results, employing performance standards, and taking appropriate enforcement actions in response to unacceptable microbiological results in meat products. In conclusion, Namibia's inspection system met all the requirements for an equivalent microbiological sampling program.

11. EXIT MEETING

FSIS held exit meetings on February 1, 2013 and August 21, 2014, with the U.S. Ambassador at the U.S. Embassy in Windhoek, Namibia and at the government headquarters in Windhoek, Namibia. The participants in the meeting at the government headquarters included the CCA, laboratory staffs, Namibia's Honorable Minister of Agriculture, Water and Forestry, and representatives from the United States Embassy in Namibia. At both meetings, FSIS presented and discussed the follow-up audit results and findings. The CCA outlined strategies and policies intended to enhance performance of the food safety and inspection tasks and to better understand FSIS requirements for importing meat products to the U.S.

12. CONCLUSIONS AND NEXT STEPS

These audits were also critical to inform an Agency decision to proceed to the next step in the initial equivalence process and initiate rulemaking to propose to add Namibia to the list of countries eligible to export meat products to the U.S. As discussed above, the CCA demonstrated its ability to implement an equivalent meat inspection system to the FSIS system. Therefore, FSIS intends to initiate the rulemaking process to propose to list Namibia in the code of *Federal Regulations* as a country eligible to export meat product to the U.S.

AJ Ogundipe, Senior Equivalence Officer, IES, OPPD

13. ATTACHMENTS TO THE AUDIT REPORT

2013 Individual Foreign Establishment Audit Checklists
2014 Individual Foreign Establishment Audit Checklists
Foreign Country Response to the Draft Final Auidt Report

2013

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Meatco Sheffield Road P.O. Box 2166 Windhoek	1/29/2013	NA 22	Namibia
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Farooq Ahmad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
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. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

2013

60. Observation of the Establishment Date: 1/29/2013 Est #: 22[S/P] (Namibia)

39/51 SPS findings identified during FSIS on-site audit of 2009 were corrected **except** one finding regarding corroded and rusty rail and switches. Rust and corrosion were observed on the carcass rail, switches, and overhead metal structure in the slaughter area where the carcasses leave the slaughter floor to the lower level. FSIS' review of last 90 days of inspection verification activities records including periodic supervisory visits showed that no non-compliance related to this finding was documented. No products are currently exported to the United States.
[Regulatory references: 9 CFR §416.2(b) and 416.17]

39/51 During the tour of the facility FSIS auditor observed the monitoring of CCP-1 (zero tolerence) for fecal material, ingesta, and milk conducted by establishment. FSIS auditor also observed the verification of CCP-1 (zero tolerence) conducted by official inspector. During these activities FSIS auditor observed that the height of fixed metal stand was not sufficient to enable establishment employee and official inspector to observe completely the hind quarter of beef carcass for fecal material, ingesta, and milk. This may had affected monitoring and verification of CCP-1 (zero tolerance) results and compliance with critical limits. FSIS auditor reviewed of last six months of inspection records and it was noted that no non-compliance related to this FSIS observation was documented. No products are currently exported to the United States.
[9 CFR §416.2]

41 Beaded condensate was observed under the refrigeration unit in the carcass chiller over the exposed carcasses. The establishment took immediate corrective action by moving the carcasses away from the refrigeration unit and maintenance was notified for further corrective actions. No product was affected. FSIS' review of last 90 days of inspection verification records identified no trend or pattern related to this finding.
[9 CFR §416.2(b) and 416.17]

45/51 In the cut-up area, one empty metal container used for edible meat had cracks and holes. The container was immediately removed from this area by the establishment employee. The last six months of inspection verification activities records showed that no non-compliance related to this finding was documented. No products are currently exported to the United States.
[9 CFR §416.3(a)]

51 FSIS auditor verified how inspection personnel document inspection schedules and noncompliance findings on Non-Conformance/Corrective Action Request using Reference Guide for Sanitation, HACCP, labeling, PR, Humane slaughter, and Residue. FSIS auditor observed that non-compliance findings were documented on inspection verification activities sheet, instead of issuing the non-compliance record (NR) in accordance with Namibia's supporting document Circular V20/2008.
[9 CFR §500.2 and *DM, volume 2, Circular V20/2008*]

58/51 The establishment consider all cattle 30 months of age and older in the SRM written program. Leakage of SRM (brain tissue) from opening of the knock-hole was observed after the head skinning operation. The establishment has SRM program in place in accordance with 9 CFR 310.22. According to section 5 of SRM program, Handling of SRM, "The Abattoir - Superintendent must ensure that all appropriate Specified Risk Materials is removed completely from the carcass as soon as practicable after slaughter and before the carcass is presented for post-mortem health inspection and marking....." The whole head which is treated as SRM, is removed completely from the carcasses and sold to local market according to SRM program. The establishment did not address potential contamination of edible portions of the head by SRM (brain tissues) during dressing procedures at the kill floor. The last 12 months of inspection verification activities records showed that inspection personnel did not document this SRM-related non-compliance; therefore no enforcement actions were taken. No products are currently exported to the United States.
[9 CFR §310.22]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Farooq Ahmad, DVM	Farooq Ahmad 3/20/2013

2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Meatco Sheffield Road P.O. Box 2166 Windhoek	8/18- 19,2014	22	Namibia
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	AJ Ogundipe		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. SRM	
59.	

60. Observation of the Establishment

Date: 8/18/2014 Est #: 22 (Namibia)

The assessment revealed that (1) Namibia's in-plant inspection personnel were verifying whether the establishment met sanitation requirements and enforcing regulatory requirements in accordance with Namibia's C*ircular V20/2008*, and (2) the corrective action plan proffered by the CCA regarding the 2013 audit finding was effectively implemented by the establishment and verified by the CCA. The audit did not detect any systemic finding in sanitation during the 2014 audit.

The auditor's assessment showed that (1) the establishment was conducting monitoring and verification procedures in accordance with its HACCP plan, and (2) Namibia's in-plant inspection personnel were verifying the establishment's compliance with HACCP requirements and enforcing regulatory HACCP requirements in accordance with Namibia's *Circular V20/2008*. The audit did not detect any systemic findings in HACCP.

The auditor observed that Namibia's in-plant inspection personnel satisfactorily performed all the inspection tasks related to residual sampling collection procedures: randomly collecting residue samples (metrics), handling of residue samples, documenting residue samples in *Inspector Daily Verification Activities*. The corrective action plan proffered by the CCA had been effectively implemented.

During the slaughter operation, the auditor observed that Namibia's in-plant inspection personnel identified smears of fecal material on exposed carcasses around the anus area after the anus removal step during the establishment's sanitary dressing procedure. Namibia's in-plant inspection personnel took regulatory enforcement action by stopping the line and notifying the establishment supervisor. The establishment trimmed the contaminated surface, and Namibia's in-plant inspection personnel verified and accepted the establishment's immediate corrective actions. Namibia's inspector informed the auditor that he would document the finding on a NR.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
AJ Ogundipe	3/12/15

REPUBLIC OF NAMIBIA

MINISTRY OF AGRICULTURE, WATER AND FORESTRY

Tel: (+264 61) 208 7111
Fax: (+264 61) 221 733
Email: jamunime@mawf.gov.na

Office of the Permanent Secretary
Luther Street
Private Bag 13184, WINDHOEK

Enquiry: Dr. A. Maseke
Email: masekea@mawf.gov.na
Reference: FSIS/3. 2015

23 March 2015

The Director
International Equivalence Staff
United States Department of Agriculture, Food Safety and Inspection Service
Washington D.C., 20250
USA

Dear Mr Andreas Keller,

RE: Draft Final Audit Report: FSIS Audit Jan 28 to Feb 1, 2013 and Aug 13-21, 2014

I would like to acknowledge receipt of your letter dated 18 March 2015, and the draft final report that describes the outcome of the two initial equivalence on-site audits of Namibia's meat inspection system conducted by Food Safety and Inspection Service (FSIS) from January 28 to February 1, 2013 and August 13-21, 2014.

The report is very much factual and accepted. We therefore request FSIS to initiate the rulemaking process to propose to list Namibia in the code of *Federal Regulations* as a country eligible to export meat and meat products to the United States of America (U.S.A)

We take this opportunity to express our appreciations and thank FSIS audit and report.

We look forward to the outcome of the rulemaking process in order to commence the export of Namibia meat to the U. S. A.

Yours sincerely

~~23-03-2015~~ 23/03/2015

Joseph S Iita
PERMANENT SECRETARY

PERMANENT SECRETARY
Republic of Namibia
Ministry of Agriculture, Water and Forestry