



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

FEB 23 2010

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

Dear Dr. Joubert:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Namibia's meat inspection system September 2 through 9, 2009. Comments received from the government of Namibia have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions, please contact me by telephone at 202.720.6400, by facsimile at 202.720.6050 or by electronic mail at internationalequivalence@fsis.usda.gov

Sincerely,

Andreas Keller, Director
International Equivalence Staff
Office of International Affairs

Enclosures



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Dr. Frans Joubert

2

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FINAL

FINAL REPORT OF AN INITIAL EQUIVALENCE ON-SITE AUDIT
CARRIED OUT IN NAMIBIA COVERING NAMIBIA'S MEAT
INSPECTION SYSTEM

SEPTEMBER 2 THROUGH 9, 2009

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. SUMMARY
 - 1.1 Description/Eligibility
 - 1.2 Comparison of the September 2009 on-site audit and the September/October 2006 on-site assessment
 - 1.3 Comparison of the September 2009 on-site audit and the September/October 2006 on-site assessment
 - 1.4 Summary Comments for the Current Audit
2. INTRODUCTION
3. OBJECTIVE OF THE AUDIT
4. PROTOCOL
5. LEGAL BASIS FOR THE AUDIT
6. AUDIT HISTORY
7. MAIN FINDINGS
 - 7.1 Government Oversight at the headquarters office
 - 7.1.1 Organizational Structure and Staffing
 - 7.1.2 Ultimate Control and Supervision
 - 7.1.3 Assignment of Competent, Qualified Inspectors
 - 7.1.4 Authority and Responsibility to Enforce U.S. Requirements
 - 7.1.5 Administrative and Technical Support
 - 7.2 Government Oversight at the local field inspection office
8. AUDIT OF THE ESTABLISHMENT OPERATIONS
9. SANITATION CONTROLS
 - 9.1 Sanitation Standard Operating Procedures (SSOP)
 - 9.2 Sanitation Performance Standards (SPS)
10. SLAUGHTER/PROCESSING CONTROLS
 - 10.1 Ante-Mortem
 - 10.2 Humane Handling
 - 10.3 Post-Mortem
 - 10.4 Hazard Analysis and Critical Control Point (HACCP) System
 - 10.5 Pathogen Reduction Program/Testing for Generic *Escherichia coli*
 - 10.6 Pathogen Reduction Program/Testing for *Salmonella* in Raw Products
11. RESIDUE CONTROLS
12. ANIMAL DISEASE CONTROLS

13. AUDIT OF THE LABORATORY OPERATIONS

13.1 Audit of Microbiology Laboratory

13.2 Audit of Residue Laboratory

14. ENFORCEMENT CONTROLS

14.1 Rules of Practice

14.2 Daily Inspection in Establishments

14.3 Zero Tolerance for Visible Fecal Material

14.4 Species Verification

14.5 Inedible Control

14.6 Periodic Supervisory Reviews

15. CLOSING MEETING

16. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AL	Agricultural Laboratory
CCA	Central Competent Authority
CVL	Central Veterinary Laboratory
CVO	Chief Veterinary Officer
DVPH	Division of Veterinary Public Health
DVS	Directorate of Veterinary Services
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
GON	Government of Namibia
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of an on-site audit conducted in Namibia from September 2 to 9, 2009. This was an initial equivalence on-site audit to assist in determining whether Namibia’s meat inspection system is equivalent to that of the United States (U.S.). Presently, Namibia is not eligible to export meat, poultry, and egg products to the U.S. Because of Animal and Plant Health Services (APHIS) has declared Namibia free of Foot and Mouth Disease and Rinderpest (excluding the region north of Veterinary Cordon Fence), Namibia will be eligible to export raw, dry cured, fully cooked, or canned/shelf stable meat products to the U.S. However, Namibia indicated to FSIS that it intends to export raw, not ground, beef products to the U.S. The comparison of the September 2009 on-site audit and the September/October 2006 on-site assessment is shown in Sections 1.2 and 1.3.

The September/October 2006 on-site assessment was funded by U.S. Department of Agriculture, Foreign Agricultural Services (FAS), and the objectives were to: (1) compare U.S. meat inspection system and Namibia meat inspection system, (2) identify the differences between the two systems, and (3) write an assessment report. FAS, Office of Capacity Building and Development used this information to develop and implement equivalence inspection training programs for Namibia.

1.2 Comparison of the September 2009 on-site audit and the September/October 2006 on-site assessment

AUDIT SCOPE		
	Sept 2009 on-site audit	Sept/Oct 2006 on-site assessment
	09/2-9/9, 2009	09/27-10/11, 2006
Levels of Government Oversight Audited		
Headquarters	1	1
Local Inspection Office	1	Not audited
Laboratories Audited		
Microbiology	1	1
Residue	2	2
Establishments Audited*		
Slaughter/processing	1	2

* Note that one establishment was audited in the 2009 audit because Namibia proposed only one establishment for certification.

1.3 Comparison of the September 2009 on-site audit and the September/October 2006 on-site assessment (Audit Findings)

AUDIT SCOPE		AUDIT FINDINGS	
		Sept 2009 on-site audit	Sept/Oct 2006 on-site assessment
		# Non-Compliance	# Non-Compliance
Government Oversight (Headquarters)			
	1. Organizational Structure and Staffing	1	1
	2. Control and Supervision	2	3
	3. Assignment of Competent, Qualified Inspectors	0	1
	4. Authority and Responsibility of the CCA to enforce U.S. reqs.	0	2
	5. Administrative and Technical Support	1	4
	6. Government Oversight (Local Inspection Office)	1	1
Sanitation Controls*			
	7. Sanitation Standard Operating Procedures (SSOP)/Design	0	1
	8. SSOP/Execution	1	5
	9. Sanitation Performance Standard (SPS)	3	4
Slaughter/Processing Controls*			
	10. Ante-Mortem	0	0
	11. Human Handling	0	1
	12. Post-Mortem	0	6
	13. HACCP/Design	0	6
	14. HACCP/Execution	3	4
	15. Pathogen Reduction programs/Generic <i>E.coli</i>	0	3
	16. Pathogen Reduction programs/ <i>Salmonella</i> Performance Std.	0	2
Residue Controls			
	17. Residue Program	3	4
Animal Disease Controls			
	18. Animal Disease	0	0
Laboratory Operations			
	19. Microbiology laboratory	3	11
	20. Residue laboratory	6	21
Enforcement Controls*			
	21. Rules of Practice	1	1
	22. NOID/Delistment**	Not Applicable	Not Applicable
	23. Daily Inspection	0	1
	24. Zero Tolerance	0	1
	25. Species Verification	0	1
	26. Inedible Control	0	2
	27. Periodic Supervisory Reviews	1	0

*Non-compliance findings in establishment 22 for 2009 audits and 2006 assessment. This establishment (22) was audited in 2009 and 2006.

** This was an initial equivalence on-site audit. Presently, Namibia is not eligible to export meat, poultry, and egg products to the U.S.

1.4 Summary Comments for the Current Audit (September 2009 on-site audit)

The results of September 2009 on-site audit showed a significant improvement in Namibia's meat inspection system (section 1.3). The significant improvement in Namibia's meat inspection system could be attributed to many factors such as effective equivalence inspection training provided by FAS and effective communication on FSIS foreign inspection requirements between FSIS and the government of Namibia (GON).

The September 2009 on-site audit findings reflected a significant **decrease** in the total numbers of non-compliance findings (section 1.3). The September 2009 on-site audit showed that **14** out of **26** areas of Namibia's inspection system audited were in **compliance** with FSIS equivalence requirements while the September/October 2006 on-site assessment indicated that **3** out of **26** areas of Namibia's inspection system audited were in **compliance**. In residue laboratory, **six non-compliance** findings were observed in the September 2009 on-site audit while **twenty-one non-compliance** findings were observed in the September/October 2006 on-site assessment. In microbiology laboratory, **three non-compliance** findings were observed in the September 2009 on-site audit while **eleven non-compliance** findings were observed in the September/October 2006 on-site assessment.

The GON had clearly demonstrated that with adequate training and understanding of FSIS foreign inspection requirements, the GON was able to implement significant numbers of FSIS equivalence inspection requirements.

2. INTRODUCTION

From September 27 through October 11, 2006, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture conducted an initial equivalence on-site assessment of Namibia's meat inspection system. FSIS provided a final assessment report including specific areas of concern in Namibia's meat inspection system to the Government of Namibia (GON). In June 30, 2009, FSIS proposed an on-site audit for September 2 to 9, 2009, and in July 14, 2009, FSIS held a teleconference meeting with the GON to discuss the on-site audit strategy.

The FSIS conducted an initial equivalence on-site audit of Namibia's meat inspection system from September 2 – 9, 2009.

An opening meeting was held on September 2, 2009, in Windhoek, Namibia with the Directorate of Veterinary Services (DVS). At this meeting, the team leader confirmed the objective and scope of the audit, the team's itineraries, and requested additional information needed to complete the on-site audit of Namibia's meat inspection system.

The DVS representatives accompanied the team members during the entire audit activities.

3. OBJECTIVE OF THE ASSESSMENT

The objective of the on-site audit was to assist in determining whether Namibia's meat inspection system is equivalent to that of the U.S.

In pursuit of the objective, the audit covered all aspects of Namibia's meat inspection system (sections 1.2 and 1.3): government oversight at the headquarters in Windhoek and local inspection office, establishment operations (one slaughter and processing establishment), laboratory operations (two residue laboratories, and one microbiological laboratory), and five risk areas (animal disease controls, sanitation controls, slaughter/processing controls, residue controls, and enforcement controls).

4. PROTOCOL

This on-site audit was conducted in three parts. One part involved the audits of government oversight at the headquarters in Windhoek and at one local inspection office. The second part involved on-site audit of one slaughter and processing establishment. The third part involved on-site audits of three laboratories (one government microbiology laboratory and two government residue laboratories).

The scope of the on-site audit included government oversight, establishment operation, laboratory operations, and five risk areas. The five risk areas included: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS), (2) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) programs, Pathogen Reduction programs such as testing procedures for generic *Escherichia coli* (*E. coli*) and *Salmonella* Performance standard, (3) residue controls (4) animal disease controls, and (5) enforcement controls including rules of practice, daily inspection, zero tolerance for visible fecal materials, inedible controls, and periodic supervisory reviews. Program effectiveness determinations of Namibia's inspection system focused on all the aspects of this scope (sections 1.2 and 1.3)

During the on-site audit of government oversight at the headquarters, FSIS team verified whether: (1) oversight and enforcement strategies were in place, (2) microbiology and residue programs were in place and effectively implemented, and (3) inspection requirements and programs were effectively communicated to local offices inspection personnel and throughout the system.

During the on-site audit of government oversight at the local inspection office, FSIS team verified whether local office inspection personnel were effectively implementing oversight and enforcement programs.

During the on-site audit of the establishment operations, FSIS team verified whether: (1) establishment food safety systems were in place and effectively implemented, (2) the designs and executions of SSOP and PR/HACCP were adequate to prevent contamination and adulteration,

and (3) Sanitation Performance Standards, humane handling, ante-mortem inspection, and post-mortem inspection, etc. met requirements.

During the on-site audit of laboratory operations, FSIS team verified whether: (1) appropriate laboratory practices were in place, (2) appropriate and effective analytical methods were being employed, and (3) the integrity of samples and the accuracy of the testing results were ensured, and (4) laboratory capacities, analyst's competency, equipment capabilities, and quality assurance programs were adequate.

Overall, the team evaluated the nature, extent, and degree to which all findings influenced food safety and public health.

At the opening meeting, the team leader explained that Namibia's meat inspection system would be audited against following standards: (1) FSIS regulatory requirements as applicable and (2) FSIS equivalence determinations specific to Namibia. FSIS requirements include, among other things, daily inspection in all certified establishments, periodic supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, SPS, and testing for generic *Escherichia coli* (*E. coli*) and *Salmonella*.

The following alternative measures for Namibia have been determined by FSIS to be equivalent under the provision of World Trade Organization Sanitary/Phytosanitary Agreement:

- *Salmonella* detection by iQ-check PCR in raw beef products: Although this method is found to be equivalent, Namibia did not implement this method during this audit. Instead, Namibia implemented FSIS laboratory method (BAX PCR screening method) to analyze *Salmonella* in raw meat product.
- 20-hour reveal method for detecting *E.coli* O157:H7 in raw beef products: Although this method is found to be equivalent, FSIS team did not evaluate the implementation. Namibia did not have a sampling program for *E.coli* O157:H7 in raw beef products in place at the time of the audit.

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the U.S. import requirements listed in 9 CFR 327 and the Pathogen Reduction/HACCP regulations.

6. AUDIT HISTORY

September/October 2006

During September/October 2006 on-site assessment, FSIS team identified the following areas of concern in Namibia's meat inspection system:

Government oversight:

- The CCA did not have a training program in place to maintain competency of inspection officials and laboratory analysts.
- Due to lack of training, the majority of the FSIS regulatory requirements were not met.
- The CCA did not have adequate oversight for the use of residue laboratories in South Africa.

Sanitation Controls:

- The SSOP regulatory requirements or equivalence sanitary measures were not met (9 CFR 416).
 - design and execution of SSOP were not adequate
- The SPS requirements or equivalence measures were not met (9 CFR 416).
 - prevention of insanitary conditions was not adequate
 - facilities were not properly maintained to preclude entrance of mice and flies

Slaughter/Processing Controls:

- The HACCP regulatory requirements or equivalence sanitary measures were not met (9 CFR 417).
 - design and execution of HACCP were not adequate
- The Humane handling requirements were not met (9 CFR 313)
 - improper stunning
- Post Mortem: Proper dressing slaughter procedures were not implemented to prevent contamination of carcasses (9 CFR 310)
- Pathogen Reduction programs: Testing for generic *E.coli* for process control and *Salmonella* in raw meat products for performance standard did not meet the requirements of 9 CFR 310.25 or equivalence sanitary measures.

Laboratory Operations-Microbiology and Residue:

- The CCA did not apply FSIS laboratory methods or equivalent measures to ensure that maximum opportunity for detection and identification of *Salmonella* specie in raw meat products.
- The CCA did not have good laboratory practices in place to ensure integrity of samples and accuracy of testing results.

Enforcement Controls:

- Daily Inspection: The CCA did not have daily inspection coverage for processing establishments.

- Zero Tolerance: No CCP or procedure was in place to control the presence of visible feces, ingesta, and milk on carcasses, and no documentation was provided to support omission.
- Species verification: No species verification was being conducted.
- Inedible Control: The establishment did not identify receptacles used for storing inedible products. The establishment did not denature inedible or stored pile of bones in a secured control location.

7. MAIN FINDINGS

7.1 Government Oversight at the headquarters office

In pursuit of the government oversight audit, the team focused on the following areas: (1) Organizational Structure and Staffing, (2) Control and Supervision, (3) Assignment of Competent, Qualified Inspectors, (4) Authority and Responsibility to Enforce U.S. Requirements, and (5) Administrative and Technical Support.

7.1.1 Title 9 CFR 327.2 Organizational Structure and Staffing

The DVS is under the purview of the Ministry of Agriculture, Water and Forestry. The DVS is the Central Competent Authority (CCA) for enforcing the laws and regulations regarding inspection activities for meat exports. The Chief Veterinary Officer (CVO) heads the DVS. The DVS is divided into four divisions: the Division of Veterinary Public Health, the Division of Animal Disease Control, the Division of Epidemiology, Import, Export, and Training, and the Division of Diagnostic Services and Research. The Deputy Chief Veterinary Officer who reports directly to the CVO heads each division. The Ministry of Health is responsible for enforcing the laws and regulations for domestic meat inspection activities. The CCA has a procedure in place to ensure that FSIS requirements and DVS inspection circulars are communicated to field inspection personnel via faxes, mail, and emails.

The Division of Veterinary Public Health (DVPH) is directly responsible for managing the implementation of export requirements and inspection oversight activities over the establishments that would be certified for export. Because of the CCA has no district or regional meat inspection offices, the inspection personnel including the Veterinarian-in-Charge (VIC) at the establishments report directly to the Chief Veterinarian, DVPH, at the headquarters, in Windhoek. The Chief Veterinarian reports to Deputy CVO, DVPH. The Veterinary Hygiene Inspector (VHI) and Veterinary Hygiene Inspection Assistant (VHIA) report to the VIC.

The inspection personnel are the official employees of the national government. The national government of Namibia through Namibia Ministry of Finance pays the inspection personnel. The overtime hours are submitted to the Chief Veterinarian, DVPH by the Office of Personnel and then forwarded to Ministry of Finance for payment.

Area of concern:

The CCA did not have a procedure in place for providing relief staff assignments for planned or unplanned absences of inspection.

7.1.2 Title 9 CFR 327.2 Ultimate Control and Supervision

The CVO has the authority over the establishments that conduct export activities, including those seeking to be certified to export meat products to the United States. The Chief Veterinarian, DVPH, at the headquarters is responsible for supervising and managing inspection oversight and enforcement activities at the field level. The CCA has verification and enforcement procedures in place to verify the compliance of food safety requirements at the establishment. The CCA's verification procedures and enforcement strategies are similar to FSIS Performance Based Inspection System (PBIS) and FSIS rules of practice, 9 CFR 500. The VIC, VHI, and VHIA accomplish implementation of verification and enforcement procedures at the export establishments. The CCA has periodic supervisory review procedures in place. In addition to periodic supervisory review procedures, the CCA has developed internal audit procedures that are similar to FSIS Foreign Establishment Audit Checklist, FSIS-Form 5000-6.

The CCA has controls in place to prevent fraud or misuse of export certificates, and to ensure the integrity of the meat products. The export documents are electronic and password protected. The VIC is in charge of the security of export certificates and stamps and the sealing of meat trucks to maintain security and integrity of meat products during transportation between establishments and port facilities.

Areas of concern:

The CCA did not have effective strategy to implement audit programs.

The CCA allowed the VIC to conduct periodic supervisory reviews and it did not follow up on the deficiencies identified by VIC in periodic supervisory reports.

The CCA did not have records to show that it verified corrective actions for the 2006 assessment.

7.1.3 Title 9 CFR 327.2 Assignment of Competent, Qualified Inspectors

The DVS is responsible for assigning qualified veterinarians, veterinary hygiene inspectors, and veterinary hygiene inspection assistants to perform inspection oversight and enforcement activities at the export establishments. All official veterinarians have veterinary medical degrees from an accredited university. In addition, the veterinarians must register and pass competency test administered by Namibia veterinary association every year. The VHI and VHIA must have at least Diploma degrees in public health. The VHI and VHIA assist VIC in performing inspection activities. The VHIA receive extensive training prior to assignment to an establishment. This training consists of one month theoretical training, and five months on the job training (OJT). With the experience and good job performance, VHIA can be promoted to VHI. Other members of the inspection staff including veterinarians undergo one month of OJT training in addition to the educational requirements. The VIC had attended various training programs to gain understanding of FSIS inspection requirements: (1) FSIS international seminar for foreign government officials, and (2) FSIS inspection requirements delivered by FAS consultants in Namibia. In addition, the VIC has a collection of FSIS training materials (DVDs and FSIS guidelines).

No finding:

The CCA has competent and qualified Inspection personnel to carry out inspection activities.

7.1.4 Title 9 CFR 327.2 Authority and Responsibility to Enforce U.S. Requirements

The CCA has the legal authority and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not prepared in export establishments. The Meat Safety Act 2000 provides for the registration of slaughter establishments, ante-mortem inspection, post-mortem inspection, processing of meat, meat import regulations, and meat export regulations. The Meat Act 1991 provides for the control and prevention of residues in meat and meat products. The CCA has oversight and enforcement strategies in place to ensure compliance of Namibia's meat inspection laws and regulations. The CCA has adopted FSIS enforcement strategies as specified in FSIS rules of practice, 9 CFR 500. The VIC at the establishment and designated headquarters personnel have the legal authority to suspend operations and delist certified establishments.

No Finding:

The CCA has the authority and responsibility to enforce the requisite laws and regulations governing meat inspection and to certify or refuse to certify establishments for export.

7.1.5 Title 9 CFR 327.2 Administrative and Technical Support

The Deputy CVO, Division of Diagnostic Services and Research is responsible for providing administrative and technical support and he/she reports to CVO. The technical staffs at the laboratory provide scientific and laboratory analysis to support inspection programs. All laboratory analysts have at least Master degrees in science, and lab technicians have diploma degrees in appropriate science courses.

The CCA is responsible for developing sampling procedures including scheduling of meat samples for field inspection personnel. The CCA and Central Veterinary Laboratory (CVL) determine the residue-sampling plan. The CCA schedules sample set for *Salmonella* Performance Standard. Upon receiving the sampling plan and request from the headquarters, field inspection personnel implement the sampling procedures by collecting and sending meat samples to the specified laboratory. The inspection personnel receive sample results from the laboratory via electronic format and fax.

Areas of concern:

Microbiology:

The CCA did not have training records to verify and maintain competence of laboratory analysts and technicians.

Residue:

The CCA provided a written procedure that describes the analyst training but no documentation was provided to verify that the training was satisfactorily completed.

7.2 Government oversight at the field local inspection office

The DVPH is directly responsible for managing the implementation of export requirements and inspection oversight activities over the establishments that would be certified for export. Because the CCA has no district or regional meat inspection offices, the inspection personnel including the VIC at the establishments report directly to the Chief Veterinarian, DVPH, at the headquarters, in Windhoek. The purpose of on-site audit of the local inspection office was to verify that all the information obtained from the headquarters were effectively communicated to the field personnel for implementation. In addition, the team determined whether verification and enforcement activities of the field inspection personnel were in place and effectively implemented to ensure that establishment was complying with food safety regulations.

The inspection documents were properly disseminated from the CCA at the headquarters to inspection personnel at the establishments. The field inspection personnel received FSIS inspection requirements and programs from the headquarters through circular and implemented this information to carry out their daily inspection activities. The verification and enforcement activities were in place and implemented to ensure that establishments were complying with Namibia's food safety laws and regulations, and exporting countries' food safety requirements. The CCA's verification procedures and enforcement strategies are similar to FSIS Performance Based Inspection System (PBIS) and FSIS rules of practice, 9 CFR 500.

Area of concern:

The local inspection personnel were not adequately verifying and enforcing some of SSOP and HACCP requirements.

8. AUDIT OF THE ESTABLISHMENT OPERATIONS

One meat establishment that is seeking certification to export meat products to the United States was audited. During the on-site audit of establishment operations, FSIS team verified whether (1) establishment food safety systems were in place and effectively implemented, (2) the designs and executions of SSOP and PR/HACCP were adequate to prevent contamination and adulteration, and (3) Sanitation Performance Standards, humane handling, ante-mortem inspection, and post-mortem inspection, etc. met food safety requirements.

In addition, the team evaluated the nature, extent, and degree to which findings influenced food safety and public health. Refer to the attachments in section 16 for foreign establishment audit checklists. The audit checklists provide detail descriptions of establishment's food safety findings.

9. SANITATION CONTROLS

As stated earlier, the scope of the audit included five risk areas. The first of these risk areas is sanitation controls. Sanitation controls are part of the establishment's food safety systems and they include Sanitation Standard Operating Procedures and Sanitation Performance Standards.

9.1 Title 9 CFR 416.11-416.17 Sanitation Standard Operating Procedures (SSOP)

The CCA adopted and implemented SSOP requirements in accordance with FSIS regulations. Therefore, the establishment was evaluated to determine if FSIS regulatory requirements for SSOP were met according to the criteria employed in the United States' domestic inspection program.

No finding (Design of SSOP):

The establishment met FSIS requirements.

Area of concern (Execution of SSOP):

The establishment did not effectively implement its SSOP to prevent direct contamination of exposed carcass from dripping condensate and contaminated boots and aprons.

9.2 Title 9 CFR 416.1-416.6 Sanitation Performance Standards (SPS)

The CCA adopted and implemented SPS requirements in accordance with FSIS regulations. The establishment was evaluated to determine if FSIS regulatory requirements for SPS were met according to the criteria employed in the United States' domestic inspection program.

Areas of concern:

Facilities were not properly maintained to prevent conditions that could lead to insanitary conditions.

Corrosion and rust on carcass rails and switches, and holes in the ceiling were observed in the sample collection room.

Beaded condensate on the doorframe and carcass rails was observed on areas where exposed products entered the chiller.

The cradle used for collecting heads was not maintained in a sanitary manner.

10. SLAUGHTER/PROCESSING CONTROLS

The second of these risk areas is slaughter/processing controls. Slaughter/Processing controls are part of the establishment's food safety systems and they include ante-mortem inspection requirements, humane slaughter of livestock, and post-mortem inspection requirements. The controls also include the implementation of Pathogen Reduction Programs and Hazard Analysis and Critical Control Point systems.

10.1 Title 9 CFR 309 Ante-Mortem

The CCA adopted and implemented ante-mortem inspection requirements in accordance with FSIS regulations. The establishment was evaluated to determine if the FSIS regulatory requirements for ante-mortem inspections were met according to the criteria employed in the United States' domestic inspection program.

No finding:

The CCA met FSIS regulatory requirements for ante-mortem inspections.

10.2 Title 9 CFR 313 Humane Handling

The CCA adopted and implemented humane handling requirements in accordance with FSIS regulations. The establishment was evaluated to determine if the FSIS regulatory requirements for humane handling were met according to the criteria employed in the United States' domestic inspection program.

No finding:

FSIS regulatory requirements for humane handling were met.

10.3 Title 9 CFR 310 Post-mortem

The CCA adopted and implemented post-mortem inspection requirements in accordance with FSIS regulations. The establishment was evaluated to determine if the FSIS regulatory requirements for post-mortem inspections were met according to the criteria employed in the United States' domestic inspection program.

No finding:

The CCA met FSIS regulatory requirements for post-mortem inspections.

10.4 Title 9 CFR 417 Hazard Analysis and Critical Control Point (HACCP) systems

The establishment that will be certified to export meat products to the United States, with the exception of facilities dedicated to cold storage, is required to have adequately developed and implemented HACCP programs. The CCA adopted and implemented HACCP requirements in accordance with FSIS regulations. The HACCP programs in the establishment were evaluated according to the criteria employed in the United States' domestic inspection program.

No finding (Design of HACCP):

The establishment met FSIS requirements.

Areas of concern (Execution of HACCP):

The establishment did not conduct ongoing verification as specified in their verification procedures for zero tolerance for fecal material, ingesta, milk, and for metal detection. The establishment failed to reassess the adequacy of its HACCP plan when the monitoring records indicated that there were 8 repeated deviations for zero tolerance for fecal material, ingesta, and milk.

10.5 Title 9 CFR 310.25 Pathogen Reduction Program/Testing for Generic *Escherichia coli* (*E.coli*)

The establishment (slaughter) that will be certified to export meat products to the United States is required to have adequately developed and implemented testing procedure for generic *E.coli* process control. The CCA adopted and implemented testing procedure for generic *E.coli* requirements in accordance with FSIS regulations. The testing procedure for generic *E.coli*

process control in the establishment was evaluated according to the criteria employed in the United States' domestic inspection program.

No finding:

The establishment met FSIS requirements.

10.6 Title 9 CFR 310.25 Pathogen Reduction Program/Testing of *Salmonella* in Raw Products

The CCA adopted and implemented testing procedure for *Salmonella* Performance Standard in accordance with FSIS regulations. The testing procedure for *Salmonella* in raw meat product was evaluated according to the criteria employed in the United States' domestic inspection program.

No finding:

The CCA met FSIS regulatory requirements.

11. Title 9 CFR 309.16, 310.21, and 327.2 RESIDUE CONTROLS

The third of these risk areas was residue controls. The CCA implemented the European Commission's (EC) residue program specified in EC directive 96/23 which has been found equivalent by FSIS.

Areas of concern (residue program):

The CCA did not assess 2008 residue results and statistical calculations in the report. The CCA did not have a random sampling selection strategy for residue samples and an enforcement procedure for repeat residue violators.

Areas of concern (residue sampling plan 2010):

The CCA did not follow *the Council Directive 93/26 EC Annex IV Sampling Levels and frequency, Chapter 1, guidelines to design the sampling for animals to be tested for residues relating to number of samples, classes, and compounds.*

The table of Residue Tolerance level did not have enough columns to describe the type analytical tests (screen, determinative, and confirmation), and their respective laboratory where the analysis would be performed.

12. ANIMAL DISEASE CONTROLS

The fourth of these risk areas was animal disease controls. These controls include ensuring adequate animal identification, control over animal disease, and control over the movement of sick, disabled, diseased or dead livestock. Because of Animal and Plant Health Services (APHIS) has declared Namibia free of Foot and Mouth Disease and Rinderpest (excluding the region north of Veterinary Cordon Fence), Namibia will be eligible to export raw, dry cured, fully cooked, or canned/shelf stable meat products to the U.S. However, Namibia indicated to FSIS that it intends to export raw, not ground, beef products to the U.S.

The DVS has mechanisms in place to control products from livestock suspected of animal and/or public health risks. The Division of Animal Disease Control communicates animal disease status from the farm to the DVPH so that veterinarians at the official establishments will have disease information of all livestock before they are slaughtered. This is achieved by tracking and tracing animal disease with a real time database system that is in place.

No finding:

The CCA met FSIS regulatory requirements.

13. AUDIT OF THE LABORATORY OPERATIONS

One government microbiology laboratory and two government residue laboratories that will be conducting required laboratory analyses on meat product samples destined for the U.S. export were audited. During the on-site audit of laboratory operations, FSIS team verified whether: (1) appropriate laboratory methods were in place, (2) appropriate and effective analytical methods were being employed, (3) the integrity of samples and the accuracy of the testing results were ensured, and (4) laboratory capacities, analyst's competency, equipment capabilities, and quality assurance programs were adequate.

13.1 Audit of Microbiology Laboratory

The FSIS team audited one government laboratory (CVL) in Windhoek, Namibia, and assessed the following parameters: analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples.

Salmonella detection by iQ-check PCR in raw beef products: Although this method is found to be equivalent, Namibia did not implement this method during this audit. Instead, Namibia implemented FSIS laboratory method (BAX PCR screening method) to analyze *Salmonella* in raw meat product.

20-hour reveal method for detecting *E.coli* O157:H7 in raw beef products: Although this method is found to be equivalent, FSIS team did not evaluate the implementation. Namibia did not have a sampling program for *E.coli* O157:H7 in raw beef products in place at the time of the audit.

Areas of concern:

The CCA provided SOPs for quality management review, re-calibration, and verification of pipettes but no documentation was provided to verify implementation.

The CCA did not maintain records (date/time/temperature) during sterilization of media and calibration and maintenance of the equipment.

The CCA did not have a procedure for intra-laboratory performance checks or internal control to monitor trends or biases.

13.2 Audit of Residue Laboratory

The FSIS team audited two government laboratories (CVL and AL) in Windhoek, Namibia, and assessed the following parameters: sample handling, sampling frequency, timely analysis and data reporting, analytical methodologies, tissue matrices, equipment operation and printouts,

detection levels, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions. In addition, the team reviewed documents from SAB contract laboratory.

Areas of concern (CVL and AL):

The CCA did not have a procedure for intra-laboratory performance checks to validate test results and to monitor trends or biases. Intra-laboratory checks are spiked samples prepared and documented by the supervisor on a regular basis. The value of the intra-laboratory samples is unknown to the technician/analyst.

The CCA did not maintain records of *annual calibration* of laboratory balances, refrigerators, freezers, ovens, and ELISA reader and *daily verification and in-lab maintenance* of the HPLCs, balances, pH meter, and ELISA reader.

The CCA did not have procedures to identify the chemical solutions, standard solutions, and instrumentation used in the analysis of a particular sample results to ensure traceability, and to report test results, calculations and data that are appropriately reviewed for accuracy and completeness before test results are released.

Areas of concern (CVL and AL):

SOPs of Residue Analytical methods:

The SOPs did not clarify how to interpret results and perform calculations.

The SOPs did not have a uniform Quality Assurance Section and a form (template) to document/trace reagents, standards solutions, instrumentation, results, calculations, with the exception of the SOPs of sulfonamide and chloranphenicol.

The test procedure in SOPs did not include blank samples.

Areas of concern (SAB Contract lab):

Analysts' proficiency testing document from SAB document did not list meat as a matrix.

SAB validation reports of the analytical methods of clenbuterol, lead, cadmium, thyreostats could not be verified.

The CCA did not provide a signed copy of MOU between CCA and SAB lab.

14. ENFORCEMENT CONTROLS

The fifth of these risk areas was enforcement controls. These controls include rules of practice, daily inspection, zero tolerance for visible fecal material, species verification, inedible control, and periodic supervisory reviews.

4.1 Title 9 CFR 327 and 500 Rules of Practice

The CCA's verification procedures and enforcement strategies are similar to FSIS Performance Based Inspection System (PBIS) and FSIS rules of practice, 9 CFR 500.

Area of concern

The local inspection personnel were not adequately verifying and enforcing some of SSOP and HACCP requirements.

14.2 Title 9 CFR 307.4 and 327 Daily Inspection in Establishment

The establishment was evaluated to determine if the FSIS requirements for daily inspection coverage were met according to the criteria employed in the United States' domestic inspection program.

No finding:

The CCA had daily inspection coverage for all export establishments and continuous inspection coverage for slaughter operations in accordance with 9 CFR Part 327.

14.3 Title 9 CFR 327 Zero Tolerance for Visible Fecal Materials

The establishment was evaluated to determine if the FSIS requirements for zero tolerance for visible fecal materials were met according to the criteria employed in the United States' domestic inspection program.

No finding:

The establishment met FSIS requirements.

14.4 Species Verifications

The establishment was evaluated to determine if species verification procedures were in place and implemented.

No finding:

The species verification control program was in place and implemented in accordance with 9 CFR Part 327.

14.5 Title 9 CFR 314 and 327 Inedible Controls

The establishment was evaluated to determine if the FSIS requirements for inedible control were met according to the criteria employed in the United States' domestic inspection program.

No finding:

The establishment met the requirements.

14.6 Title 9 CFR 327 Periodic Supervisory Reviews

The CCA was evaluated to determine if the FSIS requirements for periodic supervisory reviews were met according to the criteria employed in the United States' domestic inspection program.

Area of concern:

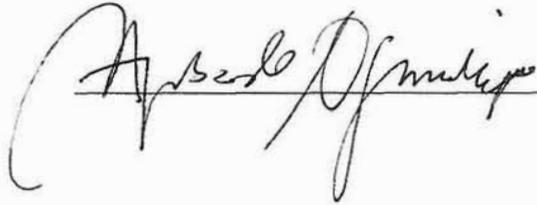
The veterinary medical officer assigned to the establishment was conducting the supervisory reviews.

15. CLOSING MEETING

A closing meeting was held on September 9, 2009, in Windhoek, Namibia with the CCA. At this meeting, the preliminary findings from the audit were presented by the team leader.

The CCA understood and accepted the audit findings.

AJ Ogundipe
Team Leader

A handwritten signature in black ink, appearing to read 'AJ Ogundipe', written over a horizontal line. The signature is cursive and stylized.

16. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Checklists
Foreign Country Response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Meatco Sheffield Road PO Box 2166 Windhoek	2. AUDIT DATE 09/3-4/2009	3. ESTABLISHMENT NO. 22	4. NAME OF COUNTRY Namibia
	5. NAME OF AUDITOR(S) Don Carlson, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.	X	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/Park 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	X
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 09/3&4/2009 Est #: 22 (Meatco [S/P/CS]) (Windhoek, Namibia) Page 1 of 2

10. Dripping condensate was observed on the ceiling, carcass rails, and pipes located over the beef carcasses as they were passing through the hot water carcass wash. The establishment stopped production, restored sanitary conditions and retained the affected carcass for microbiological evaluation. No products are currently exported to the United States. [Regulatory reference(s): 9 CFR §416.13]

10. Establishment personnel walked across the clean surface of the evisceration platform with insanitary work boots prior to verifying the temperature of the water used for the apron shower and the boot wash. No products are currently exported to the United States. [9 CFR §416.13]

10/51. The carcass evisceration stand was not equipped to adequately clean and sanitize the eviscerator's boots and aprons. The water shower used to wash the eviscerator's aprons and the boot wash for the cleaning and sanitizing of the eviscerator's boots were maintained at 40 degrees Centigrade. Soap was not routinely used between carcasses to clean the aprons. The procedure for evisceration and instructions for the eviscerators was reviewed. There was a general procedure for the sanitation of knives and the washing of eviscerator's aprons, but there was not a separate procedure for the eviscerators when the eviscerator's boots and aprons were contaminated. Establishment operational sanitation records for August 3 through September 2, 2009 were reviewed. The above described deficiency was not identified in these records. The Namibia Veterinary Service Verification records were reviewed from August 1 through September 1, 2009 and noncompliance records were reviewed from March 25, through August 10, 2009. The above described deficiencies were not identified in these records. The Namibia Veterinary Service did not adequately verify the adequacy and effectiveness of the Sanitation SOPs and the procedures specified in the establishment's Sanitation SOPs. No products are currently exported to the United States. [9 CFR §416.13 (c), 416.14, 416.17]

19/51. Ongoing verification was not conducted by the establishment as stated in their verification procedures for zero tolerance for fecal material, ingesta, and milk and for metal detection. The verification procedure stated that records verification and direct observation of the monitor will be conducted one time per day. The review of the verification records from July 31 through September 1, 2009 for zero tolerance for fecal material, ingesta, and milk and for metal detection documented that only records verification or direct observation of the monitor was conducted each day and not both activities. The Namibia Veterinary Service Verification records were reviewed from August 1 through September 1, 2009 and noncompliance records were reviewed from March 25, through August 10, 2009. The above described noncompliance was not identified in these records. The Namibia Veterinary Service did not adequately verify the adequacy of the establishment's HACCP plan's records and procedures. [9 CFR §417.4 (a) (2) (ii) (iii), 417.8]

20/21/51. Monitoring records for zero tolerance for fecal material, ingesta, and milk were reviewed from July 31 through September 1, 2009. This period included 11 slaughter days. The monitoring records document deviations from the critical limit for 8 of the 11 slaughter days. Corrective actions were implemented and verified by the establishment, but repeat deviations indicated that the preventive measures were not effective. The HACCP plan was not reassessed during this period. The Namibia Veterinary Service Verification records were reviewed from August 1 through September 1, 2009 and noncompliance records were reviewed from March 25, through August 10, 2009. The above described repeat deviations from the critical limit for zero tolerance for fecal material, ingesta, and milk were identified by the Namibia Veterinary Service, but the Namibia Veterinary Service did not identify the requirement for the reassessment of the HACCP plan in these records. The Namibia Veterinary Service did not adequately verify the adequacy of the establishment's HACCP Plan. [9 CFR §417.3 (a) (3), 417.4 (a) (3), 417.8]

39. There was a 6 inch by 8 inch hole in the plaster covering of the ceiling over a carcass rail in the room used to collect carcass microbiology samples. Establishment operational sanitation records for August 3 through September 2, 2009 were reviewed. The above described deficiency was not identified in these records. The Namibia Veterinary Service Verification records were reviewed from August 1 through September 1, 2009 and noncompliance records were reviewed from March 25, through August 10, 2009. The above described deficiency was identified in these records. [9 CFR §416.2(b)]

39. The carcass rails and switches were corroded and rusty in the room used to collect microbiology samples. Establishment operational sanitation records for August 3 through September 2, 2009 were reviewed. The above described deficiency was not identified in these records. The Namibia Veterinary Service Verification records were reviewed from August 1 through September 1, 2009 and noncompliance records were reviewed from March 25, through August 10, 2009. The above described deficiency was identified in these records. [9 CFR §416.2 (b)]

61. NAME OF AUDITOR

Don Carlson, DVM

62. AUDITOR SIGNATURE AND DATE

Don Carlson, DVM 09/04/2009

60. Observation of the Establishment

Date: 9/3&4/2009 Est #: 22 (Meatco [S/P/CS]) (Windhoek , Namibia) Page 2 of 2

41. Beaded condensate was observed on the door frame and carcass rail at the entrance to carcass chiller number five. The area of condensate was located over the area where carcasses entered the chiller. No product was affected.
 [Regulatory reference(s): 9 CFR §416.2(d)]

46. The trailing half of one beef carcass was coming into contact with the leading half of a second beef carcass at the splitting saw. This was prior to Namibia Veterinary Service final carcass inspection. No products are currently exported to the United States. [9 CFR §416.4(d)]

46. The cradle used to move the head from the head removal area to the area where the head was placed on to an elevated moving chain was not maintained in a sanitary condition. The skinned parts of the head and the unskinned parts of the head were contacting the same surfaces of the head cradle. The cradle was not cleaned and sanitized between heads. No products are currently exported to the United States. [9 CFR §416.4(d)]

51. The procedure schedule used by the Namibia Veterinary Service to conducted daily verification activities did not state whether the activities were performed, not performed, or if there was noncompliance for some of the procedures preformed. Pre-operational sanitation verification was the only activity recorded properly. Procedure schedules from August 1 through September 1, 2009 were reviewed. [9 CFR §417.8]

57. Periodic supervisory reviews were not conducted by a Namibia Veterinary Service supervisor from the CCA. The Veterinarian-In-Charge (VIC) of the establishment is currently conducting monthly reviews and reports and forwarding the reports to the CCA. Two audits were conducted by the Director of Veterinary Services in calendar year 2009, but the audits did not evaluate inspection programs or inspection performance and did not include a comprehensive evaluation of the establishment's food safety programs. Records of correspondence between the VIC and CCA were reviewed for the period of January 1 through August 31, 2009. [9 CFR §327 (a) (2) (iv) (A)]

61. NAME OF AUDITOR
 Don Carlson, DVM

62. AUDITOR SIGNATURE AND DATE

Don Carlson, DVM, 09/04/2009



REPUBLIC OF NAMIBIA

MINISTRY OF AGRICULTURE, WATER AND FORESTRY

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Government Office Park
Private Bag 12022
Ausspannplatz, Windhoek

Enquiries: Dr C Bamhare

13 January 2010

RE: Comment on FSIS Audit Report

Dear AJ Ogundipe,

The CCA of Namibia of Namibia has read the audit report and in general concurs with findings with the exception of the comment under Section 10 – Slaughter and processing.

Our comment is that Namibia's residue monitoring plan has been approved by the EU and complies with Council Directive 96/23/EC, Annex IV Sampling Levels and frequency, Chapter 1 (Commission Decision 2008/105/EC). The table includes descriptions on type of analytical tests (screen, determinative, confirmative) and various analytical laboratories.

Yours sincerely,


C Bamhare
For: Chief Veterinary Officer