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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6782 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

NAMIBIA

FROM 19 FEBRUARY TO 01 MARCH 2013

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROL SYSTEM IN PLACE, IN PARTICULAR IN RELATION TO CONTROLS ON FOOT-AND-MOUTH DISEASE

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

The objective of the audit was to evaluate the effectiveness of the animal health controls relevant for export of fresh meat from bovine, ovine and caprine animals, farmed and wild ruminants, and game trophies from ungulates, to the European Union (EU).

The Competent authority (CA) is in general well organised and acts consistently to maintain the comprehensive system aimed at maintaining the Foot-and-Mouth disease-free status of the zone recognised by the EU for export of meat. The level of guarantees is affected to some extent by weaknesses in the documentation key operations or decisions.

In particular, the insufficient implementation and/or documentation of actions following the incursion of (FMD positive) buffalo in the disease-free zone affects the reliability of the assurances given by the CA.

The system for supervision of game trophies establishments is well organised, but the certification system is not entirely reliable. Channelling system of game trophies from the infected zone to the free zone presents notable shortfalls, but has no impact on the risk of the product treated and exported.

Recommendations are made to the Competent Authorities of Namibia to address the shortcomings described in the report.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AHT	Animal Health Technician
CA	Competent Authority
CCA	Central Competent Authority
CVL	Central veterinary laboratory
DVS	Directorate of Veterinary Services
ELISA	Enzym-linked immunosorbent assay
EU	European Union
FMD	Foot-and-mouth disease
FVO	Food and Veterinary Office
GTE	Game trophies establishment
ISO 17025	*General requirements for the competence of testing and calibration laboratories,* from the *International Organisation for Standardisation.*
NSP	Non specific proteins
OIE	World Animal Health Organisation
SOP	Standard operating procedure
SVO	State Veterinary Office

1 Introduction

This audit took place in Namibia from 19 February to 1 March 2013, as part of the planned audit programme of the Food and Veterinary office (FVO). The audit was combined with the audit DG(SANCO)/2013-6774 on the controls over production of fresh bovine meat destined for export to the European Union (EU) and export procedures. The combined audit team comprised 2 FVO auditors.

The FVO audit team was accompanied by representatives from the Central Competent Authority (CCA) within the scope of this mission, the Directorate of Veterinary Services (DVS), of the Ministry of Agriculture, Water and Forestry.

2 Objectives

The objective of the audit was to evaluate the effectiveness of the animal health controls relevant for export of fresh meat from bovine, ovine and caprine animals, farmed and wild ruminants, and game trophies from ungulates, to the EU.

Particular attention was paid to:

- review the surveillance and control system in place for foot-and-mouth disease (FMD) and ovine and caprine brucellosis, with a particular focus on the measures taken following the recommendations of the FVO audit reports DG(SANCO)/2009-8326 and DG(SANCO)/2011-6120;

- review the system for the control and recording of animal movements, including those necessary for certification of the animal health requirements of Commission Regulation (EC) No 206/2010;

- review the controls in place over the production, traceability and treatment of game trophies from ungulates destined for export to the EU, and the certification of these commodities s in accordance with animal health requirements of Commission Regulation (EC) No 142/2011;

In pursuit of this objective, the audit itinerary included the following visits:

Competent Authorities	Central	1	
	Regional	2	
	Local	1	
Control point		2	1 gate point between protection and free zone, 1 border inspection post
Quarantine station		2	1 in protection zone, on in free zone
Livestock holding		3	Feed-lot, small ruminants, bovine holding
Assembly centre		1	
Game trophies plant		1	
Laboratory		1	

3 Legal Basis

The audit was carried out under the general provisions of EU legislation, and in particular Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, and Article 10 of Council Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.

Full legal references are provided in the Annex to this report. Legal acts quoted in this report refer, where applicable, to their last amended version.

4 Background

Namibia has been regionalised for the purpose of export to the EU of de-boned and matured fresh meat from bovine, ovine and caprine, farmed and wild non-domestic ruminants. The regionalisation, as stated in Commission Regulation (EU) No 206/2010, covers an area south of a cordon fence running from West to East of the Country at around 20º S latitude. This zone has been recognised by the World Animal Health Organisation (OIE) as a FMD-free zone without vaccination since 1997.

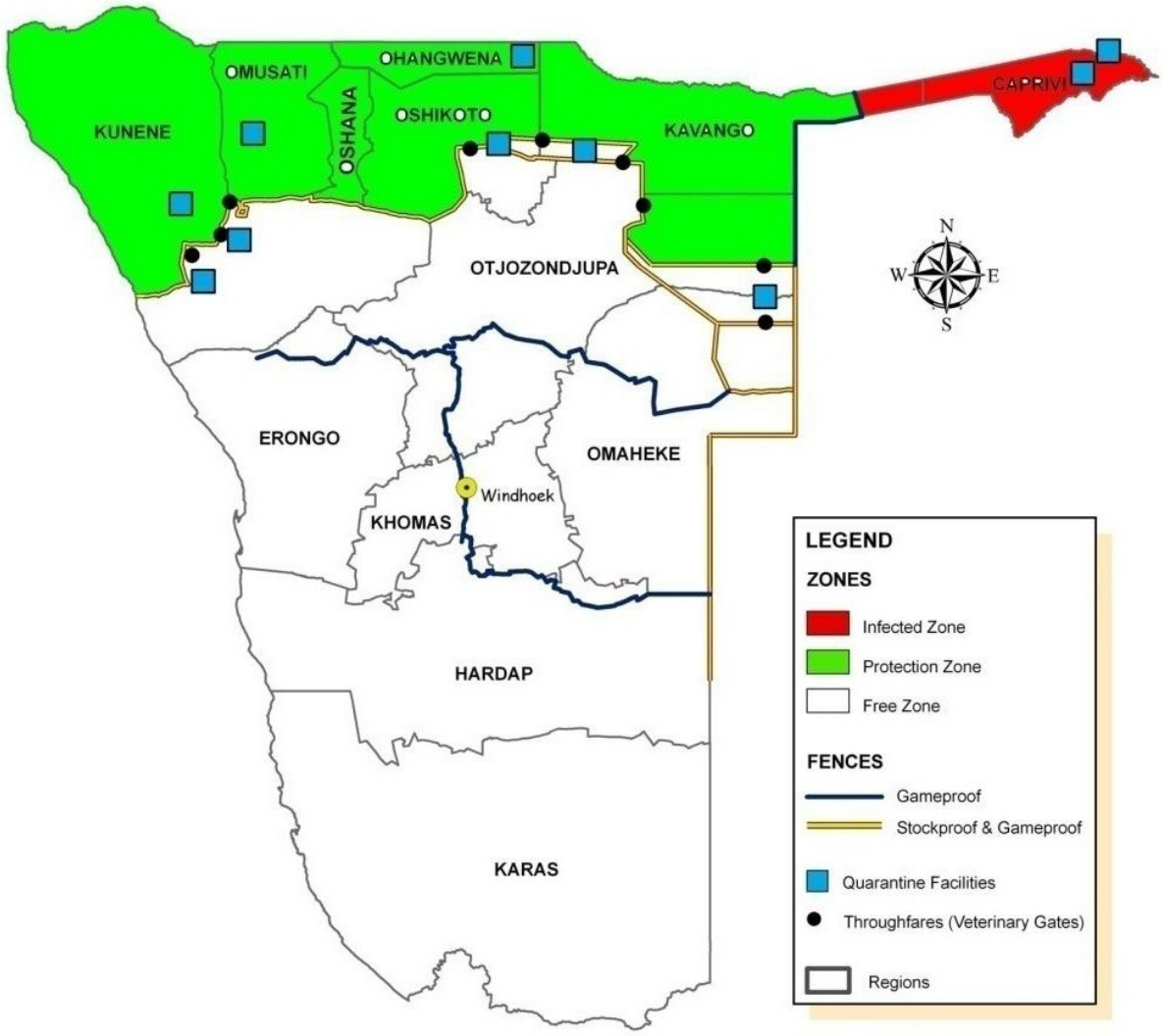
The situation and regionalisation is as described in the previous FVO audit report (DG(SANCO)2009-8326, hereafter "2009-8326 report")). Since the last audit, FMD outbreaks have been reported from Namibia only from the infected zone (one in 2010 and one in 2011), linked to the enzootic presence of FMD virus in buffaloes.

In 2011, 2 roaming buffaloes were reported in a farming area in the free zone. The animals were shot and sampled, and FMD viral antigen was detected in one of them. The CCA gave the European Commission assurance that preventive and investigative measures were taken in order to confirm the absence of FMD in cattle in the free zone.

In 2011 and 2012, Namibia exported de-boned and matured meat from bovine animals (9 to 10,000 tonnes), and from wild game (25 and 100 t).

FOOT & MOUTH DISEASE (FMD) ZONES

(With new Protection Zone)



5 Findings And Conclusions

5.1 Competent Authorities performance

5.1.1 Legal requirements

Article 10 of Council Directive 2002/99/EC and Article 46 of Regulation EC) No 882/2004 provide for the verification of compliance or equivalence of third countries legislation and systems with EU animal health rules. Particular account should be taken of:

- the legislation of the third country;
- the organisation of the competent authorities, their power and independence, the resources and training of staff, the supervision to which they are subject;
- the existence and operation of documented control procedures and control system based on priorities;
- The procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases.

5.1.2 Findings

5.1.2.1 Legislation and enforcement powers

The new Animal Health Act, drafted in 2007 to address weaknesses identified in the previous act, has been published in 2011. It will comes into operation upon Ministerial notice, which has not been published yet. The list of notifiable diseases (and species to which they apply) is also to be declared through a government notice; a draft was presented to the audit team.

Rules for holding registration, animal identification, registration and movement, and animal gatherings were last revised in March 2009 (Animal Identification Regulations 29/2009).

5.1.2.2 Designation, resources, organisation and coordination

The organisation of the services in charge of animal health has remained as described in the 2009-8326 report. The DVS remain the CA in charge of animal health matters for all animal species. They

Observations:

- The number of staff posts in the veterinary services has remained unchanged since at least 2005. (737 posts) Few posts remain vacant. The CA announced that this count is likely to increase in the near future to 1400, linked to the prioritisation of veterinary presence in the protection zone (Northern Communal Area);

- Staff at all levels generally showed skills and competence in their tasks, as well as knowledge in the procedures and administrative tools available;

- Insufficient resources and organisation were observed for some routine tasks (certification of game trophies) or emergency tasks (intensive surveillance for FMD following incursion of

buffaloes in the free zone), for which no assessment of needs was available;

- As noted in the 2009-8326 report, official vehicles are available in limited quantities and sometimes ill-suited, but this is completed by a compensation scheme for the use of private vehicles. The scale for reimbursement of expenses for use of private vehicles has not been reviewed for more than five years, which, according to several field officials, puts a strain on the field presence.

5.1.2.3 Supervision

A circular (V12/2011) sets out the frequency of meetings and supervision of each administrative level, with the documentation expected from each visit. The Chief Animal Health Technician (AHT) is to visit quarterly all subsections; the control AHT is to visit twice yearly all sections and subsections; the State Veterinarian is to visit all subsections once every year, and the regional Chief veterinarians must visit twice yearly the sections under their responsibility.

Observations:

- the prescribed frequency was usually not followed, and the scope of higher level of supervision did not include the check of supervision performed by lower level;

- Corrective actions were required in the reports, but deadlines and control for completion were seldom recorded;

5.1.2.4 Procedures and documentation of controls

The CA continues to work according documented procedures. Standard operating procedures (SOPs) and report forms are available and updated (e.g. for checks at assembly centres or auctions, or for farm inspection), reports are required and issued, activity log-books were found in offices visited. Monthly reports were sent from State veterinary offices (SVOs) to the central level, with valuable information.

Observations:

- Some records were ill-organised (e.g. registers of the quarantine facilities, with a format and records which did not allow to keep an updated registration of presence of animals, missing records, sheet and non-chronological records of controls at control post) or lacking (e.g. unrecorded checks on the veterinary movement permits, for official controls performed during movement or at destination); the organisation of records was subject to a specific recommendation in report 2009-8325;

- Many internal supervision occurrences remained undocumented. Many documents related to official controls could not be found on the spot in the offices visited, but were presented at a later stage to the audit team;

- Unreliable and inauthentic official documents were found in relation to the case of roaming buffaloes (see section 5.3.2.3). The CA was unable to explain these occurrences.

5.1.2.5 Notification system

The system for notification of international organisations and partners (including the European Commission) in case of suspicion or confirmation of FMD outbreak, is described in the contingency plan.

Observations:

- This system was not followed in 2011, when the CA identified viral antigen in a roaming buffalo in the FMD free-zone.

5.1.3 Conclusions

The CA remains well organised, but limitations in staff and resources are in some instances insufficiently addressed. The CA operates according to documented procedures, but documentation of controls still represent a weakness which is insufficiently identified by the well-structured internal supervision system. The confidence in official documents was altered by the unexplained production of some unreliable and inauthentic such documents.

5.2 HOLDING REGISTRATION, ANIMAL IDENTIFICATION, MOVEMENT CONTROLS

5.2.1 Legal requirements

Part 1 of Annex II to Regulation (EU) No 206/2010 establishes a regionalisation of Namibia for export of fresh meat from domestic bovine, ovine, caprine animals, and of certain farmed and wild non-domestic ruminants, which must come from the NA-1 region.

Part 2 of the same Annex lists the model certificates and specific requirements for each type of meat. For bovine, ovine and caprine animals, and farmed non-domestic ruminants, the animal health requirements include that:

- the meat has been obtained from animals that have remained in the same territory since birth or for at least three months before slaughter, (unless introduced from another territory approved by the EU);

- the animals have remained for at least 40 days in holdings before dispatch. Dispatch to the slaughterhouse must be either direct, or can be for domestic species through one one approved assembly centre, without coming into contact with animals of different health status.

Wild ruminants must have been killed at a distance of more than 20 km from the borders of non-authorised countries or territories for import of this fresh meat to the EU.

Article 8.5.4 of the OIE Code lays down principles and guidance with regard to the definition of FMD free zones where vaccination is not practised. Susceptible animals in both types of FMD free zones should be protected from neighbouring infected countries or zones by the application of animal health measures that effectively prevent the entry of the FMD virus, taking into consideration physical or geographical barriers.

5.2.2 Findings

5.2.2.1 Regionalisation

The system for regionalisation remains the same as described in the 2009-8325 report, with three zones in the country: the infected zone, the protection zone, and the free zone. A double cordon fence physically demarcates the limits between the zones, and the borders at risk (preventing the introduction of buffaloes); further fences are kept within the free-zone, but do not play a role in further regionalisation.

Movements of all cloven-hoofed animals or untreated products of animal origin (meat, milk, hides, trophies) out of the infected zone are prohibited. Movements of cattle from the protection zone to the free zone are also prohibited. Movement of small ruminants are allowed, following official identification (brass ear-tag) and a first quarantine period of 21 days in a station in the protection zone. The animals are kept during this period with sentinel cattle, which are sampled 14 days after arrival of the small ruminants for detection of FMD antibodies. After this first quarantine, the small ruminants are moved to the free zone where they are subject to a further 90 day-stand-still, at a quarantine station or at the farm of destination. Movement of products of animal origin from the protection zone to the free zone is also restricted.

Ten veterinary control posts are set between the zones, controlling the movement of animals and products of animal origin.

Observations:

- The maps produced by the CA to describe the regionalisation in place are not accurate: no control post is indicated between the infected and protection zone; the sketch of the border between the two zones suggests that wildlife parks harbouring virus-carrier buffaloes are located in the protection zone; some quarantine stations are indicated as being in the free-zone, when they are in the protection zone;

- The cordon fences are subject to close control, with dedicated teams patrolling along. Western/central State Veterinary Office (SVO) (close to Etosha park, a buffalo-free game park in the protection zone) regularly reports significant breaches of integrity of the fence due to wild animals and humans. The fences in the North-Eastern part of the country are being reinforced (electrification, to be completed by May 2013) following the incursion of buffaloes. One of these buffaloes could be traced back from a game reserve in the infected zone; its presence in the free zone some 400 km further South was explained by the CA by a period of flooding and extensive work on the fences of the game reserve. The buffalo was suspected to have roamed through the neighbouring country, before re-entering Namibia.

- Whereas the CA stated that movements of game cloven-hoofed animals is prohibited from the protection zone to the free zone, the Wildlife management authority indicated that such movements do occur, after quarantine (in Etosha Park) and under supervision of the DVS. No procedure describing the conditions for such movements was available.

- The procedure for movement of small ruminants from the protection zone to the free zone is based on the detection of fast contamination of sentinel cattle. New instructions require that cattle and small ruminants are kept closer (gathered together at night), in line with recommendations made by the 2009-8325 report.

- The movement protocol for small ruminants from the protection zone to the free zone does not comply with the OIE recommendations for movement of animals from an infected zone or from a zone with vaccination (requiring testing of the animals to be moved).

- The quarantine stations visited were not exclusively used for quarantine activities. The records of activities were incomplete, not reflecting this concurrent use. Officials indicated that animals under quarantine are kept in sections distinct from those with other animals in the station, but this was not documented; no procedure was in place to guarantee adequate isolation of the quarantined animals. Quarantine registers were available, but the format developed at local level did not allow the presence of animals at a set time to be determined, and the registers were incomplete: the fate of up to 40% of animals entering was unaccounted for.

- The control post between the protection and the free zone visited performed round-the-clock controls, but did not systematically document its activities. It was not required to indicate the checks performed on the movement permits, and did not record in its log-file all vehicles transporting risk material passing through the post.

5.2.2.2 Controls within the approved zone

Holdings registration, animal identification and movement controls within the free zone are described in the audit report 2011-6120 for livestock, and were reviewed during the combined audit 2013-6774. Cattle identification operations also take place in the protection zone, but are done with ear-tags of different colour. Movement restrictions, for animal health reasons or for lack of movement report, are entered in the database, thus preventing the issuance of new movement permits for non-complying holdings.

A two farms-wide band within the free zone but along the fence separating it with the protection zone, is defined by the CA as an "intensive surveillance zone". Animals may be moved from this area into the rest of the free zone only with a three-week pre-notification and isolation in the farm (or for direct slaughter at quarantine abattoir).

Farmed game animals are kept in game-proofed fenced farms. A (hand-written) movement permit is required for the movement of such animals, but is not captured in the central database.

A limited population of buffaloes is present outside the infected zone[1]: one population is located in the protection zone (Nyae Nyae conservancy), and one in a confined reserve in the free zone (Waterberg plateau).

Observations:

- The central database automatically restricts both holdings of departure and of arrival, if the movement is not confirmed within a week, or the movement permit cancelled. However, it does not flag declaration of movements from a holdings of animals which have not been previously declared as born or arrived, thus endorsing undeclared movements.

- The central database displays the history of restrictions for each holding, thus allowing to check the effective periods of application of such restrictions. However, the information displayed was not always clear, as de-restrictions did not systematically appear (history

1 http://www.nnf.org.na/RARESPECIES/InfoSys/IMAGES/buffalo/Fg12-Present%20distribution.gif

showing a series of restrictions applied, without de-restrictions between them);

- Wild game can be shot in the free zone, with no particular restriction related to the distance to the borders: special arrangements must be put in place if their meat is to be exported to the EU, to guarantee that they were not shot close to the borders.

5.2.2.3 Import controls

Import conditions are described in the audit report 2011-6120. Controls performed at the border inspection post include documentary check, and limited (and undocumented) identification and sanitary checks (as the posts do not have unloading facilities). The vehicles remain sealed until their final destination, where the SVO must check the consignment. The CA suspended all imports of animals susceptible to FMD from South Africa on March 2011, following the declaration of FMD outbreaks in this country.

A new module is under development in the central database to allow for the registration of movement of imported animals from the border inspection post to the holding of destination.

Observations:

- The documentation of controls at the border inspection post was limited: no copies of import certificates or import permits were kept; the registers of activities were kept, but on various unrelated sheets and not always in chronological order;

- The registers and monthly reports of the border inspection post showed evidence of application of the ban of import of animals from South Africa. Restriction on holdings having imported animals in the previous weeks was also ordered, and could be demonstrated in the central database for two of the four holdings concerned; the SVOs confirmed that all holdings were visited and restricted.

5.2.3 Conclusions

Effective measures are in place to give effect to regionalisation of the free-zone, and have been improved since last audit, even if their documentation was in a number of cases deficient. The standard for movements of small ruminants from the non-free zone and insufficient records (in particular for the concurrent introduction of other animals in quarantine station) represent a weakness in the system, of rather limited consequence when assessed within the frame of all measures in place. The risk represented by the (uncommon) introduction of wild animals from the non-free zone was not reviewed. The prevention of incursion of buffaloes into the free-zone remains a major challenge, which is addressed by the CA.

5.3 DISEASE SURVEILLANCE AND CONTROL

5.3.1 Legal requirements

Part 2 of Annex II to Regulation (EU) No 206/2010 establishes a regionalisation of Namibia for export of fresh meat from domestic bovine, ovine, caprine animals, and of certain farmed and wild non-domestic ruminants, which must come from the NA-1 region. The territory must have been free from FMD without any vaccination for 12 months.

For all but wild ruminants, the animal health requirements also include that:

- the animals have remained in holdings where no FMD vaccination has been performed, not under official restriction, and around which no case or outbreak of FMD has occurred in the previous 30 days;
- They have been transported in vehicles cleaned and disinfected before loading, without contact with other animals of different status, to a slaughterhouse around which no FMD case/outbreak was identified during the previous 30 days, and were submitted to ante-mortem inspection, with particular check for FMD signs.

For ovine and caprine animals and farmed non-domestic ruminants, the holdings from which they are obtained must not be subject to prohibition as a result of brucellosis during the previous 6 weeks. The holdings of farmed non-domestic ruminants must be subject to regular veterinary inspections to diagnose transmissible diseases.

Wild ruminants must have been killed in an area which has not been under restriction for FMD for the last 60 days. They must then have been transported as soon as possible to a game-handling establishment around which no case of FMD has occurred for the last 30 days (with a derogation , applying biosecurity measures for meat preparation)

EU standards concerning notification of FMD suspect cases are laid down in Article 3 of Council Directive 2003/85/EC.

Articles 8.5.42 to 8.5.47 of the OIE Code lay down principles and guidance with regard to general conditions and methods for surveillance of FMD.

5.3.2 Findings

5.3.2.1 FMD passive surveillance

As part of the general surveillance, DVS systematically inspects all holdings. All commercial farms are visited once a year by an AHT, as announced by the CA in 2009, but the frequency of inspections of the communal areas has remained the same (twice a year). Specific SOPs have been established for both type of inspections.

Commercial farms must also submit a bi-annual animal health declaration. The forms for declaration and inspection have been updated; once filled, they are sent to a central capture unit, before being sent back to the SVO for their filing.

In addition, the CA provides veterinary care (mainly to communal areas), thus increasing the frequency of presence with such areas. Livestock is also inspected in case of export. Livestock auctions are supervised by the DVS, and surveillance is also performed during ante-and post-mortem inspection in 7 export slaughterhouses (see report 2013-6774).

Observations:

- Inspection and declaration reports were not always available for the holdings selected at the SVOs, even for those dating back from 2011 or 2010. One SVO was keeping a partial copy of the declarations or inspections sent to the central capture unit, thus evidencing their reception (and absence of return into the file). The CA indicated that there is a back-log in capturing data of inspection reports into the database which make it currently not

operational for epidemiological statistics;

- The SOP for inspection of holdings requires that the AHT sees 80% of the herd. The herd composition is determined according to the declaration, and not cross-checked with the data from the central database; the inspections do not include check on identification or updates of the database (e.g. on reporting deaths);

- In one place, the AHT was documenting its inspection on the farm registers (date and signature); this best practice was not observed in other places.

5.3.2.2 FMD active surveillance

Routine active surveillance in cattle has been performed in in 2010 and in 2012 in the protection zone, at the border with Angola, and in the constituencies where vaccination is practised. The results for the 2010 survey were available.

In addition, active surveillance is performed in buffaloes, in collaboration with the wildlife management authority from the Ministry of Environment. Several populations of buffaloes have been subject to FMD testing. Over the last decade, several serological tests were performed on a representative number of buffaloes from the free zone (2004, 2006, 2008, 2010), or from the protection zone (2007, 20-10, 2011), all with negative results. Serological and probang tests have also been performed on buffalo populations from the infected zone, confirming there the presence of FMD virus of serotypes SAT 1, 2 and 3.

FMD Serological tests are also carried out on other wild animals, for instance in case of international sales (one occurred in 2012 in the park in the free-zone hosting buffaloes). A serological survey was carried out at the time of the audit in Etosha park in antelopes, with a view to declare it as FMD free.

Observations:

- The laboratory sequence used for the serological survey did not follow the designed protocol and was not in line with the OIE recommendations: instead of using virus neutralisation test as a confirmation test in case of NSP-ELISA positive, a liquid phase ELISA was used instead. This deviation from the protocol was not explained or validated;

- The NSP-ELISA results for the 2010 survey were in line with the expected specificity of the test in the regions without vaccination, but not in the vaccinated region. The follow-up of positive results was not in line with the described protocol, and insufficient to reliably conclude to the absence of virus circulation.

- Since 2010, no documented serological survey has been performed in buffaloes in the park in the free zone, situated at a comparatively small distance of the place where free-roaming buffaloes were spotted. The CA indicated that 10 buffaloes were tested in 2012 for a sale, but the laboratory tests results only referred to antelopes. The fence has been considerably reinforced since then, and testing should be performed shortly, as an international sale is planned (linked to a need of reducing the density of animals in the confined area).

5.3.2.3 FMD control

The FMD contingency plan was last updated in January 2013. Addressing the recommendation from the 2009-8326 report, the shortcomings noted during this audit have been rectified.

Out of the ten samples sent to the laboratory for suspicion of FMD in the last three years; three originated from the free zone. All suspicions were discarded on the basis of negative serology, and no formal control measures had to be applied.

In 2011, samples from buffaloes shot while roaming in the FMD free zone were sent for analysis. One of them was serologically and PCR positive. It came from an animal which had been identified (ear-tagged) during a survey performed the previous year in the a game reserve in the infected zone, and found carrier of SAT-2 virus. At the request of the European Commission, the CA described at the time the measures taken:

- immediate movement restriction from the region affected, and farms having received animals from this region; setting up of road blocks,

- intensified surveillance , including documented inspection with 100% close clinical check of cattle in the restricted area; inspections to be performed every 7 days for four times in the restricted area (981 "villages" and 152 commercial farms), and at least twice 14 days apart in farms that received animals from the area (119 farms and villages);

- serological surveillance in cattle from communal area, with 65 samples to be taken in each of the restricted epidemiological units.

Observations:

- The required SVOs had most equipment listed in the contingency plan; only non-biosecure wooden transport boxes for suspect samples were available. Transport medium manufactured by the central veterinary laboratory (CVL) was adequately stored, but no check of the pH of the finished product is performed at the time of manufacturing or at the time of use.

- The FMD contingency plan does not contain any section on the actions to be taken in case of roaming buffalo in the free zone;

- Organ (including "throat") and blood samples taken from buffaloes were sent refrigerated, without transport medium to the CVL with limited information in the accompanying disease report form (no indication that one of the buffaloes at least was identified with an ear-tag);

- No map was available at the SVO to define and demonstrate the suitability of the area subject to restriction and surveillance; no analysis of staff requirements for the extensive work to be done was available;

- Reports on surveillance of communal areas did not identify with precision the places visited, and did not report the number of cattle seen (which could have been cross-checked with the number of cattle registered);

- One farm in the restricted area was visited during the audit. The farmer recalled three

official visits, but only one was documented; this report indicated that 100% of cattle had been examined, but the total number stated corresponded to half of the cattle population on the farm. According to the farmer, cattle were observed by the official from a distance, and close clinical examination made only on suspicious animals;

- Movement restriction notices were issued to the farmers. At the farm visited, the presence of two notices for the same event, with two different dates (August and September 2011), and reference in one of them to events occurring at a date posterior to the date of the notice, cast serious doubt on the reliability of these official documents;

- 1,424 blood samples were collected; no sampling plan or record was available. As a result of undocumented management decision, only 240 of them were tested. The rest were discarded. No documentation on the origin of the samples was kept at the laboratory or at the SVO.

5.3.2.4 FMD vaccination

Vaccination against FMD is carried out in the infected zone and the two most Eastern Constituencies of the protection zone, on a bi-annual basis, with a trivalent (SAT 1, 2 and 3) vaccine. The implementation of vaccination was not reviewed during the audit.

In line with the actions proposed by the CA following the recommendations of audit 2009-8326, a post-vaccination serology was performed in 2009. Raw data were available, but not their context or interpretation (protocol, discussion, conclusion).

The CA also collected field viruses, as indicated in the action plan, but these, contrary to the action planned, were not submitted for analysis of their relationship with the vaccine strains. The CA is currently working on protocols to check the efficacy of the vaccine (with one or two injections 21 days apart), and possibly a comparative sero-neutralisation test of both field or vaccine virus strains.

5.3.2.5 Ovine and caprine brucellosis

According to the current legislation (animal disease act of 1954), brucellosis is a disease of immediate notification. Practically, this is not enforced: farmers report abortions on a 6 monthly basis. In case of confirmation, the CA advises the farmer, but does not impose measures. Few abortions of small ruminants are investigated every year by the Central veterinary laboratory (15 cases in 2012). *Brucella melitensis* was last identified in 2011.

The voluntary accreditation scheme described in the FVO report 2009-8326 was last reviewed in July 2011. Both breeding sheep and goats must be tested (and preferably males). The presence of one positive test result does not disqualify the flock from the scheme any longer: the positive animal must be removed from the flock, and a decision has to be taken on a case by case basis.

The Central database includes automatic checks of eligibility of the flock of origin of small ruminants to be moved, and automatically declassify the holding of destination if it introduces animals from non-approved holdings, thus responding to the recommendation of audit report 2011-6120.

<u>*Observations:*</u>

- The scheme was not clear regarding the definition of the flock. In a farm with several owners, the status was awarded separately and independently for each owner, making it possible to have animals of various status in the same holding;

- Brucellosis testing was also performed for breeding purposes. An accreditation was awarded to a flock which tested some animals for breeding, although the minimum number of animals to be tested had not been reached;

- Animals sampled were not always uniquely identified, making a possible follow-up problematic.

- The farmers participating in the scheme are not required to immediately notify any suspicion of outbreak of brucellosis, despite the fact that the scheme does not guarantee the absence of the pathogen;

5.3.3 Conclusions

The passive surveillance system is well structured in the free zone. The active surveillance in the protection zone presented a number of shortcomings, which have no direct impact on the status of the free zone. However, the very poor implementation and documentation of control and surveillance performed following the incursion of virus-carrier buffaloes in a disease-free area, indicate that the risk was not adequately managed at the time, and show that the guarantees provided by the CA to the European Commission were not fulfilled.

The absence of evaluation of the suitability of the vaccine compared to the recently isolated field strains of virus impacts the capacity of the CA to ensure an efficient containment vaccination programme in the non-free zone (current or in case of possible outbreak), but does not affect its capacity for export to the EU from the free-zone.

The brucellosis scheme in place to ensure that ovine or caprine meat to be exported to the EU does not come from holdings under restriction because of outbreak of brucellosis in the previous 6 weeks has been notably improved on several aspects. Implementation is not always in line with the scheme, but even if it was, the whole programme cannot be considered as providing a free status of the flocks (as per OIE or EU regulations). Therefore, the main weakness remains that the programme does not ensure that suspicions of outbreaks are promptly notified and investigated.

5.4 LABORATORIES

5.4.1 Legal requirements

Article 46 of Regulation (EC) No 882/2004 provides for the verification of compliance or equivalence of third countries legislation and systems with EU animal health legislation. Particular account should be taken of the diagnostic facilities available to Competent authorities.

Article 12 of Regulation (EC) No 882/2004 lays down the standard for EU laboratories performing analyses of samples taken during official controls: these laboratories must be designated by the competent authorities, and operate and be certified according to ISO/IEC 17025 standard.

Chapter 2.1.5 of the OIE Manual lays down the diagnostic techniques, requirements for vaccine, and vaccine matching tests for FMD.

EU standards for ovine and caprine brucellosis tests are laid down in Annex C to Council Directive 91/68/EEC. Chapter 2.7.2 of the OIE Manual lays down the diagnostic techniques for ovine and caprine brucellosis.

5.4.2 Findings

The Central Veterinary Laboratory (CVL) performs the same tests related to the scope of the mission as indicated in the 2009-8325 audit report:

- for FMD, NSP ELISA (3ABC) (around 2,000 tests per year). Samples requiring follow-up analytical tests are sent to OIE reference laboratories (one of them still not ISO 17025 accredited, the other one for which the scope of accreditation does not include virology of FMD serology).

- for brucellosis, serological, microbiological and PCR tests.

The CVL is in the final stage for reaching ISO 17025 accreditation. SOPs were available, and proficiency testing had been performed recently for both FMD and brucellosis (complement fixation test), as indicated in the response to the relevant recommendation from the 2009-8326 report.

Observations:

- The record keeping of incoming samples and outgoing samples was very poor: the log-book registering the incoming samples had very scant information, not always kept in chronological order; one sample (of buffaloes) was registered as having arrived at two different dates; no record of or copies of documentation sent together with FMD samples was kept. It was impossible to determine when the CVL received the positive FMD viral antigen result from the OIE reference laboratory. No prioritisation system was in place for FMD samples (between samples received for sero-surveillance, quarantine, or suspicion).

- The SOP for diagnosis of FMD was not clear on samples requiring follow-up analytical analysis in case of NSP ELISA negative results. The CVL staff could not determine during the audit at the laboratory, whether they sent to the OIE laboratory the organ samples of the roaming buffaloes tested negative. Documentation was later presented, showing that samples were indeed sent for for further analysis two weeks after reception.

5.4.3 Conclusions

Despite being close to being accredited for its competency, and therefore having a quality system, the laboratory showed serious deficiencies in the general quality standards for tests and activities recording and reporting, and for FMD diagnostic procedures, affecting the reliability of the active surveillance activities, as well as investigation of suspicions in buffaloes.

5.5 Controls of Game trophies exported to the EU

5.5.1 Legal requirements

Regulation (EC) No 1069/2009 of the European Parliament and of the council lays down the rules for animal by-products. Commission Regulation (EU) No 142/2011, implementing the previous one, defines the specific requirements for the importation of game trophies and other preparations from animals. These are summarised in Chapter II of Annex XIV to the Regulation.

Game trophies must come from an establishment registered by the competent authority, where the conditions of Chapter IV of Annex IX of Regulation (EC) No 142/2011 are applied (structural and operational hygiene, record keeping).

Treated game trophies from ungulates may come from any third country, whereas non-treated game trophies from the same animals must come from countries authorised for import of fresh meat of ungulates respectively.

When the game trophies consist solely in bones, horns, hooves, claws, antlers, teeth, hides and skin from birds and ungulates, these may be imported after treatment, which may consist in;

- complete taxidermy treatment;

- or, for preparation solely of bones, horns, hooves, claws, antlers and teeth : they have been boiled to remove other parts, and been disinfected (in particular with hydrogen peroxide for bones);

- or, for preparation solely of hides and skin, they have been dried, or salted for 14 days or subject to a preservation process other than tanning.

5.5.2 Findings

5.5.2.1 Registration and game trophies establishments controls

The CA developed a documented system for approval and supervision of game trophies establishments (GTE). Operators wishing to be approved need to meet structural, operational and documentary requirements. The CA reviews SOPs and inspect the premises, and issues a report. The approval is valid for one year, and renewal is based on a new official inspection. Twenty eight GTE were registered in Namibia at the time of the audit.

Observations:

- The lay-out and structure of the approved GTE visited by the audit team was satisfactory, apart from the storage of trophies before and during treatment, which could not be cleaned and disinfected.

5.5.2.2 Traceability and operations

Game trophies from FMD infected zone must be treated and quarantined for 30 days under veterinary supervision prior to movement into the free-zone. They are sent together with an internal certificate in a sealed consignment to the approved GTE at the place of destination, and unsealed

after authorisation of the SVO.

Observations:

- The inspections of the GTE did not include in their scope a check on the records and documentation kept by the operator.

- In the establishment visited, the rules for movement of game trophies from infected zone were not respected, as the operator was receiving unsealed consignment, and the SVO was not informed.

- The internal certificates detailed the treatments to which the trophies were submitted, but did not indicate in which establishment they were performed (and in particular if it was an approved establishment). The internal certificate presented to the audit team was not reliable, as it certified that the trophies went to a 30-day quarantine, when it was issued 11 days after the request from the applicant to send the trophies for treatment.

- The records at the GTE were incomplete: in addition to treating some trophies, the establishment was also receiving treated trophies from other GTEs. There was no separate records for such products, nor any document stating the treatments to which the trophies were submitted.

- The operator was not immersing the trophies (other than skins or hides) in boiling water, but in warm water with detergent, before disinfecting them. Bones were disinfected with hydrogen peroxide, but the disinfectant used for other parts was not documented.

5.5.2.3 Certification

Certificates are usually prepared by the operators of the game trophies establishment. For practical purpose, certificates from all GTE in the country were signed by the SVO in the capital city, before shipment.

Observations:

- No guidelines, instructions or procedures were defined for certification of game trophies.

- The SVO in the capital city had also copies of approval files of GTEs not located under its control. However, the SVOs are not required to forward immediately all updates on the approval of the GTEs under their responsibility.

- Physical checks on the consignments to be certified were done on a random basis, and not documented: the frequency of such checks could not be determined.

- The operator visited, which also received trophies treated in other GTE, was indicating all items as being processed in his establishment (despite the possibility to indicate several GTEs on a same certificate).

5.5.3 Conclusions

The system for supervision of game trophies establishments is well organised, but the certification

system is not entirely reliable. Channelling system of game trophies from the infected zone to the free zone presents notable shortfalls in the official supervision system, but has no impact on the risk of the product treated and exported.

The weakness in movement controls of trophies originating from the non-free zone could be somewhat mitigated by the presence of veterinary control gates, if these controls were evidenced.

6 Overall Conclusions

The Competent authority is in general well organised and acts consistently to maintain the comprehensive system aimed at maintaining the FMD-free status of the zone recognised by the EU for export of meat. The level of guarantees is affected to some extent by weaknesses in the documentation of key operations or decisions.

In particular, the insufficient implementation and/or documentation of actions following the incursion of (FMD positive) buffalo in the disease-free zone affects the reliability of the assurances given by the CA.

The system for supervision of game trophies establishments is well organised, but the certification system is not entirely reliable. Channelling system of game trophies from the infected zone to the free zone presents notable shortfalls, but has no impact on the risk of the product treated and exported.

7 Closing Meeting

A closing meeting was held on 1 March 2013 with the CCA. At this meeting, the FVO audit team presented the findings and preliminary conclusions of the audit.

The representatives of the CCA acknowledged the findings and conclusions.

8 Recommendations

The CA of Namibia are invited to submit an action plan describing the actions taken or planned in response to the recommendations of the report, and setting out a timetable for their completion, within 25 working days of receipt of the report.

N°.	Recommendation
1.	To review the records requirements, filing system and documentation of official controls at all levels (including farms, quarantine facilities, control and border inspection posts, veterinary offices, laboratory, game trophy establishments) in order to demonstrate that they are performed effectively. (Article 8(1)(b) of Council Directive 2002/99/EC, and Article 48(4)(b) of Regulation (EC) No 2004/882)

N°.	Recommendation
2.	To ensure that sufficient resources (including staff) are available both for routine and emergency animal health surveillance, control and certification tasks.(Article 8(1)(b) of Council Directive 2002/99/EC)
3.	To ensure that accurate, and when necessary, rapid information is supplied to the Commission on the existence of infectious or contagious diseases, and on the rules for prevention of diseases (including regionalisation). (Article 8(1)(h) of Council Directive 2002/99/EC)
4.	To give reliable assurances regarding the FMD health status of buffaloes located or encountered in the free zone.(Article 8(1)(g) of Council Directive 2002/99/EC)
5.	To develop rules and protocols (possibly in the contingency plan) to be followed and evaluation of resources needed in case of identification of - possibly FMD carrier - roaming buffaloes in the free zone. (Article 8(1)(i) of Directive 2002/99/EC, with equivalence to Annexes XVII and XVIII to Council Directive 2003/85/EC)
6.	To ensure that suspicions of outbreaks of brucellosis in holdings providing sheep and goat for export of meat to the EU are notified and investigated. (point II.2.3.(b) of certificate OVI from Commission Regulation (EU) No 206/2010)
7.	To review the certification system for game trophies, in order to ensure that it is based on effective and comprehensive supervision of the operations of the game trophy establishments, and that the accuracy of the data certified can be verified. (Article 4(a) of Directive 96/93/EC)

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6782

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 999/2001	OJ L 147, 31.5.2001, p. 1-40	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Reg. 206/2010	OJ L 73, 20.3.2010, p. 1–121	Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements
Reg. 142/2011	OJ L 54, 26.2.2011, p. 1-254	Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products

Legal Reference	Official Journal	Title
Dir. 2002/99/EC	OJ L 18, 23.1.2003, p. 11-20	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
Dir. 2003/85/EC	OJ L 306, 22.11.2003, p. 1-87	Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC