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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO) 2013-6792 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BOTSWANA

FROM 04 TO 11 MARCH 2013

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

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 animals and game trophies from ungulates, to the European Union (EU).

Despite a good record of the Competent Authorities for detection and control of Foot-and-Mouth Disease (FMD) outbreaks, the surveillance in place is insufficient to guarantee the maintenance of the free status of two zones at particular risk, either because of the recent and repeated incursion of (FMD carrier) buffaloes from infected zones, or because of the unexpected and unexplained multiplication of virus-carrier wild animals and goats in a containment zone. This last occurrence affects a slaughterhouse listed for EU export (but not exporting) situated at less than 10 km from the containment zone. The effective further regionalisation measures between diseases control zones within the EU-listed territories limit the geographical implication of these issues.

The efficacy of FMD control activities is undermined by the poor expert support and doubts about the quality standards of the diagnostics laboratory and the vaccine manufacturer.

The game trophies establishments were under effective official supervision, while certification of these commodities presented minor shortcomings.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
BNVL	Botswana national veterinary laboratory
BVI	Botswana vaccine institute
CA	Competent Authority
CCA	Central Competent Authority
DVO	District veterinary office
DVS	Directorate of Veterinary Services
DCZ	Disease control zone
EA	Extension area
ELISA	Enzyme-linked immuno-sorbent 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 protein
OIE	*World organisation for animal health*
PCR	Polymerase chain reaction
SOP	Standard operating procedure

1 Introduction

This audit took place in Botswana from 04 to 11 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)/2013-6866 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.

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 animals and game trophies of ungulates, to the EU.

Particular attention was paid to:

- review the surveillance and control system in place for foot-and-mouth disease (FMD), with a particular focus on the measures taken following the last outbreak notified to the Commission in the disease control zone, and on the measures taken following the recommendations of the FVO audit report DG(SANCO)/2009-8326 and 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 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		1	
Quarantine station		1	
Livestock holding		2	Feed-lots, bovine holding
Assembly centre		1	
Game trophies establishment		2	
Laboratory		2	

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.

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

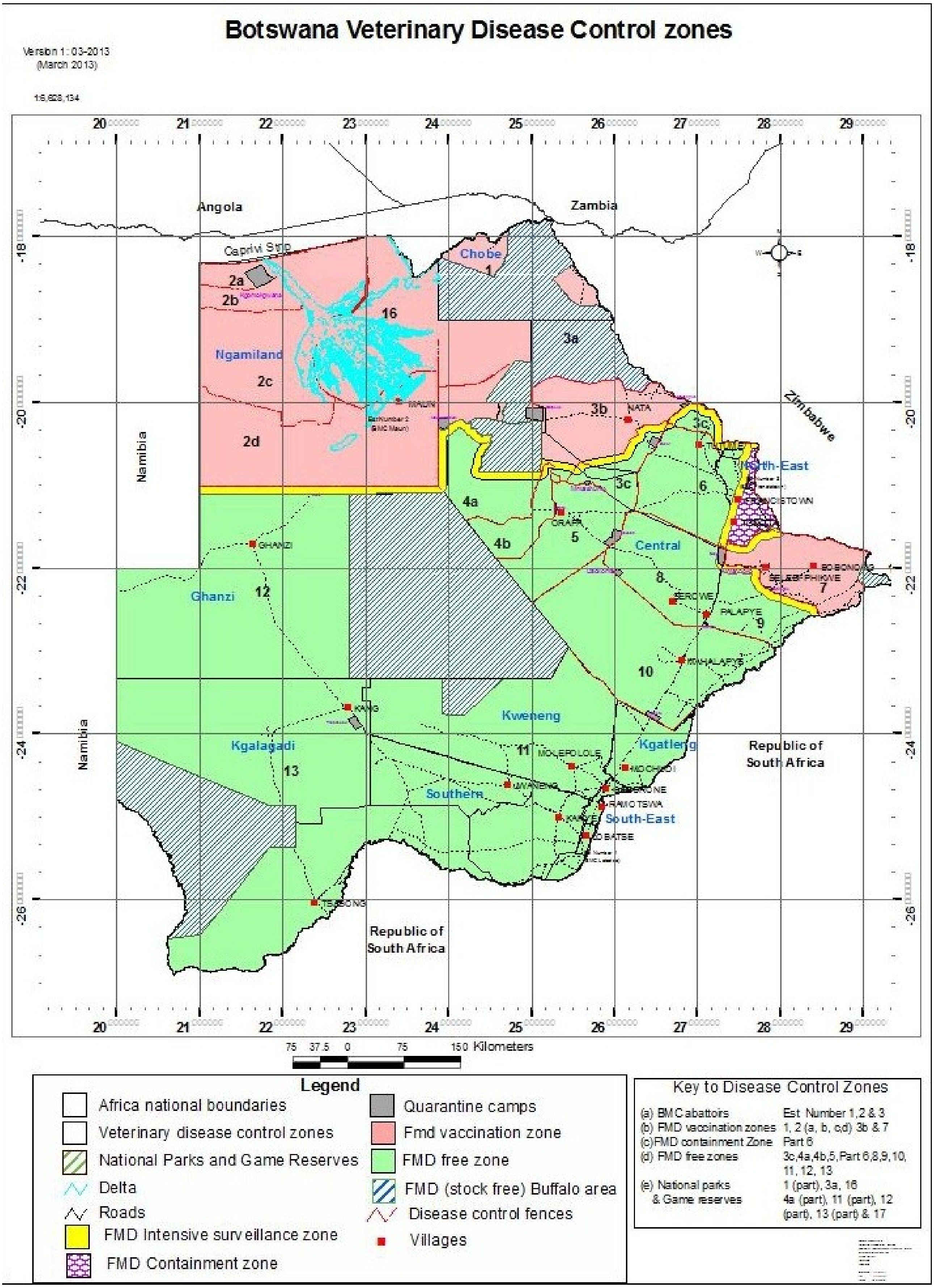
Botswana has been regionalised for the purpose of export to the EU of de-boned and matured meat from bovine, ovine and caprine, farmed and wild non-domestic ruminants, but the country only exports bovine meat. The regionalisation, as stated in Regulation (EU) No 206/2010, excludes a Northern and an Eastern area of the country.

A new territory (BW4) was authorised on 17/02/2011 for the purpose of export of meat to the EU (Amending Commission Regulation (EU) No 144/2011), after the recognition by the World organisation for animal health (OIE) of this veterinary disease control zone (zone 4a) as being FMD free without vaccination, and the CA announcement of a creation of a 10 km intensive surveillance zone segregating the free zone from other parts of the country.

The animal health situation was last described in the FVO audit report DG(SANCO)2009-8325[1] (hereafter, 2009-8325 report). Since then, the CA have notified 5 FMD outbreaks to the OIE, one of which was located in one authorised territory (BW1) for export of meat to the EU. This territory was consequently de-listed from 11/05/2011 (amending Commission Regulation (EU) No 801/2011). After control measures and exclusion of a portion of this territory, the main part of BW1 was recognised by the OIE as having regained its free status. This new BW1 territory (excluding an "intensive surveillance zone between the border with Zimbabwe and the highway A1", hereafter called "containment area"), was re-authorised for export of meat to the EU from 26/06/2012 (Amending Commission regulation (EU) No 546/2012).

Around 700 tonnes of bovine meat were exported annually from Botswana to the EU in 2011 and 2012.

1 FVO reports can be consulted at: http://ec.europa.eu/food/fvo/ir_search_en.cfm



Botswana Veterinary Disease Control zones
Version 1: 03-2013
(March 2013)
1:6,628,134
Angola
Zambia
Caprivi Strip
Chobe
Ngamiland
Namibia
Zimbabwe
North-East
Central
Ghanzi
Kweneng
Kgatleng
Kgalagadi
Southern
South-East
Republic of South Africa
MAUN
NATA
ORAPA
GHANZI
SEROWE
PALAPYE
MAHALAPYE
KANG
MOLEPOLOLE
MOCHUDI
GABORONE
RAMOTSWA
KANYE
LOBATSE
TSABONG
FRANCISTOWN
BOBONONG
SELEBI PHIKWE
1
2a
2b
2c
2d
3a
3b
3c
4a
4b
5
6
7
8
9
10
11
12
13
16
75 37.5 0 75 150 Kilometers
Legend
Africa national boundaries
Veterinary disease control zones
National Parks and Game Reserves
Delta
Roads
FMD Intensive surveillance zone
FMD Containment zone
Quarantine camps
Fmd vaccination zone
FMD free zone
FMD (stock free) Buffalo area
Disease control fences
Villages
Key to Disease Control Zones
(a) BMC abattoirs — Est Number 1,2 & 3
(b) FMD vaccination zones — 1, 2 (a, b, c,d) 3b & 7
(c) FMD containment Zone — Part 6
(d) FMD free zones — 3c,4a,4b,5,Part 6,8,9,10, 11, 12, 13
(e) National parks & Game reserves — 1 (part), 3a, 16 4a (part), 11 (part), 12 (part), 13 (part) & 17

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 legislation. 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

No new legislative act pertaining to the scope of the mission had been introduced since 2009. A modification of the cattle identification rule was under preparation, in order to replace the current electronic bolus by a double ear-tag, one of which containing a microchip. This act was expected to come into force within the next few months. Another legislative act, aiming at defining the notion of holding, was at an early stage of preparation.

5.1.2.2 Resources, organisation and supervision

The organisation of the CA has remained as described in the 2009-8325 audit. The DVS remains the CA in charge of animal health matters for all animal species. The DVS is present in the field through 17 District veterinary offices (DVOs) and 28 sub-DVOs. These offices supervise a total of 294 extension areas (EA). The staff level was of 441 posts (1.5% vacant posts), seconded by close to 3,000 support staff (for maintenance of fences, controls at gates, and vaccination and administrative tasks). An evaluation of the performance of the DVS by the OIE was completed in 2010, and published on the OIE website.

A system of supervision has been established, in response to a recommendation of the 2009-8325 report. A plan for supervision, with schedule of inspections and documentation requirements has been set in July 2011. Reports of inspection of the EAs were available in the DVOs or sub-DVOs visited; they showed that the frequency of supervision was not respected. No frequency or standard form for inspections/supervision of higher levels was set in the plan, and these were not always documented; these did not include a check on the performance of supervision to the lower level.

5.1.2.3 Procedures and documentation of controls

Procedures and guidelines for disease surveillance and epidemiological investigations were available, including forms for data collection, as announced in response to a recommendation of the

2009-8325 audit report.

Observations:

- Files for disease surveillance, epidemiological investigations and disease control were available at the offices visited;

- No geographical information system was available for field services. No large-scale maps were available at the DVOs visited, except for one DVO,where delimitation of the infected area and location of farms and crushes (communal epidemiological unit) were indicated.

- Activity reports from EA, sub-DVOs and DVOS were regularly issued. In several instances, the problems and issues related to veterinary fences reported in the EA reports were not relayed from the sb-DVO/DVOs reports to the higher levels.

5.1.2.4 Notification system

The CA notified 5 FMD outbreaks between 2010 and 2012 to the OIE. Three of them occurred in a FMD vaccination zone, one in a non-EU free zone, and one in a EU free zone. Many follow-up reports have been sent to the OIE for each outbreak, and in particular for the outbreak in the EU free zone.

Only this last case was still unresolved according to the information sent to the OIE. The last follow-up report dated from October 2012, indicating that FMD virus was isolated from a goat in the area in August 2012.

Observations:

- The FMD outbreaks in the free zones were subject to "immediate notification" to the OIE, but were notified 5 days after their confirmation; the European Commission was also kept informed of the outbreak in the EU authorised /territory within days by the CA.

- Some inconsistencies were noted in the follow-up reports from the FMD outbreak in the EU-free zone (such as the date of last clinical case).

- The follow-up report from the outbreak in the EU free zone did not indicate that the virus was of a different topotype from the one initially isolated; none of the further virus isolation episodes, from samples collected in October and November 2012 from goats and wild animals in this area (SAT1, SAT2 and SAT3), had been notified to the OIE, or to the European Commission. The subsequent vaccination campaign of small ruminants (in January/February 2013) were not notified either. (see section5.3.2.3. of the report).

5.1.3 Conclusions

The competent authorities act in a transparent way and have improved their system to verify the effectiveness of official control activities, but the supervision is still not fully functional. The lack of access to geographical information system on a routine basis is a significant constraint for the effective supervision of the performance of official controls at local level.

The usually good level of communication to international bodies has been recently marred by the

absence of reporting recent outbreaks and vaccination operations in a containment zone.

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 Botswana 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 BW-1, BW-2 or BW-3 regions. Bovine animals may also come from BW-4 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 direct, without contact with animals of different health status.

Article 8.5.4 of the OIE Code lay down, respectively, 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 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 Registration, animal identification

The CA has registered a number of farms and feed-lots, as well as "crushes" for communal land (making up about 70% of the country, for 84% of national herd). They are entered in a central database, with their geographic coordinates. Cattle are identified with zonal and owner's hot brand. Cattle vaccinated against FMD are also additionally identified with an additional specific hot brand. Cattle are also identified with an electronic ruminal bolus in the zones without FMD.

Observations:

- The CA indicated that a module for mapping holdings (geographical information system) was available at the central level. This module could not be demonstrated during the visit to the central database.

- The CA indicated that the crushes change their names and locations, making it impossible impossible to get a comprehensive list of such crushes in a defined area (such as the 10 km intensive surveillance zone, see section 5.2.2.3.). These lists were only be defined by using local knowledge;

- At the crush located in the 10 km intensive surveillance zone visited by the FVO team, 40% of the 20 animals checked did not have a bolus, where the official data from the central database indicted that 191 out of 194 animals present had a bolus. The enforcement of bolus identification was concentrated on a limited number of farms and feed-lots approved for supply to EU listed slaughterhouses (see FVO report 2013-6866). It cannot be used for disease control purpose, as the bolus identification is stopped in case of FMD outbreak in a region, for fear of risk of disease transmission.

5.2.2.2 Regionalisation

The country is divided into 21 veterinary disease control zones (DCZ), out of which 13 are FMD free without vaccination, and constitute the territories authorised for meat export to the EU. The separation between DCZ is materialised by fences, covering more than 6,000 km. The separation between FMD free and non-free DCZ is materialised by a double cordon fences. , The fences can be livestock-proof (1.2 m), game-proof (more than 2 meters), or buffalo-proof (with cables). The CA works with a priority scale for maintenance and upgrading of fences, the higher priority being the international and borders with non-free zones. In addition to regular reports from the EAs on their maintenance, the Director's office carries out annual tour to assess the status of these fences. The growing population of elephants is recognised by the CA as a major challenge for the maintenance of effective fences.

All buffaloes in Botswana are located in the Northern non free DCZ. Movements of cloven-hoofed animals from non-free zones to free zones is prohibited, except for cattle going direct to slaughter. Such movements are allowed if there is no active outbreak in the DCZ of origin, and after a three-week quarantine in one of the five official quarantine stations located at the border between two such zones. Movements of products of animal origin are also restricted.

Observations:

- The project to establish a livestock-free zone between the DCZ 2 and 12, announced by the CA in response to a recommendation of the 2009-8325 report, has not been implemented. Instead, a new protection zone is being established in the south of non free DCZ 2d (Ngamiland), to bring an additional protection to the FMD-free zones bordering this zone: new fences are being established, and FMD vaccination will be prohibited.

- The DVO in charge of DCZ 4a had no responsibility over the fences separating it from the non-free zone. The fence separating it from a game park in the adjoining non-free DCZ was under the responsibility of the Minister of Environment. The Director's office identified in February 2012 the poor state of maintenance of this fence, and recommended DVS to take over this maintenance. The recommendation was not implemented.

- Several incursions of herds of buffaloes had been reported since December 2012 from this game park into the DCZ 4a (herds of 30 to 50 heads). Some of these were shot, but no samples taken to assess their FMD status. No surveillance or restriction was applied to farms in the area. Cattle were also reported having crossed the fence from the free to the non-free DCZ.

- The fence erected along the containment zone was of limited efficacy, as it runs along or through densely populated areas, including villages, and its integrity has been compromised. Many gates had to be organised (most of them with one watchman, the other with a lock

restricting access to owners with the key). No sign was posted along the fences to indicate the presence of an infected FMD area, despite the fact that virus was recently isolated in the area (see section 5.3.2.3).

- The permanent control post between a free and non free DCZ visited was adequately equipped and manned. All vehicles were going through a disinfectant bath. Instructions and comprehensive activity records were available. However, the many gate posts between the free-zone and the containment zone seen had no biosecurity measures or activity records in place.

- At the quarantine station visited, movement registers, copies of movement permits and reports of weekly inspections were available; they showed the application of the all-in/all-out principle, but on the batches assessed, the fate of some incoming animals remained unaccounted for. No channelling protocol was in place, which could ensure that animals sent from the quarantine station had been slaughtered as foreseen;

5.2.2.3 Movement within the free zone

Since the last FVO animal health audit, an intensive surveillance zone of 10 km has been established in all EU listed territories bordering the non-listed territories. Movement of animals within a same DCZ is free, except for cattle from the intensive surveillance zone, which are only allowed to be moved with a movement permit, and only direct to slaughter, with the exclusion of slaughter for export to the EU (thus addressing a recommendation from the 2009-8325 report). Movements to farms and feed-lot approved for supplying cattle to slaughterhouses for export to the EU must also be accompanied by a movement permit (see FVO audit report 2013-6866).

Movement of cattle between FMD free DCZs is allowed only with a movement permit. The permits are issued by the CA for a set of identified animals: to this effect, they must be inspected and either have their bolus number read, or a new bolus inserted by an animal health technician. They are equipped with a portable electronic device, which reads the bolus numbers, and issues a movement authorisation after automatic checks of the status of the holding, according to information downloaded at regular intervals from the central database. This device also registers the information on the animals for which a movement permit is issued, and transmits it to the central database at the next connection session.

Observations:

- The portable electronic devices are automatically blocked if not connected with the central database after three weeks. This feature, aimed at ensuring regular update of information, is not entirely efficient, as it only ensures downloading of information into the devices, not the uploading to the central database (after three weeks of use, the device may remain unused, with its information not uploaded to the database);

- The system allows movement permits to be issued from the intensive surveillance zone to slaughter for EU export, making it ineffective for addressing the related recommendation of the 2009-8325 report (to prevent cattle originating of holding within 10 km of outbreak to be sent for slaughter for EU export).

5.2.2.4 Import controls

The conditions for import of live ungulates were described in FVO report 2011-6119. In 2011 and 2012, such animals were imported mainly South Africa (more than 1,000 cattle per year, close to 2,000 game animals, around 500 small ruminants, and less than 100 pigs), and to a lesser extend from Namibia.

The importer must obtain an import permit, which contains the import certificate to be signed by the CA of the country of origin. At any of the five designated border inspection posts (with unloading facilities), identity and clinical checks are performed; sampling is performed according a schedule. Cattle are further identified with a bolus. The post keeps a copy of the certificate, and issues a movement permit, a copy of which is sent to the DVO of destination.

Observations:

- The animal health requirements for import of animals from South Africa were not entirely in line with the OIE recommendations: isolation and FMD testing was required, but the sampling was not required to be performed at the end of the isolation period;

- The sampling schedule at border inspection post was not available, and it remained unclear whether such sampling is performed (it was not documented for a batch chosen at random by the FVO team).

- The allowance to import up to 25 kg of meat without permit or certificate from South Africa was suspended when the country lost its OIE-recognised FMD free status in 2011; however, the allowance has been since re-instated, even though the country has not recovered its free status.

- An electric fence was installed by the CA on part of the border with Zimbabwe, to prevent unauthorised entry of cattle. Because of vandalism, this fence was replaced by a buffalo-proof fence.

5.2.3 Conclusions

Effective measures are in place to apply regionalisation. Whereas the identification system based on electronic ruminal bolus is not very effective for animal health purpose or for movement controls within a zone, it is an additional tool for effective control of movements between DCZs, together with additional identification means (hot branding). The limited movements of cattle from non-free to free zone are not completely controlled.

The containment measures implemented in the new containment zone were insufficient for a zone with confirmed presence of the virus both in wild and domestic animals. The movement control system does not guarantee that holdings located within 10 km from recent outbreaks cannot send cattle for slaughter for EU export.

There is major investment in control and maintenance of fences, applying regionalisation, and allowing the control of movements from FMD infected zones. Despite a prioritisation system, a major shortcoming in the system, identified but not addressed, led to the recent exposure of a free DCZ to a significant risk of introduction of FMD carrier animals.

Import rules for animals or products are not entirely in line with OIE recommendations, but the legal imports represent a lesser risk than the uncontrolled movements from other infected countries bordering the free DCZs.

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 Botswana 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 bovine animals, 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 10 km around which no case or outbreak of FMD has occurred in the previous 12 months;
- 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.

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

In addition to response to notification of suspicions, the DVS performs annual free and compulsory vaccination campaigns (against anthrax for all cattle, and other diseases), during which identification is checked (and bolus inserted as needed). This is the occasion for the technicians or support staff to review the health status of the herds presented. Inspections are also performed when movement permits are issued. Ante and post-mortem inspections are performed in all slaughterhouses.

Additional surveillance is to be performed in the 10 km intensive surveillance zone along the non-free zones: more frequent and thorough inspections (including mouth check of all animals) must be performed.

Observations:

- The detection of outbreaks in the last three years shows the effectiveness of the passive surveillance (case identified through post-mortem inspection at local slaughterhouse, following notification of clinical suspicion, or visit). The control of these outbreaks required the mobilisation of teams from various DCZs, giving them an opportunity for on-the-spot training.

- At a feed-lot gathering cattle for slaughter for EU export, the treatment register showed that 29 animals arrived lame, and were treated without a notification to the private or official veterinarian.

- The ante mortem and post-mortem inspections at the EU slaughterhouses visited presented some shortcomings, as indicated in the FVO report 2013-6866;

- No evidence of increased surveillance was seen at the crush situated in the 10 km intensive surveillance zone visited by the FVO team:

    - The turn-out of animals at the annual vaccination campaigns was low (around 50% of the 200 cattle);

    - A movement register was available at the crush. The owner invested in his herd (purchasing three high genetic value bulls), but did not register any movement out of the crush for the last 12 years; no movement permit had been issued from this herd,

    - The crush was not visited in 2011, although an outbreak was detected in the contiguous zone that year (the CA explained that all resources were concentrated in the non-free zone);

    - 25 % mortality was recorded between 2 visits (May and October) at this crush. The owner is not required to collect boluses of dead animals. The owner indicated that it was difficult to actually determine whether the animals died, were stolen, or stranded. The CA confirmed that animals may appear to other crushes at the occasion of a subsequent vaccination campaign. In such case, they are registered as being in the new crush, even if no movement permit was issued.

    - The extension area officer explained that the mouth-check was restricted to animals receiving a bolus.

5.3.2.2 FMD active surveillance

An active serological survey plan was initiated in August 2012 in the 10 km intensive surveillance zone which is located in DCZs 12 and 4a. This serological survey is planned to be extended to the whole intensive surveillance zone, but has not been approved yet.

The 2012 plan aimed at testing a set number of cattle (every 2 months) and small ruminants (every 3 months) in a number of defined crushes. Samples were submitted to a screening test (liquid-phase ELISA for SAT1, 2 and 3 serotypes) and when positive, to a confirmation test (NSP ELISA).

Observations:

- The plan was documented, and instructions and guidelines were given to the field officials. At the DVO in charge, sampling sheets and laboratory test results for liquid-phase ELISA were available.

- In zone 4a, three rounds of sampling had been performed for cattle, and one for small ruminants.

- Many positive liquid phase ELISA were obtained in cattle. The CA indicated that this could be linked to the fact that the zone used to be a vaccination zone in the past (until 2006). However, as no age record or stratification was performed, this could not be ascertained (it could have been an indication of illegal movement from the vaccinated zones).

- No follow-up for the positive results was included in the plan and had been required or performed. The number of NSP ELISA positive cases was not available but was said by the CA to be limited.

- Animals were not individually identified on the sampling forms or on the negative laboratory test results. Small ruminants were not individually identified.

- Active surveillance is also performed on buffaloes present in the North of the country, as part of a regional project (transboundary animal diseases project of the Southern Africa Development Community), confirming the carrier status of these animals (with SAT1, SAT2, SAT 3 viruses).

5.3.2.3 FMD controls

The CA developed a contingency plan, last updated in 2007. In April 2011, an outbreak of FMD was detected in in cattle in DCZ 6, in BW-1 territory, near the border with Zimbabwe. A stamping-out and vaccination programme was implemented. The strategy included establishing a containment zone, movement ban, investigations, fencing of the zone, emergency vaccination in cattle, clinical and sero-surveillance in other susceptible species, and ultimately depopulation of cattle. In October 2011, the OIE re-established the DCZ6 (less the containment zone) as FMD-free area without vaccination.

Observations:

- The outbreak was attended in line with the provisions of the contingency plan in place: a multi-disciplinary emergency disease alert team was deployed early on the suspicious case; an evaluation of resources allowed to set up 6 additional teams staffed with personnel from other DVOs. Biosecurity measures were taken in order to avoid the spread of the disease outside the containment zone (including location of action teams within the zone, certification before moving out of the zone). Measures were rapidly implemented and documented;

- Only cattle were vaccinated. The total cattle depopulation was facilitated by the transfer of most clinically healthy and vaccinated animals to slaughterhouses in Zimbabwe following an agreement between the two countries (including arrangements to have the boluses returned), and was completed in January 2012 by shooting of the remaining semi-feral cattle;

- The extensive surveillance and follow-up in the containment zone led to the identification from August 2012 of small ruminants infected with various viruses (SAT1, SAT2, SAT3). Since then, the surveillance focused on the previously infected crushes. No information is available on the possible extension of these new outbreaks;

- The surveillance had also been extended to wildlife both in 2011 and 2012. In October 2012, a high proportion of infected kudus (three out of four sampled) and impalas (8 out of 11

sampled) were detected;

- These highly unusual events (high infection of small ruminants and wildlife, mostly without symptoms, and concomitant presence of various viruses) could not be explained by the CA, or the regional OIE reference laboratory. No external expert advice had been sought after (at the time of the FVO audit, an announcement for recruitment of such an expert was published in the national press).

- Surveillance was performed in 2011 in the 10 km zone outside the containment zone, including a sero-survey. Its documentation suggested that a number of crushes located in this zone were not included. No such surveillance has been performed since 2012. One of the EU- listed slaughterhouse is located in this zone, but had not produced any meat to be exported to the EU since April 2011.

5.3.2.4 FMD vaccine and vaccination

5.3.2.4.1 FMD vaccine

The origin of the vaccine used in Botswana is the same as indicated in 2009-8325 report. The manufacturing company has since developed in 2010 a new purified vaccine, manufactured on request, under a different brand name. It has also introduced a new SAT 2 (topotype III) strain as vaccine strain, in order to address the issue on the insufficient matching of the previous vaccine strain with some recently isolated buffalo-induced strains.

Observations:

- The vaccine has not been formally tested on small ruminants, but is also indicated for these species, with a recommended dose of a third of the one for cattle. A monovalent SAT2 vaccine was produced for its use in small ruminants in the containment zone in December 2012, for which the recommended dose was doubled (because of its use in a context of outbreak).

- The label of the vaccine indicates that the payload of the vaccine is of 3PD50 (50% protection dose), whereas the CA indicated (see 2009-8325 report) that the payload had been increased to 6PD50, in order to address an efficacy concern. The manufacturing laboratory indicated that they were legally only committed to produce a vaccine at the lower efficacy, but that they were usually producing a vaccine at the higher efficacy for the SAT2 strain only. This was supported by the presentation of the analysis results of the last batches.

- The matching test of the new SAT2 strain incorporated into the vaccine did not prove any comparative advantage compared to the previous strain. No matching test has been performed with the strains which showed that the previous vaccine strain was not protective.

- In parallel to the use of the new strain, batches of the same vaccine are also produced with the older strain SAT2. The label of the vaccine does not indicate which strain(s) of SAT2 is or are used in the vaccine,

- The purity tests performed for the new purified vaccine are significantly lower than those of the OIE recommendations (inadequate number of animals, dose and protocol).

5.3.2.4.2 FMD vaccination

Vaccination of small ruminants was performed in January/February 2013 in the containment zone. A first round of vaccination was performed with a monovalent SAT2 vaccine, followed a month later by a trivalent SAT1, SAT2, SAT2 vaccine.

Observations:

- Contrary to what is performed for cattle, and to what is required in the contingency plan, no permanent identification of vaccinated small ruminants was performed;

- Adequate controls on storage and movement of vaccines were observed at the DVO in charge (temperature records and movement registers);

- The labels of the vaccine were of too poor quality to stand the transport and storage conditions, and required the CA to write on the bottles essential information for traceabiliy

5.3.3 Conclusions

The absence of large scale maps or geographical information system at DVOs represents a major handicap for the effective implementation and supervision of the official animal health controls. This handicap was particularly evidenced for the definition of the 10 km intensive surveillance zone, for which evidence of more intensive surveillance was also lacking.

The active surveillance performed in 2012 in the DCZ particularly at risk was very welcome, as a sensible response to a sound risk analysis, but suffers from conceptual and implementation shortcomings to bring reliable guarantees. The absence of restriction and surveillance in the BW4 territory since the repeated incursions of buffaloes indicates that the FMD risk is insufficiently monitored in this zone.

Swift and comprehensive measures were taken to combat the outbreak detected in the free zone in 2011. However, the unusual recent discoveries of multiple viruses in the containment zone did not receive the same expert treatments, and the situation at the time of the FVO audit was unclear, in particular regarding the extend of the presence of the viruses. The CA was not in a position to certify the absence of outbreaks around the EU-listed slaughterhouse located in the vicinity.

The vaccine manufacturing company took several steps to improve the quality of its vaccine. However, the proofs that the improvements had been implemented or were effective were lacking, and recommendation of use in small ruminants was not scientifically supported.

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.

5.4.2 Findings

Two laboratories share the responsibility of FMD testing in Botswana. Samples from the non-infected areas, and samples tested for import or export, are sent to the Botswana national veterinary laboratory (BNVL), which performs exclusively serological tests for FMD (liquid phase and NSP ELISA). Suspect samples, or samples from infected areas are sent to the Botswana Vaccine Institute (BVI), which is an OIE regional laboratory, and can also perform virus isolation, and PCR tests. Since 2010, BVI also performs virus sequencing.

The FVO audit 2009-8325 recommended to the CA to achieve recognised standard for FMD testing laboratories. The CA indicated that both laboratories were in the process of achieving ISO 17025 accreditation.

Observations:

BNVL:

- The BNVL achieved ISO 17025 accreditation in 2012, with a scope including its liquid phase ELISA. The NSP ELISA is expected to be accredited in 2014, when the validation criteria will be fulfilled. Shortcomings identified in report 2009-8325 were rectified, which was demonstrated with adequate documentation;

- The reports issued by the BNVL for the liquid phase ELISA did not include individual identification of animals, even when these were given by the veterinary services; the reports of NSP ELISA gave only the identity of the animals with positive results;

- Delays of more than three months were observed for a number of cases between reception of samples and analysis, which can significantly affect the value of the sero-survey and the follow-up of the positive results;

BVI:

- The process of ISO 17025 accreditation, which started in 2009, is still at an early stage. The laboratory has not applied yet. It explained that it had a problem for the evaluation of the uncertainty of measurement.

- BVI participated to proficiency testing organised by the EU reference laboratory for FMD in 2010 and 2011 (and is in the process of participate to its third round). It did not send results in 2010 (the reason given was that the samples arrived thawed). The results in 2011 were very poor both for serological analysis, and for virus isolation (it did not participate to the PCR testing, for lack of time, but also because of a need to correct the primers). BVI stated that these results did not reflect the reality, as the EU-RL acknowledged a mistake in the labelling of the samples; however, this was not documented.

- None of the viruses isolated in small ruminants or wild animals has been sequenced. The laboratory closed between mid-December 2012 and end of February 2013, for maintenance purpose. No external expertise has been sought. No official result report was available for these occurrences.

- No evaluation or audit of the bio-security level of the laboratory and its activities was available.

5.4.3 Conclusions

The laboratory in charge of serological surveillance and import controls is well advanced in demonstrating its ability to consistently produce valid results. Delays in testing and shortcomings in reporting results for the active surveillance activities impact negatively on the quality of the serological survey.

The laboratory in charge of identifying outbreaks is still far from having its quality system recognised, a weakness which was particularly patent during this audit. Not only could the laboratory not prove that the highly unusual results obtained from samples from small ruminants and wild animals were not to be linked to a defect in its quality system, but poor results obtained from the last international proficiency testing, and suspension of operations for more than two months following these results cast a doubt on their reliability. The absence of further investigation of these results obtained more than three months before the FVO audit is a sign of the poor support offered by this laboratory to the Competent Authorities.

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 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 plant controls

The CA has 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 the lay-out of the establishment, inspects the premises, and issues a report. The approval is given at the central level (compliance division). Two GTEs have been approved in the country. All game trophies are sent to the EU as treated trophies.

Observations:

- The lay-out of the GTEs visited presented some weaknesses in term of cross flows, which had been identified by the CA;

- One GTE had an inadequate reception and pre-treatment area (receiving and treating unsalted/untreated trophies, with no dedicated storage facilities, despite the fact that treatment was only performed at week-ends), which could not be properly cleaned and disinfected; the other GTE had insufficient storage facilities for skins and hides before treatment;

- Inspections were usually documented (the inspection prior to the approval of one GTE was missing), shortcomings were identified and corrective actions requested, with deadlines;

- The frequency of inspections was not respected, and the filing of the inspection reports was incomplete; the checks on the completion of actions by the deadlines were not performed or not documented, and the subsequent visits did not check the implementation of the corrective actions;

5.5.2.2 Traceability and operations

Game trophies are not allowed to move from non-free DCZs if they have not been prior treated. Checks are performed at the control gates between the DCZs.

Operators must keep record and ensure traceability of their operations; they must contact the CA for each consignment they treat. An EA officer supervises a disinfection operation, consisting of dipping or spraying the trophies with a sodium carbonate solution, and issues a certificate.

Observations:

- The game trophies always arrived pre-processed at one GTE, and most of the time at the other one;

- Boiling of trophies not consisting of hides or skins was always performed at one GTE, but only when felt necessary at the other one;

- Concentrated hydrogen peroxide was used for bones and skulls at both establishments; no minimum concentration was set as a standard, but its efficacy was judged visually;

- One GTE did not manage to trace the origin of some trophies exported two years prior to the audit. The other proved to have operational archives and could trace back all consignments.

- The official supervision of the disinfection operation is not harmonised: in one region the requirement was that the trophies be impregnated with disinfectant for 48 hours, and this was ensured by the official sealing a room with the trophies for the period; in the other one, the requirement was for 24 hours, and the official presence was limited to the impregnation of the trophies.

5.5.2.3 Certification

Certificates are prepared by the operators, and signed by the official veterinarian at the DVO. The procedures for certification are not harmonised in the country, and no guidelines have been issued. One DVO indicated that there was a systematic presence of an official at the preparation of the shipment (together with a representative of the Wildlife authority and a representative of the department of trade), whereas in the other DVO, an official was sent on a random basis. The checks were not documented, and at one DVO, no copies of the certificates were kept.

5.5.3 Conclusions

Game trophy establishments are under effective supervision, and are adequately registered. Minor shortcomings were identified, but the CA was effectively working towards the improvement of standards of the establishments. The lack of guidelines for certification (defining minimal physical and documentary checks) in the context non-harmonised supervision represents a potential weaknesses, of limited impact considering the low number of establishments.

6 Overall Conclusions

Despite a good record of the CA for detection and control of FMD outbreaks, the surveillance in place is insufficient to guarantee the maintenance of the free status of two zones at particular risk, either because of the recent and repeated incursion of (FMD carrier) buffaloes from infected zones, or because of the unexpected and unexplained multiplication of virus-carrier wild animals and goats in a containment zone. This last occurrence affects a slaughterhouse listed for EU export (but not exporting) situated at less than 10 km from the containment zone. The effective further regionalisation measures between diseases control zones within the EU-listed territories limit the geographical implication of these issues.

The efficacy of FMD control activities is undermined by the poor expert support and doubts about the quality standards of the diagnostics laboratory and the vaccine manufacturer.

The game trophies establishments were under effective official supervision, while certification of these commodities presented minor shortcomings.

7 Closing Meeting

A closing meeting was held on 11 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 Botswana 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 ensure that accurate, complete, and where necessary, rapid information is supplied to the OIE and/or the Commission services on the existence of infectious diseases, and on the rules for prevention of diseases (including regionalisation)(Article 8(1)(h) of Council Directive 2002/99/EC)
2.	To ensure that the competent authorities have at their disposal adequate means to identify the areas and register the holdings on their territories to be affected by any official control related to regionalisation and FMD surveillance or control;(Article 8(1) (b) of Council Directive 2002/99/EC)
3.	To develop and implement rules, protocols and evaluation of resources needed in case of ingression of – possibly FMD carriers – 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)
4.	To establish an effective system preventing the export of meat produced from cattle originating from holdings within 10 km of a place where an FMD outbreak was identified in the previous 12 months.(Point II.2.3.(b) of BOV certificate from Commission Regulation (EC) No 206/2010)
5.	To ensure that certification of point II.2.5. of BOV certificate from Commission Regulation (EC) No 206/2010 is, when relevant, performed on the basis on a monitoring programme or effective epidemiological surveillance system. (Article 3(4) (b) of Council Directive 96/93/EEC)
6.	To ensure that the rules for prevention and control of FMD are effectively implemented, in particular for the maintenance of the fences, the rules applying to the 10 km intensive surveillance zone.(Article 8(1)(d) of Council Directive 2002/99/EC)
7.	To ensure that all laboratories performing official FMD tests achieve internationally recognised accreditation of their ability to consistently deliver valid results, ensuring the accuracy of the information regarding the existence this disease.(Article 8(1)(h) of

N°.	Recommendation
	Council Directive 2002/99/EC, with equivalence to Article 12 of Regulation (EC) No 882/2004)
8.	To review the quality standard requirements, their demonstration and documentation, for the vaccines used for the control of FMD.(Article 8(1)(i) of Council Directive 2002/99/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=2013-6792

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