EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2013)3074498

DG(SANCO) 2013-6936 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

SOUTH AFRICA

FROM 20 TO 29 MAY 2013

IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS IN PLACE IN RELATION TO EXPORT OF EQUIDAE TO THE EU, WITH PARTICULAR REFERENCE TO AFRICAN HORSE SICKNESS

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 this audit was to verify that the control systems for live equidae are functioning in a manner compatible with the EU requirements for their import, and assess the adequacy of guarantees given by the competent authorities (CA) in this regard.

The rules for movement of equidae, giving substance to the regionalisation of South Africa for African horse sickness, are in force, largely in line with EU provisions, and controlled for the formal sector. The weak enforcement powers of the competent authorities do not contribute to create a dissuasive environment.

The measures taken following the outbreak of African horse sickness in the surveillance zone in 2011 do not allow to reasonably conclude that virus is absent from this zone. The patchy results of the scanty surveillance implemented actually suggest otherwise, and the extensive vaccination of equidae in this zone compromises its status as "surveillance zone".

The surveillance of African horse sickness and other equine diseases is further affected by the unclear organisation of the laboratory network, and the significant shortcomings observed in the national laboratory, not adequately addressed by the competent authorities.

Weaknesses in resources and organisation of the Competent Authorities represent a further impediment to an effective delivery of the programme, partially compensated by formal and informal delegation of controls and activities.

The system for export of horses to the EU is well organised, but the current test for African horse sickness (and equine encephalosis) and its interpretation do not preclude the risk of presence of virus.

The risk of introduction of exotic diseases is in general well controlled but is affected by a flaw in the control of introduction from neighbouring countries; dourine is enzootic but loosely controlled in South Africa, which could affect the status of the exporting territory (which must be free from this disease for 6 months).

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AHS	African horse sickness
CA	Competent Authority
CCA	Central competent authority
CFT	Complement fixation test
control area	Area including the Protection zone (PZ), the surveillance zone (SZ) and the free area for African horse sickness, as defined in Decision 2008/698/EC
DAFF	Department of Agriculture, forestry and fisheries
ELISA	Enzyme-linked immuno-sorbent assay
Equidae	Horses, donkeys, zebra and their cross-bred
Equines	Horses, donkeys and their cross-bred
EU	European Union
FVO	Food and veterinary office
ISO/EN 17025	General requirements for the competence of testing and calibration laboratories, from the International Organisation for Standardisation
OIE	*World organisation for animal health*
OIE Code	Terrestrial animal health code 2012
OIE Manual	Manual for diagnostic tests and vaccines for terrestrial animals 2012
OV	Official veterinarian
PCA	Provincial competent authority
PCR	Polymerase chain reaction
PZ	Protection zone
SOP	Standard operating procedures
SZ	Surveillance zone

1 Introduction

This audit took place in South Africa from 20 to 29 May 2013. The audit team comprised two inspectors from the Food and Veterinary Office (FVO) and a National expert from a European Member State, and was accompanied throughout the audit by at least two representatives of the Central Competent Authority (CCA), the Directorate of Animal Health of the Department of Agriculture, Forestry and Fisheries (DAFF).

This mission took place at the request of the CCA, which notified the Commission of their wish to re-instate export of registered horses to the European Union (EU) from the previously authorised region of the Metropolitan area of Cape Town.

An opening meeting was held on 20 May 2013 with the CCA. At this meeting, the objectives of and itinerary for the audit were confirmed and additional information was requested for its satisfactory completion.

2 Objectives

The objective of this audit was to verify that the control systems for live equidae are functioning in a manner compatible with the EU requirements for their import, and to assess the adequacy of guarantees given by the competent authorities (CA) in this regard.

Council Decision 2004/211/EC lists the third countries from which Member States of the EU may import live equidae, describing different categories of importations and equidae, and equine semen, ova and embryos. South Africa used to be listed in this Decision for imports and temporary admission of registered horses, and import of semen of registered horses, from the Metropolitan area of Cape Town. The animal health conditions for such imports are respectively laid down in Commission Decision 93/197/EEC (certificate Model F), Commission Decision 92/260/EEC (certificate Model F) and Commission Decision 2010/471/EU. In addition, the conditions for regionalisation of South Africa for imports of registered horses have been detailed in Commission Decision 2008/698/EC. These authorisations were suspended in 2011, following the declaration of outbreaks of African horse sickness in the zone surrounding the Metropolitan area of Cape Town.

In pursuit of this objective, the following sites were visited:

Visits	Number	Details
Competent Central Authorities	1	DAFF
Regional Competent Authorities	1	Veterinary Services Western Cape Province
Local competent authorities	3	
Delegated bodies	2	Passport issuing organisations
Quarantine stations	3	2 post-import quarantine, one pre-export quarantine
Holdings	5	2 stop-over isolation stations, 1 holding in free area, 1 in protection zone, 1 in surveillance zone
Laboratories	2	Official laboratories for equine diseases
Vaccine manufacturer	1	AHS manufacturing company

3 Legal Basis

The audit was carried out under the general provisions of EU legislation (all legal references, which can be found in Annex 1, refer, where applicable, to the latest amended version, and can be accessed at the following internet site: http://eur-lex.europa.eu/en/index.htm), and in particular:

- Article 46 of 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;
- Article 18 of Council Directive 2009/156/EC on animal health conditions governing the movement and importation from third countries of equidae.

4 Background

4.1 Background to the present audit

The regionalisation of South Africa for AHS, and exports of registered horses from the Metropolitan area of Cape Town, were first formally recognized and approved in 1997 (Commission Decision 97/10/EC). The boundaries of the different zones have been modified in 2001 (Decision 2001/622/EC), whereas the standards to be applied for regionalisation for AHS were last set out in Decision 2008/698/EC.

Three occurrences of AHS in the surveillance zone were reported, leading to periods of prohibition of temporary admissions and imports of horses into the EU: in 1999 (Decision 1999/334/EC setting the prohibition, Decision 2001/622/EC lifting the ban), in 2004 (Decision 2004/262/EC setting the prohibition, Decision 2006/724/EC lifting the ban), and in 2011 (Decision 2011/267/EU setting the prohibition). No semen collection centre was ever approved for export of semen to the EU.

The last audit of the FVO in South Africa on export of live horses was performed in 2005 (DG(SANCO)/7605/2005[1]). This audit, performed in the wake of the 2004 outbreaks, concluded that it was not possible to ensure the absence of AHS virus from the control area, because of the reduced size of the containment zone around the outbreaks, and the weaknesses in the surveillance programme of susceptible animals and vectors.

4.2 Production and trade information

The equine population in South Africa is estimated to be around 300 000 horses, 150 000 donkeys and 14 000 mules (source: FAOSTAT[2]). Of the horse population, around 20% are registered (pure-bred) horses, of which 20 000 are thoroughbred racehorses. Zebras are found almost exclusively in national parks (estimated population of 20 000, with more than half of them being in the Kruger national park), and in private holdings (no data available). Limited population of feral donkeys or horses are kept in some reserves.

South Africa has imported around 1,000 horses per year over the last three years, from distant

1 http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1351
2 http://faostat.fao.org/site/573/DesktopDefault.aspx?PageID=573#ancor

countries, including certain EU Member States, USA, Canada, Australia and Latin America. Furthermore, the CA recorded 944 horses imported from five neighbouring countries from January 2012 to April 2013.

According to FAOSTAT database, South Africa exported around 1,000 horses per year until 2010. 126 horses were exported to the EU in 2010. In 2011, because of the AHS outbreak in the surveillance zone, direct export ceased. Horses from South Africa intended to be sent to the EU are currently exported to Mauritius, a country listed for permanent export of registered horses (after 90 days of residency). Mauritius exported 144 horses to the EU in 2011, and 68 in 2012 (the split between indigenous horses and transiting horses is not available).

4.3 Animal health information

The health situation in South Africa in 2012 regarding the main relevant diseases for the scope of this audit was indicated on the OIE website as follows:

Disease	Status 2012	Last occurrence
African horse sickness (AHS)	Present	
Rabies	Present	
Anthrax	Present	
Dourine	Present	
Contagious equine metritis	Present	
Equine viral arteritis	Absent	2001
Equine infectious anaemia	Absent	1955
Glanders	Absent	1945
Vesicular stomatitis	Absent	Never
Equine encephalomyelitides (Western, Eastern Venezuelan)	Absent	Never
Japanese encephalitis	Absent	Never

5 Findings And Conclusions

5.1 Legislation

Legal requirements

Commission Decisions 93/197/EEC and 92/260/EEC lay down certification requirements for equidae sent from third countries to the EU. They require that the equidae come from a country where the following diseases are compulsorily notifiable: African horse sickness, dourine, glanders, equine encephalomyelitides (EE) of all types, EIA, Vesicular stomatitis, rabies and anthrax.

Article 12 (c) of Council Directive 2009/156/EC indicates that particular account should be taken of the powers of the competent veterinary authorities for the listing of third countries which can export live equidae to the EU.

Findings

The Animal Diseases Act (Act 35 of 1984) defines the legal mandate for the control of animal diseases, and measures to promote animal health. Keepers and laboratories are required to report incidences or suspected incidences of controlled animal diseases, to an OV. Such diseases include: anthrax, rabies, AHS, dourine, glanders, EIA, but also EVA and contagious equine metritis and any disease not known to be endemic in South Africa (such as equine encephalomyelitides, vesicular stomatitis).

The Act predates the constitutional reform of 1996, delegating powers to the Provinces. The legal powers of the competent authorities remain uncertain, the national authorities can only delegate responsibilities and powers conferred by the Act to officers under their supervision and control. Field officers report to the Provinces which are not under the supervision and control of the CCA. One of the priority programmes agreed between all CA relates to veterinary law enforcement.

The CCA includes one law enforcement officer, and one province (Gauteng) has a law enforcement unit. Local officers have no power to apply fines or sanction. The system for enforcement requires that officials gather evidence to prove the case, but also to prove that the offender was aware of the legal requirements. Cases must be brought to criminal court, where according to local officers they rarely come to a successful conclusion. A system of "admission of guilt fines" may be put in place at provincial or municipal level, allowing the process to be shortened and even to issue on-the-spot fines. This system was not used in the control area.

Conclusions

An adequate legal basis is in place for the notification of equine diseases. The limitations and uncertainties regarding the legal powers of the CA affects their capacity to enforce the animal health regulations.

5.2 COMPETENT AUTHORITIES

Legal requirements

Article 12 (c) of Council Directive 2009/156/EC indicates that particular account should be taken of the organisation, the supervision and the means of the competent veterinary authorities (including their staff) for the listing of third countries which can export live equidae to the EU.

Findings

Within DAFF, the branch in charge of veterinary matters is the Agricultural Production, Health and Food Safety branch. Two relevant chief directorates operate under this branch: the inspection & quarantine services (in charge of the operations of post-import quarantine of equidae), and the animal production and health chief directorate, headed by the chief veterinary officer. This latter chief directorate oversees the directorates for animal health (with three sub-directorates: epidemiology, disease controls, and import/export policy unit), for animal production, and for veterinary public health (which is also in charge of animal identification).

All nine Provinces also have their own veterinary services. An implementation protocol was signed

in 2008 between the Directorate of animal health and the Provincial departments of agriculture, in order to facilitate co-ordination and implementation of the veterinary policy and legislation.

Within this framework, the CCA set the norms, audit the provincial veterinary activities, offer guidance, and liaise with trading partners. The provincial competent authorities (PCA) conduct monitoring, control and reporting of diseases, and are responsible for officials certifying exports. Both parties are jointly responsible for establishing animal disease surveillance, monitoring, evaluation and reporting system.

Routine reporting is performed on a monthly basis by PCA to the CCA, where information is analysed, approved, and used as a basis for the bi-annual reporting to the world organisation for animal health (OIE). Approved laboratories must also send all results of tests on controlled diseases to the PCA – some are copied to the CCA as well. In case of a significant epidemiological event, an emergency report ("SR1") is to be submitted by the PCA from the time of suspicion. The declaration of an outbreak is a prerogative of the Provincial Director of veterinary services. The CCA is in charge of informing trade partners and international organisations.

Observations:

- The responsibilities for import controls, and export certification were clearly established, and benefited from a well structured documented system. The official veterinarian (OV) of the local office in charge of the free area was the designated official for certification for export of horses in Western Cape Province, and a dedicated export team was to be created

- The same OV was also developing and controlling the standards for AHS regionalisation (guidelines for movement controls, for approval of stop-over isolation stations, decisions on conditions for movement of equidae into the control zone,...). Laboratory diagnosis, field advice, support for surveillance and official measures were received from the University of Pretoria. No official attribution of these tasks had been established.

- No information was sent from the PCA to the CCA on a 2013 suspect case of AHS in the control area which was found positive from PCR analysis: the case was further investigated and eventually discarded seven days later, without the CCA being informed or involved. The SR1 form of the first suspect case was sent only after confirmation, with less information than in the sample submission form (many horses had died in the vicinity in the previous two weeks). Monthly reports of outbreaks were not always accurate.

- The PCA developed a 2012/2013 active surveillance plan for the control area, and submitted it to the CCA. The plan was not yet approved at the time of the visit.

- No supervision or audit system from the CCA to the PCA was in place in the field of animal health. An ad-hoc audit had been performed recently on management of foot-and-mouth disease control measures.

- There is still a shortage of official veterinarians and animal health technicians from the veterinary services, where about 23% of the posts of both categories remain vacant. A regulatory project of compulsory veterinary service, planned for implementation from 2015, would make newly graduated veterinarians work for the veterinary services for some time, and would, according to the CCA, alleviate the problem of under-recruitment.

- The under-staffing was obvious in the Western Cape Province, for correct completion of the tasks attributed. To a limited extent this was compensated for by delegation of controls to private bodies for movement controls.

Conclusions

Whereas official controls for import and export of live horses are well structured, The AHS control and regionalisation system suffers from the unclear attribution of responsibilities, insufficient cooperation between central and provincial authorities, and insufficient staff for performing official controls. In the absence of a formal assessment of the application of the system in the field, the CCA cannot identify and correct the weaknesses in the system, and is not in a position to deliver reliable guarantees.

5.3 LABORATORIES

Legal basis

Article 11 (c) of Council Directive 2009/156/EC indicates that, for the listing of third countries which can export live equidae to the EU, particular account should be taken of the laboratory capacity.

In line with Article 15 of Directive 2009/156/EC, registered equidae imported into the EU (Annex II, F to Decision 93/197/EEC and Decision 92/260/EEC) must be tested for EIA (Coggins test), dourine (complement fixation test (CFT), AHS (ELISA test, as described in Annex IV to Directive 2009/156/EEC), equine encephalosis (ELISA test) and possibly a virus neutralisation test on blood sample, or virus isolation on semen for EVA.

Chapter 1.3 of the OIE Code states that the tests performed for international trade must be performed according to the Terrestrial Manual. Chapter 1.1. 4/5 of the OIE Manual states that validation must be obtained and retained for the assays used, including scheduled external proficiency testing.

Findings

5.3.1 System

DAFF has developed an approval system for laboratories performing tests for official controls, including export tests. These are quality management standards, based on ISO 17025, with additional requirements. The approval details the methods included in the approval, and, when fully operational, only DAFF approved (or ISO 17025 accredited) laboratories will be authorised to process official samples.

Two laboratories currently perform AHS and other equine diseases testing in South Africa. One is the national laboratory, the other one is part of University of Pretoria. A private laboratory has recently received DAFF approval for PCR testing for AHS, and the governmental provincial laboratory of Western Cape is developing the same method in view of approval. The CA has used only the first two laboratories for official testing.

5.3.2 National laboratory

The laboratory offered several tests for AHS, including hemi-nested PCR, virus isolation, indirect ELISA. The laboratory had also the possibility to test for equine encephalosis (indirect ELISA, virus isolation), dourine, glanders, EIA, EVA, CEM, rabies and anthrax.

The laboratory had a general quality management system in place. Some departments and tests of the laboratory reached ISO 17025 accreditation, including for equine diseases: PCR and ELISA for AHS, rabies and anthrax. No other tests had received DAFF approval. The laboratory was designated as OIE reference laboratory for AHS.

Within the implementation protocol agreed between the national level and the Provinces, the CCA is to support and facilitate the accreditation of this laboratory as national reference laboratory.

Observations:

- The quality of information received together with the submitted samples was variable, and often poor: the location of the animal, the reason for testing, the background were often scant or missing.

- No prioritisation system was in place; the laboratory was running a standard turn-around time of seven days to produce results. No diagnostic path (diagnosis procedure, decision tree) for AHS has been developed.

- Some results were regularly issued without indicating sampling date; results were issued without indicating the units to which the figures corresponded (AHS ELISA), or in non-existing units, not corresponding to the procedure of the accredited method (Dourine test).

- The level of coordination and communication between departments was poor, each department reporting its results separately. Suspect samples with positive PCR results were not systematically sent to the virology department.

- The laboratory only issued tests results for AHS, but did not provide interpretation. Following one request for virus isolation for AHS, the laboratory issued an official result, limited to the information that presence of cytopathic effect was observed.

- The national laboratory usually only performed the tests required by the submitting party: no differential diagnosis was performed in case of negative result, even in case of anamnesis suggesting a possible controlled disease;
- The information management system of the laboratory did not allow to trace back three of the 5 PCR positive results detected from Western Cape since 2012, and was very cumbersome.

- Of the 2 PCR positive results retrieved, one (from the infected zone) was sent to the virology department. The results were not available at the time of the audit, but the PCR results had been sent to the CA which classified the case as an outbreak.

- The other one, from the surveillance zone, was not sent to the virology department, but instead to the University laboratory for another (real-time) PCR. Following negative result, the sample was sent to a public health laboratory which identified by PCR a Shuni virus

(orthobunyavirus, Simbu group), which was retained as the final diagnosis by the provincial laboratory, which did not perform any of the tests.

- Whereas the CA sends all EIA pre-export samples to the national laboratory, all post-import samples are sent to a foreign laboratory.

- The horse positive serum used for the ELISA test was not systematically calibrated against an international reference serum.

- Access to virology laboratory, cell culture rooms, PCR rooms, was allowed without any protection (white coat, shoes), bringing a risk of contamination.

- The laboratory had no role in the validation, harmonisation or control of of AHS diagnostic methods used by other laboratories in the country.

- The national laboratory also had an entomological department. A study was performed on the relative efficacy of various products as repellents for insect vectors. The results of this study were not used by the CA, as they were using, for official purposes, products shown to be ineffective as repellent (pyrethroids). The entomological expertise was not used either for the validation of the conditions for quarantine (see point 5.8.), or for the evaluation of risk (a detailed map of AHS risk zones was developed by the national laboratory, but not used by the risk manager in charge of the movement authorisations in the control area; vector trapping was not used in the surveillance zone to validate the absence of vector circulation).

5.3.3 University laboratory

Laboratory structures at the University of Pretoria developed research and diagnostic capacity for equine diseases, following a request and indirect co-funding from the equine industry. A small integrated structure has been set up specifically for equine matters, integrating two laboratories, with overall supervision of activities from a Director for equine research. This capacity was developed outside any service agreement with the CA, but is offered free of charge to any submitter.

The laboratories are working towards ISO 17025 accreditation, and have already been approved by DAFF for EVA, AHS, equine encephalosis (viral isolation, and neutralisation test for serotyping). An audit was planned shortly after the FVO audit with a view to approving the PCR tests for the latter two diseases.

Observations:

- The CA regularly requires assistance from this structure for diagnosis, but also outbreak management. No formal background supports the service offered by the University for diagnostic purpose, as its official mandate relates to research, and no service agreement exists between the CA and the University.

- The laboratory was operating with very limited staff and a single PCR equipment.

- The validation of the real time PCR developed in house proved difficult in the absence of gold standard, as virus isolation is considered as less sensitive. The sensitivity of the real-time PCR was not assessed either against the hemi-nested PCR from the national laboratory.

- The structure had worked on the 2006 outbreak in the surveillance zone, and identified a sub-clinically infected horse which had previously been vaccinated against AHS as a probable source of infection[3]. The responsible staff member indicated that such a case would be difficult to detect through serology.

Conclusions

The laboratory diagnosis system for AHS suffers from the unclear designation of roles and responsibilities. Beyond some specific issues in relation to some individual tests or quality standards, the level of service delivered by the national laboratory is of low standard: major shortcomings were patent in the management of information and the cooperation between sectors involved in the same disease. Expert advice was not provided. The laboratory was not operating as national reference laboratory for AHS.

Some of these shortcomings may have been identified by the CA, which was sending official samples to a foreign or University laboratory when the testing capacity is available at the national laboratory. However, no corrective action plan had been defined.

The system for supervision and approval of laboratories put in place by the CA can bring a valuable alternative to assess the quality of the tests performed, as an alternative to ISO accreditation, but it will not address the wider problems affecting the standards for diagnosis of AHS or other equine diseases.

5.4 Holding registration, animal identification, movement control

Legal requirements:

Annex F to Decisions 92/260/EEC and 93/197/EEC restrict temporary admission and permanent imports from South Africa to the sole category of registered horses (as defined in Article 2(c) of Council Directive 2009/156/EC). The identification of registered horses certified for their movement to the EU must include a passport, validated by a CA (section I of the certificates).

According to Article 4(2) and 4(6) of Regulation (EC) No 504/2008, identification documents issued by authorities in third countries issuing pedigree certificates are valid for registered equidae; a list of such bodies shall be prepared under the responsibility of the CA of the third country.

Registered horses exported to the EU must have been resident for 90 days in the country of dispatch, of which 60 days in part of the country considered free from AHS. In line with Article 13 of Directive 2009/156/EC, Decision 2008/698/EC defines the geographical boundaries of the AHS free area for South Africa, (part of the Metropolitan area of Cape Town), and the surveillance and protection zones around it. All holdings in the free area must be registered and under official supervision. All equidae in this area must be identified, and record must be kept of their movement and vaccination history.

Movements into a zone of higher status should only be authorised if the equidae comply with a set of biosecurity measures. Equidae other than registered horses must meet the conditions described in Article 5(5) of Directive 2009/156/EC, including moving only during a vector safe period (June, July and August), being kept under vector-protected quarantine for 40 days and tested for AHS on 2 occasions. Registered horses must have a passport with vaccination details, be certified (within the

3 Weyer CT et al., Equine veterinary Journal, 2013, 45(1):117-119.

passport) by an official veterinarian, on (inter alia) the facts that the horse was examined and healthy within 48 hours of departure, does not come from a holding under veterinary restrictions or with cases of AHS within the last 60 days, and was vaccinated between 60 days and 24 months before entering the destination zone.

Derogation from the latter requirements may be obtained for registered horses in the surveillance zone for temporary admission into the free area, or for the re-entry of registered horses from the latter to the former: a licence may be delivered to such horses, under the condition that the horses are admitted between two hours after sunrise to two hours before sunset.

Findings

5.4.1 Holding registration

Registration of holdings with equidae is not compulsory, except for those in the free area, and holdings with zebras in the control area. The CA has some knowledge of location of equidae in rural areas, as they have a census of animals kept on all farms, which they are to visit every 2 years.

Observations:

- The CA had registered 1 holding with wild equidae, and 24 holdings with horses in the free area: 21 of them being stables for racehorses (the remaining being a mounted unit, metropolitan police, and groom school). In addition, a race-course field, and two horse quarantine stations are also in the same area.

- The CA admitted that it has only partial knowledge of holdings with zebra in the surveillance zone (SZ). Twenty-two holdings with zebra (with a count of 215 animals) were recorded, but an official estimated this information to represent about 60% of the reality. No data could be provided on the presence of zebra in the protection zone (PZ).

- The regular visit of the farms does not allow the CA to have an accurate picture of the equine population in a zone. The last outbreak of AHS in the SZ occurred in an area where the CA had recorded the presence of 80 horses; 400 were identified during the post-outbreak investigations. Despite performance agreements set for animal health technicians including the number of farm visits, the OV in the SZ could not indicate the grade of completion of the objective of visiting all farms.

5.4.2 Animal identification

Identification of equidae is not compulsory, but the national legislation (Animal identification act) foresees the possibility to identify horses by mean of lip tattoo and branding. The Directorate of Veterinary Public Health is formally responsible for identification of equidae, but does not have practical involvement in this field.

In practice, passports and microchips are widely used for identification of equidae, activities which are not regulated by national legislation or under the supervision of the CA.

Three national passport issuing organisations are recognised by the CA as issuing passports of registered horses; the National Horseracing Authority, the South African Equine Association (federating provincial horse societies), and the South African Horse Import/Export Council. The

first two organisations are recognised by international instances (International Federation of Horseracing Authorities, and *Fédération équestre internationale* respectively). Horses with passports issued by the *Fédération équestre internationale* are also recognised as registered horses.

The use of microchips for identification of equidae is unregulated and left to the private sector. All thoroughbred horses born in the country are microchipped (since 1999), whereas sport horses may be microchipped (all the higher category horses are microchipped). All imported horses not already microchipped are so done on arrival (since 2005). Other microchipping may be performed on *ad-hoc* basis, as for instance within the framework of non-governmental or governmental projects in traditional sectors.

Observations:

- Rules for issuing passports are defined by each passport issuing organisation. One of them required the the outline diagram be completed by a veterinarian, but no control was performed on the capacity of such veterinarians.

- Passports from these organisations also included sections on health certification and for AHS vaccination records; the National Horseracing Authority requires that passports are kept on the holding of residence of the racehorses, thus facilitating their control.

- Each identifying organisation maintains its own database of microchipped horses. The database of imported horses microchipped at arrival is kept at the University of Pretoria.

- The definition of registered horses and the recognition limited to certain passport issuing organisations is not explicitly laid down by the CA. However, the movement rules for access of horses to the control area (in 2001) did indicate that only horses identified by these three organisations would benefit from the rules foreseen for registered horses.

- At the time of the audit, differentiation was no longer made between registered horses and other equines: any passport could be accepted, and in case of an equine with no passport, an identification card was accepted by the CA.

- The CA indicated that the zebra located in the free area are identified by pictures. Zebra in the rest of the control area are not required to be identified.

5.4.3 Movement controls

The boundaries of each zone of the control area are defined in the Animal Disease Act, in line with those described in Decision 2008/698/EC. The national legislation foresees isolation of the infected and contact animals for outbreaks in the control area, and prohibition of movement of equidae infected with AHS into the control area if they are from outside. In such cases, contact animals must be isolated and vaccinated.

Although there is no further national or provincial legislation for movement control of equidae, Western Cape has issued guidelines on movement control policy into the control area. These indicate that all equines can be moved into the controlled zone if they are identified by a passport or a certificate of identification, and vaccinated (between 60 days and 2 years before movement) by a veterinarian or a specifically authorised animal health technician. A movement permit must be obtained from the OV of the area of departure (valid for 14 days), and an animal health certificate

(in passport or separate) must be issued by a veterinarian within 48 hours of movement. The movement must be pre-notified to the OV in charge of the programme in Western Cape. Similar rules apply for movements from PZ and SZ to a zone of higher status. Close to 3,000 pre-notifications of movements were recorded by the PCA for 2012.

From February to June, the Western Cape PCA may suspend the automatic authorisation of direct movements into the control area. As default, horses moving during the period specified by the PCA, must first undergo a stop-over isolation under official control, in a specifically approved station in the infected zone. This isolation is of 21 days minimum, but can be reduced by a PCR testing after 10 days. In any case a health certificate and pre-movement notification is also required for their further movement into the control area.

Premises for stop-over isolation are approved by the local OV (with informal agreement with the OV in charge of the programme). The conditions that they must meet are set in a procedure: they are not required to offer vector protected conditions, but no other horses should be kept in the vicinity, and the horses in isolation must be kept indoors at night. Temperature must be recorded twice a day and investigation must be performed if it goes beyond 39ºC.

In 2013, the automatic authorisation was suspended from March. In March/April 2013, about a quarter of the 320 horses moved from the infected area had to undergo the stop-over isolation.

Movements of all equidae within a same zone in the control area o not require a state veterinary movement permit (there are no official rules with regards to time of day for the movement).

Individual horses in holdings situated in the SZ may receive an annual movement licence for temporary movements into the free area (movement in and out within a day).

Zebras may only move during July, August and September into a higher zone, and following isolation and negative test for AHS.

A number of provisions for movement of equidae into the control area, foresees in Decision 2008/698/EC, have never been used: movement of equidae for slaughter (point 5.2.3 to annex I: there is no equine slaughterhouse in the controlled zone); imported horses air-freighted from Johannesburg airport (point 5.5.1.4. (ii)). A derogation was given once for a non-vaccinated horse to be admitted into quarantine in the free area (point 5.5.1.5.)

Observations:

- The boundaries of SZ and PZ are administrative boundaries, facilitating a common understanding of their geographical extent. A few road signs are located on the main roads to indicate the entry into the AHS control area.

- Very few checks are organised with the vehicle control force (stopping vehicles) or in holdings in the control area. When such checks detect illegal movements, the transporter is asked to return to the zone of origin.

- Movements outside the defined daytime period may be officially granted, for instance for customary “twilight races”.

- If illegal movements are detected in holdings, a three-week movement ban is imposed.

However, it is difficult to check the legal status of most equidae in the surveillance or protection zones as holding registers or identification of equidae is not compulsory.

- Checks at events in the free area and SZ have been formally delegated in July 2012 to the industry. One "implementation assistant" is responsible for the checks of movement documents at yearling sales and during formal races (systematic checks, approximately 104 races per year), where another one checks those at equestrian events organised within the framework of the equine association (on random basis, 77 events per year in the SZ or free area). The assistants were well aware of the rules, and refused participation of horses not complying with movement requirements. In addition, the National Horseracing Authority has a statutory right to issue fines (up to 2 000 rands) to its non-complying members. In the PZ, local CA perform checks at events on a random basis.

- Checks at events in the PZ are performed by OVs or by animal health technicians. The OV of the free area also performed checks at some of the events in the SZ.

- The register of holdings in the SZ or the free area which availed of the temporary movement licence, was a copy of the registers from the National Horseracing Authority. The checks were performed by implementation assistants. The registers do record change of residence of the horses, or participation in races, but not all movements (in particular those for training).

- As passports are not compulsory, health certificates and vaccination certificate did not need to be in the passports for horses to comply with the movement scheme (which is not in line with the requirements laid down in Decision 2008/698/EC). The CA indicated that donkeys were also benefiting from the movement rules foreseen in the Decision, but that they represented a very limited number of movements (only 7 or 8 movements, and none from the infected zone).

- The last two movement of zebras into the control zone recorded by the CA occurred in 2010 and 2011. The CA acknowledged that no quarantine was required as it was impractical to keep zebras in a vector-proof environment. The animals were tested with PCR before being authorised to move.

- Documentation of activities was kept on both approved premises visited for stop-over isolation. Unreliable documentation was kept on one farm (with three different dates of arrival from a same horse). A horse which showed temperature above 39ºC for the first 2 days was not reported to the OV, and not tested. The visits of the OV on the premises were not documented. Other horses were also kept at one of the premises: the keepers were instructed by the local OV to avoid direct contact between both categories of horses.

- On one occasion, a horse testing positive for PCR at a stop-over isolation station was allowed to move into the control area: the OV in charge of the programme was not consulted, the local decision was based on undocumented expert advice from the University of Pretoria.

- The location of approved premises for stop-over does not guarantee the absence of viral circulation. In 2011, one of the two premises stopped its activities following a declared outbreak in its close vicinity; the same year, another outbreak occurred at 10 km from the other approved premises, with similar geographical features.

- The CA acknowledged that it was difficult to manage the control of movement of horses from the controlled zone participating in events in the infected zone before coming back.

Conclusions

The rules for movements of equidae in relation to the control zone are still applied, and largely in line with the provisions of Decision 2008/698/EC. Controls performed at formal events and gatherings are a good tool for checking the observance of these rules in this cluster of equine population.

However, the absence of road checks, and the lack of requirements for identification or movement registers for equines in the control area makes it impossible to assess the general level of observance of these rules, and the weak powers of the CA do not contribute to creating a dissuasive environment.

The extension of the rules for registered horses to all equine animals is not in line with the intention of Decision 2008/698/EC, to restrict facilitation of movements to properly identified animals, with reliable vaccination records. It should be assessed in conjunction with the weak capacity of the CA to check and enforce the rules for this category of equidae.

Additional risk mitigation measures have been introduced by the CA for movements from the infected zone, in case of perceived increase risk. Their conception and implementation presents some shortcomings affecting their efficiency.

5.5 Control of African horse sickness

Legal requirements

Decision 2008/698/EC defines the surveillance standard to be applied in the control area: a monitoring programme must be set in the free area and surveillance zone (including all holdings being granted the licences for movements without certification), on at least 60 unvaccinated sentinel horses for monthly sero-monitoring. All mortality in sentinel horses and all suspect equine mortality must be officially examined. No systematic vaccination is allowed in the free and surveillance zones, but, by derogation, horses scheduled to leave the AHS free or surveillance zones may be vaccinated by a veterinarian or an official.

According to Decisions 92/260/EEC and 93/197/EEC, registered horses to be exported or temporarily admitted to the EU may be vaccinated, according to the manufacturer's instructions.

5.5.1 Passive surveillance

Findings

As a controlled disease, AHS is notifiable in the whole country. OV must be informed of suspicions or confirmations, but are only required to confirm by laboratory analysis the first cases in their region every year. After this, they may declare further cases based on clinical diagnosis.

Private veterinarians may directly send samples of suspect cases of AHS. to the laboratory of their choice. Approved laboratories send a copy of all test results to the CCA, and to the relevant local authorities.

In the control area, private veterinarians must send samples of dead horses to the CA, whenever they cannot make a diagnosis. These will be tested in case of expressed clinical suspicion.

Observations:

- The CCA acknowledges that, outside the control area, there is certainly under-reporting of cases of AHS;
- Most submission sheets for AHS testing sent to testing laboratories lacked basic information, such as the identification of the holding of the animal, background information (clinical and epidemiological) and reason for testing. Such submissions do not allow the laboratory to identify the relevant local authority;
- The CCA is not specifically informed of suspicions, and is therefore not in a position to interpret most of the information transmitted by the approved laboratories;
- The number of samples from dead horses transmitted by veterinarians to the CA, that were tested for AHS was not available; 8 post-mortems of horses were performed in 2012 at the provincial laboratory.
- In 2011, in the SZ, many horses had died in the two weeks preceding the first intervention of the OV for sampling a dead and a sick horse.

5.5.2 Action in case of outbreak

Outside the control area, the Animal Disease Act only requires restriction of movements into the control area in case of AHS outbreak (movement into the control area prohibited for infected equines, only with specific CA authorisation for contact animals). Practically, the CA also recommends owners to re-vaccinated their animals. Epidemiological investigations are only performed in case of severe outbreaks.

Within the control area, the Animal Disease Act requires that the infected and contact animals be isolated for a period to be determined by the CA and the latter animals must be vaccinated.

In case of suspicion or outbreak, the local veterinary service must send information to the epidemiology unit at central level, compiled in a standard form SR1.

Observations:

- The notion of contact animals is not defined in the legislation. As a guideline, the OV in charge of the programme suggests that no outbreak should have been detected in a radius of 30 km for the last 30 days before authorising a direct movement of horses into the control area;
- The CA has no active monitoring plan of AHS: no strategy has been defined on the identification and evolution of serotypes occurring in the country, and does not provide national information on the evolution of the disease. The latter service is provided by a non-governmental organisation, which includes non-official data. The 9 known serotypes of AHS are considered enzootic in the country;
- A contingency plan has been developed at national level, and another one at the level of the Western Cape province. The national plan does not contain features specific to AHS, contrary to the provincial one; this last one does not segregate actions according to the zone

being affected, and in particular does not lay down the measures to be applied to re-instate the free status of the control area.

- The PCA applied a 10 km radius containment zone around the 2011 outbreaks in the SZ. The decision to restrict it to this distance, instead of the 30 km foreseen for the movement of horses from an infected zone, or in the contingency plan as standard measure, was not documented.
- The ban was announced through press release. The date by which the ban was effectively published in the local press was not available. The legal value (and therefore possible enforcement) of such a notification remains uncertain.
- No evaluation of staff needed for the management of the outbreaks was available. Staff shortage was experienced for the management of the outbreak: no reinforcement of local staff was provided, because of concurrent outbreaks of foot-and-mouth disease and avian influenza in the country. However, the local CA received support for field activities from the University of Pretoria. Holdings were visited, horses identified with microchips and vaccinated, information about the disease delivered. Several epidemiological reports were issued by the PCA until the outbreaks were declared over.
- Spot checks were organised to verify the respect of the movement rules. This was performed in collaboration with a provincial authority empowered to stop vehicles, in two different locations. The number, duration, dates and results of such spot-checks were not available.
- No evaluation was performed on the risk of contamination of zebra. The epidemiological reports do not include information on the presence of holdings with zebra in or close to the containment zone.
- The origin of the 2011 outbreak could not be determined. The CA stated that they considered that the previous one (2004) was due to an infected but clinically healthy horse, introduced into an environment of vaccinated but ill-protected animals.

5.5.3 Active surveillance

A programme of sentinel horses used to be in place in the free area and the SZ until 2006, when the technician in charge of the programme left and was not replaced. After this, erratic samples were taken from a few horses until 2009, and tested for complement fixation test; the programme was no longer monitored. In 2012, the PCA developed a new surveillance protocol for the 2012/2013 season. The protocol was submitted to the national epidemiology unit, but has not been approved yet. Activities nevertheless started in September 2012, with monthly sampling of foals born after June 2011, for ELISA testing. The activities were conducted by a student from the University of Pretoria.

Observations:

- The CA acknowledged that the few holdings selected since 2012 were not well distributed in the zone, but indicated that they had problems in finding sero-negative animals; none of the sentinel animals was located in the holdings benefiting from temporary movement licence (contrary to what is foreseen in decision 2008/698/EC);
- Raw data were available for consultation for some of the horses sampled: some foals presented sero-conversion for a few months, before getting erratic results. The interpretation of these results was never discussed with the laboratory in charge of analyses or the CA.
- Entomological surveillance was performed during the outbreaks in 2011 and in 2012 in the

control area, for research purposes. The collected vectors were not tested for assessing the possible circulation of the virus.

- No active surveillance has been performed in relation to zebras in the surveillance zone during or after the outbreaks of 2011.

5.5.4 Vaccination

The Animal Diseases Act makes it compulsory to vaccinate all equines against AHS on an annual basis except in the free area and SZ, where such vaccination must be approved by the CA.

Equines requiring movement permits into or within the control zone must be vaccinated by a veterinarian, or an official.

A sole AHS vaccine is authorised for use in South Africa. It is a live modified vaccine, manufactured in the country. The complete vaccine contains 7 of the 9 known serotypes, divided into two vials, to be administered three weeks apart. The last update of the registration file for the vaccine dates from 2003. The CA may perform official controls on the manufacture and controls of batches produced by the company.

Observations:

- No legal provision is made on the general record of vaccination. The vials of vaccines are not accompanied by a sticker of proof of purchase that could be used in passport or vaccination statement. The CA acknowledged that the obligation of vaccination is not enforced, but that they encourage it.
- The vaccine manufacturer indicated that they produce every year doses for roughly 50% of the estimated equine population.
- An OV in charge considered adequate to let non-vaccinated horses participate in an event in the PZ if they were from the same zone.
- In the SZ, a non-governmental organisation dedicated to the fight against AHS organised a campaign of vaccination in 2010 in the very same area where outbreaks were detected a few months later. This campaign was organised without the knowledge of the CA.
- Since the outbreaks in 2011, the CA acknowledges that most equines in the free area and SZ have been vaccinated. As a policy, they systematically approve all requests for vaccination, even for resident equines. Vaccination licences are not monitored, but the CA considers that the vast majority of equines in the free area and SZ are vaccinated.
- The vaccine manufacturing company was developing Good Manufacture Practices, and was accredited ISO 9001; no official control had been performed.
- Batch controls were fully documented. The standards for batch controls presented minor deviations compared to OIE recommendations (essentially for safety in horses: lower volume administered, validation if temperature does not go beyond 39.5º instead of 39º for the OIE).
- An *in-vitro* cross-protection study was published in 2011, validating the protection against the 2 serotypes not present in the vaccine. The recent removal of one serotype (5) from the vaccine, and the reduction of the payload of another serotype (3) was decided in order to increase the safety of the vaccine. These latest modifications have not been validated through a challenge.

- The company had procedures and was keeping records of official complaints regarding the safety or efficacy of the vaccine, and mentioned that they received limited complaints (last one dated from 2008). No official control was performed on these complaints, and these complaints were not subject to systemic investigation (in order to detect a possible trend on regions, serotypes, or batches). A well founded complaint on side-reactions by a veterinarian, in several instances with several groups of horses, received a standard reply from the company; no analysis or re-test was performed with the vaccine bank.
- Beyond the quality controls performed by the manufacturing company, little research has been performed on the vaccine:
    - No information is available on the effect of vaccination in an infected context;
    - No information is available on the reversion of virulence of the vaccine strains;
    - No data was available on the possible duration of positive PCR results following vaccination;
    - Field studies on the level of sero-neutralising antibodies gave erratic results, which are not explained; one of the reasons could be that there is a poor link between the level of antibodies and protection, which would call into question the batch validation protocol of the potency.

Conclusions

The general weak passive surveillance and reporting system prevents obtaining an accurate picture of the situation in the whole territory at a given time, and affects the reliability of the declaration of absence of outbreaks in the area of origin of horses moved into the control zone. This factor has been taken into account by the CA with the possibility to impose a stop-over isolation during the high-risk season.

Measures taken to control the 2011 outbreak in the surveillance zone focused on the control of the clinical expression of the disease, and relied principally on vaccination. The absence of structured surveillance based on epidemiological considerations and risk analysis (with consideration of possible reservoirs), and the absence of interpretation of patchy results suggesting circulation of the virus in the zone, do not allow reasonably to conclude in the absence of the virus in the surveillance zone.

Rules for vaccination of horses are loosely controlled and respected in the whole country, including in the protection and surveillance zone.

The surveillance in place does not even meet the standards foreseen in the absence of outbreak. The extensive vaccination of equidae in the surveillance zone compromises the validation of the status of this zone as free from virus circulation, and hinders the early detection of its presence.

The control strategy relies for a large part on a vaccine which has been developed, and is produced and controlled according to existing norms, but for which a number of key uncertainties remain, in particular in relation to its interference with diagnosis and infection. Considering the recent two modifications of the vaccine composition linked to safety issues, the current standard for pharmacovigilance is too weak to detect further founded concerns, not only for safety, but also potentially for efficacy, as these modifications have not been validated *in-vivo*.

5.6 Other equine animal diseases controls

Legal requirements

In line with Articles 13 to 15 of Directive 2009/156/EEC, animal health requirements for imports of equidae into the EU include guarantees on the country basis for diseases other than AHS: free from Venezualan equine encephalomyelitis for 2 years, from dourine and glanders for 6 months. For these diseases, the Commission may decide to restrict the requirement to a region of the country. For VS, if the country is not free, the animals must be serologically tested prior to dispatch.

The animals must come from a holding under veterinary supervision, which must meet certain animal health requirements (absence of a number of prohibition orders, for EE, EIA, VS, rabies, anthrax). The holding of origin should not have had any suspicion of CEM for the last 2 months. In addition, the horse to be exported should not have had contact with equidae from such holdings.

Registered horses to be exported to the EU must be tested for equine encephalosis. Regarding EVA, if cases have been officially recorded within the last six months, stallions must be either tested for the disease, or vaccinated according to a specific programme, under official supervision.

According to Article 12 of Directive 2009/156/EC, the third country must directly inform the Commission and Member States of any proposed changes in the national sanitary rules concerning equidae, including proposed changes in importation rules, and within 24 hours of occurrence or change in vaccination policy for the equine diseases listed.

Findings:

Dourine, Anthrax, rabies, contagious equine metritis, equine infectious anaemia, equine viral arteritis and glanders are classified as controlled diseases. The first four diseases are present in the country. According to the Animal Diseases Act, equidae infected with EIA or glanders must be destroyed; stallions infected with EVA must be castrated, and contact animals tested.

5.6.1 Dourine

The disease is considered endemic in the country, but receives limited attention. Infected animals must be sterilised or slaughtered, and contact animals must be tested. No compensation is foreseen. About 10 outbreaks are reported every year.

Observations:

- Information on the epidemiological context and application of the legal measures was not available at central level. The CA acknowledged that the application of measures depended upon the cooperation of the owners.

- A few cases of dourine have been identified in mules. No SR1 form was available for these cases. The CA indicated that cases are usually not clinical cases.

- A stallion in the control area was tested positive for dourine (CFT). Repeated positive CFT tests were obtained on several occasions, both from the national and a foreign laboratory. The results were then declared as a false positive following a negative indirect fluorescent antibody test, performed by a foreign laboratory, and investigation of all the mares recently

covered by the stallion. The CFT specificity or the diagnostic procedure used in common cases was not consequently reviewed.

5.6.2 Rabies, equine encephalomyelitides

Samples of animals suspected with rabies can be analysed at the national veterinary laboratory, or in two public health laboratories.

Observations:

- As for other diseases, diagnostic tests performed in the veterinary laboratory will be performed according to the request of the sender. No differential diagnosis is performed. The laboratory staff indicated that they would not necessarily test for rabies a horse sample presenting neurological signs if this is not specifically requested.

- Over the last five years, 85% of the samples of equines sent for rabies testing were negative. No virus isolation or differential diagnosis was performed.

5.6.3 Other diseases

Glanders, EVA and EIA are exotic diseases. The number of tests performed for EVA, EIA at the national laboratory was not available; the University laboratory stated that EVA was part of the screening performed in cases of abortion reported to them. No laboratory was in a position to test glanders in South Africa, until it was re-instated by the national laboratory in 2011.

Equine encephalosis is an arbovirosis presenting similarities with AHS: similar hosts and vectors, similar orbivirus (with several serotypes). Although the clinical signs are usually absent or mild, the CA reported that severe outbreaks of equine encephalosis have been identified. The disease is endemic in the whole territory, and no official control measures are in place.

Contagious equine metritis was first detected in 2011. A comprehensive surveillance programme has been put in place, and is continuing. Instead of applying the control measures foreseen in the Animal Disease Act (destruction or castration of stallions), the infected animals have been treated and checked subsequently negative.

Collection, production, storage or trade of equine semen, ova and embryos is not subject to any animal health standard in South Africa.

Conclusions:

The surveillance of other diseases of equidae is not well structured within the country, which could lead to delay in the identification of new diseases, but also to their rapid spread through unregulated movements of semen. Dourine is loosely controlled, which affects the reliability of the status of the territory approved for export to the EU, which must be certified as free from dourine for 6 months.

5.7 IMPORT CONTROLS

Legal basis

According to Article 12 (i) of Directive 2009/156/EC, the list of third countries authorised to send

equidae to the EU is drawn up, with particular account taken of the rules of prevention and control of infectious or contagious animal diseases, including rules on importation of equidae from other third countries.

Findings

Formal general import requirements have been developed for horses, and their semen. All horses need to have been resident for 60 days in the country of origin. Holding freedom from EIA, equine encephalomyelitides, CEM, glanders, is required. Pre-export testing for EIA, EVA is systematically required, whereas testing for glanders and CEM is only required for countries not free from these diseases. If the country is not free from vesicular stomatitis, the animal must undergo a vector protected quarantine and be tested.

All horses imported undergo identification, clinical and documentary checks at arrival, followed by an official post-import quarantine of 30 days, in an officially-run quarantine station. During this quarantine, the horses will be re-tested for CEM, EIA, EVA, and dourine.

Imported horse semen must come from horses living in a country free of AHS, vesicular stomatitis, equine encephalomyelitides, glanders and dourine. The donor must originate from premises free from certain diseases, and be tested for EIA, CEM and EVA. On arrival, the doses of semen are physically checked, and a sample is taken for EVA testing. In addition, a test breed of 2 mares must be performed.

Observations:

- A set of biosecurity measures was applied at both post-import quarantine premises visited, including requirements for visitors (contact history with other horses, showering in/out, record of visits,....); manure was kept on site until the end of quarantine;
- A quarantine register was adequately kept in one of the quarantine premises, allowing to audit easily the movements and interventions on quarantined horses;
- The checks on arrival were not documented; both quarantines had microchip readers.
- The CA had no specific justification for the lower risk control for glanders, compared to other controlled diseases (absence of post-import testing).

Conclusions

A robust system for controls of imports of equidae or their semen is in place for distant countries, and is consistently applied. This gives a high level of confidence for the control of introduction of foreign disease from this possible source, except for glanders. The system is nevertheless weakened by the significantly lower standard applied to imports from neighbouring countries.

5.8 Export of registered horses

Legal basis

For permanent imports of registered equidae into the EU from South Africa, the certificate (model F of Decision 93/197/EEC) requires that the animal has been resident for 90 days in the country, of which the last 60 days must have been in the part considered as free from AHS by EU legislation. The last 40 days must be spent in approved vector-protected quarantine station (with a possibility to

get outdoors from two hours after sunrise to two hours before sunset, under official veterinarian supervision, with the use of insect repellent).

The animal must be examined on the day the certificate is established, and may not show clinical signs of disease. It should not have been in contact with equidae suffering from infectious or contagious disease for the previous 15 days. The country and holding of origin must meet the requirements described in chapters 5.3. and 5.5.1 of this report.

The animals to be exported must be tested for EIA (Coggins test), dourine (complement fixation test), with samples taken within 21 days of export. The vaccination status regarding AHS must be specified. Either they have been vaccinated within a required period (more than 80 days prior to pre-export isolation), and must be subject to two serological tests at 21/30 days apart, the last one occurring within 10 days of export, showing no increase of antibody level, or they have not been vaccinated, and are subject to only one negative serological test. Two serological tests for equine encephalosis must also be performed on the same dates and with the same results. If EVA has been officially recorded in the last 6 months, uncastrated males older than 180 days must be either vaccinated under official supervision, or subject to serological or semen testing.

The certificate must be accompanied by an owner's (or representative's) declaration confirming that the residency requirements are met, and declaring that the health and welfare of the animal will be protected until destination. In particular, the vehicle transporting the equidae must be cleaned and disinfected with a disinfectant officially approved by the CA. The method of identification must be indicated in the certificate (a passport may be attached).

The horse must be sent directly from the quarantine station to the airport, under vector-protected conditions, transported in an aircraft cleansed and disinfected in advance, and sprayed against vector insects. A possibility is foreseen to send them by sea.

The same requirements apply to horses sent for temporary admission, except for the 90 days residency in the country of origin. These horses need only to be certified regarding the 60 days prior to exportation (either in the AHS free area, a EU Member State, or a territory of a third country approved for export to the EU).

Findings

The OV in charge of the free area is the sole officer in charge of official controls and certification for export of equidae from there.

Before entering into quarantine, the horses to be exported are to be stabled in designated premises located in the free area for 20 days. A single quarantine station, listed in Decision 2008/698/EC, is exclusively used for this purpose. The station, situated in the middle of a racecourse track, is managed by the National Horseracing Authority. The animals are kept inside the vector-proof quarantine from two hours before sunset to two hours after sunrise.

A control of visitors is performed, and unauthorised entry is prevented; seals are used at night on the entrance doors of the quarantine buildings. Stables are under positive pressure, with a system under regular maintenance and a spare generator is available in case of contingency. The system is completed with a double-door entrance and use of ultraviolet light traps.

All horses exported have been vaccinated against AHS. Documentary and identity checks are

performed before entry into quarantine, and passports are issued at that point if necessary. Sampling is performed by the OV, who sends the samples to the national laboratory.

Observations:

- A fence isolates the quarantine station, and entries of unauthorised persons are forbidden. The manager permanently resides on the quarantine station during the quarantine periods.

- The maintenance of the quarantine premises was of excellent standard, as well as the documentation of activities.

- The CCA imposed an early termination of the quarantine in two recent occasions: when the 2011 AHS outbreak was declared, but also during the 2007 acute equine encephalosis outbreak.

- No programme for monitoring the efficacy of the measures to avoid contact with vectors was in place: insect traps were installed inside and outside the premises, but their content had not been analysed for three years, and not used as a control tool; no indicator of pressure inside the buildings was available; horses were sprayed with pyrethorids, proved by the national laboratory as not effective as repellent. Previous studies showed that the vector is present around the quarantine station all year round.

- No protocol defined the responsibilities and interpretation of AHS and equine encephalosis serological tests performed on seropositive horses. Both samples were not sent necessarily at the same time, and therefore not necessarily analysed in parallel at the laboratory. The national laboratory issued results as figures, with no indication of the measurement units used. The absence of "increase of antibody level" was interpreted as being complied with as long as there was no doubling of the results. The background for such decisions was not available.

- Pictures were presented to demonstrate the vector-protected transport to the airplane. The CA stated that the cleaning, disinfection and spray against vector insects were performed by the carrier as part of their normal routine; no documentation was available to support it.

- A suspension of exports of horses to the EU was imposed in 2007 following initial results suggesting an AHS outbreak. Further analyses concluded that the death of animals was due to equine encephalosis.

- No procedure was in place in relation to the possibility of dourine outbreak prohibiting the export of registered horses to the EU.

Conclusions:

The system for export of horses is well organised, and scrupulously applied and documented. However, the efficacy of methods to avoid contact with vectors in quarantine are not confirmed, and the restrictive interpretation of "absence of increased level" of serological tests results for AHS and equine encephalosis for the exported horses, lacks scientific background: the current test and its interpretation does not guarantee that the risk of the presence of the viruses for these diseases is excliuded.

6 Overall Conclusions

The rules for movement of equidae, giving substance to the regionalisation of South Africa for African horse sickness, are in force, largely in line with EU provisions, and controlled for the formal sector. The weak enforcement powers of the competent authorities do not contribute to create a dissuasive environment.

The measures taken following the outbreak of African horse sickness in the surveillance zone in 2011 do not allow to reasonably conclude that virus is absent from this zone. The patchy results of the scanty surveillance implemented actually suggest otherwise, and the extensive vaccination of equidae in this zone compromises its status as "surveillance zone".

The surveillance of African horse sickness and other equine diseases is further affected by the unclear organisation of the laboratory network, and the significant shortcomings observed in the national laboratory, not adequately addressed by the Competent Authorities.

Weaknesses in resources and organisation of the Competent Authorities represent a further impediment to an effective delivery of the programme, partially compensated by formal and informal delegation of controls and activities.

The system for export of horses to the EU is well organised, but the current test for African horse sickness (and equine encephalosis) and its interpretation do not preclude the risk of presence of virus.

The risk of introduction of exotic diseases is in general well controlled but is affected by a flaw in the control of introduction from neighbouring countries; dourine is enzootic but loosely controlled in South Africa, which could affect the status of the exporting territory (which must be free from this disease for 6 months).

7 Closing Meeting

A closing meeting was held on 29 May 2013 in Pretoria with the CCA, during which the audit team presented the main findings and conclusions of the audit.

8 Recommendations

The Competent Authorities of South Africa are invited to present an action plan describing the action taken or planned in response to the recommendations of this report and setting out a timetable, and a description of the actions taken to correct the deficiencies identified, within 25 working days of receipt of the report.

N°.	Recommendation
1.	To review the organisation of the competent authority, in order to have a clear designation of roles and responsibilities for the AHS control programme and ensure that sufficient staff are provided for its effective application.(Article 12 (2)(c) of

N°.	Recommendation
	Council Directive 2009/156/EC)
2.	To clarify and ensure that the competent authority have adequate legal powers to enforce the rules related to the AHS control programme.(Article 12 (2)(c) of Council Directive 2009/156/EC)
3.	To review the organisation and capacity of the laboratory network, in order to ensure consistent and reliable diagnosis capacity; to clarify the diagnostic procedures; to validate the tests used in the local context (vaccination / infection).(Article 12 (2)(c) of Council Directive 2009/156/EC)
4.	To organise a monthly sero-epidemiological monitoring programme for AHS, at least meeting the conditions set out in point 6.1 and 6.2. of Annex I to Council Decision 2008/698/EC, and following the recommendations of Article 12.1.15 of the OIE Code.
5.	To develop and implement a contingency plan following outbreaks in the control area, in order to demonstrate the absence of virus following the implementation of control measures.(Article 12 (2)(d) of Council Directive 2009/156/EC and equivalence to Article 9 of Council Directive 92/35/EEC)
6.	To develop and apply validated procedures ensuring that no horse will be certified if an increase of antibody level is observed between the first and second samples for AHS and equine encephalosis.(Points III (l) and (m) of Certificate F of Decision 93/197/EEC, and Points III (k) and (l) of Certification F of Decision 92/260/EEC)
7.	To ensure that the risk control measures applied in the rules for import of equidae from third countries are consistently applied (for neighbouring countries, and for all diseases, including glanders).(Article 12 (2)(i) of Council Directive 2009/156/EC)
8.	To adopt adequate measures in order to ensure the absence of dourine from the territory of dispatch.(Article 13 of Council Directive 2009/156/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=2013-6936

Annex 1 - Legal References

Legal Reference	Official Journal	Title
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
Dir. 92/35/EEC	OJ L 157, 10.6.1992, p. 19-27	Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness
Dir. 92/65/EEC	OJ L 268, 14.9.1992, p. 54-72	Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC
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
Dir. 2009/156/EC	OJ L 192, 23.7.2010, p. 1-24	Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae
Dec. 92/260/EEC	OJ L 130, 15.5.1992, p. 67-83	92/260/EEC: Commission Decision of 10 April 1992 on animal health conditions and veterinary certification for temporary admission of registered horses
Dec. 93/197/EEC	OJ L 86, 6.4.1993, p. 16-34	93/197/EEC: Commission Decision of 5 February 1993 on animal health conditions and veterinary certification for imports of registered equidae and equidae for breeding and production

Legal Reference	Official Journal	Title
Dec. 2004/211/EC	OJ L 73, 11.3.2004, p. 1-10	2004/211/EC: Commission Decision of 6 January 2004 establishing the list of third countries and parts of territory thereof from which Member States authorise imports of live equidae and semen, ova and embryos of the equine species, and amending Decisions 93/195/EEC and 94/63/EC
Dec. 2008/698/EC	OJ L 235, 2.9.2008, p. 16-25	2008/698/EC: Commission Decision of 8 August 2008 on the temporary admission and imports into the Community of registered horses from South Africa
Dec. 2010/471/EU	OJ L 228, 31.8.2010, p. 52-73	2010/471/EU: Commission Decision of 26 August 2010 on imports into the Union of semen, ova and embryos of animals of the equine species as regards lists of semen collection and storage centres and embryo collection and production teams and certification requirements