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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

THE UNITED KINGDOM

FROM 20 JUNE TO 01 JULY 2011

IN ORDER TO EVALUATE THE IMPLEMENTATION OF ANIMAL HEALTH RULES IN RESPECT OF INTRA-UNION TRADE IN EQUIDAE AND EQUINE SEMEN, EMBRYOS AND OVA

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 objectives of the mission were to evaluate the veterinary checks performed in order to ensure that the animal health conditions for intra-Union trade in live equidae, equine semen, ova and embryos are fulfilled.

The very favourable animal health situation for equidae in the UK is substantiated by an elaborate risk-based surveillance, prompt declaration and intense control activities in case of outbreak.

The certification system for live equidae in the UK provides more guarantees than those foreseen in EU legislation, making the lack of differentiation between registered equidae and equidae for breeding and production of little consequence from an animal health point of view.

However, the organisation of the identification of equidae (giving room for high variation of operational standards) and the deficiencies in related official controls are such that the system cannot ensure consistent application of the required standards in this area.

The health guarantees and the certification provided for equine semen for IUT are not fully reliable. The risk posed by this is mitigated to some extent by the reportable nature (by the laboratories to the CA) of the diseases involved, but not completely as some health tests are not performed as required. The health risk posed by these shortcomings applies in particular to EVA, and for frozen semen. The laboratories used for analyses in Great Britain were of adequate standard, but not the one in Northern Ireland.

The CA presented evidence that other Member States also encounter similar difficulties in relation to certification of equine semen. EU requirements for animal health conditions applying to donor stallions and their certification were considered by all stakeholders met to be particularly complex and difficult to interpret.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
ADNS	Animal Diseases Notification System
AHS	African horse sickness
AHVLA	Animal health and veterinary laboratories agency
CA	Competent authority
CCA	Central competent authority
CEM	Contagious equine metritis
CV	Centre veterinarian
DEFRA	Department for environment, food and rural affairs
EE	Equine encephalomyelitis
EIA	Equine infectious anaemia
EN	England
EU	European Union
EU-RL	EU reference laboratory
EVA	Equine viral arteritis
FVO	Food and veterinary office
GB	Great Britain (England, Scotland and Wales)
IUT	Intra-Union trade
LA	Local authorities
MS	Member State
NI	Northern Ireland
OIE	World animal health organisation
OV	Official veterinarian
PIO	Passport issuing organisation
SCC	Semen collection centre
SOP	Standard operating procedure
SSC	Semen storage centre
TFEU	Treaty on the Functioning of the European Union
TRACES	Trade Control and Expert System
UK	United Kingdom (Great Britain and Northern Ireland)
VI	Virus isolation
VNT	Virus neutralisation test
VS	Vesicular stomatitis

1 Introduction

This audit took place in the United Kingdom from 20 June to 1 July 2011, and was undertaken as part of the Food and Veterinary Office's (FVO`s) planned audit programme. The audit team comprised two FVO inspectors, and was accompanied throughout the audit by a representative of the central competent authority (CCA).

2 Objectives

The objectives of the mission were to evaluate the veterinary checks performed in order to ensure that the animal health conditions for intra-Union trade (IUT) in live equidae, equine semen, ova and embryos are fulfilled.

In pursuit of these objectives, the following meetings were held and sites visited:

Visits	Nb	Comments
Competent Authorities: - Central - Regional - Local	 1 2 2	 UK Northern Ireland and central office for certification in Great Britain Regional offices
Passport issuing organisations	3	
Laboratories	3	
Equine holdings	3	
Private veterinary practice	1	
Semen collection centres (SCCs)	3	
Semen storage centre (SSC)	1	
Slaughterhouse	1	

3 Legal Basis

The mission was carried out under the general provisions of Union legislation and, in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and 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 10 of Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and import from third countries of equidae.

Full legal references are provided in the Annex to this report[1], and refer to the last amended version of the act.

1 European legislation can be checked at: http://eur-lex.europa.eu

4 Background

4.1 Equine health situation

The UK situation for equine diseases subject to guarantees for IUT is as follows:

Disease	Last occurrence
Equine infectious anaemia (EIA)	2010
Contagious equine metritis (CEM)	2010
Equine viral arteritis (EVA)	2010
Anthrax	2006
Glanders	1928
Rabies	1922
African horse sickness (AHS)	Never reported
Vesicular stomatitis (VS)	Never reported
Dourine	Never reported
Equine encephalitides (EE)	Never reported

(Source: in bold, Animal Disease Notification System (ADNS); other diseases, World Animal Health Organisation (OIE)):

Three outbreaks of EIA were reported in England (EN) in 2010, which were related to horses coming from other Member States (MS). The previous outbreak of EIA occurred in Northern Ireland in 2006, and prior to that, the last occurrence in the UK was reported in 1976.

4.2 Trade patterns

Data on equidae coming from other MS or going to other MS are not readily available. Movements between UK, France and Ireland are free and require no registration. However, all movements of equidae from the UK to other MS must be subject to TRACES notification: more than 7,700 equidae, the vast majority of them considered as registered equidae, were subject to such notification in 2010 (10% more than in 2009). Movements of registered equidae from other MS may not be systematically registered in TRACES; therefore, the 3,300 equidae reported as moving from the 24 MS may not represent the total picture.

Trade 2010	Consignments	Germany	Netherlands	France	Other
Equidae from UK	7 763 equidae	1 545	1 212	-	1 279
Equidae into UK	3 379 equidae	1 092	70	-	BE: 1 182
Equine semen from UK	5 286 doses	920	280	2 758	IE: 745
Equine semen into UK	9 890 doses	2 645	3 714	1 074	IE: 1319

Trade in equine semen must be reported in TRACES. The number of consignments recorded in 2010 represents an increase of 20% to 25% compared to similar data from the previous year, but data do not allow a comparative analysis on the number of doses traded.

In addition to trade from other MS, a significant number of equidae are imported from third countries into the UK (2 000 in 2010), principally from USA (30% of imports, Argentina and United Arab Emirates (20% each)). The total population of equidae in the UK is estimated to be below 850 000 heads (source: OIE).

5 Findings And Conclusions

5.1 Legislation

5.1.1 Legal requirements and basis

Council Directive 2009/156/EC, repealing Directive 90/426/EEC, lays down the animal health conditions for movement of equidae between MS. It lists 7 diseases or groups of diseases that are compulsorily notifiable, and in the event of which restriction in IUT is to be applied to the holding of origin, until its health status is restored following the conditions described in the Directive. AHS, which is also a compulsorily notifiable disease in the Directive, is subject to specific rules, and restrictions, laid down in this Directive (for movements) and in Council Directive 92/35/EEC (for control rules).

Council Directive 92/65/EEC lays down the conditions applicable to equine semen collection and storage centres, to donor stallions and to semen, in view of IUT of this commodity. These conditions have been amended by Commission Regulation (EU) No 176/2010.

Commission Regulation (EC) No 504/2008 defines the methods to be applied in the EU for identification of equidae.

5.1.2 Findings

In EN, the "infectious diseases of horses" order (1987) makes compulsorily and immediately notifiable the diseases of Annex I to Directive 2009/156/EC, with the exception of anthrax and rabies (covered by the "anthrax" and "rabies (importation of dogs, cats and other mammals)" orders). This obligation refers to owners or keepers, and veterinarians. In addition, CEM must be notified by testing laboratories. The "equine viral arteritis" order (1995) makes the suspicion of this disease notifiable in some cases (stallions, or mare within two weeks after breeding).

The measures described in Article 4(5) of Directive 2009/156/EC in case of outbreak of equine diseases are not laid down as such in the national legislation. However, the "infectious diseases of horses" and "movement of animals (restrictions)" orders give powers to the CA for the application of movement restriction or prohibition as deemed necessary. In addition, the "specified diseases (notification and slaughter)" order also foresees the possibility to slaughter equidae infected or exposed to EIA, AHS or VS (but not for EE). The CA stated that, although West Nile Fever was not specifically mentioned in the legislation, it would consider it as being an EE.

The Horse passports regulation (2009) lays down implementing rules to Regulation (EC) No 504/2008, and includes some additional requirements, such as the obligation to notify the change of ownership, the restriction of implantation of transponders to veterinarians registered in the country, and the exclusion of equidae from the food chain when first identified outside the time limits. It also provides for more flexibility compared to the Regulation on some (minor) points, such as the possibility to return an invalidated passport to the owner, or the possibility to remove wild or semi-wild equidae from derogated areas without identification, if an application has been documented.

In Northern Ireland (NI), the "diseases of animals" order (1981), and the "specified diseases (notification)" order (2004) make the diseases of Annex I to Directive 2009/156/EC (and CEM) compulsorily notifiable (with additional acts for anthrax and rabies, as in EN). Slaughter can be ordered for all diseases (except for EIA), in which case compensation is foreseen. The "equine viral

arteritis" order (1996) mirrors the one in EN. Powers to restrict movements of animals in case of any disease is given to the CA by the "movement of animals (restrictions)" order (2004).

The "horse passport" regulations (2009) lays down implementing rules similar to those in the EN regulation.

When no disease is suspected or confirmed, movements of equidae, and collection, processing, storage or movement of equine semen within the UK, are not legally subject to controls or health requirements.

For IUT, Directive 2009/156/EC and Directive 92/65/EEC are applicable in EN as per "trade in animal and related products regulations 2011" in EN. The same Regulation also transposes Council Directive 90/425/EEC on the veterinary checks applicable to IUT. In NI, the "animals and animal products (import and export) regulations 2006", amended in 2011, serves the same purpose. However, this piece of legislation still incorrectly refers to the repealed Directive 90/426/EEC. The CCA indicated to the mission team that Council Directive 92/35/EEC has not yet been transposed into national legislation, but that they are working on it.

5.1.3 Conclusions

Although Directive 2009/156/EC has not been formally transposed into NI legislation, adequate legislation is in place to implement EU rules for identification of equidae, collection, processing and storage of equine semen, and for animal health conditions and controls related to IUT, in the territories visited by the mission team. The fact that Directive 92/35/EEC has not been transposed has no impact on IUT, as AHS is compulsorily notifiable, and would trigger a total ban until control rules defined in this Directive are applied.

5.2 COMPETENT AUTHORITIES

5.2.1 Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires MS to designate the CA responsible for official controls, and sets out minimum operational criteria. Staff carrying out official controls must be free from any conflict of interest; effective coordination between authorities and effectiveness, and quality and consistency of official controls, shall be ensured.

Article 5 of Regulation (EC) No 882/2004 defines the conditions under which the CA may delegate specific tasks related to official controls to a control body.

Article 6 of Regulation (EC) No 882/2004 requires that appropriate training is given to the staff in their area of competence, enabling them to undertake their duties competently.

Article 8 of Regulation (EC) No 882/2004 requires that CA carry out official controls in accordance with documented procedures, with instructions for staff. They must verify the effectiveness of official controls.

5.2.2 Findings

The designation and general organisation of the CA at the time of the mission was described in the FVO country profile (http://ec.europa.eu/food/fvo/act_getProfile.cfm?pdf_id=55, valid as from

April 2011). In the field of equine identification, the CCA has delegated the tasks related to evaluation and supervision of the passport issuing organisations (PIOs) in Great Britain (GB) to a private body.

Observations:

- The level of delegation from the CCA (DEFRA: Department for Environment, Food and Rural Affairs) to its executive agency (AHVLA: Animal Health and Veterinary Laboratories Agency), of the delivery of the policy regarding equine semen. DEFRA was still in charge of the approvals of semen collection and storage centres, and developed guidelines for certification of equine semen; AHVLA developed guidelines for official supervision of the semen centres. In other species, DEFRA had delegated the whole range of activities to AHVLA.

- No formal agreement (contract, service level agreement,...) between the CCA and the private body in charge of official controls of the PIOs had been developed. No description of tasks, or evidence of standard of operation of the body was available.

- The CCA confirmed that a "veterinary service supply project", aiming at developing the training and quality delivery of certifying veterinarians, with new arrangements expected to be in place from 2012 (as reported in the country profile) is under way, but no details were available yet.

- Private veterinarians are used as official veterinarians (OV) for certification purpose. They may not certify animals or commodities that they own, or belonging to a person or organisation from which they get the majority of their income. They must abide by general commitments (on the principles for certification, including avoiding conflict of interest). The CA indicated that further reflection is on-going on the subject, in order to define more criteria.

- Training was organised at local level for private veterinarians acting as official veterinarians, but no formal training was available for veterinary officers in charge of official supervision of equine semen centres.

- The CA in charge of official controls or enforcement in the field (Local Authorities (LA), or Regional offices from AHVLA) have only limited access to the information contained in the national equine database. They do not have the legal power to access information including personnel data, although this information is covered by professional secrecy. The same CA have full access to the information contained in the animal databases developed for other species.

- The LA indicated that the current system for registration of enforcement activities does not provide for such registration in case of holdings which have only equidae (as they are not registered); no alternative system has been put in place in this sector.

- As detailed in the following chapters, information and instructions are largely developed and distributed by the CA in the fields covered by this audit. Procedures were in place and applied in GB to verify the certification for IUT, and to take corrective action when needed. However, no procedure was in place to verify the implementation of official controls for equine semen, and the guidelines or instructions developed were insufficient to guarantee

consistency of these same official controls.

5.2.3 Conclusions

The CA in the UK largely operate in accordance with the the general obligations stated down in Regulation (EC) No 882/2004. Progress has been made in order to ensure quality and consistency of certification, and work is on-going on the issue of conflict of interest in this frame.

However, weaknesses were identified in the general obligations in the very specific field of official controls in equine semen (designation of CA, training and instructions for staff, verification procedures), and for identification of equidae (coordination between CAs, and legal powers of staff performing official controls). Weaknesses were also identified in the operational criteria for official controls on identification of equidae.

5.3 IDENTIFICATION AND REGISTRATION OF EQUIDAE

5.3.1 Legal requirements

Regulation (EC) No 504/2008 requires that the equidae are to be identified and defines the system or identification of equidae, which includes an identification document (passport), a method to ensure the link between the passport and the animal (a transponder, unless derogation), and a database, recording each equid under a universal equine life number (UELN) and the first recipient of the passport.

Passports must be issued for registered equidae and equidae for breeding and production (as defined in article 2(c) and (e) of Council Directive 2009/156/EC). For registered equidae, passports are issued by bodies approved or recognised by the CA, or the official agency of the MS, or a branch of an EU-based international association managing horses for competition or racing. For equidae for breeding and production, the issuing body is to be designated by the CA. Passport issuing bodies (PIOs) must record information in their own database, and immediately incorporate it into a central database.

Regulation (EC) No 504/2008 was applicable since 01/07/2009. Since that date, passports must be issued to foals in the year they are born, or within 6 months of age. Equidae which were older at that time and had no passport (which were previously only required in case of movement of equidae), were to be identified before the end of 2009.

The passport contains sections as set out in its Annex I to the Regulation. These have been modified compared to the previous formats, with a new section VIII, where the official veterinarian may temporarily invalidate the passport in accordance with Article 4(4) of Directive 2009/156/EC. The passport must accompany registered equidae and equidae for breeding and production at all times, with a derogation possible for equidae for slaughter under 12 months, under certain conditions.

5.3.2 Findings

5.3.2.1 System in place

In accordance with Article 4(5) of Regulation (EC) No 504/2008, the list of Passport issuing bodies (PIOs) are available to the public on the CA website (http://www.defra.gov.uk/wildlife-

pets/pets/horses/). The list includes 64 active PIOs approved or recognised for maintaining or establishing studbooks, and 18 active PIOs authorised under "domestic horse passport regulations".

A central database, privately run, is operational for the UK. Basic information on equidae can be checked online. (http://www.nedonline.co.uk/public/Home.aspx)

The evaluation for authorisation of PIOs, and their supervision, has been delegated to a private body in EN, while it remained the direct responsibility of the CA in NI.

Enforcement of identification of equidae is under the responsibility of the Local Authorities (LA).

5.3.2.2 Observations on PIO management

- No guidance is available in EN to distinguish between PIOs identifying registered equidae and those identifying equidae for breeding and production. Whereas most of the PIOs with studbook may fulfil the conditions for registered equidae (with some more questionable, such as the one for donkeys (not a breed)), the evaluation of the other PIOs, which identify only certain categories of equidae, is subject to interpretation. The notes for guidance for certification in NI did indicate which PIOs could be considered as for registered equidae, but they restricted their guidance to the PIOs established in NI (whereas owners can identify their equidae with any PIO in the UK).

- At least 14 active PIOs are authorised to identify any type of equidae, where Regulation (EC) No 504/2008 only foresees one such organisation for equidae for breeding and production.

- The list contains some PIOs that ceased their activities, with an indication of the PIO that took over their tasks, for business continuity. However, this was not available for all PIOs that ceased their activities[2].

- The control body had a rolling programme of audits of PIOs in place: in 2009 and 2010, 9 PIOs were subject to such audits. No criteria or operational guidelines are available for the PIOs authorised under the "domestic horse passport regulations".

- Guidelines from the CA were available both in EN and NI for applicants for recognition as a "breed organisation or association". However, in both places, these guidelines were referring to repealed legislation, and in particular did not refer to the identification requirements introduced by Regulation (EC) No 504/2008[3];

- In NI, a declaration and undertaking was requested from the authorised PIOs, but no effective monitoring of the PIOs was in place.

- Some PIOs on both lists were situated in another MS; no arrangement was in place for ensuring their supervision, or their interaction with the national database. In addition, the mission team was informed that owners could get identification of horses born and raised in

2 In their response to the draft report, the CA of the UK indicated that they have since published an updated list where all PIOs which had their recognition removed are listed.

3 In their response to the draft report, the CA of the UK indicated that the recognition pack for new PIOs shown to the inspection team included an older version of the guidance, but that this shortcoming has been rectified since. They also indicated that refreshed guidance notes were issued to all PIOs in 2009 following implementation of Regulation (EC) No 504/2008.

UK by PIOs situated in other MS, and not appearing on the national list of authorised PIOs.

– A PIO for registered horses was keeping and updating much more information in their database than the minimum required in Article 21 of Regulation (EC) No 504/2008: additional identification process (including DNA markers) was used, holdings and their locations, movements (including at national level)were registered. The other PIOs had also their own database.

– One PIO visited was within the same ownership as a horse slaughterhouse, but no horse identified from this PIO had been accepted by the official veterinarian in charge for the last four years.

5.3.2.3 Observations on passports

– The procedures in NI foresee that a sample passport must accompany an application for PIO authorisation. However, the first passports that a PIO in NI issued were of an incorrect format (A4 format sheets, with no binding between pages);

– The standard of passports presented important variations among PIOs. Some were in line with Regulation (EC) No 504/2008, and presented good protection against possible alterations. A PIO visited was issuing passports of incorrect format, (without section VII or VIII, incorrect format of sections I, II and IX), and for which pages could be easily removed or printed and changed. Similar findings were found on passports from various PIOs, by the local CA in charge of EIA outbreak.

– UELN were used in all passports seen by the mission team, when issued after 06/2009. Some PIOs were issuing passports without evidence of microchipping of the animals, or without evidence that the microchip had been administered by a veterinarian (although required by national legislation). Some of them were not excluding the equidae from the food chain when identified outside the time limits.

5.3.2.4 Observations on national database

– The National database allows basic queries on line, using the microchip number, the UELN or the name of the equid;

– The PIOs are required to update the database at least once a month. Some PIOs had direct network connection to the database to send the updates; another PIO indicated that it was sending information at least on a monthly basis, but horses identified more than a month ago were still not included in the central database.

– The status of "registered equidae" or "equidae for breeding and production" is not indicated in the central database[4];

4 In their response to the draft report, the CA of the UK indicated that the distinction between the two categories is to be rectified in the database, and that a process has been agreed in that respect.

5.3.2.5 Observation on enforcement

- The CCA indicated that enforcement of identification of equidae is not a national priority, and that the focus is rather on education and information of owners. The level of checks is left to the decision of each LA, which are equipped with transponder readers.

- As registration of holdings of equidae is not compulsory, the LA cannot register their official controls in the database used for this purpose, unless the holdings are registered for some other purpose. No other formal communication channel has been set up between LA and the CCA for this purpose.

- The CA at local level does not have unrestricted access to the data in the national database (they cannot check the last owner registered in the database). The local officials indicated that they could send request, but a reply could take up to five days, and was deterrent to efficient control and enforcement activities. The CCA explained that the limited access was due to legal constraints.

- The local CA in charge of an outbreak of EIA identified a number of shortcomings on the passports issued by some PIOs. Despite a thorough evaluation of the management of the outbreak and documentation on the lessons learnt (see section 5.4.2.), the problems related to identification were not identified as an issue.

5.3.3 Conclusions

A system for identification is in place, and by adopting further requirements (notification of change of ownership), has the potential to produce further support for animal health control purposes. However, its purpose and efficacy is weakened by the shortcomings identified in the enforcement activities and system (delayed update and restricted access to the central database; low priority of the enforcement of the obligations, and absence of integrated reporting system of enforcement activities).

The standard of operation of these PIOs varies greatly, and the identification issued by some PIOs is not compliant with the EU requirements. The fact that many PIOs are authorised to issue passports for horses for breeding and production, with insufficient controls, and while the Regulation foresees this category to be identified by one PIO, creates an unfavourable environment for the quality of identification of this category of equidae. The absence of clear definition of the equidae for breeding and production at this stage, hinders their further correct classification/recognition as such.

5.4 ANIMAL HEALTH CONTROLS

5.4.1 Legal requirements

Council Directive 82/894/EEC requires the MS to notify the Commission and other MS within 24 hours of confirmed primary outbreaks of any diseases listed in its Annex I, and the removal of restrictions in relation to the outbreak after eradication. The diseases affecting equidae which are in this annex include: AHS, dourine, EE, EIA, glanders, VS.

Article 4(5) of Council Directive 2009/156/EC states the extent and duration of restriction to be applied in case of outbreaks of diseases, for the purpose of IUT. Council Directive 90/425/EEC foresees the possibility of MS to perform non-discriminatory checks on arrival of animals or animal

products from other MS.

Article 12 of Directive 90/425/EEC requires that all dealers engaging in IUT to be registered in an official register and keep a record of deliveries and subsequent destinations of animals and products originating in another MS.

5.4.2 Findings

Surveillance of diseases of equidae is performed through general passive surveillance (including possible presence of animal health officers from LA at markets), and active surveillance through statutory tests (pre-export, post import testing, or testing in the frame of semen collection for IUT), or private testing (standards applied by some individuals or associations for gathering, pre-vaccination, sales or breeding).

A central unit of the CA performs a daily monitoring of worldwide exotic notifiable disease outbreaks, and produces reports on the risk assessment according to the evolution of the international situation.

http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/monitoring/poa.htm)

According to these reports and the level of risk, actions are taken by the CCA in order to ensure proper enforcement of import and trade rules, increase the surveillance, or to implement disease control measures.

Advance notification is required from operators intending to receive equidae or equine semen from another MS. Checks at destination are decided either at the local level, according to a risk assessment, or by the CCA, as a result of the monitoring of risk. In such cases, samples may be taken and movement restrictions applied.

All suspicions of notifiable exotic diseases (including non-negative results from laboratories) are reported to a central unit of the CA (Veterinary exotic notifiable diseases unit), which documents, and may review or direct further investigations. All diseases listed in Annex I to Directive 2009/156/EC (except anthrax), and the additional equine diseases covered in Directive 92/65/EEC (EVA and CEM), are included in this scope.

Suspicious cases of EVA which are reported are followed in so far it is possible or necessary (if stallions left the country or are gelded, or were vaccinated in accordance with agreed protocol, or mares were not mated within 14 days prior to blood sampling, the suspicions cases are closed). Cases not closed are confirmed following virus isolation in semen. Restriction on natural mating or semen collection is imposed, as well as restriction of transfer of ownership. Movement of infected stallions must be notified to the CA. In case of CEM, the CA refers to the industry code of practice for restriction, treatment and prevention of spread of the disease.

At national level, equine disease surveillance reports are jointly produced by the CA and non-governmental organisations, and are made public (http://www.aht.org.uk/equine_disease.html).

In case of suspicion or confirmation of an outbreak of a notifiable disease, movements or restrictions are officially notified, and enforced with the participation of the LA. The management of EIA outbreaks in 2010 was subject to publication and analysis, which are available on internet: (http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/eia/index.htm)

Observations:

- The number of tests on equine diseases performed in the frame of national surveillance was not readily available;

- The current risk-based checks at destination for equidae in UK included systematic visits and sampling of live equidae coming from Romania (for EIA in place before it became compulsory, as per Commission Decision 2010/346/EU) and Italy (for EIA and dourine). In addition, these equidae are subject to movement restriction until the analysis results are available; equine semen from Italy was not subject to any control.

- Additional checks on arrival are performed by the local CA according to their perception of risk (including local knowledge, and history of previous non-compliances). These checks and their results are reported in TRACES database.

- Checks at destination are also done on equine semen. The CA noted a number of irregularities for semen coming from other MS, calling into question the integrity or legality of the consignments. Two letters have been sent to the chief veterinary officers of the MS of origin.

- The CA and operators of SCC indicated to the mission team that it was quite common that semen were coming from MS without a health certificate; in most cases it was difficult to gather material evidence for the CA to take action. Some occurrences were linked to the delays in getting a health certificate on time accompanying a consignment of fresh semen.

- The 2010 outbreaks of EIA were reported by the CA in the ADNS database. Reports on their management, and the on-the-spot review by the mission team of one of them show that the restrictions applied were in line with measures foreseen in Directive 2009/156/EC. In addition, extensive epidemiological review, surveillance and controls were performed. Official notice of movement restriction was delivered, a census and identification of all equidae was performed. However, the movement restriction was not entered in the section VIII of the passports of the equidae already identified, as none of the passports presented such a section (including the 22 equidae which had a passport issued after June 2009, from 2 PIOs from UK, and 2 PIOS from other MSs).

- Equidae infected with EIA were rapidly killed and destroyed (within one day of confirmation). In EN, a regulation foresees a standard compensation of 1 pound per animal. NI does not foresee any compensation to the owner of horses killed because of EIA, but this did not prove to be a problem for the slaughter of the two infected animals in 2006.

- The experience learnt from the outbreaks of EIA identified the particular risk represented by dealers involved in IUT. However, in the absence of a legal definition of dealer of equidae, the CA cannot apply further requirements to these operators.

- Documentation on a case of EVA was also reviewed by the mission team, demonstrating the measures taken in accordance with the national legislation.

5.4.3 Conclusions

The surveillance system in place substantiates the favourable equine disease context in the UK. The risk analysis linked to accrued surveillance, and the prompt reaction and declaration in case outbreak, brings further confidence. The risk linked to introduction of equine semen not meeting the health conditions has been identified, but is not fully controlled.

Considering the absence of traceability system for equidae at national or EU level, and the health situation in the UK, the movement restriction accompanying the checks at destinations performed on equidae coming from other MS cannot be considered as discriminatory.

The absence of compensation for killing equidae infected with EIA is a risk factor, but did not prove to be deterrent for the application of swift eradication measures in the few outbreaks experienced in the last few years in the country.

5.5 Semen collection and storage centres, embryo collection and production teams

5.5.1 Legal requirements

Article 11 of Council Directive 92/65/EEC lays down the criteria that equine semen must meet in order to be subject to IUT. These criteria include structural and operational conditions for the semen collection centre (SCC) or semen storage centre (SSC), for the health status of the animals collected, and for collection, processing, storage and transport of semen. These conditions are detailed in the Annex D to the Directive. The centres must be under permanent supervision of a centre veterinarian (CV) authorised by the CA.

Donor stallions must meet health conditions and be subjected to health tests for EIA, EVA and CEM, the frequency of which is established according to the type of semen (frozen or not), and in the latter case also to the minimum residency period before first collection, the type of residency (continuous or not), and the possible contact with equidae of lower health status.

If the SCC shares a site with artificial insemination or service centre, the animals for the latter activities should also meet the same health conditions (but not subjected to health tests).

The conditions described in Annex D to the Directive have been amended by Commission Regulation (EU) No 176/2010, to be applied from 01/09/2010.These amendments included the creation of conditions for approval and supervision of SSCs, the requirements that the CV be authorised by the CA and his supervision of SCCs be permanent, a modification of the health test regimes for donor stallions, and more detailed criteria on the use of antibiotics in processed semen.

5.5.2 Findings

5.5.2.1 Approvals and official supervision

The list of semen collection centres (SCCs) and semen storage centres (SSCs) is available to the public (http://animalhealth.defra.gov.uk/about/premises/approved-premises.html). At the time of the mission, the list contained 14 SCCs and 4 SSCs. No approved embryo production or collection team was listed.

In EN, following a request for approval from an operator, a visit and follow-up is made by the AHVLA at local level. When the local CA is satisfied that the centre meets the requirements for approval, it requests DEFRA to issue an approval number. In NI, the approval of SCCs and SSCs is devolved to one officer, specialist of the equine sector. Similarly, DEFRA is contacted to issue an approval number.

Annual supervision visits are performed by the same level as approval. Guidelines and check-lists have been developed by AHVLA in GB. The check-list is used to document the visit. In case of non-compliance, the matter is discussed with the operator, and if estimated as not being minor, a report is issued and transmitted to the operator, with a deadline for corrective action.

Observations:

- The list is being kept updated, as three months before the mission, 22 SCCs were listed. Whereas in the previous versions of the list, SCCs ceasing their activities were maintained in the list, with the date of termination indicated in the "remarks" section (which allowed a check on frozen semen that may have been produced during their approved period), the latter version removed all reference to SCCs no longer approved. The update was not complete, as a SCC which ceased all activities a year ago was still indicated (as active) on the list.

- The notification of approval to the SCCs or SSCs is not formally documented by the CA in EN; in NI, an official approval was issued on annual basis, and renewed following the official supervision visit (making the centres technically no longer approved when the visit was delayed).

- A map of approved premises was available at the local CA level for all centres visited.

- The AHVLA guidelines developed minimum acceptable standards for isolation of the SCCs. Little additional guidance was available on other aspects, and in particular, no further guidance was available on a number of issues which are subject to interpretation, as for instance:

  - The frequency of official supervision (in particular for stallions the semen of which is collected out-of breeding season for freezing) (Chapter I (II)(1.3) of Annex D to Directive 92/65/EEC),

  - The authorisation by the CA of the CV, "permanent" nature of his supervision (Chapter I (1.1) and (2)(b) of Annex D to Directive 92/65/EEC), or the scope of their supervision (Chapter I (II) of Annex D to Directive 92/65/EEC);

  - The testing programmes, the separation between stallions of various health status in a same SCC, or the conditions under which SCCs can also admit and collect stallions for national trade,

  - Some processing aspects, such as the sourcing of products of animal origin so that there is no animal health risk, or the (differential) marking of doses of semen in such SCCs (Chapter I (II) (1.2)(e) and (h) of Annex D to Directive 92/65/EEC);

- The minimum guarantees that should accompany semen produced in an approved SCC, and going for further storage in another SCC or a SSC.

- The guidelines for certification of equine semen developed in NI, and by DEFRA in EN, address some of these points (see chapter 5.7.2);

- No monitoring was in place on the completion of annual (or bi-annual) official visits in equine SCCs or SSCs, but veterinary officers may contact central level in case of doubts or queries. No specific training for officers in charge of approval and supervision of equine SCCs and SSCs was available; no higher level (supervision) inspections was in place to ensure consistency in the adequacy of official supervision of all SCCs and SSCs.

- In the office where this was checked by the mission team, the only supervision visit that was documented was the one of this year, whereas the centre had been approved six years ago. The mission team was also informed that a SCC approved in 2007 (and removed in 2011) had never been subject to annual inspection, as it never sent semen to other MS.

- The recent reports of annual official supervision did not in general identify the main non-compliances, in terms of infrastructure, operations or health status, observed by the mission team in the SCCs and SSC visited. However, the approval of a SCC was recently removed because of operational non-compliance (collection of semen outside the SCC).

5.5.2.2 Structure and maintenance

The structural standards varied in the centres visited by the mission team.

- In some places, some deficiencies were noted: These deficiencies had been identified by the operators, who had plans to remedy the shortcomings; however, the deficiencies were not indicated in the official visit reports;

  - in a SCC, a collection room had walls which could not be readily cleaned and disinfected;

  - in another SCC, the construction and isolation of the place for storage of semen presented weaknesses in terms of isolation and hygiene. The slip-proof flooring could not be readily cleaned and disinfected, and, together with the dummy mare, needed further maintenance.

- A SCC and the SSC visited had inadequate structural standard:

  - The SSC consisted of a single horse stall located in a stable. The stall was not completely closed, and its structure made it difficult to be cleansed and disinfected (rough concrete floor, no ceiling but a roof with beams).

  - The SCC was not isolated (cattle pens were in the perimeter of the SCC, the stallions shared a shed with equipment for the adjoining farm, and had to leave the perimeter of the SCC to move to the collection area; the entry of unauthorised visitors could not be prevented); no separate room for cleansing and disinfection, or sterilisation of equipment was available; The isolation facilities were not on site and in derelict state; the maintenance and hygiene of the semen processing room was very poor.

5.5.2.3 Supervision and monitoring

The centre veterinarians of all centres visited were veterinary practitioners. In NI, the CA recorded all veterinarians of a local practice as CV of a SCC; in EN, the CV were not formally recorded or authorised as such.

No endorsement by the CV, or formal agreement between the CV and the operator, detailing the scope of supervision devolved to the CV, was in place. The frequency of visits of the CV was not set. In SCCs where the mission checked it, the visits of the CV were not recorded

In most place, the understanding was that the CV was responsible for the clinical checks and sampling of stallions. No or little evidence of involvement of CV on other aspects was available. Such overlooked aspects included:

- the conditions for authorising visitors in the SCC (Chapter I(II)(1.1)(b) of Annex D to Directive 92/65/EEC);
- The training of staff (or its verification) on disinfection and hygiene techniques to prevent the spread of diseases(Chapter I(II)(1.1)(c) of Annex D to Directive 92/65/EEC);
- The guarantee of the health status for semen stored in SSC, or in SCCs acting as SSCs;
- The operational or hygienic aspects related to collection, processing and storing of semen.

5.5.2.4 Operational requirements and donor stallions

The national guidelines request a written declaration from the owners of incoming stallions, regarding the holding of origin, and the date of last natural mating, in order to comply with points (1.3) and (1.4) of Chapter II (I) of Annex D to Directive 92/65/EEC. Such forms, duly completed, were available in the SCCs. The CV was not systematically present at the time of admission to perform a clinical check, and no instruction was available on the checks to be performed in his absence.

All SCCs visited hosted stallions of various status (and testing regimes): permanent and temporary residents, resident for more or less than 30 days in the SCC, for semen to be used chilled (during the breeding season) or frozen (all year round or outside the breeding season). They could host stallions of various health status: for exclusive national use, for EU, or for other export markets (US, Australia, New Zealand, Canada).

One of the SCC had developed elaborate procedures for the care of the stallions of various health status within the SCC (including a quarantine area for the stallions to be tested in the centre before the first semen collection, individual grooming and cleaning material).

Individual files of movement and health test history were kept in all SCCs visited. However (except in one SCC, and for the last season), the records kept were insufficient to show all movements of animals entering or leaving the centre, and were not auditable;

In the SCCs visited, the CV was in charge of the sampling of stallions for health tests within the SCC. There was no evidence of their involvement in the development or approval of testing

regimes. Two of the SCCs had written a protocol or schedule for testing, but none was complete or could demonstrate that they complied with all EU testing requirements according to the category of residency or semen processing.

Elements of non-compliances with the testing regime for stallions were identified in the SCCs visited. They included:

- the absence of post-collection testing for stallions residing for less than 30 days and/or collected for trade in frozen semen (Chapter II (I)(1.6)(c) of Annex D to Directive 92/65/EEC);

- Semen collection before first testing of the stallion (Chapter II (I)(1.6) of Annex D to Directive 92/65/EEC);

- Absence of VI test on seropositive stallions for EVA (Chapter II (I)(1.5)(b) of Annex D to Directive 92/65/EEC);

In one SCC, the operator decided not to perform the (very expensive) VI test on stallions for which EVA vaccination records could demonstrate that they had been vaccinated according to the manufacturer's instruction. However, this vaccination is not performed under official control (in particular for the first sampling prior to vaccination to demonstrate the non-infective status of the stallion; the delay and use of stallion after this sampling until vaccination; and the vaccination itself).

5.5.2.5 Semen collection, processing, storage and transport

Records of semen collection, storage and destination of semen were available in all SCCs. In one of them, these records had been altered by the operator.

Two SCCs visited had developed internal operational and hygienic procedures on various activities related to collection, processing and storage of semen. Indications of weaknesses in hygienic standards of operations were observed (need to fight against flies invasion in one processing room, centrifuge for semen not clean, processing area cramped with stationery material).

Animal health guarantees were sought by the operator for the products of animal origin used in extenders (egg-yolk from certified Newcastle disease-free flock), in the SCC where the mission team checked it. Mixture of antibiotics were usually added to the extender used for processing semen. The name and concentrations were not available in one SCC, in the other ones, mixture differing from the ones described in Chapter III (1.1) of Annex D to Directive 92/65/EEC were used; in at least one case, it could not be considered at least equivalent to the mixture required (combination of penicillin and streptomycin only).

Identification of frozen semen was usually in line with the EU requirements (Chapter I (II)(1.2)(h) of Annex D to Directive 92/65/EEC), but some shortcomings were noted:

- in one SCC, the doses were not marked so that the date of collection of semen could be readily established (use of combination of straw and tap colours codes, to be referred to internal records of the SCC to establish the date). In another SCC, the breed was not indicated.

– One SCC did not indicate its approval number on EU-eligible semen;

– On the other hand, SCCs were identifying semen of stallions kept in the SCC, but not complying with EU standards, with their EU approval number.

The SCCs had no documented procedures to ensure proper separation of semen collection, processing and storage of semen of stallions kept or brought into the centre for national trade only. In one SCC, the operator stated that he would process the lower status semen at the end of the working day, and ensure proper disinfection of the laboratory after.

In the SSC and all SCCs, semen restricted to national use was also stored in the storage room, but in separate liquid nitrogen containers. The storage of semen of stallions of lower health status is prohibited in SSCs (Chapter I (I)(2.1)(a) of Annex D to Directive 92/65/EEC). Operational and structural hygiene deficiencies were noted in all semen storage places visited, of particular importance in two places.

In addition to the SSC, SCC were also receiving and storing semen from other national and international SCCs, in view of their further use or IUT. The documentation accompanying these incoming consignments at national level differed from place to place. In one SCC, the semen was accompanied by a commercial document, without assurance on the health status of the donor stallion. In another SCC, the CV of the despatching SCC issued a letter (posterior to the arrival of the semen), certifying that the semen was compliant with EU requirement, but not giving any detail on the test regime performed).

5.5.3 Conclusions

The SCCs and SSC visited were of various standards of hygiene, operation and biosecurity, but the system for supervision of this activity is generally inadequate.

The guidelines provide little clarification or indication of minimal standards on a number of requirements of Directive 92/65/EEC, including essential ones such as the supervision, the test regimes applicable under various circumstances, and the conditions under which the SCC may also collect, process and store semen from stallions of lower health status.

The management of approvals and its list presents shortcomings, and the correct frequency and consistency of official supervisions is not ensured. Its scope does not cover satisfactorily all aspects. The organisation of the records in the SCCs could not be efficiently audited.

The CV are generally not authorised as such, and are not fully aware of their role. Their permanent supervision is not ensured, and their involvement limited.

The insufficient health guarantees for stallions in the SCCs or incoming semen into the SSC were not identified by the CV or the OV.

5.6 Laboratory performance

5.6.1 Legal requirements

Article 12 of Regulation (EC) No 884/2004 requires laboratories performing analyses for official controls to operate and be accredited following the ISO 17025 standard.

The laboratory tests to be performed for donor stallions in view of semen collection for IUT are described in Chapter II (I)(1.5) of Annex D to Directive 92/65/EEC. They must be carried out and certified in a laboratory recognised by the CA.

5.6.2 Findings

In UK, one laboratory is recognised for statutory analyses for the equine diseases contained in Annex I to Directive 2009/156/EC. This same laboratory also performs statutory analyses for EVA, and a separate single laboratory performs statutory analyses of CEM. These last two diseases are analysed in a separate laboratory for samples taken in NI.

5.6.2.1 Observations regarding laboratories for CEM

In EN, the laboratory confirmed positive culture (using three media), with biochemical properties and PCR. The laboratory was accredited according to ISO 17025, and the scope of accreditation included the culture for CEM. The laboratory indicted that PCR method was validated, but not accredited.

Although the form did not include the reason for sampling or any epidemiological indication, the laboratory staff indicated that they would identify a test performed following disinfection (by the absence of any growth), and would make an enquiry in this case to the submitting veterinarian;

The quality assurance elements checked by the mission team were adequate (including documentation of tests, use of controls, internal proficiency).

The laboratory participated in privately organised proficiency testing (PT), but did not participate in the PT organised recently by the EU-reference laboratory (EU-RL). Although the PT related to evaluation of the culture and biochemical characterization, the laboratory needed PCR confirmation (in one case seen) to reach a proper diagnosis.

In NI, the laboratory was accredited, but not the section where the CEM was performed. CEM tests were performed by culture (using 6 media), and a confirmation by a commercial sero-agglutination test. The laboratory also participated to privately organised proficiency testing (PT), but was not aware of the PT recently organised by the EU-RL

Elements of quality assurance were missing in the NI laboratory. Examinations were not recorded in working sheets on a daily basis, contrary to the requirement of the SOP; dates of examinations were not indicated); results were issued after 6 days when the SOP required a minimum of 7 days incubation; no positive control was available (for parallel culture, or for quality control on the culture media prepared in-house); no documentation on the internal proficiency testing was available. Submission forms presented also weaknesses (there was a date of submission, but no date and time of sampling, for which the SOP requires a check). The table for use of media in the SOP did not consider all the statutory samples (urethral fossa, pre-ejaculatory fluid or semen were not listed).

5.6.2.2 Observations regarding laboratories for other equine diseases

The national reference laboratory in GB is accredited. Its scope of accreditation includes tests methods for the equine diseases listed in Annex I to Directive 2009/156/EC, and for EVA (viral isolation test (VNT) and virus isolation (VI). The laboratory participated to various international PT, including those organised by the EU-RL in recent years (on EIA, and one EVA – VNT, and gene amplification/VI). The laboratory developed a PCR test for EVA in semen, which is currently under validation. This test could prove to be more sensitive than the VI, and significantly cheaper.

The SOP of EIA agar-gel immuno-diffusion test does not specify the timing for reading (it indicates a minimum of 14 hours for plate incubation). The test manufacturer recommends 24-48 hours of plate incubation, and the OIE manual indicates that "a weakly positive reaction may take 48 hours to form". During the EIA outbreak reviewed by the mission team, the first negative results (following removal of infected animal) were issued by the laboratory 24 hours after reception of the sample. However, the last negative tests (3 months after removal of infected animals) were issued 48 hours after reception of the sample.

The SOP for EVA VI, in line with requirement of Directive 92/65/EEC, requires full semen (whole ejaculate). However, no check is foreseen in the SOP to ensure this is the case, contrary to the recommendation of the OIE.

In NI, the sections of the laboratory performing EVA and EIA diagnosis was not part of the ISO 17025 accreditation. The laboratory participated to some PT, but was not aware of the EU-RL PT organised recently. Elements of quality assurance were already introduced, and the laboratory was expecting to include the EIA test in the scope of accreditation soon.

The procedure available for VNT was not standardised, and did not reflect the current procedure used in the laboratory (with shorter incubation practised). VI was performed on samples of frozen processed semen. No validation of such samples was available. Considering that processed semen may include centrifugation of semen and removal of supernatant, there is reasonable ground to expect an impact on the sensitivity of the detection (without ensuring elimination of virus).

The laboratory did not issue formal result reports: results were indicated on the submission sheet, and sent by fax; they did not include the signature or the qualification of the authorising officer.

5.6.3 Conclusions

The laboratories in charge of statutory tests for equine diseases operate according to adequate standards in Great Britain, but not in Northern Ireland, where a number of deficiencies related to quality assurance were identified for CEM and EVA. Virus isolation performed there is not reliable. Results issued by the laboratory in Northern Ireland are not certified.

5.7 Intra-Union trade controls

5.7.1 Legal requirements

Directive 2009/156/EEC lays down the general animal health conditions for movement of equidae between MS. These include prohibition of movements from holdings affected by certain diseases.

An inspection must also be performed on the equidae in the 48 hours prior to their loading. Article 8 of the same Directive requires the registered equidae to be accompanied by a health attestation, and other equidae by a health certificate, drawn up no later than one working day before embarkation of the equidae.

MS implementing an alternative control system providing guarantees equivalent to the ones related to the prohibition of movements from holdings affected by certain diseases within their territory, may grant on a reciprocal basis derogations for pre-movement inspection and certification.

Equidae must be transported from the holding of origin either directly or via an approved marshalling centre, as defined in Article 2 (2) (o) of Council Directive 64/432/EEC to the place of destination.

Directive 90/425/EEC requires that in order to be subject to trade, animals and products must come from holdings, centres or organisations which are subject to regular official veterinary checks on identification, traceability and health certification. The CA of the MS of origin shall communicate data of the movement to the MS of destination on the day the certificate is issued. At the request of the CA, the consignees should give at least one day prior notification of the arrival of the animals (advance notification is not required for registered horses) and keep the health certificates or documents for a period of not less than 6 months. The CA at the place of destination may perform non-discriminatory spot checks and take samples.

The model of certificates for IUT for equine semen have been last established in Commission Decision 2010/470/EU. Three models are available: one for semen collected from the date of applicability of the new health conditions (01/09/2010), the second one for semen collected before this date, and a third one for semen dispatched from a SSC. In this last case, the certificate must be accompanied by the original or official copy of the health certificate or official document which accompanied the semen to the SSC. For the former two certificates, the stallion test regime must be indicated, together with the dates of sampling. For semen collected under the new regime, the combination and concentration of antibiotics must be indicated.

Council Directive 96/93/EC requires the certifying officers not to certify data for which they have no personal knowledge, or data which have not been ascertained by them or another person authorised by the CA. They must not sign blank or incomplete certificates, and when a certificate is signed on the basis of another certificate or attestation, the certifying officer shall be in possession of that document before signing.

5.7.2 Findings

The private veterinarians wishing to act as official veterinarians and sign certificates for IUT must be authorised and registered on a panel according to the type of commodities (one panel for equidae, another one for semen and embryos). Training of veterinarians wishing to be on a panel is organised by regional veterinary offices, on one day for basic aspects, and few additional hours on the aspects specific to the panel.

In EN, an operator wishing to send equidae or equine semen performs a request to a central office ("Specialist service centre for exports"), and may indicate the veterinarian he wishes to use as official veterinarian. Some operators are connected to TRACES, and may prepare the part I of the certificate as part of their request. The central service will perform checks and issue a certification pack to the selected OV, including a pre-certification on the health status of the country or region,

guidelines and check-list to be used, and a model certificate.

The veterinarian performs the checks, completes the certificate, and returns a fax copy to the central office on the same day. The office completes the information into TRACES, and sends the notification. A portion of the certificates are subject to desk-based audits at the central office: 30% of the certificates are subject to administrative checks, with a risk based approach (newly appointed veterinarians, antecedents, sensitive places). 10% of these are in addition subject to a check on the content of the certification.

In NI, a similar system is managed through the local veterinary offices (District veterinary offices), instead of a central structure. No programme is set for checks on the certificates.

UK, France and Ireland have signed a tripartite agreement, granting one another derogations for pre-movement inspection and certification, for all category of equidae except equidae for slaughter. Equidae may move without notification between these MS.

For all other MS, all categories of equidae are subject to TRACES notification and certification. The animal health attestation (Annex II to Directive 2009/156/EC for registered equidae, not requiring a place of destination to be indicated) is not used.

Guidance for certifying veterinarians and exporters of equine semen have been issued by DEFRA for GB, and by the CA in NI. The current version is from March/April 2011. Practically, most of equine semen is certified by the centre veterinarians, or by another veterinarian from the same practice.

Observations:

- The exclusion of equidae for slaughter from the tripartite agreement cannot be controlled, in the absence of residency requirement or traceability of horses.

- The guidelines for issuing certificates for equidae do not explain how to differentiate between registered equidae, and equidae for breeding and production. The vast majority of certificates issued indicated that the equidae were registered equidae, even when they were identified by PIOs issuing identification for any category of equidae.

- The same guidelines in EN clarify the requirement of Article 4(2) of Directive 2009/156/EC, regarding the absence of contact with equidae suffering from infectious or contagious disease during the 15 days immediately preceding inspection, by specifying that this statement refers to the diseases listed in the Directive. However, the required declaration from the owner or breeder does not need to be documented. In NI, a written declaration is required, but is also accepted if issued by the exporter.

- The NI guidelines indicate that for frozen semen, the testing option to be applied is the one described in Chapter II (1.6)(c) of Annex D to Directive 92/65/EEC. The EN guidelines are less precise on this matter.

- The guidelines in NI foresee the issuance of a veterinary service support certificate regarding the approval of the SCC and its health status, issued by the local veterinary office to the certifying veterinarian. They also foresee an owner's or exporter's declaration (but not by the CV) on the compliance of a number of operational and health conditions. The

guidelines in EN do not indicate the verifications to be done in order to certify the conditions related to approval and supervision of SCCs or SSCs, and the ones for collection, processing and storage of semen;

- Guidelines in EN indicate that in order to be certified, semen from a SSC coming from a national SCC must have been legally processed in an EU approved SCC, without considering that SCC also legally produce semen of stallions which do not comply with the EU health requirements (for national market). The guidelines in NI request semen in a SSC be certified only in presence of a IUT certificate in case it was produced in a UK SCC.

- The check-list for semen in EN indicates that semen from UK can be certified from a SSC only if a completed check-list from the SCC is available to the veterinarian. However, this check-list does not cover all aspects to be certified, does not contain details on antibiotics used, and it is indicated that it must not accompany the health certificate.

- No indication is available on the frequency or type of physical check that should be performed on the semen to be exported, or on the sealing of the container. Sealing of containers is left to the responsibility of the operators.

Out of 148 certificates issued in 2011 for equine semen, 15 were subject to complete audit by the central office. Nine of them contained errors or incorrect statements, and warning letters had been issued to the certifying veterinarians, and local veterinary offices informed. The mission team checked some of the certificates assessed as correct, and identified further mistakes or incorrect statements. In addition, by cross-checking elements certified with evidence available in the SCC, the mission team identified further incorrect certification. Some examples of these incorrect certification included:

- Use of the wrong model for certification;

- No identification of the stallion or semen in the certificate (in NI);

- Animal health attestation not completed;

- More than one testing regime certified for the same batch and stallion,

- Dates of testing not indicated; or dates of testing not complying with the delays required and indicated in the certificate;

- Two batches of semen collected from the same stallion and the same period, was certified from the SCC of origin, and from a SSC. The certificates differed on the residency/testing regime applied to the stallion, and the dates of sampling for the tests;

- Testing regime certified not complying with the status of the stallion/semen;

- Dates of testing indicated in a certificate, for which no support or documentation could be found, and which were not recorded at the SCC.

TRACES notifications could be delayed in some cases, but evidence of checks and corrective measures were seen in EN and NI. Most of the certificates do not include the approval number of the SCC or SSC of origin, and many of them indicate the wrong species (donkeys instead of horse

semen). The TRACES notifications in EN incorrectly indicate, instead of the certifying veterinarian, the name of the administrative officer who entered the data; in NI indicates the name of the local office which notified (this issue has been raised in the context of development of TRACES).

5.7.3 Conclusions

The certification system of live equidae from the UK provides some guarantees in addition to the ones foreseen in EU legislation (with notification and place of destination indicated for all categories of equidae, including registered equidae) which makes the insufficient categorisation of equidae of little relevance from an animal health point of view (but not on an animal welfare point, as only registered equidae are exempt from a route plan). However, the system omits substantiation the declaration of the owner or breeder on the possible contacts of their animals in the days preceding the export.

The guidelines for IUT in semen provides more clarifications on some aspects subject to supervision and monitoring of the SCCs and SSCs. As these aspects were not clarified for the official and routine supervision, the clarifications are made at a stage too late, illustrating an insufficient coordination between the CAs which developed them, and indicating a need for a global vision of the way the system can bring adequate guarantees.

The inadequate documentation of procedures and organisation of records, linked to the absence of clear definition of the responsibilities and the limited involvement of the centre veterinarian, and the insufficient official supervision of the centres, make it extremely difficult for any veterinarian to have access to sufficient knowledge to certify the required data.

The standard of many certificates issued by veterinarians acting as official veterinarians was not acceptable, as incomplete certificates have been issued, and inaccurate data on health tests have been certified.

6 Overall Conclusions

The very favourable animal health situation for equidae in the UK is substantiated by an elaborate risk-based surveillance, prompt declaration and intense control activities in case of outbreak.

The certification system for live equidae in the UK provides more guarantees than those foreseen in EU legislation, making the lack of differentiation between registered equidae and equidae for breeding and production of little consequence from an animal health point of view.

However, the organisation of the identification of equidae (giving room for high variation of operational standards) and the deficiencies in related official controls are such that the system cannot ensure consistent application of the required standards in this area.

The health guarantees and the certification provided for equine semen for IUT are not fully reliable. The risk posed by this is mitigated to some extent by the reportable nature (by the laboratories to the CA) of the diseases involved, but not completely as some health tests are not performed as required. The health risk posed by these shortcomings applies in particular to EVA, and for frozen semen. The laboratories used for analyses in Great Britain were of adequate standard, but not the one in Northern Ireland.

The CA presented evidence that other Member States also encounter similar difficulties in relation to certification of equine semen. EU requirements for animal health conditions applying to donor stallions and their certification were considered by all stakeholders met to be particularly complex and difficult to interpret.

7 Closing Meeting

A closing meeting was held on 1 July 2011, where the main findings and conclusions of the mission were presented to the competent authorities.

8 Recommendations

The Competent Authorities of the UK 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.	Ensure an effective coordination with CAs performing official controls on identification of equidae (article 4 (5) of Regulation (EC) No 882/2004); ensure that staff carrying out official controls on equine identification have appropriate legal powers (article 4 (2)(e) of Regulation (EC) No 882/2004), including for consultation of the central database; ensure that passports issuing bodies communicate immediately their information to the central database (Article 21 (3) of Regulation (EC) No 504/2008).
2.	Ensure that identification documents for registered equidae are only issued by bodies from UK as described in Article 4(1) of Regulation (EC) No 504/2008, and for equidae for breeding and production, only by the body designated by the CA, as described in Article 4(3) of the same Regulation.
3.	Ensure that all passport issuing bodies comply with their obligations, as described in Regulation (EC) No 504/2008; when tasks for official controls are delegated, ensure that this delegation is performed in accordance with the criteria laid down in Article 5 of Regulation (EC) No 882/2004.
4.	Ensure that all health tests performed in the framework of Council Directives 2009/156/EEC and 92/65/EEC are analysed in laboratories meeting the requirement of Article 12(2) of Regulation (EC) No 882/2004, and that the tests results are certified by the laboratory (Chapter II (I)(1.5) of Annex D to Directive 92/65/EEC).
5.	Ensure the quality and consistency of official controls of equine semen collection and storage centres (Article 4(4) of Regulation (EC) No 882/2004), and their frequency (Chapter I (II)(1.3) and (2.4) of Annex D to Directive 92/65/EEC) by, inter alia, reviewing the training (Article 6(2) of the Regulation) and instructions (article 8(1) of the Regulation) for staff , and organising verification procedures (Article 8(3)(a) of the

N°.	Recommendation
	Regulation).
6.	Ensure that Semen collection centres and semen storage centres are under permanent supervision of a centre veterinarian, authorised by the competent authority (Chapter I, (I) (1.1) and (2)(b) of Annex D to Council Directive 82/65/EEC), with a clear a common understanding of the extent of supervision required.
7.	Ensure a correct and consistent selection of one of the three testing programmes applied for stallions (Chapter II (I) (1.6) of Annex D to Directive 92/65/EEC), taking into consideration the nature of the semen and the presence of other equidae of lower status.
8.	Ensure that the supervision and monitoring of semen storage centres ensure that all incoming semen, including from national origin, comply with conditions laid down in Chapter I (II)(2)(2.1)(a) and (2.2)(b) of Annex D to Directive 92/65/EEC.
9.	Ensure that the list of approved semen collection and storage centres is kept up to date, as required by Article 11 (4) of Directive 92/65/EEC.
10.	Ensure that certification of live equidae is not performed without a declaration from the owner or breeder of the equidae, required by Article 4(2) of Council Directive 2009/156/EC.
11.	Ensure that the certifying officers for equine semen have a satisfactory knowledge of the legislation and are informed on the extent of the enquiries they should carry out before certification (article 3(1) of Council Directive 96/93/EEC); consider in this context defining the organisation of records to be kept in the centres permitting enquiries, and the respective responsibilities of centre veterinarians and veterinarians performing official supervision, and certifying veterinarians, for ascertaining all data.

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

http://ec.europa.eu/food/fvo/ap/ap_gb_2011-6056.pdf

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Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dir. 82/894/EEC	OJ L 378, 31.12.1982, p. 58-62	Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community
Dir. 90/425/EEC	OJ L 224, 18.8.1990, p. 29-41	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market
Dir. 90/427/EEC	OJ L 224, 18.8.1990, p. 55-59	Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae
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
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

Legal Reference	Official Journal	Title
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae
Dec. 2010/346/EU	OJ L 155, 22.6.2010, p. 48-53	2010/346/EU: Commission Decision of 18 June 2010 on protective measures with regard to equine infectious anaemia in Romania
Dec. 2010/470/EU	OJ L 228, 31.8.2010, p. 15-51	2010/470/EU: Commission Decision of 26 August 2010 laying down model health certificates for trade within the Union in semen, ova and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species
Dir. 64/432/EEC	OJ 121, 29.7.1964, p. 1977-2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine