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FINAL REPORT OF A MISSION
CARRIED OUT IN
ROMANIA
FROM 30 NOVEMBER TO 10 DECEMBER 2010
IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS ON INTRA-UNION TRADE
IN LIVE EQUIDAE

Executive Summary

The objective of this mission was to evaluate the animal health controls on intra-Union trade (IUT) in live equidae, to follow-up the previous Food and Veterinary Office (FVO) mission in that respect and, in particular, to review the implementation of protective measures with regard to equine infectious anaemia (EIA) in Romania set out in Commission Decision 2010/346/EU.

Concerning the outcome of the mission, the mission team concluded as follows:

In many Romanian counties, EIA is still endemic. Since the adoption of Commission Decision 2010/346/EU in June 2010 laying down restrictive measures for IUT, no commercial trade of equidae from Romania to other Member States (MSs) has taken place.

In Romania, the eradication of EIA is now of high priority. The competent authority (CA) has made an effort to put in place an EIA eradication programme in order to resume full participation in IUT of live equidae. However, official efforts to control the disease have been unsuccessful.

An unknown number of equidae are not under the control of the CA. Official veterinarians (OVs) have no power of access to individual homes without the consent of the owner when the equidae are kept in his/her home. These equidae might be not identified, not tested and, when tested positive for EIA, illegally moved or home slaughtered. The official controls and enforcement measures taken by the CA were in general insufficient to tackle these problems.

Although the newly reorganised compensation scheme is increasingly accepted by the owners of backyard holdings, thousands of EIA infected equidae have not yet been slaughtered.

There is a potential risk for the spread of the disease in Romania and, should IUT in live equidae commence again, to the rest of Europe, if the requirements of Commission Decision 2010/346/EU are not strictly applied.

The approvals of all equine holdings using the provisions of Article 2 of Commission Decision 2010/346/EU were granted without taking into account the isolation requirements set out in this Decision.

The CA undertook, at the request of the mission team, to inform the Director of the FVO by letter within 10 days following the closing meeting about the outcome of a review of all approvals granted to holdings using the derogation set out in Article 2 of Commission Decision 2010/346/EU.

The report makes a number of recommendations aimed at rectifying the shortcomings identified.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AGID assay	Agar Gel Immuno Diffusion assay
AHWD	Animal Health and Welfare Directorate
CA	Competent Authority
CAHS	County Animal Health Service
CCA	Central Competent Authority
CICS	County Inspection and Control Service
EIA	Equine Infectious Anemia
ELISA	Enzyme-Linked Immuno-Sorbent Assay
FIE	World Equestrian Federation
FVO	Food and Veterinary Office
ID	Identification Document ('passport')
IUT	Intra-Union Trade
MS	Member State of the European Union
NAIRZ	National Agency for Improvement and Reproduction in Zootechnics
NRL	National Reference Laboratory
NSVFSA	National Sanitary Veterinary and Food Safety Authority
OARZ	County Offices for Improvement and Reproduction
OIE	World Organisation of Animal Health
OV(s)	Official Veterinarian(s)
RENAR	Romanian Accreditation Association
SOP	Standard Operational Procedures
SVGD	Sanitary Veterinary General Directorate
TRACES	Trade Control and Expert System of the European Commission
ZSVC	Zonal Veterinary and Food Safety Circumscription

1 INTRODUCTION

The mission took place in Romania from 30 November to 10 December 2010. The mission team comprised 2 inspectors from the FVO and one trainee and was carried out in accordance with the FVO's mission programme. Throughout the mission the CA accompanied the mission team,

2 OBJECTIVES OF THE MISSION

The objectives of the mission were:

- to evaluate the animal health controls on IUT in live equidae;
- to follow-up the conclusions and recommendations of FVO mission report DG(SANCO)/2009-8256 on the implementation of animal health and animal welfare rules in respect of trade in horses¹ (hereinafter referred to as report 2009);
- to review the implementation of protective measures with regard to EIA in Romania set out in Commission Decision 2010/346/EU.

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

Visits			Comments
CA	National Sanitary Veterinary and Food Safety Authority (NSVFSA)	3	Opening, clarification and closing meeting
	County Sanitary Veterinary and Food Safety Directorates (CAHS)	9	Arad, Brasov, Bucharest, Calarasi, Covasna, Dambovita, Mamamures, Satu Mare, and Timis
	National Agency for Improvement and Reproduction in Zootechnics	2	
Slaughterhouses		2	Approved for horse slaughter
County laboratories		3	Authorised for EIA diagnosis
Equine holdings		7	1 approved assembly / marshalling centre 1 approved holding 2 holdings approved for IUT in registered horses 3 equine holdings under EIA restrictions
Private veterinary practitioners		7	Involved in execution of the EIA eradication programme

3 LEGAL BASIS FOR THE MISSION

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

¹This report is available under its reference numbers on the DG Health and Consumer Protection website: http://ec.europa.eu/comm/food/fvo/index_en.htm

conditions governing the movement and import from third countries of equidae.

Full legal references are provided in the Annex to this report², and refer to the last amended version of the act.

4 BACKGROUND

4.1 EQUINE HEALTH SITUATION

In Romania, according to the information about equine diseases provided by the OIE³, the last occurrence of glanders was in 1960, of dourine in 1965, of equine viral arteritis in 2004 and anthrax in 2009. African horse sickness, contagious equine metritis, vesicular stomatitis, encephalomyelitis (western), equine encephalomyelitis (eastern), Japanese encephalitis, Nipah virus encephalitis and Venezuelan equine encephalomyelitis have never been reported. Rabies is endemic in Romania and EIA is still endemic in at least 12 Romanian counties. West Nile fever is widespread in certain parts of Romania (see details in report 2009).

As EIA has been endemic in many Romanian counties, the country has voluntarily continued, after accession to the EU, to implement measures against EIA provided for in Commission Decision 2004/825/EC. As the disease situation in Romania presented an animal health risk for equidae in the EU, in 2007 additional protective measures with regard to EIA were adopted (Commission Decision 2007/269/EC).

In May 2009 the FVO carried out a mission to Romania (DG(SANCO)/2009-8256) on the implementation of animal health and animal welfare rules in respect of trade in horses. Report 2009 made several recommendations which were not satisfactorily addressed in the action plan provided in 2009. However, an up-dated action plan requested by the mission team and provided by the CA during the preparatory phase of the current mission followed-up the 2009 action plan.

At the beginning of 2010, several MSs reported outbreaks of EIA, which were traced back to horses traded from Romania. In consequence, in June 2010, the Commission adopted Decision 2010/346/EU imposing more stringent measures in order to minimise the risk of the virus spreading in Romania and to other MS.

4.2 TRADE PATTERN

Whilst in 2009, 20 000 horses were traded from Romania to several Member States (MSs), mainly to Italy (12 000) and Bulgaria (2 700) for slaughter, since May 2010 a total of 68 Romanian registered horses entered IUT. In 2009, a total of 202 horses, mainly registered horses and horses for breeding and production, arrived in Romania from other MSs.

Table 1: Most active MSs trading live equidae January 2009 to June 2010 compared with trade following entry into force of Commission Decision 346/2010/EU (July to November 2010)

	Italy		Bulgaria		Belgium		Poland		Germany	
	Jan 2009 to Jun	July to Nov	Jan 2009 to Jun	July to Nov						

² European legislation can be checked at: <http://eur-lex.europa.eu>

³ WAHID interface: <http://www.oie.int>

	2010	2010	2010	2010	2010	2010	2010	2010	2010	2010
Equidae traded from Romania	16 600	9	2 700	24	193	0	91	0	195	3
of which for direct slaughter	12 000	0	2 700	0	0	0	85	0	0	0
of which for breeding and production	4 600	0	0	0	191	0	0	0	194	0
of which were registered equidae	0	9	0	24	2	0	6	0	1	3

Source: rounded data from TRACES

According to the information provided by the CA, in recent years no equidae have been imported into Romania from third countries.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES' PERFORMANCE

5.1.1 Legal requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency using documented procedures.

Article 4 of Regulation (EC) No 882/2004 requires MSs to designate the CA responsible for official controls, and sets out the minimum operational criteria that each competent authority must meet. Competent authorities are required to carry out internal audits, or have external audits carried out.

Article 8 of Regulation (EC) No 882/2004 requires that CAs have procedures in place to verify the effectiveness of official controls and to ensure the effectiveness of corrective action.

Point 2 of Article 8 of Regulation (EC) No 882/2004 requires the MSs to ensure that they have legal procedures in place in order to ensure that staff of the competent authorities have access to premises of and documentation kept by feed and food business operators so as to be able to accomplish their tasks properly.

Article 54 of Regulation (EC) No 882/2004 requires a CA which identifies non-compliance to take appropriate action to ensure that the operator remedies the situation. Any sanctions enforced must be effective, proportionate and dissuasive, in accordance with Article 55 of the same Regulation.

5.1.2 Findings

Within the National Sanitary Veterinary and Food Safety Authority (NSVFSA), which reports directly to the Government, the Sanitary Veterinary General Directorate (SVGD) with its Animal Health and Welfare Directorate (AHWD) is the central CA responsible for official controls in the field of animal health. In the 42 counties, the NSVFSA is represented by County Animal Health Services (CAHS) which are supported by Zonal Veterinary and Food Safety Circumscriptions (ZSVCs). At county level, the CAHS shares the competencies with the County Inspection and

Control Service (CICS), under the responsibility of the Inspection Service of the NSVFSA. Veterinary practitioners are authorised to carry out, under the supervision of the responsible ZSVC, specific tasks in the surveillance and eradication of EIA such as providing information and blood sampling.

Within the Ministry of Agriculture, the National Agency for the Improvement and Reproduction in Zootechnics (NAIRZ) with its county offices (OARZ) is responsible for the identification and registration of equidae and runs the equine database, where the movements of equidae between counties are recorded.

The mission team noted that

- concerning the power of the CA,
 - in Romania OV's have access⁴ to animal holdings in order to carry out official controls as required by Article 13 of Regulation (EC) No 882/2004. However, a backyard within the "home" of an animal keeper is not considered as an animal holding⁵. In accordance with Romanian law⁶ access to these private properties is only possible with the permission of the owner of the property. In consequence, the CA stated that there have been cases where OV's were not allowed to enter holdings for measures to be taken in the course of the execution of the EIA eradication programme.
- concerning supervision, verification of official controls and audits within the CA,
 - there is a system of supervision within the veterinary service in place. The ZSVCs carry out annual supervision of the authorised veterinarians. Their reports, which include findings and deadlines for corrective actions, are subject to further assessment by the CAHS. The ZSVCs are annually supervised by the inspectors of the CAHS supported by those of the CICS. The mission team checked supervision reports on authorised veterinarians and OV's of the CAHSs and identified that their performance in relation to the implementation of the EIA eradication programmes was not subject to verification.
 - epidemiological data in respect of the EIA surveillance and eradication were gathered at the CA. However, at central level no further epidemiological analysis on raw data was performed (e.g. the EIA animal incidence rate per month) in order to be in a position to verify the results of official controls and, in particular, the effectiveness of the implementation of the EIA programmes.
 - in the counties visited, the approach for combating EIA differed significantly from one county to another in respect of enforcement measures taken, movement control of equidae kept in restricted holdings and data filing.
 - at two CAHS visited, many data were not easily accessible and cross-checks carried out by the mission team revealed that some information was not up-to-date, not analysed and possibly misleading. However, at a third CAHS, these data were presented in a table containing the official controls in respect of EIA eradication and

4 Article 16 (c) of Ordinance No 42 of 29 January 2004 on the organisation of veterinary activity, published in the Romanian Official Journal No 34 of 31 January 2004 permits free, permanent and unlimited access of the veterinary service for official controls in the holdings listed in Article 18 (1).

5 Article 16 (c) of Ordinance No 42 of 29 January 2004 lists several kinds of animal holdings (but the keeping of animals in backyards integrated in the home of the keeper is not mentioned)

6 Criminal Code, adopted in 2004 and entered into force in July 2005: Article 208 (1) The act of penetrating, without right, in any manner, into a home, room, an outbuilding or a enclosed space annexed to these, without consent of the person using them, or refusal to leave them at the latter's request, shall be punished by strict imprisonment from 1 to 5 years.

follow-up measures taken at holding level.

- in January 2010, the NSVFSA established an internal audit unit, which has carried out several audits in the field of animal health. However, no audits have yet been performed in respect of the implementation of the EIA surveillance and eradication programmes. The CA stated that a series of audits in this regard is scheduled for the beginning of 2011.
- concerning the use of written procedures,
 - in the field of animal health, the written procedures such as Orders and Service Notes provide guidance for the OV's to carry out official controls. However, no instructions have been issued in respect of the approval of holdings as set out in Articles 2 and 3 of Commission Decision 2010/346/EU.
 - at one slaughterhouse visited, the written procedures to be followed by the OV during inspections did not sufficiently cover measures to be applied in order to prevent the spread of the EIA virus such as the slaughtering of infected equidae at the end of the slaughter batch and the cleaning and disinfection of the means of transport and the lairage.
- concerning the official inspections and enforcement measures taken by the CA,
 - according to the CA, in 2010, in each county the CAHS carried out on average 55 inspections of equine holdings and identified on average 7 non-compliances. Nevertheless, the mission team identified that in one county, where 386 EIA infected equidae were missing, from backyard holdings only 121 inspections were performed and 32 sanctions were applied (with the total of fines of 2 200 RON), and in another county 294 inspections of equine holdings were performed but no non-compliances were identified.
 - at one equine assembly centre visited, approved in the sense of Article 11 of Council Directive 64/432/EEC the official controls did not detect that the holding register used for the last assembly for IUT in January 2010 did not comply with the relevant legislation and this non-compliance made the tracing of the animals impossible (see also chapter 5.3.2.2 of this report).
 - the official inspections of one slaughterhouse visited which is approved for the slaughter of equidae did not cover issues in respect of specific measures which should be applied, in accordance with a risk assessment, when slaughtering EIA infected animals such as the measurement of the temperature of EIA reactor animals during the *ante-mortem* inspection, the slaughtering of infected equidae as the last animals to be slaughtered of the batch or cleaning and disinfection of the means of transport and the lairage. In another slaughterhouse, the official inspections covered these aspects but had not revealed that the disinfectants used for the cleaning and disinfection of the means of transport and the lairage were not approved and listed by the CA as disinfectant effective against Retroviruses.
 - an unknown number of equidae kept in backyard holdings are under limited official control in respect of missing identification and illegal movement and slaughter, even of infected equidae. Visits to these holdings must be accompanied by the police for gaining access to the premises and security reasons. According to the CA, in more than 95 % of the cases, fines imposed for illegal movements of EIA infected horses kept in backyard holdings were never paid due to the refusal or the inability of the owner to pay. The CA explained that some of these animal keepers could be

convinced to give up their EIA infected horses by granting sufficient compensation.

5.1.3 Conclusions

The CA in the field of animal health is well structured and their responsibilities are clearly allocated.

The Romanian definition of an equine holding is not in line with Article 2 (a) of Council Directive 2009/156/EC where it is laid down that an equine holding is any facility in which equidae are habitually kept. The fact that the CA does not have the power to enter any facility in which equidae are kept in order to carry out official controls for animal health and welfare reasons, even in the case of emergencies, is an obstacle to disease control and the protection of the well-being of animals and may contribute to the spread of diseases. The recommendation made in report 2009 with regard to the lack of power to implement animal health legislation properly has not been addressed in respect of the power of the CA to have appropriate access to all animal holdings.

The system for supervision within the NSVFSA which includes the authorised veterinarians is adequately established. However, as no procedures for the evaluation of the raw data related to the implementation of the EIA programmes have been established and, in addition, these data at some CAHSs visited were not auditable, the CA is in general not in a position to verify the effectiveness of official controls and to ensure the effectiveness of corrective actions which might be necessary to target resources for the most effective implementation of the programmes. Internal audits, if performed, could contribute to an increase in uniformity in respect of the implementation of the EIA surveillance and eradication programme.

Procedures are in place for the implementation of the EIA surveillance and eradication programmes. However, no written procedures are available in respect of the approval of holdings for breeding and production equidae in the sense of Commission Decision 2010/346/EU which has led to the inappropriate approval of the approved holdings visited (see also chapter 5.3.2.2 of this report).

Official controls related to EIA were not always carried out on a risk basis and, in respect of their quantity (at backyard holdings) and their quality (at approved holdings and slaughterhouses), were insufficient. With respect to the lack of risk based controls, report 2009 already recommended compliance with Article 3 (1) of Regulation (EC) No 882/2004. The situation has remained unchanged and EU legislation is still insufficiently implemented.

Although in some counties visited the CAHS impose adequate disease control measures, the enforcement measures taken in respect of a lack of cooperation with the eradication programme are considered to be in some particular cases inadequate to ensure compliance with veterinary legislation and the sanctions provided were, in general, not effective, proportionate and dissuasive.

5.2 IDENTIFICATION AND REGISTRATION OF EQUIDAE

5.2.1 Legal requirements

Premises raising equidae which have not been excluded from the food chain must be registered in accordance with Article 6 (2) of Regulation (EC) No 852/2004.

Regulation (EC) No 504/2008 requires that the equidae are to be identified and defines the system for identification of equidae (Article 3), the identification document shall accompany registered equidae and equidae for breeding and production at all times (Article 13), the identification

document contain entries for the insertion of the information set out in its Annex I (Article 5), and, when issuing the identification document, certain information should be recorded in the database (Article 21).

Article 6 of Regulation (EC) No 882/2004 requires that CA staff receive appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner.

5.2.2 Findings

Each CAHS keeps a register of equine holdings under its responsibility. The NAIRZ with its 41 County Offices for Improvement and Reproduction (OARZ) is the only body in Romania responsible for the identification and registration of equidae. It also runs the equine database to which the different services of the NSVFSA have access.

In the equine database, the data of about 440 000 backyard holdings keeping 99 % of the Romanian equine population are registered. Currently the data of the horses contained in the registers of 16 horse associations (about 9 000 horses) are being transferred into the NAIRZ database.

Legislation⁷ is in place with regard to the movement of equidae on the Romanian territory. They have to be identified and to originate from a holding free from EIA for at least the last 3 months and they must be accompanied by a movement document and veterinary health certificate in line with the model certificate set out in the Annex III to Council Directive 2009/156/EC. Both documents are issued by authorised veterinarians.

The mission team noted that

- concerning the identification documents (IDs) issued by agents of NAIRZ
 - horses checked during the mission bore transponders which matched in all cases with number recorded in the ID and were recorded in the database.
 - whilst at the backyard holdings visited the IDs were always available, at one holding authorised for movements of registered horses for international competitions in the sense of Article 3 of Commission Decision 346/2010/EU where 59 high value sport horses were kept only 4 passports were available. It was explained that the other passports were with the owners of the horses.
 - the IDs in use did not follow the model ID for equidae set out in Annex I to Regulation (EC) No 504/2008: they did not contain information in respect of (1) the recording of identity checks (Section IV of the model certificate), (2) the invalidation/revalidation of the document for movement purposes (Section VIII), (3) the administration of veterinary medicinal products (all Parts of Section IX) and (4) voluntarily, the basic health requirements (Section X). The CA explained that these 'passports' printed before 2007 do not contain the information set out in Section IV, VIII, IX and X; however following the recommendation of FVO mission DG(SANCO)/2010-8441 a sheet of paper was added to the passport requiring, however, only the information requested in Section IX. More than 300 000 passports with such addendum are in use for the time being.
 - although the operators of OARZ responsible for issuing the IDs had received training on their tasks, in the IDs checked by the mission team some entries (colour, breed,

⁷ Order No 37/2010 concerning the movement of equines on Romanian territory, published in the Romanian Official Journal No 223 of 9 April 2010

name and address of the issuing person etc.), stamps and signatures were missing. The diagrams filled in by the operator of NAIRZ were often sketchy or, in the cases where the horse had no distinguishing marks, this was not recorded in the diagram. Furthermore, the entries in respect of the EIA testing were not always added.

- concerning transponders (microchips),
 - all horses checked during the mission bore microchips in general between poll and withers in the middle of the left neck in the area of the nuchal ligament. Most of the transponders checked transmitted 15 digits of code and others transmitted 8 digits of code. The representative of NAIRZ explained that before the NAIRZ took over the responsibility for the identification of equidae from the National Equine Authority in 2006 transponders transmitting 8 digits of code were implanted.
 - at the moment, there are 158 operators of the NAIRZ responsible for the identification of equidae. At the equine holdings visited, the operators, the OV's and the authorised veterinarians have been equipped with reading systems suitable to cope with both types of transponders.
 - at the holdings and slaughterhouses visited approximately 50 % of the horses checked by means of readers or records bore transponders transmitting the country code for Romania "642".
 - according to the NAIRZ, on 1 November 2010 a total of 629 723 transponders have been implanted. However, as, according to the CA, an unknown number of equidae bore more than one transponder, the number of equidae identified with transponders is fewer than this number.
 - 9 000 registered horses are additionally marked by hot brand.
- concerning the equine database,
 - according to the CA, all equidae identified by means of transponders have been registered in the database. The number of 629 723 equidae identified by transponder includes the entries of equidae which left Romania (about 6 000), which were slaughtered in Romania (about 20 000) or which are notified as 'missing' (61) in the time period from 2008 until November 2010. This does not agree with the figures provided by NAIRZ at the final meeting which stated that there were about 594 000 "active" equidae registered in the database on 1 November 2010. In addition, these figures do not fit with the census information provided by the NSVFSA (661 000 equidae) which reflects the total number of equidae counted in the course of the execution of the EIA surveillance programme and the vaccination campaigns for anthrax and influenza.
 - it is possible to extract data from the database for a given time period in respect of the number of (1) the equidae slaughtered in Romania, (2) the equidae slaughtered in Romania which were infected by EIA, (3) the equidae which left Romania and (4) the equidae which were missing; however not (5) the equidae which died, (6) the equidae with a duplicate or a replacement of the ID and (7) the equidae which arrived in Romania. It was explained that this data may only be made available for individual equidae; the software programme of the database is not designed to deliver such extracts.

5.2.3. Conclusions

As an unknown number of equidae are still not identified the system for identification and registration of equidae is not adequately implemented.

The IDs in use do not contain all the information required by Annex A to Regulation (EC) No 504/2008. In addition, they are not properly completed by the operators of OARZ indicating that, although the recommendation with that regard made in report 2009 was addressed, there is a need for further training enabling them to undertake their duties competently and in a consistent manner.

The data contained in the equine database is of limited use for the needs of disease control as the number of “active” equidae recorded is significantly lower than the number provided by the NSVFSA.

5.3 ANIMAL HEALTH CONTROLS

5.3.1 Legal requirements

Article 4 (5) of Council Directive 2009/156/EC covering the general rules for the participation of live equidae in IUT details the prohibition orders expected in the event of outbreaks of these diseases. In the case of EIA, the prohibition is to last until infected animals have been slaughtered, and the remaining animals have shown a negative reaction to two tests carried out three months apart.

Article 2 (1) (a) of Commission Decision 2010/346/EU requires by way of derogation from the general ban on Romanian equidae entering IUT that the entire consignment of equidae must have been isolated under official supervision on a holding approved by the CA as being free of EIA and kept at a minimum distance from any other equidae of lesser health status of at least 200 m for a period of at least 90 days prior to dispatch.

Article 2 (1) (c) of Commission Decision 2010/346/EU requires that the equidae comprising the consignment are dispatched from the approved holding directly to the place of destination without passing through a market or marshalling centre.

Article 7 of Council Directive 2009/156/EC requires that 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. Article 11 of Council Directive 64/432/EEC sets out the conditions for assembly centres.

Article 3 of Commission Decision 2010/346/EU sets out that Romania may, by way of derogation, authorise the dispatch to other Member States consignments of registered horses for participating in competitions organised under the auspices of the World Equestrian Federation (FEI) or in major international horse race events.

Article 3 of Council Directive 96/93/EC requires (1) the certifying officers not to certify data of which they have no personal knowledge and (2) the OV to only certify data which have been ascertained by another person authorised by the CA and acting under the control of the OV.

5.3.2 Findings

5.3.2.1 National EIA eradication and surveillance programmes

In 2003, Romania put in place a programme for the eradication of EIA⁸. According to the CA, in 2006 in some counties the promised compensation payments for slaughtered EIA infected equidae had either not been paid or paid after long delays. In consequence, the owners of infected equidae refused to give up their equidae for slaughter during the current slaughter campaign.

As from 2009, new provisions for the compensation of animals slaughtered, or culled in the course of eradication measurements were adopted⁹. NSVFSA is now responsible for the payment of the compensation to the owners of the animals to be slaughtered / killed within 30 days after notification of the EIA outbreak. The valuation of infected animals which have tested positive is performed by an independent commission which agrees on the value of the equidae with the owner taking into account their actual market price.

In June 2010, the NSVFSA strengthened the EIA eradication programme¹⁰. According to its provisions, (1) the movement of equidae which have tested positive is not allowed, except for slaughter, (2) equidae which are EIA infected have to be identified with a microchip and are marked with one special mark 10 cm high, in letter A format, on the left front hoof, (3) positive EIA test results and a movement ban have to be registered in Section VII and Section VIII of the ID, (4) equidae tested EIA positive have to be slaughtered within 10 days, (5) equidae with clinical signs of disease must be killed, (6) equidae with negative serological test results present on EIA infected holdings are not allowed to leave the holding unless they have been tested negative twice with a 3 month interval between tests following the slaughter of the infected animals.

The EIA Surveillance Programme¹¹ requires serological testing of equines aged over 6 months (1) from holdings (including studs, hippodromes, equine associations) twice a year, and (2) from backyards holdings once a year.

The mission team noted that

- on 1 January 2010, in Romania, about 11 600 equidae were known to be EIA infected, representing more than 1,7 % of the entire equidae population (about 660 000 equidae, according to the NSVFSA). However, the CA explained that the figure of 11 600 EIA infected equidae includes all equidae which have tested positive to EIA during the last four years, of which an unknown number may have died, been slaughtered or disappeared. In addition some animals may have been tested and registered as positive animals more than once. The CA recognised that it will be in 2011 before sound epidemiological data about the number of EIA infected equidae can be provided in Romania.
- according to the CA, in 2010 (up to 1 December) about 7 200 infected horses were slaughtered out of the total of about 15 000 positive tested equidae which includes 11 600 infected horses in stock on 1 January 2010 and the 3 400 equidae newly infected in 2010.

8 Order No 686 of 18 September 2003 concerning the approval of the plan for the accelerate eradication of EIA on the Romanian territory, published in the Romanian Official Journal No 688 of 1 October 2003.

9 Government Ordinance No 1214/2009 concerning the methodology for the establishing and the payment of compensation designated to the owners of slaughtered animals, killed or otherwise affected in the scope of rapid extinction of transmissible animal diseases, published in the Romanian Official Journal No 741 of 30 October 2009.

10 Order No 52 from 9 June 2010 concerning the approval of the EIA eradication plan on the Romanian territory, published in the Romanian Official Journal No 400 of 16 June 2010.

11 Order No 51 of 9 June 2010 concerning the amendment of metodological norms for the implementation of the programme for surveillance, prevention and control activities for animal diseases, for those transmissible from animals to humans and animals and in respect of environmental protection for 2010, approved by .Order No 2 published in the Romanian Official Journal No 392 of 14 June 2010.

This indicates that thousands of EIA infected equidae which should have been slaughtered have not yet been slaughtered. This situation was illustrated in four of the counties visited.

Table 2: Figures provided by the CA concerning the equine population, the identification of equidae, EIA testing, the destination of EIA infected equidae and official controls carried out in 2010 in 4 of the counties visited

	BV	MM	AR	TM
Equine population and identification				
Number of equidae on 1 November 2010 provided by the NSVFSA¹	8 547	13 000	8 455	8 144
Number of 'active' equidae registered in the database on 1 November 2010 provided by NAIRZ²	10 075	16 060	8 908	8 612
Number of equidae bearing a transponder on 1 November 2010	10 503	16 875	9 886	9 794
Number of equidae with identification document on 1 November 2010	10 320	15 344	9 297	9 752
EIA testing and destination of EIA infected equidae				
Number of equidae tested for EIA in 2010	15 683	13 237	8 490	6 097
Number of equidae tested positive for EIA in 2010	314	681	157	18
Number of equidae tested positive for EIA on 31 December 2009	0	1 151	313	423
Number of equidae to be slaughtered in 2010	314	1 832	470	441
Number of infected equidae slaughtered in 2010	218	708	402 + 10 ³	97 + 15 ³
Number of infected equidae which died in 2010	25	-	21	-
Number of infected equidae missing in 2010	71	47 + 39 ⁴	109	382
Official controls				
Number of inspections of equine holdings carried out in 2010	10	83	19	121
Number of non-compliances identified in 2010	9	409	13	5
Number of sanctions applied in 2010	9	40	15	32
Total of fees applied in 2010 (in RON)	21 600	38 400	18 480	2 200

¹ This figure reflects the total equine population known by the CAHS.

² This figure reflects the number of equidae alive and older than 6 months of age.

³ This figure reflects the number of EIA positive tested equidae waiting for slaughter on 1 November 2010.

⁴ This figure reflects the number of EIA positive tested equidae whose owner refused their slaughter.

- the problem related to illegal movement of EIA positive tested equidae, their death or home slaughter, is acknowledged by the CA and is considered to be one of the main obstacles for the eradication of EIA in Romania.
- concerning the number of equidae tested in the course of the execution of the EIA surveillance, in 2010, a total of about 552 000 equidae were tested. Although the number of equidae eligible for the EIA test (equidae older than six months of age) in 2010 has not been

provided by the CA, on the basis of the total number of live equidae (about 660 000 equidae, on 1 November 2010) it is estimated that in 2010 tens of thousands of equidae which should have been tested have not yet been tested.

- no epidemiological indicators have been developed to monitor and evaluate disease trends which are necessary tools for the effective implementation of the eradication programme; in particular no analysis of the EIA positive “missing” animals or the risk they pose for the spread of EIA was performed.
- at the two slaughterhouses visited, which were both approved for the slaughter of equidae, only a few EIA infected equidae sent for slaughter had been marked, as required by the national EIA eradication programme. In addition, the IDs were stamped with the wording “ANEMIE INFECTIOASA” on the front page by the OVs of one slaughterhouse visited before sending them to OARZ and not by the OVs responsible for official controls at the EIA infected holdings in order to indicate that the animal is only allowed to move directly for slaughter.
- according to the CA, EIA infected equidae were slaughtered within an average of 25 days following notification of the positive test result to their owners. The animal keepers met during the mission confirmed that in 2010 the payment of compensation for the EIA infected equidae was executed within 30 days following their slaughter and that the value of the animal was fairly assessed.
- concerning the enforcement of the movement restrictions on EIA infected holdings, in one county visited, the CA stated that for the time being the slaughter of infected equidae has priority and no additional staff capacity has been made available for movement controls on equidae that may remain on restricted holdings following the slaughter of positive tested equidae. However, in another county visited information could be provided about the EIA testing, with negative results, of the remaining equidae in 52 holdings under restrictions.

5.3.2.2 *IUT in live equidae*

According to the CA official controls relating to IUT in live equidae are performed on equidae prior to dispatch. The certifying OV issues the veterinary health certificate following (1) a clinical inspection and (2) the reading of the transponder of the animal to be traded, (3) a documentary check of the ID, the laboratory results of the EIA testing and the internal health certificate of the animal and (4) verification of compliance with the specific requirements set out in Commission Decision 2010/346/EU. The OV who signs the IUT certificate also notifies the movement in the TRACES system.

At the moment, 3 assembly centres and one holding are approved for IUT in live equidae in the sense of Article 2, and, in addition, 40 holdings in the sense of Article 3 of this Decision. However, no trade had taken place using the provisions of Article 2 at the time of the mission.

The mission team noted that

- concerning the approval of holdings in the sense of Article 2 of Commission Decision 2010/346/EU,
 - the NSVFSA and the CAHSs have informed OVs and operators of assembly centres about the new approval requirements for participating in IUT in live equidae set out in Commission Decision 2010/346/EU in June 2010.
 - one approved holding visited did not have adequate isolation facilities because the

only stable was occupied by horses of an equestrian sport club. However, according to the responsible OV, a new stable which would fulfil the conditions will be built soon, indicating that the approval was granted to a non-existent facility.

- one assembly centre, which was approved in accordance with Directive 64/432/EEC until November 2010, was listed by the CA as an approved holding although the approval conditions in respect of the isolation requirements set out in Commission Decision 2010/345/EU were not respected as the operator had been running a riding school at the approved facility since December 2009.
- another holding visited was newly approved as an assembly centre for IUT in live equidae in July 2010 in the sense of Article 11 of Council Directive 64/432/EEC, although Article 2 (1) (c) of Commission Decision 2010/346/EU excludes the use of assembly centres for the IUT in live equidae from Romania for the time being.
- concerning the official inspections of the approved holdings
 - at approved holdings official inspections were carried out regularly and reports were produced.
 - at two of the three holdings visited (approved under Article 3) the required documents (IDs and veterinary health certificates for internal movement in Romania) were present and it could be demonstrated that the sport events visited were organised by the World Equestrian Federation (FEI).
 - at the approved assembly centre visited, the last participation in IUT of live equidae was in January 2010. Its holding register contained no information about the place where the equidae came from, nor about the place of destination in the cases where the equidae were not traded for commercial reasons. At this centre, it could not be demonstrated that the stable from where equidae were dispatched was cleaned and disinfected. Two consignments with different animal health status (different arrival and dispatch dates and different dates of testing for EIA of the two batches) were kept in the same stable without isolation.
 - there was the suspicion that from this assembly centre EIA positive horses were delivered to Belgium in October 2009. A comprehensive investigation was performed by different bodies of the CA which identified major deficiencies in respect of the approval and operation of the centre but the epidemiological link could not be established in respect of suspected EIA positive horses sent to Belgium in 2009.
- concerning certification of the veterinary health certificates for IUT
 - at one approved holding visited, using the provisions of Article 3 of Commission Decision 2010/346/EU on the veterinary health certificates for registered horses the required addition of the wording 'Equidae dispatched in accordance with Commission Decision 2010/346/EU' was missing on the copies of the original certificate which had accompanied the consignment of equidae; at another one the copies of the certificates checked by the mission team contained this notice.
 - at one approved holding visited, using the provisions of Article 3 of Commission Decision 2010/346/EU, the official veterinarian was not in a position to certify the AGID assay performed on horses between 90 and 180 days before the date of the intended movement in cases where a horse was brought to the holding within 90 days before that date. This was because neither the ID containing the information about the EIA testing nor the sanitary veterinary health certificate requested for internal movements issued by authorised veterinary practitioner were available at the holding.

At another one, the certifying official could provide evidence of the required testing (because the IDs were available), even in respect of the testing of horses kept within the 200 m radius of this holding.

- at one holding approved in the sense of Article 3 of Commission Decision 2010/346/EU, the pre-notification of movement to the place of destination was carried out by launching the veterinary health certificate in the TRACES system 36 hrs prior to dispatch of the sport horses.

5.3.3 Conclusions

Following a period of four years of application of insufficient EIA control measures, the eradication of EIA is now of high priority in Romania. In order to accelerate the eradication of EIA in Romania, the CA has reorganised the compensation scheme, has launched a slaughter campaign of EIA infected equidae and has implemented EIA surveillance and eradication programmes.

It appears that the animal keepers increasingly accept the proposed compensation for infected equidae which is considered as an important step forward for the successful eradication of EIA. However, taking into account (1) the thousands of equidae tested positive for EIA which were not yet slaughtered, (2) the estimated tens of thousands of equidae which were not tested in 2010, (3) the inadequate restrictions on infected holdings, and (4) the lack of tools to monitor the effectiveness of disease control measures, the implementation of the EIA surveillance and eradication programmes is incomplete. Moreover, the adequate implementation of the programmes is a prerequisite for the granting of the derogations for trade of equidae set out in Commission Decision 2010/346/EU.

As thousands of EIA infected equidae have not yet been slaughtered there is a serious risk that the disease will continue to spread in Romania and, if IUT in live equidae should commence again, to the rest of Europe, if the requirements of Commission Decision 2010/346/EU are not strictly applied. However, all approvals of equine holdings using the provisions of Article 2 of Commission Decision 2010/346/EU were granted without taking into account the specific conditions set out in this Decision.

Official controls on the approved holdings were in general carried out as required by Article 11 of Council Directive 64/432/EEC. However, the reports produced at one holding which has been actually approved as an assembly centre, showed that major deficiencies identified by the mission team were overlooked by the CA in respect of the traceability of equidae passing through, the isolation of equidae with different health status and the documentation of the cleaning and disinfection of the holding after use. Similar deficiencies were identified in report 2009 and a recommendation was made in respect of reviewing the procedures and supervision of assembly centres. The situation has remained unchanged and the requirements on marshalling centres set out in Article 11 of Council Directive 64/432/EEC have been inadequately met.

The principles of certification as laid down by Council Directive 96/93/EC were not always respected because the certifying veterinarians do not have always sufficient knowledge about the EIA tests performed on all equidae on the approved holding as required by Article 3 (b) of Commission Decision 2010/346/EU before signing the veterinary health certificate for IUT.

5.4 LABORATORY PERFORMANCE

5.4.1 *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.

Article 2 of Decision 2010/346/EU requires all equidae, before entering IUT to be subjected to AGID assays on two occasions 90 days apart.

5.4.2 *Findings*

In Romania, laboratory tests performed in the course of the execution of the EIA surveillance and eradication programmes are carried out in the 41 county laboratories technically under the supervision of the Institute for Diagnosis and Animal Health which is the National Reference Laboratory for EIA (NRL-EIA). Whilst the EIA tests with respect to IUT in live equidae are carried out at the NRL-EIA, the EIA tests for the EIA programmes are performed at the county laboratories.

The NRL-EIA and 35 out of the 41 county laboratories are accredited by the Romanian Accreditation Association (RENAR) for the time being.

The mission team noted that

- one of the county laboratories visited was yet not accredited due to the fact that following the movement of the laboratory to new facilities in 2011 the costly granting of the accreditation would need to be renewed.
- although the EIA eradication programme provides for using the EIA Enzyme-Linked Immuno-Sorbent Assay (ELISA) and for confirmation of positive results the Agar Gel Immuno Diffusion assays (AGID assays), at the moment all county laboratories use only the AGID assays for screening.
- the laboratories visited validate the test kits which they obtain commercially from three private companies. The standard operational procedures (SOPs) for the AGID assay checked by the mission team were in line with the OIE's 'Manual of Diagnostic Tests and Vaccines for Terrestrial Animals'.
- the results of the proficiency tests organized by the EIA-NRL annually, in which all county laboratories participate, were satisfactory.
- according to the CA, the blood samples taken in the course of EIA testing of horses intended for participating in international competitions in other MSs were stored for 90 days at the NRL.
- the staff performing the test were qualified and were trained in the test procedure.
- concerning the resources made available for the eradication of EIA in Romania, a significant number of AGID assays are performed with a delay up to one month due to both a shortage in funds to acquire the necessary test kits and a lack of laboratory staff.

5.4.3 *Conclusions*

The laboratory performance was considered satisfactory. Although not all county laboratories are yet accredited they were in a position to diagnose EIA.

6 OVERALL CONCLUSIONS

In many Romanian counties, EIA is still endemic. Since the adoption of Commission Decision 2010/346/EU in June 2010 laying down restrictive measures for IUT, no commercial trade of equidae from Romania to other Member States (MSs) has taken place.

In Romania, the eradication of EIA is now of high priority. The competent authority (CA) has made an effort to put in place an EIA eradication programme in order to resume full participation in IUT of live equidae. However, official efforts to control the disease have been unsuccessful.

An unknown number of equidae are not under the control of the CA. Official veterinarians (OVs) have no power of access to backyards without the consent of the owner when the equidae are kept in his/her home. These equidae might be not identified, not tested and, when tested positiv for EIA illegally moved or home slaughtered. The official controls and enforcement measures taken by the CA were in general insufficient to tackle these problems.

Although the newly reorganised compensation scheme is increasingly accepted by the owners of backyard holdings, thousands of EIA infected equidae have not yet been slaughtered.

There is a potential risk for the spread of the disease in Romania and, should IUT in live equidae commence again, to the rest of Europe, if the requirements of Commission Decision 2010/346/EU are not strictly applied.

The approvals of all equine holdings using the provisions of Article 2 of Commission Decision 2010/346/EU were granted without taking into account the isolation requirements set out in this Decision.

7 CLOSING MEETING

A closing meeting was held on 10 December 2010 in Bucharest with the representatives of the CA, during which the mission team presented its main findings and preliminary conclusions. The CA undertook at request of the mission team, to inform the Director of the FVO by letter within 10 days following the closing meeting about the outcome of a review of all approvals granted to holdings using the derogation set out in Article 2 of Commission Decision 2010/346/EU.

8 RECOMMENDATIONS

The Romanian CA is invited to submit an action plan describing the actions taken or planned in response to the recommendations of the report and setting out a timetable for their completion. This information should be presented to the Commission within 25 working days of receipt of the draft report.

Nº.	Recommendation
1.	To ensure that staff of the CA have access to premises of keepers of animals so as to be able to accomplish their tasks as required by Article 8 (2) of Regulation (EC) No

N°.	Recommendation
	882/2004.
2.	To ensure that the holdings from where equidae are traded are approved in accordance with the requirements set out in Commission Decision 2010/346/EU.
3.	To develop epidemiological indicators to monitor and evaluate disease trends in order to verify the effectiveness of official controls as required by Article 8 (3) (a) of Regulation (EC) No 882/2004.
4.	To ensure that the IDs contain all information as set out in Article 5 of Regulation (EC) No 504/2008.
5.	To ensure that the operators of the OARZ responsible for issuing the IDs receive, for their area of competence, appropriate training enabling them to undertake their duties completely and in a consistent manner; so that they are able to properly complete the IDs as required by Article 5 of Regulation (EC) No 504/2008.
6.	To ensure that all EIA sero-positive equidae are slaughtered as a matter of urgency, as required by the Romanian eradication programme, the implementation of which is a prerequisite for granting the derogations set out in Commission Decision 2010/346/EU.
7.	To work towards the inclusion of all eligible equidae in the EIA testing regime, the conducting of the EIA tests without delay, the removal and slaughter of all EIA newly infected equidae within 10 days following the notification to their owners and the marking of equidae which have tested positive for EIA as required by the EIA surveillance and eradication programmes.
8.	To ensure that the certifying officer is in possession of the necessary information before signing the veterinary health certificate for IUT as required by Article 3 of Council Directive 96/93/EC.

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

http://ec.europa.eu/food/fvo/ap/ap_ro_2010-8822.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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
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. 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
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
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Dec. 2007/269/EC	OJ L 115, 3.5.2007, p. 18-19	2007/269/EC: Commission Decision of 23 April 2007 on protective measures with regard to equine infectious anaemia in Romania
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

Legal Reference	Official Journal	Title
		infectious anaemia in Romania