COMMISSION DECISION

of 18 June 2010

on protective measures with regard to equine infectious anaemia in Romania

(notified under document C(2010) 3767)

(Text with EEA relevance)

(2010/346/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union.

Having regard to 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 (1), and in particular Article 10(4) thereof,

Whereas:

- (1) Equine infectious anaemia ('EIA') is a viral disease affecting only animals of the family Equidae. The incubation period is normally one to three weeks, but may be as long as three months. Infected equidae remain infectious for life and can potentially transmit the infection to other equidae. Infection with EIA tends to become inapparent if death does not result from one of the acute clinical attacks during viraemia, and thus the likelihood of transmission is substantially increased. Local transmission occurs by the transfer of blood from an infected equine animal via interrupted feeding of bloodsucking horseflies and in utero to the foetus. The main means of the long distance spread of the disease is the movement of infected animals, their semen, ova and embryos, and the use of contaminated needles or infusion of blood products containing the virus.
- (2) EIA is a compulsorily notifiable disease in accordance with Annex A to Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae (²). In addition, Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (³) provides that outbreaks of EIA are to be notified to the Commission and other Member States through the Animal Disease Notification System ('ADNS').
- (3) Article 4(5) of Directive 90/426/EEC provides for restrictions concerning the movement of equidae from holdings where the presence of EIA has been

confirmed until, following the slaughter of the infected animals, the remaining animals have undergone two Coggins tests with negative results.

- (4) Unlike the animal health situation in other Member States, EIA is endemic in Romania and the immediate slaughter of infectious equidae is not implemented. For that reason, Commission Decision 2007/269/EC of 23 April 2007 on protective measures with regard to equine infectious anaemia in Romania (4) was adopted.
- (5) However, recent cases of EIA in equidae for breeding and production dispatched from Romania to other Member States, and the recently published outcome of a veterinary inspection mission carried out by the Commission's services in 2009 in that Member State in accordance with Article 10 of Directive 90/426/EEC (5), indicate that Decision 2007/269/EC is poorly implemented, enforced and monitored.
- (6) In view of trade in live equidae, their semen, ova and embryos, the disease situation in Romania presents an animal health risk for equidae in the Union. It is therefore appropriate to adopt protective measures laying down a specific regime for the movement of and trade in equidae and equine semen, ova and embryos, as well as certain equine blood products from Romania in order to safeguard the health and welfare of equidae in the Union.
- (7) The prevalence of the disease is not equally distributed throughout Romania and between various categories of equidae in that Member State. This situation allows applying less stringent conditions for the movement of certain registered horses for competition and races and should allow, in future, defining disease free regions.
- (8) In accordance with Article 7(2) of Directive 90/426/EEC, the Member State of destination may, on a general or restricted basis, grant derogation from some of the requirements of Article 4(5) for any animal bearing a special mark indicating that it is scheduled for slaughter, provided that the health certificate mentions such derogation. In the case of granting such derogation equidae for slaughter must be transported directly to the designated slaughterhouse and be slaughtered within five days of arrival at the slaughterhouse.

⁽¹⁾ OJ L 224, 18.8.1990, p. 29.

⁽²⁾ OJ L 224, 18.8.1990, p. 42.

⁽³⁾ OJ L 378, 31.12.1982, p. 58.

⁽⁴⁾ OJ L 115, 3.5.2007, p. 18.

⁽⁵⁾ DG(SANCO) 2009-8256 - MR FINAL (http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2341).

- Article 12 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (1) lays down the accreditation requirements for laboratories carrying out analysis of samples taken during official controls.
- The Annex to Commission Regulation (EC) No (10)180/2008 of 28 February 2008 concerning the Community reference laboratory for equine diseases other than African horse sickness (2) lays down the functions, tasks and procedures of the reference laboratory in the Union for equine diseases as regards collaboration with laboratories responsible for diagnosing infectious diseases of equidae in the Member States. Those functions include, amongst others, promoting the harmonisation of diagnosis and ensuring proficiency of testing within the Union by organising and operating periodic comparative trials and by periodic transmission of the results of such trials to the Commission, the Member States and national/central laboratories. The work programme agreed between the Commission and that laboratory provides that the first proficiency testing for EIA is to take place in 2010.
- In the absence of specific Union standards for testing for EIA, reference should be made to the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2009 of the World Organisation for Animal Health (OIE). That Chapter, which is currently Chapter 2.5.6, prescribes the agar gel immunodiffusion (AGID) for the detection of EIA in horses, which is an accurate and reliable test except in certain circumstances specified in the Manual. This Decision should therefore provide for two AGID tests for EIA with negative results to compensate for the limitations of that test.
- Commission Regulation (EC) No 504/2008 of 6 June (12)2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae (3) requires equidae to be identified by an identification document. To reinforce the link between the identification document and the animal, adult horses intended for transport from Romania to other Member States should be marked by injection of an electronic transponder.
- Article 14 of Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations (4) sets out the checks and other measures related to the journey log to be carried out by the competent authority before long journeys.

- The certification requirements for the movement and transport of equidae are laid down in Article 8 of Directive 90/426/EEC. In order to enhance the traceability of registered equidae from areas in Romania affected by EIA to other Member States, the attestation provided for in Annex B to Directive 90/426/EEC should be replaced by an animal health certification complying with Annex C to that Directive.
- The integrated computerised veterinary Trade Control and Expert System ('TRACES') introduced in accordance with Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system (5) may be instrumental for the 'channelling' of equidae from Romania to slaughterhouses in other Member States.
- The movement of equidae other than equidae for slaughter from Romania to other Member States should not be considered completed until a test for EIA, carried out on a sample collected during post-arrival isolation at the place of destination, has confirmed the absence of that disease.
- As the affected sector is fully aware of the risks posed by the disease situation in Romania, it is appropriate to allow those involved in the movement of equidae from Romania to share responsibility and the cost incurred by the competent authorities in relation to such movements.
- 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 (6), as amended by Commission Regulation (EU) No 176/2010 (7), introduced test requirements for EIA also for donor mares from which ova or embryos are collected. However, those amendments are only to apply from 1 September 2010. Therefore, where ova and embryos are collected from mares kept in Romania, it is necessary to complement the animal health requirements laid down in Commission Decision 95/294/EC of 24 July 1995 determining the specimen animal health certificate for trade in ova and embryos of the equine species (8) with a test requirement for EIA.
- In addition, the animal health requirements in Union legislation for blood products derived from equidae are currently being reviewed. At present, Chapter V(A) of Annex VIII to Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal byproducts not intended for human consumption (9) sets out the requirements for serum of equidae.

⁽¹⁾ OJ L 165, 30.4.2004, p. 1. (2) OJ L 56, 29.2.2008, p. 4.

⁽³⁾ OJ L 149, 7.6.2008, p. 3. (4) OJ L 3, 5.1.2005, p. 1.

⁽⁵⁾ OJ L 94, 31.3.2004, p. 63.

⁽⁶⁾ OJ L 268, 14.9.1992, p. 54.

^{(&}lt;sup>7</sup>) OJ L 52, 3.3.2010, p. 14.

⁽⁸⁾ OJ L 182, 2.8.1995, p. 27. (9) OJ L 273, 10.10.2002, p. 1.

- (20) In the interests of clarity of Union legislation, Decision 2007/269/EC should be repealed and replaced by this Decision.
- (21) It appears unnecessary to introduce transitional conditions as the measures provided for take due account of the recently adopted Romanian programme for the eradication of EIA in that country.
- (22) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Protective measures applicable to equidae, semen, ova and embryos of animals of the equine species and blood products derived from equidae

- 1. Romania shall not dispatch the following commodities to other Member States:
- (a) equidae from the regions listed in the Annex;
- (b) semen of animals of the equine species;
- (c) ova and embryos of animals of the equine species;
- (d) blood products derived from equidae.
- 2. The prohibition laid down in paragraph 1(a) shall not apply to equidae from holdings situated outside Romania that either:
- (a) transit through Romania on major routes and highways; or
- (b) are transported through Romania directly and without any interruption to their journey to a slaughterhouse for immediate slaughter and are accompanied by an animal health certificate completed in accordance with the model set out in Annex C to Directive 90/426/EEC.

Article 2

Derogations for movements of equidae from the regions listed in the Annex to other Member States

- 1. By way of derogation from Article 1(1)(a), Romania may authorise the dispatch of consignments of equidae to other Member States, subject to compliance with the following conditions:
- (a) the entire consignment of equidae must have been:
 - (i) isolated under official supervision on a holding approved by the competent authority as being free of equine infectious anaemia ('EIA') ('approved holding'); and

- (ii) kept at a minimum distance to any other equidae of a lesser health status of at least 200 m for a period of at least 90 days prior to the date of dispatch;
- (b) all equidae comprising the consignment must have undergone an agar gel immunodiffusion test for EIA ('the AGID test') carried out with negative results on blood samples taken on two occasions 90 days apart; the second sample of which must have been collected within 10 days prior to the date of dispatch of the consignment from the approved holding; the AGID test must meet the criteria established by the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2009 of the World Organisation for Animal Health (OIE) ('the Manual');
- (c) the transporter must document the arrangements made to ensure 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;
- (d) in the case the consignment includes registered equidae or equidae for breeding and production, all other equidae present on the approved holding during the isolation period referred to in point (a)(i) must have undergone an AGID test carried out with negative result on blood samples taken either before they are removed from the holding during the isolation period or within 10 days prior to the date of dispatch of the consignment from the approved holding;
- (e) all equidae comprising the consignment must be marked by implanting an electronic transponder and identified by means of the single identification document for equidae or passport provided for in Article 5(1) of Regulation (EC) No 504/2008 which must state:
 - (i) the number displayed when reading the implanted electronic transponder in point (5) of Part A of Section I of that document:
 - (ii) the AGID test provided for in points (b) and (d) of this paragraph and their results in Section VII of that document;
- (f) the checks concerning the journey log carried out in accordance with Article 14(1)(a) of Regulation (EC) No 1/2005 must be satisfactory and must not require details to be sent to a control post situated in a Member State of transit in accordance with Article 14(1)(d) of that Regulation;

(g) the equidae comprising the consignment must be accompanied by a duly completed animal health certificate in accordance with the model set out in Annex C to Directive 90/426/EEC, which must indicate the place of destination and bear the following additional wording:

Equidae dispatched in accordance with Commission Decision 2010/346/EU (*)

(*) OJ L 155, 22.6.2010, p. 48.'

- 2. By way of derogation from point 1(b), the first AGID test, to be carried out on samples taken at least 90 days before dispatch, may not be required under the following conditions:
- (a) the Member State of destination has granted such derogation in application of the measures provided for in Article 7(2) of Directive 90/426/EEC, or
- (b) the equidae are destined for direct transport to the slaughterhouse and have been assembled on the approved holding from holdings certified free of EIA in accordance with the national EIA control programme in force.

Article 3

Derogation from the movement of equidae from the regions listed in the Annex to other Member States as regards registered horses participating in certain competitions and events

By way of derogation from Article 2(1)(a), (b), (c), (d) and (f), Romania may authorise the dispatch to other Member States of consignments of registered horses for participation in competitions organised under the auspices of the World Equestrian Federation (FEI), or in major international horse race events, subject to compliance with the following conditions:

- (a) the horses must have undergone an AGID test, carried out with negative results in accordance with the criteria established by the Manual, on a blood sample taken within 10 days prior to the date of dispatch from the approved holding;
- (b) all equidae on the approved holding and within a perimeter of 200 m around the approved holding have undergone an AGID test carried out with negative results on a blood sample taken between 90 and 180 days before the date of intended movement:
- (c) the conditions laid down in Article 2(1)(e) and (g).

Article 4

Restrictions in the event of positive results to the AGID

In the event of a positive result to any of the AGID tests provided for in Article 2(1)(b) and (d) and Article 3(a) of this

Decision, the entire approved holding shall be placed under a movement restriction until the measures provided for in the third indent of Article 4(5)(a) of Directive 90/426/EEC have been completed.

Article 5

Derogations for frozen semen, ova and embryos of the equine species and blood products derived from equidae

- 1. By way of derogation from Article 1(1)(b), Romania may authorise the dispatch to other Member States of frozen semen of equidae complying with the requirements of points 1.6(c), 1.7 and 1.8 of Chapter II (I) of Annex D to Directive 92/65/EEC.
- 2. By way of derogation from Article 1(1)(c), Romania may authorise the dispatch to other Member States of frozen embryos collected from donor mares which have undergone an AGID test carried out with negative result on blood samples taken 90 days apart; the second sample must have been taken between 30 and 45 days after the date of collection of the embryos.
- 3. Consignments of frozen semen or embryos referred to in paragraphs 1 and 2 shall be accompanied by an animal health certificate established for the consignment in question in accordance with Article 11(5) of Directive 92/65/EEC, which shall bear the additional wording:

'Semen/embryos (delete what is not applicable) of the equine species dispatched in accordance with Commission Decision 2010/346/EU (*).

(*) OJ L 155, 22.6.2010, p. 48.'

4. By way of derogation from Article 1(1)(d), Romania may authorise the dispatch to other Member States of serum of equidae complying with the requirements of Chapter V(A) of Annex VIII to Regulation (EC) No 1774/2002.

Article 6

Additional obligations on Romania

Romania shall ensure that:

- (a) the name and geographical location of approved holdings and the name and professional capacity of the official veterinarian responsible for the approved holding and signing the animal health certificate referred to in Article 2(1)(g) and Article 5(3) are communicated to the Commission and the other Member States;
- (b) the official laboratory carrying out the AGID tests provided for in Article 2(1)(b) and (d) and Article 3:

- (i) complies with the requirements of Article 12 of Regulation (EC) No 882/2004;
- (ii) undergoes by 31 December 2010 and each year thereafter, an annual proficiency testing in collaboration with the European Union Reference Laboratory for equine diseases other than African horse sickness;
- (c) duplicate blood samples are stored in the official laboratory referred to in point (b) for each AGID test carried out within 10 days of the date of dispatch in accordance with Article 2(1)(b) and (d) and Article 3 for a period of at least 90 days, unless;
 - (i) the death of that animal has been notified in accordance with Article 19 of Regulation (EC) No 504/2008; or
 - (ii) a negative result was reported for the AGID test referred to in Article 7(1)(b) before the 90-day period elapsed;
- (d) the movement is pre-notified to the place of destination through TRACES at least 36 hours in advance of the time of arrival.

Article 7

Obligations of Member States of the place of destination

- 1. Member States of the place destination shall ensure that where the movement of equidae referred to in Article 2(1)(b) is pre-notified in accordance with Article 6(d), the equidae are, upon their arrival at the place of destination, either:
- (a) slaughtered within not more than 72 hours of the time of arrival at the slaughterhouse notified to the competent authorities through TRACES; 10 % of consignments arriving at the slaughterhouse in accordance with this Decision must be subject to post-arrival AGID testing; or
- (b) isolated under official veterinary supervision on the holding of destination indicated in the animal health certificate referred to in Article 2(1)(g) for at least 30 days and at a distance of least 200 m away from any other equidae or under vector protected conditions, and are subjected to a AGID test with negative results carried out on a blood sample taken not earlier than 28 days following the date of commencement of the isolation period.
- 2. Without prejudice to Article 1(1)(b), Member States must ensure that during a period of 90 days following the date of arrival of equidae referred to in Article 2(1)(b) at the holding of destination referred to in paragraph 1(b) of this Article, equidae may only be dispatched from that holding to another Member State if:

- (a) they have undergone an AGID test with negative results carried out on a blood sample taken within 10 days prior to the date of dispatch; and
- (b) they are accompanied by a duly completed animal health certificate in accordance with the model set out in Annex C to Directive 90/426/EEC.

Article 8

Reporting obligations

Member States affected by trade in equidae and their semen, ova and embryos in accordance with this Decision shall regularly, but at least each 3 months, report to the Commission and the other Member States at the meetings of the Standing Committee on the Food Chain and Animal Health.

Article 9

Costs of administrative procedures

- 1. Romania shall take the necessary measures, including where necessary legal measures, to ensure that the costs of the additional administrative procedures, including any necessary laboratory testing or follow-up investigation, related to the movement of consignments of equidae, semen, ova and embryos and serum derived from equidae from that Member State in accordance with Articles 2, 3 and 5 are fully borne by the consignor of the equidae or their products.
- 2. Member States of the place of destination shall take the necessary measures, including where necessary legal measures, to ensure that the costs of the additional administrative procedures, including any necessary laboratory testing or follow-up investigation until the measures provided for in Article 7 are completed, related to the movement of the equidae from Romania in accordance with Articles 2 and 3 are fully borne by the consignee of the equidae.

Article 10

Repeal

Decision 2007/269/EC is repealed.

Article 11

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 18 June 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX

Regions as referred to in Article 1(1)(a):

Member State	Region	Remark
Romania	Whole of territory	