Commission Implementing Regulation (EU) No 846/2014 of 4 August 2014 amending Annex D to Council Directive 92/65/EEC as regards the conditions for donor animals of the equine species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 846/2014

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amending Annex D to Council Directive 92/65/EEC as regards the conditions for donor animals of the equine species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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[(1)], and in particular the first subparagraph of Article 22 thereof,

Whereas:

(1) Directive 92/65/EEC lays down the animal health requirements governing trade in and imports into the European Union of animals, semen, ova and embryos not subject to the animal health requirements laid down in the specific acts of the European Union referred to in that Directive.

(2) Chapter I of Annex D to Directive 92/65/EEC lays down the conditions governing the approval and supervision of centres for the collection of semen of animals of, amongst others, the equine species. Since the collection of semen of animals of the equine species is largely seasonal, the required permanence of the supervision by a centre veterinarian, frequently being contracted by the semen collection centre, appeared to be disproportionate compared to the limited added level of confidence in the animal health guarantees. As long as supervision is guaranteed during the activities of the semen collection centre in respect of semen of animals of the equine species intended for trade the competent authorities should be allowed to establish details of that supervision during the approval process.

(3) Directive 92/65/EEC also provides that semen of donor animals of the equine species must have been collected from animals meeting the conditions laid down in Chapter II(I) of Annex D to that Directive. Those conditions should be reviewed as regards donor stallions taking into account international standards for health testing set up in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals[(2)], and the capacity development in laboratories in the Member States.

(4) In accordance with Article 12 of Regulation (EC) No 882/2004 of the European Parliament and of the Council[3], the competent authorities may only designate laboratories to carry out the analysis of samples taken during official controls that operate and are assessed and accredited in accordance with EN ISO/IEC 17025.

(5) In Chapter III of Annex D to Directive 92/65/EEC requirements applicable to, amongst others, processing of embryos are laid down. Those requirements should be reviewed taking into account international standards for processing of embryos set out in Chapter 4.7 of the Terrestrial Animal Health Code[4].

(6) The recent update of Annex D to Directive 92/65/EEC by Commission Regulation (EU) No 176/2010[5] did not sufficiently take into account the discontinuous nature of collection of semen, ova and embryos of the equine species for trade and thus frequent testing of donor stallions is unnecessarily required. Additionally, since its adoption laboratory capacities to carry out advanced, highly sensitive, but less laborious tests for contagious equine metritis and equine viral arteritis have developed.

(7) Annex D to Directive 92/65/EEC should be therefore amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex D to Directive 92/65/EEC is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 October 2014.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 August 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annex D to Directive 92/65/EEC is amended as follows:

(1) In Chapter I(I), point 1.1 is replaced by the following:

1.1. be placed under the supervision of a centre veterinarian authorised by the competent authority;;

(2) Chapter II(I) is amended as follows:

(a) point 1.5 is replaced by the following:

1.5. it shall be subjected to the following tests, carried out and certified in a laboratory which is recognised by the competent authority and has the tests referred to hereinafter included in its accreditation in accordance with Article 12 of Regulation (EC) No 882/2004 of the European Parliament and of the Council[(6)], according to the programme provided for in point 1.6:

(a) an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia with negative result;

(b) a test for the isolation of the equine arteritis virus or the detection of its genome by polymerase chain reaction (PCR) or real-time PCR carried out with negative result on an aliquot of the entire semen of the donor stallion, unless the donor stallion has reacted with negative result at a serum dilution of one in four in a serum neutralisation test for equine viral arteritis;

(c) an agent identification test for contagious equine metritis, carried out with negative result in each case on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than seven days, and in no case earlier than seven days (systemic treatment) or 21 days (local treatment) after possible antimicrobial treatment of the donor stallion, from at least the following sites:

— the penile sheath (prepuce),
— the urethra,
— the fossa glandis.

The specimens shall be placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.

The specimens shall be subjected to at least one of the following tests:

(i) culture under microaerophilic conditions for at least 7 days for the isolation of *Taylorella equigenitalis*, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport; or

(ii) polymerase chain reaction (PCR) or real-time PCR for the detection of genome of *Taylorella equigenitalis*,

carried out within 48 hours after taking the specimens from the donor animal.

(b) in point 1.6, the points (a), (b) and (c) are replaced by the following:

(a) if the donor stallion is continuously resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, and no equidae on the semen collection centre come into direct contact with equidae of lower health status than the donor stallion, the tests required in point 1.5 shall be carried out on samples taken from the donor stallion at least once a year at the beginning of the breeding season or prior to the first collection of semen intended for trade in fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection;

(b) if the donor stallion is resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, but may leave the centre occasionally under the responsibility of the centre veterinarian for a continuous period of less than 14 days, and/or other equidae on the collection centre come into direct contact with equidae of lower health status, the tests required in point 1.5 shall be carried out as follows:

(i) at least once a year on samples taken from the donor stallion at the beginning of the breeding season or prior to the first collection of semen intended for trade in fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection; and

(ii) during the period of collection of semen intended for trade in fresh, chilled or frozen semen as follows:

— the test required in point 1.5(a) on samples taken not more than 90 days prior to the collection of semen for trade,

— the test required in point 1.5(b) on samples taken not more than 30 days prior to the collection of semen for trade, unless the non-shedder state of a donor stallion is confirmed by virus isolation test, PCR or real-time PCR carried out on samples of an aliquot of the entire semen taken not more than 6 months prior to the collection of semen for trade and the donor stallion has reacted with positive result at a serum dilution of at least one in four in a serum neutralisation test for equine viral arteritis,

— the test required in point 1.5(c) on samples taken not more than 60 days prior to the collection of semen for trade, which in the case of PCR or real-time PCR may be carried out

on three specimens (swabs) taken on a single occasion;

(c) if the donor stallion does not meet the conditions in points (a) and (b) and the semen is collected for trade in frozen semen, the tests required in point 1.5 shall be carried out on samples collected from the donor stallion as follows:

(i) at least once a year at the beginning of the breeding season;

(ii) during the storage period provided for in point 1.3(b) of Section I of Chapter III and before the semen is removed from the centre or used, on samples taken not earlier than 14 days and not later than 90 days following the date of collection of the semen.

By way of derogation from point (ii) of the first subparagraph, post-collection sampling and testing for equine viral arteritis as described in 1.5(b) is not required in case the non-shedder state of a seropositive donor stallion is confirmed by virus isolation test, PCR or real-time PCR carried out with negative result on samples of an aliquot of the entire semen of the donor stallion taken twice a year at an interval of at least four months and the donor stallion has reacted with positive result at a serum dilution of at least one in four in a serum neutralisation test for equine viral arteritis.

(3) Chapter III(II) is amended as follows:

(a) point 1.8 is replaced by the following:

1.8. The embryos shall be washed and have an intact *zona pellucida*, or the embryonic capsule in case of equine embryos, before and immediately after washing. In accordance with the IETS Manual, the standard washing procedure shall be modified to include additional washes with the enzyme trypsin where recommended for the inactivation or removal of certain pathogens.;

(b) point 1.10 is replaced by the following:

1.10. The *zona pellucida* of each embryo, or the embryonic capsule in case of equine embryos, shall be examined over its entire surface area at not less than 50 × magnification and certified to be intact and free of adherent material..

(4) In Chapter IV, point 4 is replaced by the following:

4. In addition to the requirements laid down in Directive 90/426/EEC, donor mares shall:

4.1. not be used for natural breeding during at least 30 days prior to the date of collection of ova or embryos and between the date of the first sample referred to in points 4.2 and 4.3 and the date of the collection of ova and embryos;

4.2. be subjected with negative result to an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia carried out on a blood sample taken not less than 14 days following the date of the

commencement of the period of at least 30 days referred to in point 4.1 and not more than 90 days prior to the collection of ova or embryos for trade;

4.3. be subjected to an agent identification test for contagious equine metritis, carried out with negative result in each case in a laboratory referred to in point 1.5 of Chapter (II)(I) on at least two specimens (swabs) taken from the donor mare in no case earlier than seven days (systemic treatment) or 21 days (local treatment) after possible antimicrobial treatment of the donor mare, from at least the following sites:

— the mucosal surfaces of the clitoral fossa,

— the clitoral sinuses.

The specimens shall be taken during the period referred to in point 4.1 on two occasions with an interval of not less than seven days in the case of the test referred to in point (i), or on one occasion in the case of the test referred to in point (ii).

The specimens shall be placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.

The specimens shall be subjected to at least one of the following tests:

(i) culture under microaerophilic conditions for at least seven days for the isolation of *Taylorella equigenitalis*, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport; or

(ii) polymerase chain reaction (PCR) or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within 48 hours after taking the specimens from the donor animal.

(**1**) OJ L 268, 14.9.1992, p. 54.

(**2**) Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Edition 2013, World Organisation for Animal Health.

(**3**) 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 (OJ L 165, 30.4.2004, p. 1).

(**4**) Terrestrial Animal Health Code, Edition 2013, World Organisation for Animal Health.

(**5**) Commission Regulation (EU) No 176/2010 of 2 March 2010 amending Annex D to Council Directive 92/65/EEC as regards semen collection and storage centres, embryo collection and production teams, and conditions for donor animals of the equine, ovine and caprine species and for handling semen, ova and embryos of those species (OJ L 52, 3.3.2010, p. 14).

(**6**) 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 (OJ L 165, 30.4.2004, p. 1).’

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
Commission Implementing Regulation (EU) No 846/2014 is up to date with all changes known to be in force on or before 09 December 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.