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 (Text with EEA relevance)

COMMISSION REGULATION (EU) No 176/2010

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(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) It lays down the conditions governing the approval and supervision of centres for the collection of semen of animals of the equine, ovine and caprine species (semen collection centres).

(3) Certain semen collection centres only carry out storage operations of semen collected from those species. Therefore, it is appropriate to lay down separate conditions for the official approval and supervision of such centres.

(4) Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species[(2)] contains a definition of semen storage centres. In the interest of consistency of Union law the centres for storage of semen of animals concerned by this Regulation should be referred to as ‘semen storage centres’ in line with that definition.

Changes to legislation: *Commission Regulation (EU) No 176/2010 is up to date with all changes known to be in force on or before 24 December 2020. 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. (See end of Document for details) View outstanding changes*

(5) In addition, Directive 88/407/EEC lays down conditions for the approval and supervision of semen storage centres for the bovine species. Those conditions should be used as a guideline for the conditions for approval and supervision of semen storage centres for the equine, ovine and caprine species provided for in this Regulation. Chapter I, Sections I and II of Annex D to Directive 92/65/EEC should be amended accordingly.

(6) Directive 92/65/EEC, as amended by Directive 2008/73/EC[(3)], provides that ova and embryos of the ovine, caprine, equine and porcine species are to be removed by a collection team or produced by a production team approved by the competent authority of a Member State.

(7) It is therefore necessary to set out in Annex D to Directive 92/65/EEC the conditions for the approval of those teams. The Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE), 18th edition, 2009 (the Terrestrial Code) contains the current technology and international standards as regards the collection and processing of embryos. Chapters 4.7, 4.8 and 4.9 of that Code contain recommendations concerning collection and processing of *in vivo* derived embryos, collection and processing of *in vitro* produced embryos and collection and processing of micromanipulated embryos. Those recommendations should be taken into account for the purpose of Chapter III of Annex D to Directive 92/65/EEC. Those sections should therefore be amended accordingly.

(8) The International Embryo Transfer Society (IETS) is an international organisation and a professional forum which, inter alia, further the science of embryo production and coordinates standardisation of embryo handling and record procedures internationally. IETS has worked for several years to formulate practical and scientifically based protocols in order to avoid risks of disease transmission by embryo transfer from donors to recipients. Those protocols are largely based on the sanitary methods of embryo handling set out in the third edition of the IETS Manual and further reflected in the Terrestrial Code. The methods of handling embryos recommended by the IETS can for some diseases substitute traditional preventative measures, such as diagnostic testing of donors whereas for other measures the recommended methods should be used only to strengthen and complement such traditional measures.

(9) Directive 92/65/EEC also provides that semen of donor animals of the equine, ovine and caprine species must have been collected from animals meeting the conditions laid down in Chapter II of Annex D to that Directive. Those conditions should be reviewed as regards donor stallions, rams and bucks taking into account international standards laid down in Chapter 4.5 of the Terrestrial Code. Chapter II, Sections A and B of Annex D should be amended accordingly.

(10) In application of this Regulation, as regards donor animals of ovine and caprine species, account should be taken of the provisions of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[(4)], Commission Regulation (EC) No 546/2006 of 31 March 2006 implementing Regulation (EC) No 999/2001 of the European Parliament and of the

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Council as regards national scrapie control programmes and additional guarantees and derogating from certain requirements of Decision 2003/100/EC and repealing Regulation (EC) No 1874/2003[(5)], and Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue[(6)].

(11) In application of this Regulation, as regards the use of antibiotics in the semen or in media used in the collection, freezing and storage of embryo account should be taken of the provisions of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(7)].

(12) In application of this Regulation, as regards donor females of porcine species, account should be taken of the provisions of Commission Decision 2008/185/EC of 21 February 2008 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease and criteria to provide information on this disease[(8)].

(13) Directive 92/65/EEC provides that only semen, ova and embryos meeting certain conditions laid down in that Directive, may be the subject of trade. In particular, it provides that stallions in order to be used for the collection of semen are to be subjected to certain tests, including tests for equine infectious anaemia and contagious equine metritis. Similarly, Directive 92/65/EEC provides that donor females in order to be used for the collection of ova and embryos are to comply with certain conditions. However, there is currently no requirement to subject donor females to testing for equine infectious anaemia and contagious equine metritis. As there is no scientific evidence to suggest that treatment of embryos could eliminate the risks arising from transfer of an embryo collected from an infected donor female, the animal health conditions for trade in ova and embryos of the equine species should be extended to include the tests for equine infectious anaemia and contagious equine metritis of donor females. Chapter II, Section C of Annex D should therefore be amended accordingly.

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

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 September 2010.

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

Done at Brussels, 2 March 2010.

For the Commission

The President

José Manuel BARROSO

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ANNEX

Annex D to Directive 92/65/EEC is replaced by the following:

ANNEX DCHAPTER IConditions applicable to semen collection centres, semen storage centres, embryo collection teams and embryo production teamsI.Conditions for the approval of semen collection and storage centres1.

In order to be given approval and the veterinary registration number referred to in Article 11(4) each semen collection centre shall:

2.

In order to be given approval each semen storage centre shall:

II.Conditions for the supervision of semen collection and storage centres1.

Semen collection centres shall:

2.

Semen storage centres shall:

III.Conditions for the approval and the supervision of embryo collection teams and embryo production teams1.

In order to be given approval each embryo collection team shall comply with the following requirements:

2.

In order to be given approval each embryo production team shall also comply with the following additional requirements:

CHAPTER II

Conditions applicable to donor animals

I. *Conditions applicable to donor stallions*

1. In order to be used for the collection of semen, the donor stallion shall, to the satisfaction of the centre veterinarian, meet the following requirements:

1.1. it shall not show any clinical sign of an infectious or contagious disease at the time of admission and on the day the semen is collected;

1.2. it shall come from the territory or, in the case of regionalisation, from the part of the territory of a Member State or a third country and from a holding under veterinary supervision each of which satisfy the requirements of Directive 90/426/EEC;

1.3. it shall be kept for 30 days prior to the date of semen collection in holdings where no equine has shown any clinical sign of equine viral arteritis or contagious equine metritis during that period;

1.4. it shall not be used for natural mating during the 30 days prior to the first semen collection and during the collection period;

1.5. it shall be subjected to the following tests, carried out and certified in a laboratory recognised by the competent authority, according to the program 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 virus isolation test for equine viral arteritis carried out with negative results on an aliquot of the entire semen of the donor stallion, unless a negative