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

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)

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.

(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

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.

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

ANNEX

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

ANNEX D

CHAPTER I

Conditions applicable to semen collection centres, semen storage centres, embryo collection teams and embryo production teams

I. Conditions for the approval of semen collection and storage centres

1.

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

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

1.2. have at least:

(a) lockable animal accommodation and if required for equidae an exercise area which is physically separated from the collection facilities, the processing and storage rooms;

(b) isolation facilities which have no direct communication with the normal animal accommodation;

(c) semen collection facilities, that may be open air protected from adverse weather effects, with slip-proof flooring which protects from dramatic injury in case of fall, at and around the place of semen collection, without prejudice to the requirements in point 1.4;

(d) a separate room for the cleansing and disinfection or sterilisation of equipment;

(e) a semen processing room separated from the collection facilities and the room for cleansing equipment referred to in point (d) which need not necessarily be on the same site;

(f) a semen storage room which need not necessarily be on the same site;

1.3. be so constructed or isolated that contact with outside livestock is prevented;

1.4. be so constructed that the entire semen collection centre except the office rooms and, in the case of equidae the exercise area, can be readily cleansed and disinfected.

2.

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

(a) in the case the storage is not limited to semen of a single species collected at semen collection centres approved in accordance with this Directive, or embryos are stored at the centre in compliance with this Directive, be given distinct veterinary registration numbers referred to in Article 11(4) for each of the species the semen of which is stored at the centre;

(b) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;

(c) have a semen storage room furnished with the necessary installation to store the semen and/or the embryos, which is so constructed that it protects those products and the installation from adverse weather and environment effects;

(d) be so constructed that contact with outside livestock or other animals is prevented;

(e) be so constructed that the entire centre except the office rooms and, in the case of equidae the exercise area, can be readily cleansed and disinfected;

(f) be so constructed that unauthorised access of people is effectively prevented.

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

Semen collection centres shall:

1.1. be supervised to ensure that:

(a) they contain only animals of the species whose semen is to be collected;

Other domestic animals may none the less also be admitted, provided that they present no risk of infection to those species whose semen is to be collected, and that they comply with the conditions laid down by the centre veterinarian.

If in the case of equidae the semen collection centre shares a site with an artificial insemination or service centre, then female equidae (mares) and uncastrated male equidae (stallions) for teasing or natural service shall be admitted provided that they meet the requirements of points 1.1, 1.2, 1.3 and 1.4 of Section I of Chapter II;

(b) the entry of unauthorised persons is prevented and that authorised visitors are required to comply with the conditions laid down by the centre veterinarian;

(c) only competent staff is employed who have received adequate training on disinfection and hygiene techniques to prevent the spread of disease;

1.2. be monitored to ensure that:

(a) records are kept which show:

(i) the species, breed, date of birth and identification of each animal present in the centre;

(ii) any movement of animals entering or leaving the centre;

(iii) the health history and all diagnostic tests and the results thereof, treatments and vaccinations carried out on animals kept;

(iv) the date of collecting and processing semen;

(v) the destination of semen;

(vi) the storage of semen;

(b) none of the animals kept in the centre is used for natural breeding at least 30 days prior to the date of the first semen collection and during the collection period;

(c) the collection, processing and storage of semen is carried out only in premises set aside for these purposes;

(d) all instruments which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilised prior to use, except for instruments which are new, disposable and discarded after use (single-use instruments);

Where, in the case of equidae, the collection centre shares a site with an artificial insemination centre or a service centre, there shall be a strict separation between the semen and instruments and equipment for artificial insemination or natural service and instruments and equipment coming into contact with donor animals or other animals kept in the collection centre;

(e) products of animal origin used in the processing of semen, including diluents, additives or extenders, are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;

(f) cryogenic agents used for the preservation or storage of semen have not been previously used for other products of animal origin;

(g) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for containers which are new, disposable and discarded after use (single-use containers);

(h) each individual dose of semen or each ejaculate of fresh semen intended for further processing is clearly marked in such a way that the date of collection of the semen, the species, the breed and identification of the donor animal and the approval number of the semen collection centre can be readily established;

1.3. be inspected by an official veterinarian during the breeding season at least once every calendar year in the case of animals with seasonal breeding and twice every calendar year in the case of a non-seasonal reproduction in order to consider and verify, where necessary on the base of records, standard operating procedures and internal audits, all matters relating to the conditions of approval, supervision and monitoring.

2.

Semen storage centres shall:

2.1. be supervised to ensure that:

(a) the status of the donor animals whose semen is stored at the centre complies with the requirements of this Directive;

(b) the requirements laid down in points 1.1(b) and (c) are complied with;

(c) records are kept of all movement of semen entering and leaving the storage centre;

2.2. be monitored that:

(a) only semen collected in and coming from approved semen collection or storage centres and transported in conditions offering every possible health guarantee, having had no contact with semen not complying with this Directive, is brought into an approved semen storage centre;

(b) storage of semen takes place only on the premises set aside for the purpose and under strict conditions of hygiene;

(c) all instruments which come into contact with the semen are properly disinfected or sterilised prior to use, except for single-use instruments;

(d) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;

(e) cryogenic agents used for preservation or storage of semen have not been previously used for other products of animal origin;

(f) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the species, the breed and identification of the donor animal, the approval number of the semen collection centre can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory;

2.3. by way of derogation from point 2.2(a), the storage of embryos in the approved semen storage centre is authorised provided they meet the requirements of this Directive and are stored in separate storage containers;

2.4. be inspected by an official veterinarian at least twice every calendar year in order to consider and verify, where necessary based on records, standard operating procedures and internal audits, all matters relating to the conditions of approval, supervision and monitoring.

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:

1.1. the collection, processing and storage of embryos shall be carried out either by a team veterinarian or under his responsibility by one or more technicians who are competent and trained by the team veterinarian in methods and techniques of hygiene and in techniques and principles of disease control;

1.2. the team veterinarian shall be responsible for all team operations, including amongst others:

(a) verification of the identity and health status of the donor animal;

(b) sanitary handling and surgery of donor animals;

(c) disinfection and hygienic procedures;

(d) keeping records which shows:

(i) the species, breed, date of birth and identification of each donor animal;

(ii) the health history and all diagnostic tests and the results thereof, treatments and vaccinations carried out on donor animals;

(iii) the place and date of collecting, processing and storing of oocytes, ova and embryos;

(iv) the identification of embryos and details of their destination if known;

1.3. the team shall be placed under the general supervision of the official veterinarian, who shall inspect it at least once every calendar year to ensure, where necessary based on records, standard operating procedures and internal audits, compliance with the sanitary conditions regarding collection, processing and storage of embryos and to verify all matters relating to the conditions of approval and supervision;

1.4. the team shall have at its disposal a permanently sited laboratory or a mobile laboratory where embryos can be examined, processed and packed, consisting of at least a work surface, an optical or stereo microscope and cryogenic equipment where necessary;

1.5. in the case of a permanently sited laboratory, it shall have:

(a) a room where embryos can be processed which is physically separate from the area used to handle the donor animals during collection;

(b) a room or area for cleansing and sterilising instruments, except when using only single-use equipment;

(c) a room for storing embryos;

1.6. in the case of a mobile laboratory, it shall:

(a) have a specially equipped part of the vehicle consisting of two separate sections:

(i) one for the examination and processing of embryos which shall be a clean section; and

(ii) the other for accommodating equipment and materials used in contact with the donor animals;

(b) use only single-use equipment, unless the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and processing of embryos can be ensured by the contact with a permanently sited laboratory;

1.7. the design and layout of buildings and laboratories shall be laid out and team operations carried out so as to ensure that cross-contaminations of embryos are prevented;

1.8. the team shall have at its disposal storage premises which shall:

(a) comprise at least one lockable room for the storage of ova and embryos;

(b) be easy to cleanse and disinfect;

(c) have permanent records of all incoming and outgoing ova or embryos;

(d) have storage containers for ova and embryos which are stored in a place which is under the control of the team veterinarian and which is subject to regular inspections by an official veterinarian;

1.9. the competent authority may authorise storage of semen in storage premises referred to in point 1.8 provided that the semen:

(a) meets the requirements of this Directive for either ovine and caprine species or equine species, or of Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species[9] for porcine species;

(b) is stored for the operation of the team in separate storage containers in the premises for storing approved embryos.

2.

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

2.1. the team members have received adequate training on disease control and laboratory techniques, particularly in procedures for working in sterile conditions;

2.2. the team shall have at its disposal a permanently sited laboratory which shall:

(a) have adequate equipment and facilities, including separate rooms for:

— recovering oocytes from ovaries,

— processing oocytes, ova and embryos,

— storing embryos;

(b) have a laminar-flow or other suitable facilities where all technical operations associated with specific sterile conditions (processing of ova, embryos and semen) are conducted.

However, the centrifugation of semen may be carried out outside the laminar-flow facility or other facility, as long as full hygienic precautions are taken;

2.3. where ova and other tissues are to be collected in a slaughterhouse, it shall have at its disposal suitable equipment for the collection and transport of the

ovaries and other tissues to the processing laboratory in a hygienic and safe manner.

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 result at a serum dilution of 1 in 4 is achieved in a serum neutralisation test for equine viral arteritis;

(c) a test for contagious equine metritis carried out on two occasions on samples collected from the donor stallion with an interval of seven days by isolation of *Taylorella equigenitalis* from pre-ejaculatory fluid or a semen sample and from genital swabs taken at least from the penile sheath, urethra and urethral fossa with negative result in each case;

1.6. it shall be subjected to one of the following testing programmes:

(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 collected from the donor stallion prior to the first semen collection and at least 14 days following the date of the commencement of the residence period of at least 30 days;

(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 on samples collected from the donor stallion as follows:

(i) at least once a year at the beginning of the breeding season or prior to the first semen collection and at least 14 days following the date of the commencement of the residence period of at least 30 days; and

(ii) during the period of semen collection as follows:

— for the test required in point 1.5(a) at least every 90 days,

— for the test required in point 1.5(b) at least every 30 days, unless the non-shedder state of a seropositive stallion for equine viral arteritis is confirmed by a biannual virus isolation test, and

— for the test required in point 1.5(c) at least every 60 days;

(c) if the donor stallion does not meet the conditions in points (a) and (b) and/or 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), 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 stallion for equine viral arteritis is confirmed by a biannual virus isolation test;

1.7. if any of the tests provided for in point 1.5 is positive, the donor stallion shall be isolated, and the semen collected from it since the date of the last negative test shall not be subject for trade with the exception, for equine viral arteritis, of semen from every ejaculate which has undergone the equine arteritis virus isolation test with negative result.

Semen collected from all other stallions at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests provided for in point 1.5. shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 1.5;

1.8. semen collected from stallions at a semen collection centre subject to a prohibition order in accordance with Article 4 or 5 of Directive 90/426/EEC shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored by the official veterinarian in accordance with Directive 90/426/EEC and the semen stored has undergone the appropriate official

investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex A to Directive 90/426/EEC.

II. *Conditions applicable to male ovine and caprine donor animals*

1. For all ovine and caprine animals admitted to a semen collection centre the following requirements shall apply:

1.1. they have been kept in quarantine for a period of at least 28 days in accommodation specifically approved for the purpose by the competent authority, and where only animals having at least the same health status are present (quarantine accommodation);

1.2. prior to their stay in the quarantine accommodation, they have belonged to an officially brucellosis-free ovine or caprine holding pursuant to Article 2 of Directive 91/68/EEC and they shall not be previously kept in a holding of a lower health status as regards brucellosis;

1.3. they come from a holding where during the 60 days prior to their stay in the quarantine accommodation they have undergone a serological test for contagious epidydimitis (*B. ovis*) carried out in accordance with Annex D to Directive 91/68/EEC or any other test with an equivalent documented sensitivity and specificity;

1.4. they have undergone the following tests carried out on a blood sample collected within the 28 days preceding the commencement of the period of quarantine specified in point 1.1, with negative results in each case, except for the test for Border disease referred to in point (c)(ii):

(a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

(b) for contagious epidydimitis (*B. ovis*), a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

(c) for Border disease:

(i) a virus isolation test or a test for virus antigen; and

(ii) a serological test to determine the presence or absence of antibodies (antibody test).

The competent authority may authorise that the tests referred to in this point are carried out on samples collected in the quarantine accommodation. If such authorisation is granted, the period of quarantine referred to in point 1.1 shall not commence before the date of sampling. However, if any of the tests referred to in this point prove positive, the animal concerned shall be immediately removed from the quarantine accommodation. In the event of group isolation, the quarantine period referred to in point 1.1 shall not commence for the remaining animals until the animal which tested positive has been removed;

1.5. they have undergone the following tests carried out on samples taken during the period of quarantine specified in point 1.1, and at least 21 days after being admitted to the quarantine accommodation, with negative results:

(a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

(b) for contagious epididymitis (*B. ovis*), a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

1.6. they have undergone the tests for Border disease referred in points 1.4(c)(i) and (ii) carried out on the blood samples taken during the period of quarantine specified in point 1.1, and at least 21 days after being admitted to the quarantine accommodation.

Any animal (seronegative or seropositive) shall only be allowed entry to the semen collection centre if no sero-conversion occurs in animals which tested seronegative before the day of entry into the quarantine accommodation.

If sero-conversion occurs, all animals that remain seronegative shall be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three weeks from the day the sero-conversion occurred.

Serologically positive animals shall be allowed entry into the semen collection centre subject to a negative result in a test referred in point 1.4(c)(i).

2. Animals shall only be admitted to the semen collection centre with the express permission of the centre veterinarian. All movements into and out of the semen collection centre shall be recorded.

3. No animals admitted to the semen collection centre shall show any clinical sign of disease on the date of admission.

All animals shall, without prejudice to point 4, have come from quarantine accommodation, which on the day of dispatch of the animals to the semen collection centre complies with the following conditions:

(a) it is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius;

(b) it has for the past three months been free from foot-and-mouth disease and brucellosis;

(c) it has for the past 30 days been free from compulsory notifiable diseases as defined in Article 2(b)(6) of Directive 91/68/EEC.

4. Provided, that the conditions set out in point 3 are complied with and the routine tests referred to in point 5 have been carried out during 12 months prior to the movement of the animals, animals may be moved from one approved semen collection centre to another of equal health status, without isolation or testing if the transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used shall be disinfected before use. If an animal is moved from one semen collection centre to a semen collection centre in another Member State that movement shall be carried out in accordance with Directive 91/68/EEC.

5. All ovine and caprine animals kept at an approved semen collection centre shall be subjected at least once every calendar year to the following tests, with negative results:

(a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

(b) for contagious epididymitis (*B. ovis*) a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

(c) for Border disease, the antibody test referred to in point 1.4(c)(ii) which is applied only to seronegative animals.

6. All tests referred to in this section shall be carried out by an approved laboratory.

7. If any of the tests described in point 5 is positive, the animal shall be isolated and the semen collected from it since the date of the last negative test shall not be subject for trade.

The animal referred to in the first paragraph shall be removed from the centre, except in the case of Border disease, in which case the animal shall be subjected with negative result to a test referred in point 1.4(c)(i).

Semen collected from all other animals at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests described in point 5 shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 5.

8. Semen shall be obtained from animals which:

(a) show no clinical signs of disease on the date the semen was collected;

(b) during the 12 months prior to the date of the collection of the semen:

(i) either have not been vaccinated against foot-and-mouth disease; or

(ii) have been vaccinated against foot-and-mouth disease at least 30 days prior to the collection, in which case 5 % (with a minimum of five straws) of each semen collection shall be submitted to a virus isolation test for foot-and-mouth disease with negative results;

(c) have been kept at an approved semen collection centre for a continuous period of at least 30 days prior to the date of collection of the semen, in the case of collection of fresh semen;

(d) meet the requirements laid down in Articles 4, 5 and 6 of Directive 91/68/EEC;

(e) if kept on holdings referred to in the first indent of Article 11(2), had undergone with negative results during the 30 days prior to the date of collection of the semen:

(i) a serological test for brucellosis (*B. melitensis*) carried out in accordance with Annex C to Directive 91/68/EEC;

(ii) a serological test for contagious epididymitis (*B. ovis*) carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

(iii) a test for the Border disease virus;

(f) shall not be used for natural breeding during at least 30 days prior to the date of first semen collection and between the date of the first sample referred to in points 1.5 and 1.6 or in point (e) and until the end of the collection period.

9. Semen collected from male ovine and caprine donor animals at a semen collection centre or holding referred to in first indent of Article 11(2) subject to a prohibition on animal health grounds in accordance with Article 4 of Directive 91/68/EEC shall be

kept in separate storage and shall not be subject for trade until the health status of the semen collection centre or the holding has been restored by the official veterinarian in accordance with Directive 91/68/EEC and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex B(I) to Directive 91/68/EEC.

CHAPTER III

Requirements applicable to semen, ova and embryos

I. *Conditions for the collection, processing, preservation, storage and transport of semen*

1.1. Where, without prejudice to Directive 2001/82/EC of the European Parliament and of the Council[10], antibiotics or a mixture of antibiotics are added with a bactericidal activity at least equivalent to that of the following mixtures in each ml of semen: gentamicin (250 μg), tylosin (50 μg), lincomycin-spectinomycin (150/300 μg); penicillin (500 IU), streptomycin (500 μg), lincomycin-spectinomycin (150/300 μg); or amikacin (75 μg), divekacin (25 μg), the names of the antibiotics added and their concentration shall be stated in the health certificate referred to in the fourth indent of Article 11(2).

1.2. All instruments used for the collection, processing, preservation or freezing of semen shall be either disinfected or sterilised as appropriate before use, except for single-use instruments.

1.3. Frozen semen shall:

(a) be placed and stored in storage containers:

(i) which have been cleansed and disinfected or sterilised before use, or are single-use containers;

(ii) with a cryogenic agent; which shall not be previously used for other products of animal origin;

(b) prior to dispatch or use, be stored in approved conditions for a minimum period of 30 days from the date of collection.

1.4. Semen to be subject for trade shall:

(a) be transported to the Member State of destination in transport containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved semen collection or storage centres;

(b) be marked in such a way that the number on the straws or other packages coincides with the number on the health certificate referred to in the fourth indent of Article 11(2) and with the container in which they are stored and transported.

II. *Conditions for ova and embryos*

1. Collection and processing of *in vivo* derived embryos

In vivo derived embryos shall be conceived as a result of artificial insemination with semen meeting the requirements of this Directive and shall be collected, processed and preserved in accordance with the following:

1.1. Embryos shall be collected and processed by an approved embryo collection team, without coming into contact with any other batch of embryos not complying with the requirements of this Directive.

1.2. Embryos shall be collected in a place, which is separated from other parts of the premises or holding where the embryo is collected and which shall be in good repair and constructed with materials which permit its effective and easy cleansing and disinfection.

1.3. Embryos shall be processed (examined, washed, treated and placed in identified and sterile straws, ampoules or other packages) in either a permanently sited laboratory or a mobile laboratory, which, as regards susceptible species, is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius.

1.4. All equipment used to collect, handle, wash, freeze and store embryos shall either be sterilised or properly cleansed and disinfected prior to use according to the IETS Manual[(11)], or be single-use equipment.

1.5. Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos shall be free of pathogenic micro-organisms. Media and solutions used in the collection, freezing and storage of embryos shall be sterilised by approved methods according to the IETS Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics might be added, when appropriate, to collection, processing, washing and storage media according to the IETS Manual.

1.6. The cryogenic agents used for preservation or storage of embryos shall not be previously used for other products of animal origin.

1.7. Each embryo straw, ampoule or other package shall be clearly identified by labels according to the standardised system according to the IETS Manual.

1.8. The embryos shall be washed according to the IETS Manual and have an intact *zona pellucida* before and immediately after washing. The standard washing procedure shall be modified to include additional washes with the enzyme trypsin, according to the IETS Manual, when inactivation or removal of certain viruses is required.

1.9. Embryos from different donor animals shall not be washed together.

1.10. The *zona pellucida* of each embryo shall be examined over its entire surface area at not less than 40 × magnification and certified to be intact and free of adherent material.

1.11. Embryos of a batch that has successfully undergone the examination set out in point 1.10 shall be placed in a sterile straw, ampoule or other package marked in accordance with point 1.7 which shall be sealed immediately.

1.12. Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian.

1.13. Each embryo collection team shall submit for official examination for bacterial and viral contamination routine samples of non-viable embryos or ova, flushing fluids or washing fluids resulting from its activities according to the IETS Manual.

1.14. Each embryo collection team shall keep a record of its activities in respect of embryo collection for a period of two years after the embryos have been the subject of trade or import, including:

(a) the breed, age and individual identification of the donor animals concerned;

(b) the place of collection, processing and storage of embryos collected by the team;

(c) the identification of the embryos together with details of the consignee of the shipment.

2. Collection and processing of ova, ovaries and other tissues, with the aim of producing *in vitro* derived embryos

The conditions set out in points 1.1 to 1.14 shall apply *mutatis mutandis* to the collection and processing of ova, ovaries and other tissues for use in *in vitro* fertilisation and/or *in vitro* culture. In addition, the following shall apply:

2.1. The competent authority shall have knowledge of, and authority over, the holding(s) of origin of the donor animals.

2.2. When ovaries and other tissues are collected at a slaughterhouse, either from individual animals or from batches of donors (batch collection), the slaughterhouse shall be officially approved in accordance with Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[(12)] and under the supervision of a veterinarian whose responsibility it is to ensure that *ante-mortem* and *post-mortem* inspections of potential donor animals are carried out and to certify them to be free of signs of the relevant contagious diseases transmissible to animals. The slaughterhouse shall, as regards susceptible species, be situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius.

2.3. Batches of ovaries shall not be brought into the processing laboratory until *post-mortem* inspection of donor animals is completed.

2.4. Equipment for removal and transport of ovaries and other tissues shall be cleansed and disinfected or sterilised before use and exclusively used for these purposes.

3. Processing of *in vitro* derived embryos

The conditions laid down in points 1.1 to 1.14 shall apply *mutatis mutandis* to the processing of *in vitro* derived embryos. In addition, the following shall apply:

3.1. *In vitro* derived embryos shall be conceived as a result of *in vitro* fertilisation with semen meeting the requirements of this Directive.

3.2. After the *in vitro* culture period is completed but prior to freezing, storage and transport of the embryos, they shall be washed and undergo the treatments referred to in points 1.8, 1.10 and 1.11.

3.3. Embryos from different donor animals, in the case of individual animal recovery, or from different batch collections shall not be washed together.

3.4. Embryos from different donor animals, in the case of individual animal recovery, or from different batch collections shall not be stored in the same straw, ampoule or other package.

4. Processing of micromanipulated embryos

Prior to any micromanipulation which compromises the integrity of the *zona pellucida*, all embryos or ova shall be collected and processed according to the sanitary conditions set out in points 1, 2 and 3. In addition, the following conditions shall apply:

4.1. Where micromanipulation of the embryo which involves penetration of the *zona pellucida* is carried out, this shall be done in suitable laboratory facilities under supervision of an approved team veterinarian.

4.2. Each embryo collection team shall keep records of its activities according to point 1.14, including details of micromanipulation techniques which involve penetration of the *zona pellucida* and which have been performed on the embryos. In the case of embryos derived by *in vitro* fertilisation, the identification of the embryos may be done on the basis of a batch, but shall contain details of the date and place of collection of ovaries and/or ova. It shall also be possible to identify the holding of origin of the donor animals.

5. Storage of embryos

5.1. Each embryo collection and production teams shall ensure that the embryos are stored at suitable temperatures in storage premises referred to in point 1.8 of Section III of Chapter I.

5.2. Frozen embryos shall, prior to dispatch, be stored in approved conditions for a minimum period of 30 days from the date of their collection or production.

6. Transport of embryos

6.1. Embryos to be subject for trade shall be transported to the Member State of destination in containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved storage premises.

6.2. The straws, ampoules or other packages shall be marked in such a way that the number on the straws, ampoules or other packages coincides with the number on the health certificate referred to in the third indent of Article 11(3) and with the container in which they are stored and transported.

CHAPTER IV

Requirements applicable to donor females

1. Donor females shall only be used for the collection of embryos or ova if they and the holdings from which they originate meet, to the satisfaction of the official veterinarian, the requirements of the relevant Directives on intra-Union trade in live animals for breeding and production for the species concerned.

2. In addition to the requirements laid down in Directive 64/432/EEC, donor females of porcine species shall, except *in vivo* derived embryos subject to a trypsin treatment, comply with the requirements for Aujeszky's disease laid down in accordance with Article 9 or 10 of that Directive.

3. The provisions of Directive 91/68/EEC shall apply to donor females of ovine and caprine species.

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 date of the first sample referred to in 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 samples taken initially during the past 30 days prior to the date of the first collection of ova or embryos and then every 90 days during the collection period;

4.3. be subjected to a test for contagious equine metritis by isolation of *Taylorella equigenitalis* carried out on samples collected from mucosal surfaces of the clitoral fossa and clitoral sinuses on two consecutives oestrus periods, and during one of oestrus periods an additional culture specimen taken from the endometrial cervix, all with negative results after a cultivation of 7 to 14 days.

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

(**2**) OJ L 194, 22.7.1988, p. 10.

(**3**) OJ L 219, 14.8.2008, p. 40.

(**4**) OJ L 147, 31.5.2001, p. 1.

(**5**) OJ L 94, 1.4.2006, p. 28.

(**6**) OJ L 283, 27.10.2007, p. 37.

(**7**) OJ L 311, 28.11.2001, p. 1.

(**8**) OJ L 59, 4.3.2008, p. 19.

(**9**) OJ L 224, 18.8.1990, p. 62.

(**10**) OJ L 311, 28.11.2001, p. 1.

(**11**) Manual of the International Embryo Transfer Society — A procedural guide and general information for the use of embryo transfer technology emphasising sanitary procedures, published by the International Embryo Transfer Society, 1111 North Dunlap Avenue, Savoy, Illinois 61874 USA (http://www.iets.org/).

(**12**) OJ L 139, 30.4.2004, p. 206.

Changes to legislation:
Commission Regulation (EU) No 176/2010 is up to date with all changes known to be in force on or before 15 September 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.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation implicit repeal by EUR 2016/429 Regulation