# [F1ANNEX D

**Textual Amendments**

**F1** Substituted by 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).

## 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. **[**F2be placed under the 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.

**Textual Amendments**

**F2** Substituted by 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).

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 centres*

1. 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 teams*

1. 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[(1)] 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.**]**

**(1)** **[**[F1]OJ L 224, 18.8.1990, p. 62.**]**

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