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## IF1ANNEX 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

- 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;
- 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;

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- (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:

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- (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.]