[F1ANNEX A

Textual Amendments

F1 Substituted by Council Directive 2003/43/EC of 26 May 2003 amending Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species.

CHAPTER I

CONDITIONS FOR THE OFFICIAL APPROVAL OF CENTRES

- 1. Semen collection centres must:
- (a) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;
- (b) have at least:
 - (i) animal housing, including isolation facilities;
 - (ii) semen collection facilities, including a separate room for the cleaning and disinfection or sterilisation of equipment;
 - (iii) a semen processing room which need not necessarily be on the same site;
 - (iv) a semen storage room which need not necessarily be on the same site;
- (c) be so constructed or isolated that contact with livestock outside is prevented;
- (d) be so constructed that the animal housing and the semen collecting, processing and storage facilities can be readily cleaned and disinfected;
- (e) have isolation accommodation which has no direct communication with the normal animal accommodation;
- (f) be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.
- 2. Semen storage centres must:
- (a) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;
- (b) be so constructed or isolated that contact with livestock outside is prevented;
- (c) be so constructed that the storage facilities can be readily cleaned and disinfected.

CHAPTER II

CONDITIONS RELATING TO THE OFFICIAL SUPERVISION OF CENTRES

1. Collection centres must:

- (a) be so supervised that they contain only animals of the species whose semen is to be collected. Other domestic animals which are strictly necessary for the normal operation of the collection centre may nonetheless also be admitted, provided that they present no risk of infection to those species whose semen is to be collected, and that they fulfil the conditions laid down by the centre veterinarian;
- (b) be so supervised that a record is kept of all bovine animals at the centre, giving details of the breed, date of birth and identification of each of the animals, and also a record of all checks for diseases and all vaccinations carried out for each animal;
- (c) be regularly inspected by an official veterinarian, at least twice a year, in the context of standing checks on the conditions of approval and supervision;
- (d) be so supervised that the entry of unauthorised persons is prevented. Furthermore, authorised visitors must be required to comply with the conditions laid down by the centre veterinarian;
- (e) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;
- (f) be so supervised that:
 - (i) only semen collected at an approved centre is processed and stored in approved centres, without coming into contact with any other consignment of semen. However, semen not collected in an approved centre may be processed in approved collection centres provided that:
 - such semen is produced from bovine animals which fulfil the conditions laid down in Chapter I.1(d) of Annex B,
 - processing is carried out with separate equipment or at a different time from semen intended for intra-Community trade, the equipment in the latter case being cleaned and sterilised after use,
 - such semen may not be the subject of intra-Community trade and cannot at any time come into contact with, or be stored with, semen intended for intra-Community trade,
 - such semen is identifiable by a marking different from that provided for in point (vii);

Deep-frozen embryos may also be stored in approved centres provided that:

- such storage is authorised by the competent authority,
- the embryos meet the requirements of Council Directive 89/556/ EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species⁽¹⁾,
- the embryos are stored in separate storage containers in the premises for storing approved semen;
- (ii) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under the strictest conditions of hygiene;
- (iii) 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 single-use instruments;

- (iv) products of animal origin used in the processing of semen including additives or a diluent are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;
- (v) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;
- (vi) the cryogenic agent used has not been previously used for other products of animal origin;
- (vii) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal and the approval number of the 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;
- (viii) the storage unit must comply with specific conditions relating to the supervision of semen storage centres provided for in point 2.
- 2. Storage centres must:
- (a) be so supervised that a record is kept of all movement of semen (in and out the centre) and of the status of the donor bulls whose semen is stored there, and which must comply with the requirements of this Directive;
- (b) be regularly inspected by an official veterinarian, at least twice a year, in the context of the standing checks on the conditions of approval and supervision;
- (c) be so supervised that the entry of unauthorised persons is prevented. Furthermore, authorised visitors must be required to comply with the conditions laid down by the centre veterinarian;
- (d) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;
- (e) be so supervised that:
 - (i) only semen collected at collection centres approved in accordance with this Directive is stored in approved storage centres, without coming into contact with any other semen.

In addition, only semen coming from an approved collection or storage centre and transported in conditions offering every possible health guarantee, having had no contact with any other semen, may be brought into an approved storage centre.

Deep-frozen embryos may also be stored in approved centres provided that:

- such storage is authorised by the competent authority,
- the embryos meet the requirements of Council Directive 89/556/ EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species,
- the embryos are stored in separate storage containers in the premises for storing approved semen;

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- storage of semen takes place only on the premises set aside for the purpose and under the strictest conditions of hygiene;
- (iii) all instruments which come into contact with the semen are properly disinfected or sterilised prior to use, except for single-use instruments;
- (iv) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;
- (v) the cryogenic agent used has not been previously used for other products of animal origin;
- (vi) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal and the approval number of the 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.]

(1) $[^{F1}OJ L 302, 19.10.1989, p. 1. Directive as last amended by Commission Decision 94/113/EC (OJ L 53, 24.2.1994, p. 23).]$

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