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(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 6 April 1995

amending Annexes C and D of Council Directive 92/65/EEC 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

(95/176/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health conditions 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⁾, as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 22 thereof,

Whereas in the conditions governing approval of bodies, institutes or centres, references should be made, if they keep animals intended for experimental laboratories, to Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes⁽²⁾, in order to align these conditions in the Community and for third countries;

Whereas certain technical adaptations are necessary concerning the approval and supervision of collection centres, the admission of stallions and the requirements applicable to semen, ova and embryos;

Whereas it is necessary to replace the Chapters I, II.A, C, III and IV of the Annex D;

Whereas this Decision is in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

Directive 92/65/EEC is amended as follows:

1. In Annex C.1, the following point is added:

'(j) if it keeps animals intended for experimental laboratories conform to the provisions of Article 5 of Council Directive 86/609/EEC.'

2. Annex D, Chapter I is replaced by Annex I to this Decision.

3. Annex D, Chapter II, point A is replaced by Annex II to this Decision.

⁽¹⁾ OJ No L 268, 14. 9. 1992, p. 54.

⁽²⁾ OJ No L 358, 18. 12. 1986, p. 1.

4. Annex D, Chapter II, point C is replaced by Annex III to this Decision.

5. Annex D, Chapter III is replaced by Annex IV to this Decision.

6. Annex D, Chapter IV is replaced by Annex V to this Decision.

Article 2

The present Decision comes into force on 1 October 1995.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 6 April 1995.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX I

CHAPTER I

I. *Conditions governing the approval of semen collection centres*

Semen collection centres must:

1. be placed under the supervision of a "centre veterinarian";
2. have at least
 - (a) lockable animal accommodation and if required for equidae an exercise area which are physically separated from the collection facilities, the processing and storing rooms;
 - (b) isolation facilities which have no direct communication with the normal animal accommodation;
 - (c) semen collection facilities including a separate room for the cleansing and disinfection or sterilization of equipment;
 - (d) a semen processing room separated from the collection facilities which need not necessarily be on the same site;
 - (e) a semen storage room which need not necessarily be on the same site;
3. be so constructed or isolated that contact with outside livestock is prevented;
4. be so constructed that the entire centre except the office rooms and, in the case of equidae, the exercise area can be readily cleaned and disinfected.

II. *Conditions for the supervision of semen collection centres*

Semen collection centres must:

1. be supervised that they contain only animals of the species whose semen is to be collected;
However, other domestic animals may be admitted, provided that they present no risk of infection to those species whose semen is to be collected and they fulfil the conditions laid down by the centre veterinarian.
If in the case of equidae the collection centre shares a site with an artificial insemination or service centre, then mares, teaser stallions and stallions for natural service are admitted provided they meet the requirements of Annex D Chapter II paragraph A(1), (2), (3) and (4);
2. be monitored to ensure that records are kept which show:
 - the species, breed, date of birth and identification of each animal present in the centre,
 - any movement of animals entering or leaving the centre,
 - the health history and all diagnostic tests and the results thereof, treatments and vaccinations carried out on animals kept,
 - the date of collecting and processing semen,
 - the destination of semen,
 - the storage of semen;
3. be inspected by an official veterinarian during the breeding season at least once a year in the case of animals with seasonal breeding and twice a year in the case of a nonseasonal reproduction in order to consider and verify all matters relating to the conditions of approval and supervision;
4. be so supervised that the entry of unauthorized persons is prevented. Furthermore, authorized visitors must be required to comply with the conditions laid down by the centre veterinarian;
5. employ competent staff who have received adequate training on disinfection and hygiene techniques to prevent the spread of disease;
6. be monitored to ensure that:
 - none of the animals kept in the centre is used for natural breeding at least 30 days prior to first semen collection and during the collection period,
 - the collection, processing and storage of semen is carried out only in premises set aside for these purposes,

- all utensils coming into contact with the semen or the donor animal during collection or processing are either properly disinfected or sterilized prior to use or new, disposable and discarded after use,
If, in the case of equidae, the collection centre shares a site with an artificial insemination centre or a service centre, there must be a strict separation between 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 and the semen,
 - products of animal origin such as diluents, additives or extenders are used in the processing of the semen, which present no animal health risk or which have undergone prior treatment to preclude such risk,
 - in the case of frozen or chilled semen cryogenic agents are used, which had not been used previously for other products of animal origin,
 - any receptacle for the storage or transport of semen is either disinfected or sterilized as appropriate prior to use or new, disposable and discarded after use ;
7. ensure that each individual dose of semen is indelibly identified in such a way that the Member State of origin, date of collection, the species, the breed, the identity of the donor animal and the name and/or number of the approved centre which collected the semen may be established.'
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ANNEX II

A. STALLIONS

Only a stallion which to the satisfaction of the centre veterinarian meets the following requirements may be used for the collection of semen :

1. it must not show any sign of an infectious or contagious disease at the time of admission and on the day the semen is collected ;
2. it must come from the territory or, in the case of regionalization, 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 Council Directive 90/426/EEC ;
3. it must have been kept for 30 days prior to semen collection in holdings where no equine has shown any clinical sign of equine viral arteritis during that period ;
4. it must have been kept for 60 days prior to semen collection in holdings where no equine has shown any clinical sign of contagious equine metritis during that period ;
5. it must not be used for natural mating during 30 days prior to the first semen collection and during the collection period ;
6. it must be subjected to the following tests, carried out and certified in a laboratory recognized by the competent authority according to the programme set up in paragraph 7 :
 - (i) an agar-gel immuno-diffusion test (Coggins test) for equine infectious anaemia with negative result ;
 - (ii) a serum neutralization test for equine viral arteritis. Unless a negative result at a serum dilution of 1 in 4 is achieved, a virus isolation test for equine viral arteritis shall be carried out with negative result on an aliquot of the entire semen of the donor stallion ;
 - (iii) a test for contagious equine metritis carried out on two occasions 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 ;
7. it must have been subjected to one of the following testing programmes :
 - (i) Where semen is collected for trade in fresh or chilled semen :
 - and the donor stallion is continuously resident on the collection centre for at least 30 days prior to the first semen collection and during the collection period, and no equidae on the collection centre come into direct contact with equidae of lower health status than the donor stallion, the tests required in paragraphs 6 (i), (ii) and (iii) shall be carried out at least 14 days after the start of the above residence period and at least once a year at the beginning of the breeding season.
 - and the donor stallion is not continuously resident on the collection centre, and/or other equidae on the collection centre come into direct contact with equidae of lower health status, the tests required in paragraphs 6 (i), (ii) and (iii) shall be carried out within the 14 day period before the first semen collection and at least once a year at the beginning of the breeding season. Furthermore, the test required in paragraph 6 (i) shall be repeated at least every 120 days during the period of semen collection. The test required in paragraph 6 (ii) shall be carried out not more than 30 days before each semen collection, unless the non-shedder state of a seropositive stallion for equine viral arteritis is confirmed by virus isolation test which must be carried out annually.
 - (ii) Where semen is collected for trade in frozen semen, the testing programmes as described in paragraph 7 (i) first and second indent shall apply or, alternatively, the tests required in paragraph 6 (i), (ii) and (iii) shall be carried out during the mandatory 30 days storage period of the semen and not less than 14 days after the collection of the semen, irrespective of the residence status of the stallion.

ANNEX III

- 'C. If any of the tests referred to in A or B proves positive, that animal must be isolated and the semen, collected from it since the last negative test shall not be subject of trade. The same applies to semen collected from the other animals susceptible to the disease concerned at the holding or collection centre since the date on which the positive test was carried out. Trade shall not resume until the health status of the centre has been re-established.'

*ANNEX IV***'CHAPTER III****REQUIREMENTS APPLICABLE TO SEMEN, OVA AND EMBRYOS**

Semen, ova and embryos must have been collected, processed and preserved in accordance with the following principles :

- (a) The washing of ova and embryos even in the case of equidae must be carried out in accordance with conditions to be laid down in accordance with the procedure laid down in Article 26. Pending the adoption of such condition, international standards are applicable.

The zona pellucida of ova and embryos must remain intact before and after washing.

Only ova and embryos from the same donor may be washed at the same time.

After washing, the zona pellucida of each ovum or embryo must be examined over its entire surface area under a magnification of at least 50 and be certified as being intact and free from any adherent material.

- (b) The medium and solutions used for collection, processing (examination, washing and treatment), conservation or freezing of ova and embryos must be sterilized in accordance with approved methods and handled in such a way that they remain sterile.

Antibiotics must be added to the collection, washing and conservation mediums for ova and embryos and to the diluents for semen. If necessary detailed rules will be determined under the procedure provided for in Article 26.

- (c) All materials used for the collection, processing, conservation or freezing of semen, ova and embryos must be either disinfected or sterilized as appropriate before use or new, disposable and discarded after use.

- (d) Additional tests may be established under the procedure provided for in Article 26, in particular as regards the collection of washing liquids, so as to establish that no pathogens are present.

- (e) Ova and embryos, which have successfully undergone the examination provided for in (a), and semen shall be placed in sterile containers, which are duly identified, contain only products from one male or female donor and are sealed immediately.

The identification to be established under the procedure provided for in Article 26 shall ensure that at least the country of origin, the date of collection, the species, the breed, the identity of the donor animal and the name and/or the number of the collection centre/team may be established.

- (f) Frozen semen, ova and embryos must be placed in sterile liquid nitrogen containers which present no risk of contamination to the product.
- (g) Frozen semen, ova and embryos must be stored in approved conditions for a minimum period of 30 days prior to dispatch.
- (h) Semen, ova and embryos must be transported in containers which either have been cleaned, disinfected or sterilized as appropriate before use or are new, disposable and discarded after use.'
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ANNEX V

'CHAPTER IV

DONOR FEMALES

Females may be used for the collection of embryos or ova only if they and the herds from which they originate meet, to the satisfaction of the official veterinarian, the requirements of the relevant Directives on intra-Community trade in live animals for breeding and production for the species concerned.

The provisions of Council Directive 64/432/EEC apply for swine and the provisions of Council Directive 91/68/EEC apply for ovine and caprine animals.

In addition to the requirements established by Council Directive 90/426/EEC equidae must have been kept prior to the collection of ova or embryos in holdings free from clinical signs of contagious equine meritis for 60 days. They must not be used for natural breeding during the period of 30 days prior to the collection of ova or embryos.
