

# COMMISSION

## COMMISSION DECISION

of 8 February 1994

**amending Council Directive 89/556/EEC on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species**

(Text with EEA relevance)

(94/113/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/556/EEC of 25 September 1989 laying down the animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species<sup>(1)</sup>, as last amended by Directive 93/52/EEC<sup>(2)</sup>, and in particular Article 16 thereof,

Whereas Article 1 of Directive 89/556/EEC excluded embryos derived by certain techniques from the scope of the said Directive; whereas embryos which are to be subjected to techniques which involve the penetration of the *zona pellucida* and those derived by *in vitro* fertilization may be introduced into trade or be imported, provided that they meet the requirements of Directive 89/556/EEC, with certain additional safeguards;

Whereas the scope of Directive 89/556/EEC has been enlarged by Directive 93/52/EEC to include all bovine embryos except those derived by transfer of nuclei;

Whereas it is necessary to amend the Annexes to the Directive in order to lay down the necessary additional safeguards for such embryos;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

### *Article 1*

The Annexes to Directive 89/556/EEC are hereby amended as shown in the Annex hereto.

### *Article 2*

This Decision shall apply from 1 March 1994.

It shall not apply to embryos collected, processed and stored before 1 March 1994.

### *Article 3*

This Decision is addressed to the Member States.

Done at Brussels, 8 February 1994.

*For the Commission*

René STEICHEN

*Member of the Commission*

<sup>(1)</sup> OJ No L 302, 19. 10. 1989, p. 1.

<sup>(2)</sup> OJ No L 175, 19. 7. 1993, p. 21.

## ANNEX

1. In Annex A, Chapter I, the title is changed to 'Conditions for the approval of embryo collection and embryo production teams.'
2. In Annex A, Chapter I, paragraph (d), the following is added :
  - '— where micromanipulation of the embryo which involves penetration of the *zona pellucida* is to be carried out, this shall be done in suitable laminar-flow facilities which shall be properly cleaned and disinfected between batches.'
3. In Annex A, Chapter I, the following is added after paragraph (e) :

'Furthermore, to be approved as a team for the production and processing of embryos derived by *in vitro* fertilization and/or *in vitro* culture, an embryo production team must fulfil the following additional requirements :

  - (f) the personnel must be trained in appropriate disease control and laboratory techniques, particularly in procedures for working in sterile conditions ;
  - (g) it must have at its disposal a permanently-sited processing laboratory which must :
    - have adequate equipment and facilities, including a separate room for recovering oocytes from ovaries, and separate rooms or areas for processing oocytes and embryos, and storing embryos,
    - have laminar-flow facilities under which all oocytes, semen and embryos must be processed ; however, the centrifugation of semen may be carried out outside the laminar-flow facility, as long as full hygienic precautions are taken ;
  - (h) where oocytes and other tissues are to be collected in an abattoir, it must 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.'
4. In Annex A, Chapter II, 'or production' is added after 'collection' in the title.
5. In Annex A, Chapter II, paragraph 1, the following is added to subparagraph (e) :

'All media and solutions shall be sterilized by approved methods according to the recommendations of the manual of the International Embryo Transfer Society (IETS). Antibiotics may be added to the media in accordance with the IETS manual.'
6. In Annex A, Chapter II, paragraph 1, 'at a magnification of at least  $\times 50$ ' is added after 'microscopic examination' in subparagraph (j).
7. In Annex A, Chapter II, paragraph 1, the following is added to subparagraph (j) :

'Any micromanipulation which involves penetration of the *zona pellucida* must be carried out in the facilities approved for the purpose, and after the last wash and examination. Such micromanipulation may only be carried out on an embryo having an intact *zona pellucida*.'
8. In Annex A, Chapter II, paragraph 1, the following indent is added to subparagraph (o) :
  - '— details of micromanipulation techniques which involve penetration of the *zona pellucida* or other techniques such as *in vitro* fertilization and/or *in vitro* culture which have been performed on the embryos. In the case of embryos derived by *in vitro* fertilization, the identification may be done on the basis of a batch, but must contain details of the date and place of collection of ovaries and/or oocytes. It must also be possible to identify the herd of origin of the donor animals.'
9. In Annex A, Chapter II, paragraph 1, the following is added after subparagraph (o) :

'The conditions laid down in subparagraphs (a) to (o) shall apply as appropriate to the collection, processing, storage and transport of ovaries, oocytes and other tissues for use in *in vitro* fertilization and/or *in vitro* culture. Furthermore, the following additional conditions shall apply :

  - (p) when ovaries and other tissues are to be collected at an abattoir, the abattoir should be officially approved and under the control of an official veterinarian whose responsibility it is to carry out ante- and post-mortem inspection of donors ;
  - (q) materials and equipment coming into direct contact with ovaries and other tissues shall be sterilized before use and after sterilization, used exclusively for those purposes. Separate equipment shall be used to handle oocytes and embryos from different batches of donor animals ;

- (r) ovaries and other tissues shall not be allowed to enter the processing laboratory until completion of the post-mortem inspection of the batch. If relevant disease is found in the batch of donors, or in any animals slaughtered in that abattoir on that day, all tissues from that batch must be traced and discarded;
- (s) the washing and examination procedure laid down in subparagraphs (i) and (j) shall be carried out after the culture procedure has been completed;
- (t) any micromanipulation which involves penetration of the *zona pellucida* shall be carried out in accordance with the provisions of subparagraph (j), after the procedures laid down in subparagraph (s) have been completed;
- (u) only embryos from the same batch of donors should be stored in the same ampoule/straw.

10. In Annex A, Chapter II, paragraph 2, 'or production' is added after the word 'collection'.

11. Annex B is replaced by the following:

#### **ANNEX B**

#### **CONDITIONS APPLYING TO DONOR ANIMALS**

1. For the purposes of embryo collection, donor animals must meet the following requirements:
    - (a) they must have spent at least the previous six months within Community territory or in the third country of collection;
    - (b) they must have been present in the herd of origin for at least 30 days prior to collection;
    - (c) they must come from herds which are:
      - officially tuberculosis free,
      - officially brucellosis free or brucellosis free,
      - enzootic bovine leucosis free
 in derogation from the third indent, they may come from a herd (or herds) which is/are not leucosis-free but for which certification has been obtained that there has not been any clinical case of enzootic bovine leucosis during the past three years;
    - (d) during the previous year, they must not have been present in a herd (or herds) which have shown any clinical sign of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis.
  2. On the day of embryo collection the donor cow:
    - (a) shall be kept in a holding which is not subject to veterinary prohibition or quarantine measures;
    - (b) shall show no clinical signs of disease.
  3. Furthermore, the above conditions shall apply to live animals intended as donors of oocytes by ovum pickup or ovariectomy.
  4. In the case of donors of ovaries and other tissues to be collected after slaughter in an abattoir, they should not have been designated for slaughter as part of a national disease eradication programme, nor should they have come from a holding subject to restrictions because of animal disease.
  5. The abattoir where the ovaries and other tissues are collected must not be situated in a zone subject to prohibition or quarantine measures.
12. The following is inserted into the certificate in Annex C, Section 12:
- "<sup>(1)</sup> (d) Embryos derived by natural/*in vitro*<sup>(2)</sup> fertilization and subjected to/not subjected to <sup>(2)</sup> penetration of the *zona pellucida*."
13. In the certificate in Annex C, the words after "89/556/EEC" in paragraph 13 (a) are deleted.
14. The following are added as footnotes to Annex C:
- "<sup>(1)</sup> This need not be completed for embryos collected, processed and stored before 1 March 1994.
- "<sup>(2)</sup> Delete as appropriate."