

Council Directive 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 (89/556/EEC)

COUNCIL DIRECTIVE

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

(89/556/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission<sup>(1)</sup>,

Having regard to the opinion of the European Parliament<sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(3)</sup>,

Whereas the use of embryos of domestic animals of the bovine species is part of an efficient breeding policy which leads to better productivity and increased margins in this sector; whereas, in addition, the free movement of such embryos should encourage a rational development by taking into account the use of optimum production factors;

Whereas the provisions relating to animal health problems in intra-Community trade in bovine animals and swine appear in Directive 64/432/EEC<sup>(4)</sup>, as last amended by Directive 89/360/EEC<sup>(5)</sup>; whereas in addition, Directive 72/462/EEC<sup>(6)</sup>, as last amended by Directive 89/227/EEC<sup>(7)</sup> contains provisions relating to veterinary inspection problems upon importation of bovine animals and swine from third countries;

Whereas the abovementioned provisions have ensured, with regard to intra-Community trade and imports into the Community of bovine animals and swine from third countries, that the country of provenance guarantees that animal health criteria have been fulfilled, so that the risk of animal disease spreading has been virtually eliminated; whereas there is nevertheless a certain risk of the spread of such disease in the case of trade in embryos;

Whereas in the context of the Community policy of harmonizing national animal health provisions governing intra-Community trade in animals and animal products, it is now necessary to create a harmonized system for intra-Community trade and imports into the Community of embryos of bovine animals;

Whereas in the context of intra-Community trade in embryos, the Member State where the embryos are collected should be under an obligation to ensure that such embryos have been collected and processed by approved and supervised embryo collection teams, that they have been obtained from animals whose health status is such as to ensure that the risk of spread of

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animal disease is eliminated, that they have been collected, processed, stored and transported in accordance with the rules which preserve their health status and are accompanied during transport to the country of destination by an animal health certificate in order to ensure that this obligation has been fulfilled;

Whereas the difference in the policies pursued within the Community with regard to vaccination against foot-and-mouth disease justifies the maintenance, for fresh embryos, of derogations, limited in time, authorizing the requirement by the Member States of additional protection against that disease;

Whereas a list of third countries should be drawn up, taking into account animal health criteria, from which embryos may be imported into the Community; whereas without prejudice to such a list the Member States must not authorize importation unless the embryos have been collected, processed and stored by embryo collection teams which reach certain standards and which are officially supervised; whereas, in addition, in respect of countries on that list, specific animal health conditions should be laid down according to circumstances; whereas on-the-spot checks may be carried out in order to verify compliance with those standards;

Whereas in order to prevent the transmission of certain contagious diseases, import controls should be carried out when a consignment of embryos arrives on the territory of the Community, except in the case of external transit;

Whereas, in the case of internal transit, the measures to be taken by Member States after such controls must be defined;

Whereas the Commission should be entrusted with taking certain measures for implementing this Directive; whereas to that end procedures should be established for cooperation between the Commission and the Member States;

Whereas this Directive does not affect trade in embryos obtained, treated or stored before the date on which the Member States must comply with it,

HAS ADOPTED THIS DIRECTIVE:

## CHAPTER I

### General provisions

#### *Article 1*

1 This Directive defines the animal health conditions governing intra-Community trade in and importation from third countries of fresh and frozen embryos of domestic animals of the bovine species.

[<sup>F12</sup> This Directive shall not apply to embryos derived by transfer of nuclei.]

### Textual Amendments

- F1** Substituted by [Council Directive 93/52/EEC of 24 June 1993 amending 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.](#)

### Article 2

For the purposes of this Directive, the definitions contained in Article 2 of Directive 64/432/EEC and Article 2 of Directive 72/462/EEC shall apply as necessary.

Moreover:

- (a) 'embryo' means the initial stage of development of a domestic animal of the bovine species while it is capable of being transferred to a recipient dam;
- (b) 'embryo collection team' means an officially approved group of technicians or structure supervised by a team veterinarian competent to perform the collection, processing and storage of embryos according to the conditions set out in Annex A;
- (c) 'team veterinarian' means the veterinarian responsible for the supervision of an embryo collection team in accordance with the conditions laid down in Annex A;
- (d) 'consignment of embryos' means a quantity of embryos removed in one operation from a single donor and covered by a single certificate;
- (e) 'country of collection' means the Member State or third country in which embryos are produced, collected, processed and, where necessary, stored, and from which they are sent to a Member State;
- (f) 'approved diagnostic laboratory' means a laboratory situated in the territory of a Member State or third country approved by the competent veterinary authority to carry out the diagnostic tests laid down in this Directive<sup>[F1];</sup>
- (g) '<sup>[F2]</sup>embryo production team' means an officially approved embryo collection team for *in vitro* fertilization in accordance with the conditions laid down in the relevant Annex.]

### Textual Amendments

- F1** Substituted by [Council Directive 93/52/EEC of 24 June 1993 amending 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.](#)
- F2** Inserted by [Council Directive 93/52/EEC of 24 June 1993 amending 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.](#)

## CHAPTER II

### Rules for intra-Community trade

#### Article 3

Each Member State shall ensure that embryos shall not be sent from its territory to that of another Member State unless they meet the following conditions:

- (a) [<sup>F1</sup>they must have been conceived as a result of artificial insemination or *in vitro* fertilization with semen from a donor sire standing at a semen collection centre approved by the competent authority for the collection, processing and storage of semen or by semen imported in accordance with Directive 88/407/EEC<sup>(8)</sup>.]

In accordance with the procedure laid down in Article 18, the Commission may authorize trade in embryos of certain specific species conceived as a result of natural service by bulls whose health status complies with Annex B to that Directive;

- (b) they must have been collected from domestic animals of the bovine species whose health status complies with Annex B of this Directive;
- (c) they must have been collected, processed and stored by an embryo collection team approved in accordance with Article 5 (1);
- (d) they must have been collected, processed and stored by the embryo collection team in accordance with Annex A of this Directive;
- (e) they must be accompanied, during transport to the Member State of destination, by an animal health certificate complying with Article 6 (1).

#### Textual Amendments

- F1** Substituted by [Council Directive 93/52/EEC of 24 June 1993 amending 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.](#)

#### <sup>F3</sup> Article 4

#### Textual Amendments

- F3** Deleted by [Council Directive 93/52/EEC of 24 June 1993 amending 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.](#)

#### Article 5

1 Approval of an embryo collection team as provided for in Article 3 (c) shall be granted only where the provisions of Annex A, Chapter I are observed and where the embryo collection team is able to satisfy the other provisions of this Directive.

Any major change in the organization of the team is to be notified to the competent authority.

The approval of the team shall be renewed whenever the team veterinarian is replaced or whenever any major changes are made in its organization or the laboratories or equipment at its disposal.

The official veterinarian shall supervise observance of the provisions outlined above. Approval shall be withdrawn where one or more of the provisions is no longer observed.

[<sup>F42</sup> The competent authority of each Member State concerned shall register embryo collection teams and give a veterinary registration number to each team.

Each Member State shall draw up and keep up to date a list of embryo collection teams and their veterinary registration numbers and make it available to the other Member States and to the public.]

[<sup>F5</sup> . . . . .  
<sup>F5</sup> . . . . .  
<sup>F5</sup> . . . . .]

The veterinary experts must be nationals of a Member State other than those involved in the dispute.

[<sup>F2a</sup> Approval of an embryo production team for embryos derived by *in vitro* fertilization shall be granted only where the provisions of the relevant Annex to this Directive are observed and where the embryo production team is able to satisfy the other relevant provisions of this Directive and in particular the provisions of paragraphs 1 and 2 of this Article, which shall apply *mutatis mutandis*.]

3 The detailed rules for applying this Article shall be adopted in accordance with the procedure laid down in Article 18.

#### Textual Amendments

- F2** Inserted by Council Directive 93/52/EEC of 24 June 1993 amending 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.
- F4** Substituted by Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC (Text with EEA relevance).
- F5** Deleted by Council Directive of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (90/425/EEC).

#### Article 6

1 An animal health certificate drawn up by an official veterinarian of the Member State of collection on a form conforming to the specimen in Annex C shall accompany each consignment of embryos. A separate certificate shall be issued for each consignment.

2 The animal health certificate must:

- a consist of a single form and be drawn up in at least the official language(s) of the Member State of destination;

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- b be made out to a single consignee;
- c accompany the consignment of embryos to its destination in its original form.

## CHAPTER III

### Rules for importation from third countries

#### *Article 7*

1 Embryos shall be imported only from those third countries or parts thereof which appear on a list drawn up in accordance with the procedure laid down in Article 18. That list may be supplemented or amended in accordance with the same procedure.

2 In deciding whether a third country or parts thereof may appear on the list referred to in paragraph 1, particular account shall be taken of:

- a the state of health of the livestock, other domestic animals and wildlife in the third country, with particular reference to exotic animal diseases, and of the environmental health situation in that country, which might endanger animal health in the Member States;
- b the regularity and rapidity of the information supplied by the third country concerning the existence of contagious animal diseases in its territory, in particular those diseases mentioned in lists A and B of the International Office of Epizootic Diseases;
- c the rules of the third country on animal disease prevention and control;
- d the structure of the veterinary services in the third country and their powers;
- e the organization and implementation of measures to prevent and control contagious animal diseases; and
- f the guarantees which the third country can give with regard to compliance with the rules set out in this Directive.

3 The list referred to in paragraph 1 and all amendments thereto shall be published in the *Official Journal of the European Communities*.

#### *Article 8*

1 Member States shall only authorise imports of embryos dispatched from an embryo collection or production team situated in one of the third countries appearing on the list referred to in Article 7 and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions are met:

- a it meets the conditions:
  - (i) for the approval of embryo collection and embryo production teams set out in Chapter I of Annex A;
  - (ii) relating to the collection, processing, storage and transport of embryos by such teams set out in Chapter II of that Annex;
- b it has been officially approved by the competent authority of the third country for exports to the Community;
- c it is subject to inspections by an official veterinarian of the third country at least twice a year.

2 The list of embryo collection or production teams that the competent authority of the third country appearing on the list referred to in Article 7 has approved in accordance with the

conditions set out in paragraph 1 of this Article and from which embryos may be dispatched to the Community shall be communicated to the Commission.

The approval of an embryo collection or production team must be immediately suspended or withdrawn by the competent authority of the third country where it no longer complies with the conditions set out in paragraph 1 and the Commission must be immediately informed thereof.

The Commission shall provide the Member States with any new and updated lists that it receives from the competent authority of the third country concerned in accordance with this paragraph and shall make them available to the public for information purposes.

3 Detailed rules for the uniform application of this Article may be adopted in accordance with the procedure referred to in Article 18(2).]

#### **Textual Amendments**

- F4** Substituted by [Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC \(Text with EEA relevance\).](#)

#### *Article 9*

1 Importation of embryos from the territory of a third country or part thereof on the list drawn up in accordance with Article 7 (1) shall take place only if the embryos:

- a come from donor animals which, immediately prior to the collection of their embryos, have remained for at least six months in the territory of the third country concerned, and in a maximum of two herds complying with at least the requirements set out in paragraph 2;
- b comply with the animal health requirements adopted in accordance with the procedure laid down in Article 18 for imports of embryos from that country.

In adopting the requirements referred to in the first subparagraph, consideration shall be given to:

- a the health situation in the area surrounding the place of embryo collection, with particular reference to the diseases appearing on list A of the International Office of Epizootic Diseases;
- b the state of health of the herd concerned in the embryo collection, including testing requirements;
- c the state of health of the donor animal and testing requirements;
- d collecting, processing and storing requirements in relation to embryos.

2 The reference basis for fixing animal health conditions in accordance with paragraph 1 for tuberculosis, bovine brucellosis and enzootic bovine leucosis shall be the standards laid down in Annexes A and G to Directive 64/432/EEC. Under the procedure laid down in Article 18 and on a case-by-case basis, derogations from those provisions may be decided upon where an interested third country provides similar and at least equivalent guarantees with reference to animal health.

[<sup>F13</sup> In laying down animal health provisions concerning foot-and-mouth disease in accordance with paragraph 1, it must be taken into account that:

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- only frozen embryos may be imported from third countries where vaccination against foot-and-mouth disease is practised. The embryos must be stored under approved conditions for a minimum of 30 days before consignment,
- donor animals must come from a holding in which no animal has been vaccinated against foot-and-mouth disease during the 30 days prior to collection, and which is not subject to any prohibition or quarantine measures.]

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**Textual Amendments**

- F1** Substituted by [Council Directive 93/52/EEC of 24 June 1993 amending 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.](#)

*Article 10*

1 Importation of embryos shall be authorized only on submission of an animal health certificate drawn up and signed by an official veterinarian of the third country of collection.

The certificate must:

- a be drawn up in at least the official language or languages of the Member State of destination and the official language or languages of the Member State where the import control provided for in Article 11 is carried out;
  - b be made out to a single consignee;
  - c accompany the embryos in the original.
- 2 The animal health certificate must be on a form conforming to a specimen drawn up in accordance with the procedure laid down in Article 18.

*[<sup>F4</sup> Article 11*

The rules laid down in Directive 97/78/EC shall apply, in particular to the organisation of, and follow-up to the checks to be carried out by the Member States and the safeguard measures to be applied in accordance with the procedure referred to in Article 22 of that Directive.]

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**Textual Amendments**

- F4** Substituted by [Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC \(Text with EEA relevance\).](#)

CHAPTER IV

**Rules on safeguard and control measures**

*<sup>F5</sup> Article 14*

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#### Textual Amendments

- F5** Deleted by [Council Directive of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market \(90/425/EEC\)](#).

#### *[<sup>F6</sup>Article 14*

The rules laid down in Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market<sup>(9)</sup>, shall apply in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out by the country of destination, and to the safeguard measures to be implemented.]

#### Textual Amendments

- F6** Inserted by [Council Directive of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market \(90/425/EEC\)](#).

#### *Article 15*

1 Veterinary experts from the Commission may, in cooperation with the competent authorities of the Member States or third countries, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of this Directive.

The country of collection within whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the country of collection concerned of the results of the investigation.

The country of collection concerned shall take any measures which may prove necessary to take account of the results of the investigation. If the country of collection does not take those measures, the Commission may, after the situation has been examined by the Standing Veterinary Committee, authorize Member States to refuse entry into their territory for embryos obtained, processed or stored by the collection team in question or withdraw approval in the case of third countries.

2 The general provisions for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph of paragraph 1, shall be laid down in accordance with the procedure set out in Article 18.

## CHAPTER V

### Final provisions

#### *Article 16*

Amendments to the Annexes, in particular to adapt them to advances in technology, shall be decided in accordance with the procedure set out in Article 18.

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### *[<sup>F7</sup> Article 17*

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002<sup>(10)</sup>.

2 Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC<sup>(11)</sup> shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

3 The Committee shall adopt its Rules of Procedure.

#### **Textual Amendments**

**F7** Substituted by [Council Regulation \(EC\) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure \(qualified majority\).](#)

### *Article 18*

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2 Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.]

#### **Textual Amendments**

**F7** Substituted by [Council Regulation \(EC\) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure \(qualified majority\).](#)

### *Article 19*

1 This Directive shall not apply to embryos collected, processed and stored in a Member State before 1 January 1991.

2 Until the date of entry into force of the decisions adopted pursuant to Articles 7, 8 and 9, the Member States shall not apply to imports of embryos from third countries more favourable conditions than those resulting from the application of Chapter II.

### *Article 20*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 1 January 1991. They shall forthwith inform the Commission thereof.

### *Article 21*

This Directive is addressed to the Member States.



## ANNEX A

## CHAPTER I

**[<sup>F8</sup>Conditions for the approval of embryo collection and embryo production teams]**

In order to be given approval each embryo collection team must fulfil the following requirements:

- (a) the collection, processing and storage of embryos must 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;
- (b) it must be placed under the general supervision and authority of the official veterinarian;
- (c) it must have at its disposal permanent or mobile laboratory facilities where embryos can be examined, processed and packed, consisting of at least a work surface, a microscope and cryogenic equipment;
- (d) in the case of a permanently sited laboratory, it must have at its disposal:
  - a room where embryos can be manipulated which is adjacent to but physically separate from the area used to handle the donor animals during collection,
  - a room or area equipped for cleansing and sterilizing instruments and equipment used in embryo collection and manipulation[<sup>F8</sup>]
  - [<sup>F9</sup>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;]
- (e) it must have at its disposal in the case of a mobile laboratory a specially equipped part of the vehicle consisting of two separate sections,
  - one for the examination and manipulation of embryos which shall be a clean section, and
  - the other for accommodating equipment and materials used in contact with the donor animals.

A mobile laboratory shall always have contact with a permanently sited laboratory to ensure the sterilization of its equipment and the provision of fluids and other products necessary for the collection and manipulation of embryos.

**Textual Amendments**

- F9** Inserted by [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 \(Text with EEA relevance\) \(94/113/EC\)](#).

[<sup>F9</sup>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;

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- (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.]

#### Textual Amendments

- F8** Substituted by [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 \(Text with EEA relevance\) \(94/113/EC\)](#).

## CHAPTER II

### Conditions relating to the collection, processing, storage and transport of embryos by the approved embryo collection<sup>F9</sup> or production] team

1. Collection and processing
  - (a) Embryos shall be collected and processed by an approved collection team, without coming into contact with any other consignment of embryos not meeting the requirements of this Directive.
  - (b) Embryos shall be collected in a place which is isolated from other parts of the premises or holding and which must be in good repair and easy to cleanse and disinfect.
  - (c) Embryos shall be processed (examined, washed, treated and placed in identified and sterile containers) in either a permanent laboratory facility or a mobile laboratory facility, which is not situated in a zone subject to prohibition or quarantine measures.
  - (d) All implements which come into contact with the embryos or the donor animal during collection and processing shall be disposable or shall be properly disinfected or sterilized prior to use.
  - (e) Products of animal origin used during collection of the embryos and in the transport medium shall be obtained from sources which present no animal health risk or are to be so treated prior to use so that such risk is prevented.<sup>F9</sup>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.]
  - (f) Storage flasks and transport flasks shall be properly disinfected or sterilized before the commencement of each filling operation.
  - (g) The cryogenic agent used shall not have been previously used for other products of animal origin.

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- (h) Each embryo container and the containers in which they are stored and transported shall be clearly code-marked in such a way that the date of collection of the embryos and the breed and identification of the donor sire and donor dam, as well as the registration number of the team can be readily established. The characteristics and form of this code-marking shall be established in accordance with the procedure laid down in Article 18.
- (i) Each embryo shall be washed at least 10 times in a special fluid for embryos which shall be changed each time and which, unless decided otherwise under point (m), shall contain trypsin, in accordance with internationally recognized procedures. Each wash shall be a 100-fold dilution of the previous wash and a sterile micropipette shall be used to transfer the embryo on each occasion.
- (j) After the last wash each embryo shall be subjected to microscopic examination<sup>[F9]</sup> at a magnification of at least  $\times 50$ ] over its entire surface to determine that the 'zona pellucida' is intact and is free from any adherent material.<sup>[F9]</sup> 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*.]
- (k) Each consignment of embryos that has successfully undergone the examination provided for in (j) shall be placed in a sterile container marked in accordance with (h) and which shall be sealed immediately.
- (l) Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian and which is subject to regular inspection by an official veterinarian.
- (m) In accordance with the procedure laid down in Article 18 a protocol shall be drawn up before the date provided for in Article 20 concerning authorized flushing and washing fluids, washing techniques and, where necessary, enzymatic treatments together with authorized transportation media.
- Pending the adoption of a protocol on enzymatic treatments, the national rules on the use of trypsin shall continue to apply, in compliance with the general provisions of the Treaty.
- (n) Each collection team must submit routine samples of flushing fluids, washing fluids, disintegrated embryos, non-fertilized ova etc., resulting from its activities for official examination for bacterial and viral contamination. The procedure for collecting of samples, conducting such examinations, together with the standards to be achieved shall be decided in accordance with the procedure laid down in Article 18. If the standards laid down are not achieved the competent authority which granted the official approval to the team shall withdraw that approval.
- (o) Each collection team must keep a record of its activities in respect of embryo collection during the 12 months before and 12 months after storage including:
- the breed, age and identification of the donor animals concerned,
  - the place of collection, processing and storage of embryos collected by the team,
  - the identification of the embryos together with details of their destination if known<sup>[F8]</sup>.]

- [F<sup>9</sup>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.]

[F<sup>9</sup>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.]

## 2. Storage

Each embryo collection [F<sup>9</sup> or production] team shall ensure that the embryos are stored at suitable temperatures in premises approved for the purpose by the competent authority.

In order to be approved these premises must:

- (i) comprise at least one lockable room intended exclusively for embryo storage;
- (ii) be easy to cleanse and disinfect;
- (iii) have permanent records of all incoming and outgoing movements of embryos. The final destination of the embryos in particular shall be specified in such records;
- (iv) be subject to inspection by the official veterinarian.

The competent authority may authorize the storage of semen that fulfils the requirements of Directive 88/407/EEC in the approved storage premises.

## 3. Transport

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Embryos for trade must be transported in satisfactory hygienic conditions in sealed containers from the approved storage premises until their arrival at their destination.

The containers must be marked in such a way that the number coincides with the number on the animal health certificate.

## [<sup>F8</sup>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.]



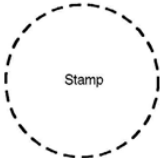
[<sup>F10</sup> ANNEX C]

**Textual Amendments**

**F10** Substituted by Commission Decision of 2 February 2006 amending Annex C to Council Directive 89/556/EEC as regards the model animal health certificate for intra-Community trade in embryos of domestic animals of the bovine species (notified under document number C(2006) 193) (Text with EEA relevance) (2006/60/EC).

EUROPEAN COMMUNITY		Domestic bovine embryos	
Part II: Certification	II. Health information	II.a. Certificate reference number	II.b. Local reference number
	<p>I, the undersigned official veterinarian, hereby certify that the embryos described in this certificate:</p> <p>II.1 were collected, processed and stored in compliance with Annex A to Directive 89/556/EEC;</p> <p>II.2 were sent to the place of loading in sealed containers in compliance with Annex A to Directive 89/556/EEC;</p> <p>II.3 come from donors of the bovine species which comply with Annex B to Directive 89/556/EEC;</p> <p>II.4 were conceived either by artificial insemination or by <i>in vitro</i> fertilisation <sup>(1)</sup> using semen coming from semen collection or storage centres approved in accordance with Directive 88/407/EEC and located in a Member State of the European Community or in a third country listed in Annex I to Commission Decision 2004/639/EC <sup>(2)</sup>.</p>		
<p><b>Notes</b></p> <p><sup>(1)</sup> Delete as necessary.</p> <p><sup>(2)</sup> OJ L 292, 15.9.2004, p. 21.</p> <p><sup>(3)</sup> [Box I.6. in Part I]: in the case of imported embryos, insert the number of the import certificate.</p> <p><sup>(4)</sup> [Box I.31. in Part I]: Identification mark: corresponding to the details identifying the donor cows and the date of collection on the straw. Category: specify whether there is (a) penetration or (b) non-penetration of <i>zona pellucida</i>.</p>			
<p>Official veterinarian</p> <p>Name (in capital letters): Local Veterinary Unit: Date:</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Stamp</p> </div> <div style="text-align: center;"> <p>Qualification and title: No of the LVU: Signature:*</p> </div> </div>			

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EUROPEAN COMMUNITY		Domestic bovine embryos	
Part II: Certification	II. Health information	II.a. Certificate reference number	II.b. Local reference number
	<p>I, the undersigned official veterinarian, hereby certify that the embryos described in this certificate:</p> <p>II.1 were collected, processed and stored in compliance with Annex A to Directive 89/556/EEC;</p> <p>II.2 were sent to the place of loading in sealed containers in compliance with Annex A to Directive 89/556/EEC;</p> <p>II.3 come from donors of the bovine species which comply with Annex B to Directive 89/556/EEC;</p> <p>II.4 were conceived either by artificial insemination or by <i>in vitro</i> fertilisation <sup>(1)</sup> using semen coming from semen collection or storage centres approved in accordance with Directive 88/407/EEC and located in a Member State of the European Community or in a third country listed in Annex I to Commission Decision 2004/639/EC <sup>(2)</sup> <sup>(3)</sup>.</p>		
<p><b>Notes</b></p> <p><sup>(1)</sup> Delete as necessary.</p> <p><sup>(2)</sup> OJ L 292, 15.9.2004, p. 21.</p> <p><sup>(3)</sup> [Box I.6. in Part I]: In the case of imported embryos, insert the number of the import certificate.</p> <p><sup>(4)</sup> [Box I.31. in Part I]: Identification mark corresponding to the details identifying the donor cows and the date of collection on the straw. Category: specify whether there is (a) penetration or (b) non-penetration of <i>zona pellucida</i>.</p>			
<p>Official veterinarian</p> <p>Name (in capital letters): Local Veterinary Unit: Date:</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Stamp</p> </div> <div style="text-align: center;"> <p>Qualification and title: No of the LVU: Signature:</p> </div> </div>			

- (1) OJ No C 76, 28.3.1989, p. 1.
- (2) OJ No C 120, 16.5.1989, p. 313.
- (3) OJ No C 139, 5.6.1989, p. 56.
- (4) OJ No 121, 29.7.1964, p. 1977/64.
- (5) OJ No L 153, 6.6.1989, p. 29.
- (6) OJ No L 302, 31.12.1972, p. 28.
- (7) OJ No L 93, 6.4.1989, p. 25.
- (8) [<sup>F1</sup>OJ No L 194, 22.7.1988, p. 10. Directive as last amended by Directive 90/425/EEC (OJ No L 224, 18.8.1990, p. 29).]
- (9) [<sup>F6</sup>OJ No L 224, 18.8.1990, p. 29.]
- (10) [<sup>F7</sup>OJ L 31, 1.2.2002, p. 1.]
- (11) [<sup>F7</sup>OJ L 184, 17.7.1999, p. 23.]

#### Textual Amendments

- F1** Substituted by Council Directive 93/52/EEC of 24 June 1993 amending 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.
- F6** Inserted by Council Directive of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (90/425/EEC).
- F7** Substituted by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority).