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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)

(OJ L 302, 19.10.1989, p. 1)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Council Directive 90/425/EEC of 26 June 1990	L 224	29	18.8.1990
►**M2**	Council Directive 93/52/EEC of 24 June 1993	L 175	21	19.7.1993

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COUNCIL DIRECTIVE

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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 [1],

Having regard to the opinion of the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

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 [4], as last amended by Directive 89/360/EEC [5]; whereas in addition, Directive 72/462/EEC [6], as last amended by Directive 89/227/EEC [7] 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 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, author-

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(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.

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izing 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.

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2. This Directive shall not apply to embryos derived by transfer of nuclei.

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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;

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(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;

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(g) '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.

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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:

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(a) 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 [1].

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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).

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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.

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[1] 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).

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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.

2. All approved embryo collection teams shall be registered by the competent authority of the Member State concerned, each team being given a veterinary registration number. A list of embryo collection teams and their veterinary registration numbers shall be sent by each Member State to the other Member States and to the Commission, which shall also be notified of any amendment made to that list.

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

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2a. 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*.

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

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;

(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;

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(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. In accordance with the procedure laid down in Article 18, a list shall be drawn up of embryo collection teams which are authorized to collect, process or store in third countries embryos which are destined for the Member States. The list may be amended or supplemented in accordance with the same procedure.

2. In deciding whether an embryo collection team in a third country may appear on the list referred to in paragraph 1, particular account shall be taken of the veterinary supervision of embryo collection systems in that country, the powers of the veterinary services and the supervision to which embryo collection teams are subject.

3. An embryo collection team may appear on the list provided for in paragraph 1 only if:

(a) it carries out its activities in one of the countries or parts thereof on the list referred to in Article 7 (1);

(b) it fulfils the requirements of Annex A;

(c) it has been officially approved for exports to the Community by the veterinary services of the third country concerned; and

(d) it is subject to inspections at least twice a year by an official veterinarian of the third country concerned.

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 brucèllosis 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

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similar and at least equivalent guarantees with reference to animal health.

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3. In laying down animal health provisions concerning foot-and-mouth disease in accordance with paragraph 1, it must be taken into account that:

— 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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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.

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Article 11

The principles and rules laid down by Directive 90/675/EEC [1] shall apply, in particular as regards the organization of the checks to be carried out by Member States and the follow-up to those checks as well as the safeguard measures to be implemented.

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CHAPTER IV

Rules on safeguard and control measures

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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 [2], 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.

[1] OJ No L 373, 31. 12. 1990, p. 1. Directive as last amended by Regulation (EEC) No 1601/92 (OJ No L 173, 27. 6. 1992, p. 13).

[2] OJ No L 224, 18. 8. 1990, p. 29.

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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 implenting 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.

Article 17

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter forthwith to the committee either on his initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

4. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, within 15 days of the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 18

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter without delay to the committee either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman

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may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

4. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, within three months of the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

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.

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ANNEX A

CHAPTER I

Conditions for the approval of an embryo collection team

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;

(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.

CHAPTER II

Conditions relating to the collection, processing, storage and transport of embryos by the approved embryo collection 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.

(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.

(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.

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(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 over its entire surface to determine that the *'zona pellucida'* is intact and is free from any adherent material.

(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.

2. *Storage*

Each embryo collection 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*

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.

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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 the previous six months within Community territory or in the third country of collection in at least one herd:

   — which is officially tuberculosis free, and

   — which is officially brucellosis free or brucellosis free,

   — which is enzootic bovine leucosis free or which, during the three previous years, has shown no clinical signs of enzootic bovine leucosis;

   — which, during the previous year, has shown no clinical signs of infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis;

   (b) during the six months preceding embryo collection, donor cows may have spent successive periods in a maximum of two different herds meeting the requirements set out above.

2. On the day of embryo collection the donor cow:

   (a) shall be resident in a holding which is not subject to veterinary prohibition or quarantine measures;

   (b) shall show no clinical signs of disease.

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ANNEX C

1. Consignor (name and full address)	**ANIMAL HEALTH CERTIFICATE** No ORIGINAL
	2. Member State of collection
3. Consignee (name and full address)	4. COMPETENT AUTHORITY
NOTES (a) A separate certificate must be issued for each consignment of embryos (b) The original of this certificate must accompany the consignment to the place of destination	5. COMPETENT LOCAL AUTHORITY
6. Place of loading	
8. Means of transport	7. Name and address of embryo collection team
9. Place and Member State of destination	
11. Number and code-mark of embryo containers	10. Registration number of embryo collection team

12. Identification of consignment		
(a) Number of embryos	(b) Date(s) of collection	(c) Breed

13. I, the undersigned official veterinarian, certify that:

(a) the embryos described above were collected, processed and stored under conditions which comply with the standards laid down in Directive No 89/556/EEC and, where consigned to a Member State which does not vaccinate against foot-and-mouth disease, with the requirements set out in the second indent of Article 4 (1) of that Directive;

(b) the embryos described above were sent to the place of loading in sealed containers under conditions which comply with the provisions of Directive No 89/556/EEC.

Done at ....., ...

Signature: .....

Stamp

Name and qualification (in block letters):

.....

.....