COMMISSION DECISION

of 28 April 1994

amending Commission Decision 92/471/EEC concerning animal health conditions and veterinary certification for importation of bovine embryos from third countries

(Text with EEA relevance)

(94/280/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 on animal health conditions governing intra Community trade in and importation from third countries of embryos of domestic animals of the bovine species [1], as last amended by Directive 93/52/EEC [2], and in particular Article 9 thereof,

Whereas Directive 89/556/EEC excluded embryos derived by certain techniques from the scope of the said Directive;

Whereas, by Directive 93/52/EEC, the scope of Directive 89/556/EEC has been enlarged to include all bovine embryos except those derived by transfer of nuclei; 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 as long as they meet the requirements of Directive 89/556/EEC, with certain additional safeguards;

Whereas Commission Decision 94/113/EC [3] amends the Annexes to the Directive to lay down the necessary additional safeguards;

Whereas it is necessary to amend Commission Decision 92/471/EEC of 2 September 1992 concerning animal health conditions and veterinary certification for importation of bovine embryos from third countries [4] to take into account the additional safeguards;

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 Decision 92/471/EEC are hereby replaced by the Annexes to this Decision.

Article 2

This Decision shall apply from the thirtieth day following its notification.

Article 3

This Decision is addressed to Member States.

Done at Brussels, 28 April 1994.

For the Commission

René STEICHEN

Member of the Commission

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[1] OJ No L 302, 19. 10. 1989, p. 1.
[2] OJ No L 175, 19. 7. 1993, p. 21.
[3] OJ No L 53, 24. 2. 1994, p. 23.
[4] OJ No L 270, 15. 9. 1992, p. 27.

ANNEX A

PART I

1. Consignor (name and full address)	**ANIMAL HEALTH CERTIFICATE** No ORIGINAL
	2. Third country 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	5. COMPETENT LOCAL AUTHORITY
6. Place and date of loading	
8. Means of transport	7. Name and address of embryo collection team or embryo production team (1)
9. Place and Member State of destination	
11. Number and codemark of embryo containers	10. Registration number of embryo collection team or embryo production team (1)

12. Identification of consignment:

Embryos (a) derived by *in vitro* fertilization yes/no (1)
(b) subjected to penetration of zona pellucida yes/no (1)

(a) Number of embryos	(b) Date(s) of collection	(c) Breed

13. I, the undersigned official veterinarian of the Government of .....
(name of exporting country)
certify that:

1. the embryo collection/production team identified above:
   - is approved in accordance with Chapter I of Annex A to Directive 89/556/EEC,
   - carried out the collection, processing, or production and storing and transport of the embryos described above in accordance with Chapter II of Annex A to Directive 89/556/EEC,
   - is subjected at least twice per year to inspection by an official veterinarian;
2. according to official findings .....
has:
(name of exporting country)

(1) Delete as appropriate.

(a) been free during 12 months immediately prior to collection of the embryos to be exported from rinderpest;

(b) either (1):

(i) has been free from foot-and-mouth disease during the 12 months immediately prior to collection of the embryos to be exported and does not practise vaccination against it

or

(ii) has not been free from foot-and-mouth disease for the 12 months immediately prior to the collection of the embryos and/or practises vaccination against it and

— the donor females and the donors of ovaries, oocytes and other tissues used in the production of embryos come from a holding in which no animal has been vaccinated against foot-and-mouth disease during the 30 days prior to collection, and

— the embryos have been stored in approved conditions for a minimum period of 30 days immediately after collection;

(c) either (1):

(i) has been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection of the embryos to be exported and does not practise vaccination against them

or

(ii) has not been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection of the embryos to be exported and/or practises vaccination against them and

— the embryos have been stored in approved conditions for a minimum period of 30 days immediately after collection, and

— the donor females and the donors of ovaries, oocytes or other tissues used in the production of embryos were subjected with negative results to an agar gel immuno diffusion test and a serum neutralization test for epizootic haemorrhagic disease antibodies on a blood sample taken not less than 21 days following collection;

3. (a) the premises on which the embryos to be exported or the ovaries, oocytes or other tissues used in the production of embryos to be exported were collected and processed was at the time of collection situated in the centre of an area of 20 km diameter in which according to official findings there had been no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, contagious vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia for 30 days immediately prior to collection and in the case of embryos certified under 2 (b) (ii) and (c) (ii) for 30 days after collection;

(b) between the time of collection or production of the embryos to be exported and their dispatch, they were stored continuously in approved premises which were situated in the centre of an area of 20 km in diameter in which according to official findings there was no incidence of foot-and-mouth disease, contagious vesicular stomatitis or Rift Valley fever;

4. the donor females and the donors of ovaries, oocytes or other tissues used in production of embryos:

(a) during the 30 days immediately prior to collection of the embryos to be exported, were located in premises situated in the centre of an area of 20 km in diameter in which according to official findings there was no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, contagious vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia;

(b) showed no clinical sign of disease on the day of collection;

(c) have spent the six months immediately prior to collection in the territory of .....
..... in a maximum of two herds which are:
(name of exporting country)

— according to official findings free from tuberculosis,

— according to official findings free from brucellosis,

— free from enzootic bovine leukosis or a herd or herds which has/have shown no clinical signs of enzootic bovine leukosis during the previous three years,

— a herd or herds which has/have shown no clinical sign of infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis during the previous 12 months;

5. the embryos to be exported were 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 with semen imported from the European Community.

Done at .....

.....

Stamp (2)

Signature (2) .....

Name and qualification (in block letters):

.....

.....

(1) Delete as appropriate.

(2) The signature and the stamp must be in a colour different to that of printing.

Note: This certificate must:

(a) be drawn up in at least the official language of the Member State of destination and the Member State where the embryos will enter Community territory;

(b) be made out to a single consignee;

(c) accompany the embryos in the original.

PART II

List of countries approved to use the model animal health certificate at Part I of Annex A

Austria
Bosnia-Herzegovina
Canada
Croatia
Czech Republic
Finland
Hungary
Israel
New Zealand
Norway
Poland
Romania
Slovak Republik
Slovenia
Sweden
Switzerland
United States of America
Former Yugoslav Republic of Macedonia

ANNEX B

PART I

1. Consignor (name and full address)	**ANIMAL HEALTH CERTIFICATE** No ORIGINAL
	2. Third country 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	5. COMPETENT LOCAL AUTHORITY
6. Place and date of loading	
8. Means of transport	7. Name and address of embryo collection team or embryo production team (1)
9. Place and Member State of destination	
11. Number and codemark of embryo containers	10. Registration number of embryo collection team or embryo production team (1)

12. Identification of consignment:

Embryos (a) derived by *in vitro* fertilization yes/no (1)

(b) subjected to penetration of zona pellucida yes/no (1)

(a) Number of embryos	(b) Date(s) of collection	(c) Breed

13. I, the undersigned official veterinarian of the Government of .....,
certify that: (name of exporting country)

1. the embryo collection/production team identified above:
   - is approved in accordance with Chapter I of Annex A to Directive 89/556/EEC,
   - carried out the collection, processing, or production and storing and transport of the embryos described above in accordance with Chapter II of Annex A to Directive 89/556/EEC,
   - is subjected at least twice per year to inspection by an official veterinarian;
2. according to official findings ..... has: (name of exporting country)

(1) Delete as appropriate.

(a) been free during 12 months immediately prior to collection of the embryos to be exported from rinderpest;

(b) either (1):

(i) has been free from foot-and-mouth disease during the 12 months immediately prior to collection of the embryos to be exported and does not practise vaccination against it

or

(ii) has not been free from foot-and-mouth disease for the 12 months immediately prior to the collection of the embryos and/or practises vaccination against it and

— the donor females and the donors of ovaries, oocytes or other tissues used in the production of embryos come from a holding in which no animal has been vaccinated against foot-and-mouth disease during the 30 days prior to collection, and

— the embryos have been stored in approved conditions for a minimum period of 30 days immediately after collection;

(c) either (1):

(i) been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection of the embryos to be exported and does not practise vaccination against them

or

(ii) has not been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection of the embryos to be exported and/or practises vaccination against them and

— the embryos have been stored in approved conditions for a minimum period of 30 days immediately after collection, and

— the donor females and the donors of ovaries, oocytes or other tissues used in the production of embryos were subjected with negative results to an agar gel immuno diffusion test and a serum neutralization test for epizootic haemorrhagic disease antibodies on a blood sample taken not less than 21 days following collection;

3. (a) the premises on which the embryos to be exported or the ovaries, oocytes or other tissues in the production of embryos to be exported were collected and processed was at the time of collection situated in the centre of an area of 20 km diameter in which according to official findings there had been no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, contagious vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia for 30 days immediately prior to collection and in the case of embryos certified under 2 (b) (ii) and (c) (ii) for 30 days after collection;

(b) between the time of collection or production of the embryos to be exported and their dispatch, they were stored continuously in approved premises which were situated in the centre of an area of 20 km in diameter in which according to official findings there was no incidence of foot-and-mouth disease, contagious vesicular stomatitis or Rift Valley fever;

4. the donor females and the donors of ovaries, oocytes or other tissues used in production of embryos:

(a) during the 30 days immediately prior to collection of the embryos to be exported, were located in premises situated in the centre of an area of 20 km in diameter in which according to official findings there was no incidence of foot-and-mouth disease, blue tongue, epizootic haemorrhagic disease, contagious vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia;

(b) showed no clinical sign of disease on the day of collection;

(c) have spent the six months immediately prior to collection in the territory of .....
..... in a maximum of two herds which are:
(name of exporting country)

— according to official findings free from tuberculosis,

— according to official findings free from brucellosis,

— free from enzootic bovine leukosis or a herd or herds which has/have shown no clinical signs of enzootic bovine leukosis during the previous three years,

— a herd or herds which has/have shown no clinical sign of infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis during the previous 12 months;

(d) were subjected to a serum neutralization test for Akabane on a blood sample taken not less than 21 days following collection.

5. The embryos to be exported were 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 with semen imported from the European Community.

Done at .....

.....

Stamp (2)

Signature (2) .....

Name and qualification (in block letters):

.....

.....

(1) Delete as appropriate.

(2) The signature and the stamp must be in a colour different to that of printing.

Note: This certificate must:

(a) be drawn up in at least the official language of the Member State of destination and the Member State where the embryos will enter Community territory;

(b) be made out to a single consignee;

(c) accompany the embryos in the original.

PART II

List of countries approved to use the model animal health certificate at Part I of Annex B

Australia