COMMISSION DECISION

of 9 March 2005

establishing the animal health conditions and the veterinary certification requirements for imports into the Community of bovine embryos

(notified under document number C(2005) 543)

(Text with EEA relevance)

(2005/217/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], and in particular Article 7(1) and point (b) of the first subparagraph of Article 9 (1) thereof,

Whereas:

(1) Commission Decision 91/270/EEC of 14 May 1991 drawing up a list of third countries from which Member States authorise importation of embryos of domestic animals of the bovine species [2], provides that Member States are only to import embryos of domestic bovine species from the third countries listed in the Annex to that Decision.

(2) Directive 89/556/EEC provides for a list to be drawn up of bovine embryo collection and production teams which are authorised to collect, process or store in third countries bovine embryos destined for the Community. Commission Decision 92/452/EEC of 30 July 1992 establishing lists of embryo collection teams and embryo production teams approved in third countries for export of bovine embryos to the Community [3], establishes that list.

(3) 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], provides that Member States may only authorise the importation of bovine embryos conforming to the guarantees laid down in the animal health certificates in the Annexes to that Decision. Those Annexes also include lists of third countries approved to use the veterinary certificates set out in that Decision.

(4) Directive 89/556/EEC provides that bovine embryos are not to be sent from one Member State to another unless they have been conceived as a result of artificial insemination or *in vitro* fertilisation 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 Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species [5].

(5) The International Embryo Transfer Society (IETS) assessed the risk of the transmission of certain contagious diseases via embryos as negligible, provided that embryos are properly handled between collection and transfer. Nevertheless, in the interests of animal health, appropriate upstream safeguards should be taken with regard to semen used for fertilisation.

(6) Community requirements for imports of bovine embryos should be at least as strict as those applicable to intra-Community trade in bovine embryos, in particular with regard to semen used for fertilisation. Following the application of new stricter requirements provided for in Decision 92/471/EEC, as amended by Decision 2004/786/EC, trade problems have been encountered.

(7) As a result of those problems, exporters and importers have requested a transitional period to adapt to these new stricter requirements for bovine semen used to fertilise oocytes for exports of embryos to the Community. It is therefore appropriate to allow, for a certain period and subject to certain conditions, the importation of bovine embryos collected or produced under the conditions set out in Annex III to this Decision.

(8) In the interests of clarity of Community legislation, it is appropriate to repeal Decisions 91/270/EEC and 92/471/EEC and replace them by this Decision.

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[1] OJ L 302, 19.10.1989, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

[2] OJ L 134, 29.5.1991, p. 56. Decision as last amended by Decision 2004/52/EC (OJ L 10, 16.1.2004, p. 67).

[3] OJ L 250, 29.8.1992, p. 40. Decision as last amended by Decision 2005/29/EC (OJ L 15, 19.1.2005, p. 34).

[4] OJ L 270, 15.9.1992, p. 27. Decision as last amended by Decision 2004/786/EC (OJ L 346, 23.11.2004, p. 32).

[5] OJ L 194, 22.7.1988, p. 10. Directive as last amended by Commission Decision 2004/101/EC (OJ L 30, 4.2.2004, p. 15).

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Member States shall only import embryos of domestic animals of the bovine species (the embryos) which were collected or produced in third countries listed in Annex I to this Decision by approved embryo collection or production teams listed in the Annex to Decision 92/452/EEC.

Article 2

Member States shall authorise the importation of embryos complying with the additional guarantees set out in the model veterinary certificate in Annex II.

Article 3

By way of derogation from Article 2, Member States shall authorise until 31 December 2006 the importation from third countries listed in Annex I of embryos complying with:

(a) the additional guarantees set out in the model veterinary certificate in Annex III; and

(b) the following conditions:

(i) embryos must be collected or produced before 1 January 2006;

(ii) embryos must only be used for implantation into female bovine animals resident in the Member State of destination indicated in the veterinary certificate;

(iii) embryos must not be subject to intra-Community trade.

Article 4

Decisions 91/270/EEC and 92/471/EEC are repealed.

Article 5

This Decision shall apply from 5 April 2005.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 9 March 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

ISO code	Country	Applicable veterinary certificate		Remarks
AR	Argentina	ANNEX II	ANNEX III (***)	
AU	Australia	ANNEX II	ANNEX III (***)	The additional guarantees in accordance with point 11.5.2 of the certificate in Annex II or III are compulsory.
CA	Canada	ANNEX II	ANNEX III (***)	
CH	Switzerland (**)	ANNEX II	ANNEX III (***)	
HR	Croatia	ANNEX II	ANNEX III (***)	
IL	Israel	ANNEX II	ANNEX III (***)	
MK	Former Yugoslav Republic of Macedonia (*)	ANNEX II	ANNEX III (***)	
NZ	New Zealand	ANNEX II	ANNEX III (***)	
RO	Romania	ANNEX II	ANNEX III (***)	
US	United States of America	ANNEX II	ANNEX III (***)	

(*) Provisional code that does not affect the definitive denomination of the country to be attributed after the conclusion of the negotiations currently taking place in the United Nations.
(**) Without prejudice to specific certification requirements provided for by any relevant Community agreement with third countries
(***) Applicable until the date indicated in Article 4 of Decision 2005/217/EC.

ANNEX II

VETERINARY CERTIFICATE

Embryos of domestic animals of the bovine species for imports collected or produced in accordance with Council Directive 89/556/EEC

1. Country of provenance and competent authority	2. Health certificate No
A. ORIGIN OF EMBRYOS	
3. Approval number of the embryo collection team or embryo production team (1):	
4. Name and address of the embryo collection team or embryo production team (1):	5. Name and address of the consignor
6. Country and place of loading	7. Means of transport
B. DESTINATION OF EMBRYOS	
8. Member State of destination	9. Name and address of the consignee

C. IDENTIFICATION OF EMBRYOS		
10.1. Identification mark of embryos (2)	10.2. Number of embryos	10.3. Produced embryos (1) (a) Derived by *in vitro* fertilisation (b) Subjected to penetration of *zona pellucida*
		(a) yes/no (1) (b) yes/no (1)
		(a) yes/no (1) (b) yes/no (1)
		(a) yes/no (1) (b) yes/no (1)
		(a) yes/no (1) (b) yes/no (1)
		(a) yes/no (1) (b) yes/no (1)
		(a) yes/no (1) (b) yes/no (1)
		(a) yes/no (1) (b) yes/no (1)

D. HEALTH INFORMATION

11. I, the undersigned official veterinarian of the Government of .....
(insert name of exporting country)

certify that:

11.1. the embryo collection (1)/production (1) 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.

11.2. The embryos to be exported were collected (1) or produced (1) in the exporting country, which according to official findings:

11.2.1. has been free from rinderpest during 12 months immediately prior to the collection (1) or production (1) of the embryos;

11.2.2.1. either has been free from foot-and-mouth disease during the 12 months immediately prior to collection (1) or production (1) of the embryos and has not practised vaccination against foot-and-mouth disease during this period (1),

or

11.2.2.2. has not been free from foot-and-mouth disease for the 12 months immediately prior to the collection (1) or production (1) of the embryos and/or has practised vaccination against foot-and-mouth disease during this period, 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 and other tissues used in the production of embryos come from a holding in which no animal has shown clinical signs of foot-and-mouth disease nor was vaccinated against foot-and-mouth disease during the 30 days prior to collection (1);

11.2.3.1. has been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection (1) or production (1) of the embryos to be exported and does not practise vaccination against them (1),

or

11.2.3.2. has not been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection (1) or production (1) 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 donors of ovaries, oocytes and other tissues used in the production of embryos were subjected to an agar gel immuno-diffusion test and a serum neutralisation test for the detection of antibodies against the epizootic haemorrhagic disease virus carried out with negative results on a blood sample taken not less than 21 days following collection (1);

11.3.

11.3.1. the premises on which the embryos to be exported or the ovaries, oocytes and other tissues used in the production of embryos to be exported were collected and processed were 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, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia for 30 days immediately prior to collection and in the case of embryos certified under 11.2.2.2 and 11.2.3.2 for 30 days after collection;

11.3.2. 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;

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

11.4.1. were located during the 30 days immediately prior to collection of the embryos to be exported 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 during this period;

11.4.2. showed no clinical sign of disease on the day of collection;

11.4.3. have spent the six months immediately prior to collection in the territory of the exporting country in a maximum of two herds:

— which, according to official findings, have been free from tuberculosis,

— which, according to official findings, have been free from brucellosis,

— which have been free from enzootic bovine leukosis or in which no animal has shown clinical signs of enzootic bovine leukosis during the previous three years,

— in which no bovine animal has shown clinical signs of infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis during the previous 12 months.

11.5. The embryos comply with the following additional guarantees ([3]):

11.5.1. either the embryos to be exported were collected ([1]) or produced ([1]) in the exporting country, which according to official findings is free of Akabane disease ([1]),

or

11.5.2. the embryos to be exported were collected ([1]) or produced ([1]) in the exporting country, which according to official findings is not free of Akabane disease; and

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

— the donor females and donors of ovaries, oocytes and other tissues used in the production of embryos were subjected to a serum neutralisation test for Akabane disease carried out with negative results on a blood sample taken not less than 21 days following collection ([1]).

11.6. The embryos to be exported were conceived as a result of artificial insemination or *in vitro* fertilisation with semen complying with the following requirements:

— it was collected from donor sires standing at a semen collection centre approved by the competent authority for the collection, processing and storage of semen in accordance with Directive 88/407/EEC, and

— it comes from semen collection or storage centres which are situated either in a Member State of the European Community or a third country and which are approved in accordance with Article 5(1) and Article 9(1) respectively of Directive 88/407/EEC ([5]).

E. VALIDITY

12. Date and place	13. Name and qualification of the official veterinarian	14. Signature and stamp of the official veterinarian ([4])

Note for guidance:

([1]) Delete as appropriate.

([2]) Corresponding to the identification of the donor cows and date of collection.

([3]) See the remarks for the exporting country concerned in Annex I to Decision 2005/217/EC.

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

([5]) Semen collection and storage centres approved in accordance with EC legislation are listed in the Commission's website http://europa.eu.int/comm/food/index_en.htm

Note: This certificate must:

(a) be drawn up in at least one of the official languages 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.

ANNEX III

VETERINARY CERTIFICATE

Embryos of domestic animals of the bovine species for imports collected or produced before 1 January 2006

1. Country of provenance and competent authority	2. Health certificate No:

A. ORIGIN OF EMBRYOS

3. Approval number of the embryo collection team or embryo production team (1):	
4. Name and address of the embryo collection team or embryo production team (1):	5. Name and address of the consignor
6. Country and place of loading	7. Means of transport

B. DESTINATION OF EMBRYOS

8. Member State of destination	9. Name and address of the consignee

C. IDENTIFICATION OF EMBRYOS

10.1. Identification mark of embryos (2)	10.2. Number of embryos	10.3. Produced embryos (1) (a) Derived by *in vitro* fertilisation (b) Subjected to penetration of *zona pellucida*	10.4. Date of collection or production
		(a) yes/no (1) (b) yes/no (1)	
		(a) yes/no (1) (b) yes/no (1)	
		(a) yes/no (1) (b) yes/no (1)	
		(a) yes/no (1) (b) yes/no (1)	
		(a) yes/no (1) (b) yes/no (1)	
		(a) yes/no (1) (b) yes/no (1)	
		(a) yes/no (1) (b) yes/no (1)	
		(a) yes/no (1) (b) yes/no (1)	
		(a) yes/no (1) (b) yes/no (1)	

D. HEALTH INFORMATION

11. I, the undersigned official veterinarian of the Government of .....
(*insert name of exporting country*)

certify that:

11.1. the embryo collection (1) production (1) team identified above:

— is approved in accordance with Chapter I of Annex A to Directive 89/556/EEC,

— carried out the collection, processing, production (1) 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.

11.2. The embryos to be exported were collected (1) or produced (1) in the exporting country, which according to official findings:

11.2.1. has been free from rinderpest during 12 months immediately prior to the collection (1) or production (1) of the embryos;

11.2.2.1. either has been free from foot-and-mouth disease during the 12 months immediately prior to collection (1) or production (1) of the embryos and has not practised vaccination against foot-and-mouth disease during this period (1),

or

11.2.2.2. has not been free from foot-and-mouth disease for the 12 months immediately prior to the collection (1) or production (1) of the embryos and/or has practised vaccination against foot-and-mouth disease during this period, 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 and other tissues used in the production of embryos come from a holding in which no animal has shown clinical signs of foot-and-mouth disease nor was vaccinated against foot-and-mouth disease during the 30 days prior to collection (1);

11.2.3.1. either has been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection (1) or production (1) of the embryos to be exported and has not practiced vaccination against these diseases during this period (1),

or

11.2.3.2. has not been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection (1) or production (1) of the embryos to be exported and/or has practised vaccination against these diseases during this period, 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 and other tissues used in the production of embryos were subjected to an agar gel immuno-diffusion test and a serum neutralisation test for the detection of antibodies against the epizootic haemorrhagic disease virus carried out with negative results on a blood sample taken not less than 21 days following collection (1);

11.3.

11.3.1. the premises on which the embryos to be exported or the ovaries, oocytes and other tissues used in the production of embryos to be exported were collected and processed were 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, vesicular stomatitis , Rift Valley fever or contagious bovine pleuropneumonia for 30 days immediately prior to collection and in the case of embryos certified under 11.2.2.2 and 11.2.3.2 for 30 days after collection;

11.3.2. 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, vesicular stomatitis or Rift Valley fever;

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

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

11.4.2. showed no clinical sign of disease on the day of collection;

11.4.3. have spent the six months immediately prior to collection in the territory of the exporting country in a maximum of two herds:

— which, according to official findings, have been free from tuberculosis,

— which, according to official findings, have been free from brucellosis,

— which have been free from enzootic bovine leukosis or in which no bovine animal has shown clinical signs of enzootic bovine leukosis during the previous three years,

— in which no bovine animal has shown clinical signs of infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis during the previous 12 months.

11.5. The embryos comply with the following additional guarantees ([3]):

11.5.1. either the embryos to be exported were collected ([1]) or produced ([1]) in the exporting country, which according to official findings is free of Akabane disease ([1]),

or

11.5.2. the embryos to be exported were collected ([1]) or produced ([1]) in the exporting country, which according to official findings is not free of Akabane disease, and

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

— the donor females and donors of ovaries, oocytes and other tissues used in the production of embryos were subjected to a serum neutralisation test for Akabane disease carried out with negative results on a blood sample taken not less than 21 days following collection ([1]).

11.6. The embryos to be exported were conceived as a result of artificial insemination or in vitro fertilisation 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.

E. VALIDITY

12. Date and place	13. Name and qualification of the official veterinarian	14. Signature and stamp of the official veterinarian ([4])

Note for guidance:

([1]) Delete as appropriate.

([2]) Corresponding to the identification of the donor cows and date of collection.

([3]) See the remarks for the exporting country concerned in Annex I to Decision 2005/217/EC.

([4]) 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 one of the official languages 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;

(d) not to be used after the date indicated in Article 3 of Decision 2005/217/EC.

Information: In accordance with Article 3(a) of Council Directive 89/556/EEC, embryos imported under the conditions laid down in this certificate are not eligible for intra-Community trade.