COMMISSION DECISION

of 18 November 2004

amending Decision 92/471/EEC as regards model veterinary certificates for imports of bovine embryos

(notified under document number C(2004) 4380)

(Text with EEA relevance)

(2004/786/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 9(1)(b) thereof,

Whereas:

(1) Commission Decision 92/471/EEC of 2 September 1992 concerning animal health conditions and veterinary certification for importation of bovine embryos from third countries [2] provides that Member States are only to authorise the importation of bovine embryos conforming to the guarantees laid down in the animal health certificates in accordance with Part I of Annexes A and B to that Decision.

(2) The animal health conditions laid down in Directive 89/556/EEC for intra-Community trade in bovine embryos are stricter than those which apply to imports of such embryos.

(3) Under Directive 89/556/EEC bovine embryos are not to be sent from the territory of a Member State to that of another Member State 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 or with semen stored in a semen storage centre, both of which centres have been approved by the competent authority 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 [3].

(4) Although the risk of transmission of certain contagious diseases via embryos assessed by the International Embryo Transfer Society (IETS) is negligible provided that embryos are properly handled between collection and transfer, appropriate upstream safeguards should be taken with regard to semen used for fertilisation.

(5) It is necessary, in the interests of animal health, that the same conditions as apply to intra-Community trade in bovine embryos also apply to imports of such embryos, in particular with regard to semen used for fertilisation which should comply with Directive 88/407/EEC.

(6) Decision 92/471/EEC should therefore be amended accordingly.

(7) 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

Annexes A and B to Decision 92/471/EEC are amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 26 November 2004.

---

[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 270, 15.9.1992, p. 27. Decision as last amended by Decision 2004/52/EC (OJ L 10, 16.1.2004, p. 67).

[3] 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).

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 18 November 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Annexes A and B to Decision 92/471/EEC are amended as follows:

1. Part I of Annex A is replaced by the following:

'Part I

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. Derived by *in vitro* fertilisation (a) Subjected to penetration of *zona pellucida* (b)
D. **HEALTH INFORMATION**		
11. I, the undersigned official veterinarian, of the Government of ..... (name of exporting country) certify that: 11.1. 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.		
11.2. according to official findings ..... (name of exporting country) has: 11.2.1. been free during 12 months immediately prior to collection of the embryos to be exported from rinderpest; 11.2.2. either (1): 11.2.2.1. 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		

11.2.2.2. 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;

11.2.3. either [1]:

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

11.2.3.2. 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 and other tissues used in the production of embryos were subjected with negative results to an agar gel immuno diffusion test and a serum neutralisation test for epizootic haemorrhagic disease antibodies on a blood sample taken not less than 21 days following collection.

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 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 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 the donors of ovaries, oocytes and other tissues used in the production of embryos:

11.4.1. 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;

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 .....
(name of exporting country)

in a maximum of two herds which are:

— 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.

11.5. the embryos to be exported were conceived as a result of artificial insemination or in vitro fertilisation with semen complying with the requirements of Council Directive 88/407/EEC and coming from semen collection or storage centres originating in Member States or third countries, in accordance with Article 9(1) of Directive 88/407/EEC, and listed in the Commission's website http://europa.eu.int/comm/food/index_en.htm.

E. **VALIDITY**

12. Date and place	13. Name and qualification of the official veterinarian	14. Signature and stamp of the official veterinarian

[1] Delete as necessary.
[2] Corresponding to the identification of the donor cows and date of collection.'

2. Part I of Annex B is replaced by the following:

'Part I

<table>
<tr><td colspan="3">VETERINARY CERTIFICATE
embryos of domestic animals of the bovine species for imports collected or produced in accordance with council directive 89/556/EEC</td></tr>
<tr><td colspan="2">1. Country of provenance and competent authority</td><td>2. Health certificate No</td></tr>
<tr><td colspan="3">A. ORIGIN OF EMBRYOS</td></tr>
<tr><td colspan="3">3. Approval number of the embryo collection team or embryo production team (1):</td></tr>
<tr><td colspan="2">4. Name and address of the embryo collection team or embryo production team (1)</td><td>5. Name and address of the consignor</td></tr>
<tr><td colspan="2">6. Country and place of loading</td><td>7. Means of transport</td></tr>
<tr><td colspan="3">B. DESTINATION OF EMBRYOS</td></tr>
<tr><td colspan="2">8. Member State of destination</td><td>9. Name and address of the consignee</td></tr>
<tr><td colspan="3">C. IDENTIFICATION OF EMBRYOS</td></tr>
<tr><td>10.1. Identification mark of embryos (2)</td><td>10.2. Number of embryos</td><td>10.3. Derived by in vitro fertilisation (a) Subjected to penetration of zona pellucida (b)</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td colspan="3">D. HEALTH INFORMATION</td></tr>
<tr><td colspan="3">11. I, the undersigned official veterinarian, of the Government of .....
(name of exporting country)

certify that:
11.1. 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.</td></tr>
<tr><td colspan="3">11.2. according to official findings .....
(name of exporting country)</td></tr>
<tr><td colspan="3">has:
11.2.1. been free during 12 months immediately prior to collection of the embryos to be exported from rinderpest;
11.2.2. either (1):
11.2.2.1. 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</td></tr>
</table>

11.2.2.2. 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;

11.2.3. either [1]:

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

11.2.3.2. 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 and other tissues used in the production of embryos were subjected with negative results to an agar gel immuno diffusion test and a serum neutralisation test for epizootic haemorrhagic disease antibodies on a blood sample taken not less than 21 days following collection.

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 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 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 the donors of ovaries, oocytes and other tissues used in the production of embryos:

11.4.1. 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;

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 .....
(name of exporting country)

in a maximum of two herds which are:

— 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.

11.4.4. were subjected to a serum neutralisation test for Akabane on a blood sample taken not less than 21 days following collection.

11.5. the embryos to be exported were conceived as a result of artificial insemination or in vitro fertilisation with semen complying with the requirements of Council Directive 88/407/EEC and coming from semen collection or storage centres originating in Member States or third countries, in accordance with Article 9(1) of Directive 88/407/EEC, and listed in the Commission's website http://europa.eu.int/comm/food/index_en.htm.

E. **VALIDITY**

12. Date and place	13. Name and qualification of the official veterinarian	14. Signature and stamp of the official veterinarian

[1] Delete as necessary.
[2] Corresponding to the identification of the donor cows and date of collection.'