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COMMISSION DECISION

of 4 January 2006

establishing the animal health and veterinary certification requirements for imports into the Community of bovine embryos and repealing Decision 2005/217/EC

(notified under document number C(2005) 5796)

(Text with EEA relevance)

(2006/168/EC)

(OJ L 57, 28.2.2006, p. 19)

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(Text with EEA relevance)

(2006/168/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 Article 9(1) (b) thereof,

Whereas:

(1) Directive 89/556/EEC sets out 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.

(2) That Directive provides, *inter alia*, that bovine embryos are not to be sent from one Member State to another unless they have been conceived by artificial insemination or *in vitro* fertilisation using 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 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 semen of domestic animals of the bovine species ([2]).

(3) 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]), provides that Member States are to import such embryos from third countries only if they have been collected, processed, including *in vitro* fertilisation, and stored by embryo collection teams included in the lists in that Decision.

(4) Following trade problems relating to new, stricter requirements for bovine semen used for fertilisation introduced by Commission Decision 92/471/EEC ([4]), the Commission adopted Decision 2005/217/EC of 9 March 2005 establishing the animal health conditions and the veterinary certification requirements for imports into the Community of bovine embryos ([5]).

([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 194, 22.7.1988, p. 10. Directive as last amended by Commission Decision 2004/101/EC (OJ L 30, 4.2.2004, p. 15).
([3]) OJ L 250, 29.8.1992, p. 40. Decision as last amended by Decision 2005/774/EC (OJ L 291, 5.11.2005, p. 46).
([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 69, 16.3.2005, p. 41.

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(5) Decision 2005/217/EC allows for a transitional period expiring on 31 December 2006 for imports of bovine embryos collected or produced before 1 January 2006 and conceived using semen not fully complying with Directive 88/407/EEC on condition that such embryos are implanted into female bovine animals present in the Member State of destination and are excluded from intra-Community trade.

(6) The International Embryo Transfer Society (IETS) has assessed as negligible the risk of transmission of certain contagious diseases via embryos to recipients or offspring, provided that the embryos are handled properly between their collection and their transfer. That position is also that of the World Organisation for Animal Health (OIE) as far as *in vivo* derived embryos are concerned. Nevertheless, in the interests of animal health, appropriate safeguards should be taken upstream with regard to semen used for fertilisation, in particular with respect to *in vitro* generated embryos.

(7) Community requirements for imports of bovine embryos derived by natural (*in vivo*) fertilisation and produced by *in vitro* fertilisation, in particular as regards semen used for fertilisation, should therefore be adapted.

(8) In the light of the risk assessment carried out by the IETS and in line with the recommendations of the OIE, the conditions governing imports of *in vivo* derived bovine embryos should be simplified while stricter animal health requirements should be maintained for imports of *in vitro* produced embryos, with special restrictions where the *zona pellucida* has been damaged during the process.

(9) In the interests of clarity of Community legislation, Decision 2005/217/EC should be repealed and replaced by this Decision.

(10) However, in order to enable economic operators to adapt to the new requirements set out in this Decision it is appropriate to provide for a transitional period whereby imports of embryos of domestic animals of the bovine species collected or produced before 1 January 2006 may, subject to certain conditions, be imported into the Community according to the requirements set out in Annex V to this Decision.

(11) 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

General conditions for imports of embryos

Member States shall authorise imports of embryos of domestic animals of the bovine species (embryos) collected or produced in a third country 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

Imports of *in vivo* derived embryos

Member States shall authorise imports of embryos derived by *in vivo* fertilisation and complying with the animal health requirements set out in the model veterinary certificate in Annex II.

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Article 3

Imports of *in vitro* produced embryos

1. Member States shall authorise imports of embryos which are produced by *in vitro* fertilisation using semen complying with Directive 88/407/EEC and which meet the animal health requirements set out in the model veterinary certificate in Annex III to this Decision.

2. Member States shall authorise imports of embryos which are produced by *in vitro* fertilisation using semen produced in approved semen collection centres or stored in semen storage centres in third countries listed in Annex I to Commission Decision 2004/639/EC [1] and which comply with the animal health requirements set out in the model veterinary certificate in Annex IV to this Decision on condition that such embryos are:

(a) excluded from intra-Community trade; and

(b) implanted exclusively into female bovine animals present in the Member State of destination indicated in the veterinary certificate.

Article 4

Transitional measures

By way of derogation from Articles 2 and 3, Member States shall authorise, until 31 December 2006, the importation of embryos from the third countries listed in Annex I provided that such embryos comply with:

(a) the animal health requirements set out in the model veterinary certificate in Annex V; and

(b) the following conditions:

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

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

(iii) they must be excluded from intra-Community trade;

(iv) they must be accompanied by such a certificate duly completed before 1 January 2007.

Article 5

Repeal

Decision 2005/217/EC is repealed.

Article 6

Applicability

This Decision shall apply from 1 January 2006.

Article 7

Addressees

This Decision is addressed to the Member States.

[1] OJ L 292, 15.9.2004, p. 21.

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ANNEX I

ISO code	Country	Applicable Veterinary Certificate			Remarks
AR	Argentina	ANNEX II	ANNEX III	ANNEX IV	
AU	Australia	ANNEX II	ANNEX III	ANNEX IV	The additional guarantees set out in point 11.5.2 of the certificate in Annex II and in points 11.6.2 of the certificates in Annexes III and IV are compulsory.
CA	Canada	ANNEX II	ANNEX III	ANNEX IV	
CH	Switzerland (*)	ANNEX II	ANNEX III	ANNEX IV	
HR	Croatia	ANNEX II	ANNEX III	ANNEX IV	
IL	Israel	ANNEX II	ANNEX III	ANNEX IV	
MK	Former Yugoslav Republic of Macedonia (**)	ANNEX II	ANNEX III	ANNEX IV	
NZ	New Zealand	ANNEX II	ANNEX III	ANNEX IV	
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▼B US	United States of America	ANNEX II	ANNEX III	ANNEX IV	

(*) Without prejudice to specific certification requirements provided for by any relevant Community agreement with third countries.

(**) 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.

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ANNEX II

In vivo derived embryos of domestic animals of the bovine species for import, collected in accordance with Council Directive 89/556/EEC

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code		I.2.	I.2.a. Local reference number:
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Embryo team ☐ Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Holding ☐ Embryo team ☐ Approved body ☐ Name Approval number Address Postal code	
I.13.		I.14. Estimated date and time of arrival	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. I.17.	
I.18. Description of commodity			I.19. Commodity code (HS code) I.20. Quantity
I.21.			I.22. Number of packages
I.23. Identification of container/Seal number			I.24.
I.25. Commodity certified for Artificial reproduction ☐			
I.26. For transit to third Country vis-à-vis EU ☐ third country ISO code		I.27. For import or admission into EU ☐ Definitive import ☐	
I.28. Identification of the animals/products Species (Scientific name) Identification mark Category Approval number of the team			

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COUNTRY **In vivo-derived bovine embryos**

Part II: Certification

II. Health information ☐	II.a. Certificate reference number	II.b. Local reference number

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

certify that:

1.1. the embryo collection team identified above:

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

— carried out the collection, processing, storing and transport of the embryos described above in accordance with Chapter II of Annex A to Directive 89/556/EEC,

— subject to inspection by an official veterinarian at least twice a year;

1.2. the embryos to be exported were collected in the exporting country, which according to official findings:

1.2.1. was free from rinderpest during the 12 months immediately prior to their collection;

1.2.2.

1.2.2.1. either was free from foot-and-mouth disease during the 12 months immediately prior to their collection and did not carry out vaccination against foot-and-mouth disease during that period [1];

1.2.2.2. or was not free from foot-and-mouth disease during the 12 months immediately prior to their collection and/or carried out vaccination against foot-and-mouth disease during that period, and

— the embryos were not subjected to penetration of the *zona pellucida*,

— the embryos were stored under approved conditions for at least 30 days immediately after their collection, and

— the donor females come from holdings on which no animal was vaccinated against foot-and-mouth disease during the 30 days prior to collection and no animal of a susceptible species showed clinical signs of foot-and-mouth disease during the 30 days prior to, and at least the 30 days after, the embryos were collected [1];

1.3.

1.3.1. within a 10 km radius of the premises on which the embryos to be exported were collected and processed, according to official findings there was no incidence of foot-and-mouth disease, epizootic haemorrhagic disease, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia in the 30 days immediately prior to their collection and, in the case of embryos certified under 1.2.2.2, in the 30 days after their collection as well;

1.3.2. from the time of collection until 30 days thereafter (or, in the case of fresh embryos, until the day of dispatch), the embryos to be exported were stored at all times on approved premises within a 10-km radius of which, according to official findings, there was no incidence of foot-and-mouth disease, vesicular stomatitis or Rift Valley fever;

1.4. the donor females:

1.4.1. were located, during the 30 days immediately prior to collection of the embryos to be exported, on premises within a 10 km radius of which, according to official findings, there was no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia;

1.4.2. showed no clinical signs of disease on the day of collection:

1.4.3. spent the six months immediately prior to collection within the territory of the exporting country in no more than two herds:

— which, according to official findings, were free from tuberculosis during that time,

— which, according to official findings, were free from brucellosis during that time,

— which were free from enzootic bovine leukosis or in which no animal showed clinical signs of enzootic bovine leukosis during the previous three years,

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

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1.5. the embryos to be exported provide the following additional guarantees (3):

1.5.1. either the embryos were collected in the exporting country, which according to official findings is free from Akabane disease (1),

1.5.2. or the embryos were collected in the exporting country, which according to official findings is not free from Akabane disease (1), and

— the embryos were not subjected to penetration of the *zona pellucida*,

— the embryos were stored under approved conditions for at least 30 days immediately after their collection, and

— the donor females underwent a serum neutralisation test for Akabane disease, carried out on a blood sample taken not less than 21 days following their collection (1) and giving negative results;

1.6. the embryos to be exported were conceived by artificial insemination using semen coming from semen collection or storage centres approved for the collection, processing and/or storage of semen by the competent authority of a country listed in Annex I to Commission Decision 2004/639/EC (4) or by the competent authority of a Member State of the European Community.

Notes

(1) Delete as appropriate.
(2) (Box reference No I.28 in Part I):
Identification mark: corresponding to the identification on the straw of the donor cows and the date of collection.
Category: specify if (a) penetration or (b) non penetration of *zona pellucida*.
Approval number of the team: to be filled in if different from box No I.11.
(3) See remarks for exporting country concerned in Annex I to Decision 2006/168/EC.
(4) OJ L 292, 15.9.2004, p. 21.
(5) The signature and the stamp must be of a different colour from that of the printed form.

NB: This certificate must:

(a) be drawn up in at least one official language of the Member State of destination and of 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.

Official veterinarian

Name (in capital letters): Qualification and title

Date: Signature:

Stamp

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ANNEX III

In vitro produced embryos of domestic animals of the bovine species for import, conceived using semen complying with Council Directive 88/407/EEC

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code		I.2.	I.2.a. Local reference number:
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Embryo team ☐ Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Holding ☐ Embryo team ☐ Approved body ☐ Name Approval number Address Postal code	
I.13.		I.14. Estimated date and time of arrival	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. I.17.	
I.18. Description of commodity			I.19. Commodity code (HS code) I.20. Quantity
I.21.			I.22. Number of packages
I.23. Identification of container/Seal number			I.24.
I.25. Commodity certified for Artificial reproduction ☐			
I.26. For transit to third country vis-à-vis EU ☐ third country ISO code		I.27. For import or admission into EU ☐ Definitive import ☐	
I.28. Identification of the animals/products Species (Scientific name) Identification mark Category			

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COUNTRY **In vitro produced bovine embryos**

Part II: Certification

II. Health information ☐	II.a. Certificate reference number	II.b. Local reference number

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

certify that:

1.1. the embryo production team identified above:

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

— carried out the production, processing, storing and transport of the embryos described above in accordance with Chapter II of Annex A to Directive 89/556/EEC,

— is subject to inspection by an official veterinarian at least twice a year.

1.2. the embryos to be exported were produced in the exporting country, which according to official findings:

1.2.1. was free from rinderpest during the 12 months immediately prior to their production;

1.2.2.

1.2.2.1. either was free from foot-and-mouth disease during the 12 months immediately prior to their production and did not carry out vaccination against foot-and-mouth disease during that period (1),

1.2.2.2. or was not free from foot-and-mouth disease during the 12 months immediately prior to their production and/or carried out vaccination against foot-and-mouth disease during that period, and

— the embryos were produced without penetration of the *zona pellucida*,

— the embryos were stored under approved conditions for at least 30 days immediately after their production, and

— the donor females come from holdings on which no animal was vaccinated against foot-and-mouth disease during the 30 days prior to collection and no animal of a susceptible species showed clinical signs of foot-and-mouth disease during the 30 days prior to, and at least the 30 days after, the oocytes were collected (1);

1.3. the oocytes used in the production of the embryos to be exported were collected from donor females complying with the following requirements:

1.3.1. the donor females:

— were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during, collection of the oocytes (1),

or

1.3.2.

— were kept during a seasonally free period or protected from the competent vector *Culicoides* for at least 60 days prior to, and during, the collection of the oocytes, and the embryos were produced without penetration of the *zona pellucida*, except if the donors underwent a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals between 21 and 60 days after collection and giving negative results and the embryos were stored for at least 30 days (1),

or

1.3.3.

— underwent a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals between 21 and 60 days after collection and giving negative results, and the embryos were stored for at least 30 days (1),

or

1.3.4.

— underwent an agent identification test, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on a blood sample taken on the day of collection or the day of slaughtering and giving negative results – the embryos having been produced, in the latter case, without penetration of the *zona pellucida* (1);

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1.4.

1.4.1. within a 10 km radius of the premises on which the oocytes used in the production of the embryos to be exported were collected and processed, according to official findings there was no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia in the 30 days immediately prior to their collection and, in the case of embryos certified under 11.2.2.2, in the 30 days after their collection as well;

1.4.2. from the time of collection until 30 days thereafter, the embryos to be exported were stored at all times on approved premises within a 10 km radius of which, according to official findings, there was no incidence of foot-and-mouth disease, vesicular stomatitis or Rift Valley fever;

1.5. the donors of oocytes used in the production of the embryos to be exported:

1.5.1. were located, during the 30 days immediately prior to collection of the oocytes, on premises within a 10 km radius of 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;

1.5.2. showed no clinical signs of disease on the day of collection;

1.5.3. spent the six months immediately prior to collection within the territory of the exporting country in no more than two herds:

— which, according to official findings, were free from tuberculosis during that time,

— which, according to official findings, were free from brucellosis during that time,

— which were free from enzootic bovine leukosis or in which no animal showed clinical signs of enzootic bovine leukosis during the previous three years,

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

1.6. the embryos to be exported provide the following additional guarantees ([3]):

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

1.6.2. or the embryos were produced in the exporting country, which according to official findings is not free from Akabane disease ([1]), and

— the embryos were produced without penetration of the *zona pellucida*;

— the embryos were stored under approved conditions for at least 30 days immediately after production, and

— the donors of the oocytes used in the production of embryos underwent a serum neutralisation test for Akabane disease giving negative results and carried out on a blood sample taken not less than 21 days following their collection, or an agent identification test carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on a blood sample taken on the day of slaughtering ([1]);

1.7. the embryos to be exported were conceived by *in vitro* fertilisation using semen coming from semen collection or storage centres located in a Member State of the European Community or in a third country and approved in accordance with Article 5(1) and Article 9(1) respectively of Directive 88/407/EEC ([5]).

Notes

([1]) Delete as appropriate.
([2]) (Box reference No I.28 in Part I):
Identification mark: corresponding to the identification of the donor cows and the date of collection.
Category: specify if a) penetration or b) non penetration of *zona pellucida.*
([3]) See remarks for exporting country concerned in Annex I to Decision 2006/168/EC.
([4]) The signature and the stamp must be of a different colour from that of the printed form.
([5]) Semen collection and storage centres approved in accordance with EC legislation are listed on the Commission's website http://europa.eu.int/comm/food/index_en.htm.

NB: This certificate must:

(a) be drawn up in at least one official language of the Member State of destination and of 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.

Official veterinarian

Name (in capital letters): Qualification and title

Date: Signature:

Stamp

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ANNEX IV

In vitro produced embryos of domestic animals of the bovine species conceived using semen coming from semen collection or storage centres approved by the competent authority of the exporting country

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code		I.2.	I.2.a. Local reference number:
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Embryo team ☐ Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Holding ☐ Embryo team ☐ Approved body ☐ Name Approval number Address Postal code	
I.13.		I.14. Estimated date and time of arrival	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	I.20. Quantity
I.21.			I.22. Number of packages
I.23. Identification of container/Seal number			I.24.
I.25. Commodity certified for Artificial reproduction ☐			
I.26. For transit to third country vis-à-vis EU ☐ third country ISO code		I.27. For import or admission into EU ☐ Definitive import ☐	
I.28. Identification of the animals/products Species (Scientific name) Identification mark Category			

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COUNTRY

In vitro produced bovine embryos using semen from semen centres approved by the exporting country

Part II: Certification

II. Health information ☐	II.a. Certificate reference number	II.b. Local reference number

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

certify that:

1.1. the embryo production team identified above:

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

— carried out the production, processing, storing and transport of the embryos described above in accordance with Chapter II of Annex A to Directive 89/556/EEC,

— is subject to inspection by an official veterinarian at least twice a year;

1.2. the embryos to be exported were produced in the exporting country, which according to official findings:

1.2.1. was free from rinderpest during the 12 months immediately prior to the production of the embryos;

1.2.2.

1.2.2.1. either was free from foot-and-mouth disease during the 12 months immediately prior to the production of the embryos and did not carry out vaccination against foot-and-mouth disease during that period (1),

1.2.2.2. or was not free from foot-and-mouth disease during the 12 months immediately prior to the production of the embryos and/or carried out vaccination against foot-and-mouth disease during that period, and

— the embryos were produced without penetration of the *zona pellucida*,

— the embryos were stored under approved conditions for at least 30 days immediately after production, and

— the donor females come from holdings on which no animal was vaccinated against foot-and-mouth disease during the 30 days prior to collection and no animal of a susceptible species showed clinical signs of foot-and-mouth disease during the 30 days prior to, and at least the 30 days after, the oocytes were collected (1);

1.3. the oocytes used in the production of the embryos to be exported were collected from donor females complying with the following requirements:

1.3.1. the donor females:

— were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during, the collection of the oocytes (1),

or

1.3.2.

— were kept during a seasonally free period or protected from the competent vector *Culicoides* for at least 60 days prior to, and during, the collection of the oocytes and the embryos were produced without penetration of the *zona pellucida,* except if the donors underwent a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals between 21 and 60 days after collection and giving negative results, and the embryos were stored for at least 30 days (1),

or

1.3.3.

— underwent a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals between 21 and 60 days after collection and giving negative results, and the embryos were stored for at least 30 days (1),

or

1.3.4.

— underwent an agent identification test, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on a blood sample taken on the day of collection or the day of slaughtering and giving negative results — the embryos having been produced, in the latter case, without penetration of the *zona pellucida* (1);

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1.4.

1.4.1. within a 10 km radius of the premises on which the oocytes used in the production of the embryos to be exported were collected and processed, according to official findings there was no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia in the 30 days immediately prior to their collection and, in the case of embryos certified under 11.2.2.2, in the 30 days after their collection as well;

1.4.2. from the time of collection until 30 days thereafter, the embryos to be exported were stored at all times on approved premises within a 10 km radius of which, according to official findings, there was no incidence of foot-and-mouth disease, vesicular stomatitis or Rift Valley fever;

1.5. the donors of oocytes used in the production of the embryos to be exported:

1.5.1. were located, during the 30 days immediately prior to collection of the oocytes, on premises within a 10 km radius of 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;

1.5.2. showed no clinical signs of disease on the day of collection;

1.5.3. spent the six months immediately prior to collection within the territory of the exporting country in no more than two herds:

— which, according to official findings, were free from tuberculosis during that time,

— which, according to official findings, were free from brucellosis during that time,

— which were free from enzootic bovine leukosis or in which no animal showed clinical signs of enzootic bovine leukosis during the previous three years,

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

1.6. the embryos to be exported provide the following additional guarantees ([3]):

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

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

— they were produced without penetration of the *zona pellucida*;

— they were stored under approved conditions for at least 30 days immediately after production, and

— the donors of the oocytes used in the production of the embryos underwent a serum neutralisation test for Akabane disease giving negative results, carried out on a blood sample taken not less than 21 days following their collection, or an agent identification test carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on a blood sample taken on the day of slaughtering ([1]);

1.7. the embryos to be exported were conceived by *in vitro* fertilisation using semen coming from semen collection or storage centres approved for the collection, processing and/or storage of semen by the competent authority of a country listed in Annex I to Commission Decision 2004/639/EC ([5]) or by the competent authority of a Member State of the European Community.

Notes

([1]) Delete as appropriate.
([2]) (Box reference No I.28 in Part I):
Identification mark: corresponding to the identification of the donor cows and the date of collection.
Category: specify if (a) penetration or (b) non penetration of *zona pellucida*.
([3]) See remarks for exporting country concerned in Annex I to Decision 2006/168/EC.
([4]) The signature and the stamp must be of a different colour from that of the printed form.
([5]) OJ L 292, 15.9.2004, p. 21.

NB: This certificate must:

(a) be drawn up in at least one official language of the Member State of destination and of 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.

Information: in accordance with Article 3(a) of Council Directive 89/556/EEC, embryos imported under the conditions laid down in this certificate are excluded from intra-Community trade.

Official veterinarian

Name (in capital letters): Qualification and title

Date: Signature:

Stamp

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ANNEX V

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)	

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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 Council Directive 89/556/EEC (3),

— 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 a 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.

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 practiced 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.

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;

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11.4. the donor females and the 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 (4):

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 (1), 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 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 (5)

Note for guidance:

(1) Delete as appropriate.
(2) Corresponding to the identification of the donor cows and date of collection.
(3) OJ L 302, 19.10.1989, p. 1.
(4) See the remarks for the exporting country concerned in Annex I to Decision 2006/168/EC (OJ L 57, 28.2.2006, p. 19).
(5) 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 4 of Decision 2006/168/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.