►**B**

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)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Regulation (EC) No 1792/2006 of 23 October 2006	L 362	1	20.12.2006
►**M2**	Commission Decision 2009/873/EC of 30 November 2009	L 315	22	2.12.2009
►**M3**	Commission Implementing Decision 2012/414/EU of 17 July 2012	L 194	12	21.7.2012

Corrected by:

►**C1** Corrigendum, OJ L 75, 19.3.2013, p. 38 (2012/414/EU)

▼B

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)

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.

([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).

▼B

(4) Following trade problems relating to new, stricter requirements for bovine semen used for fertilisation introduced by Commission Decision 92/471/EEC [1], 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 [2].

(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.

[1] 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).

[2] OJ L 69, 16.3.2005, p. 41.

▼B

(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:

▼M2

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 embryo collection or production teams approved in accordance with Article 8 of Directive 89/556/EEC.

▼B

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.

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

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

▼B

(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.

▼**M3**

ANNEX I

ISO code	Third country	Applicable veterinary certificate		
AR	Argentina	ANNEX II	ANNEX III	ANNEX IV
AU	Australia	ANNEX II	ANNEX III	ANNEX IV
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	the former Yugoslav Republic of Macedonia (**)	ANNEX II	ANNEX III	ANNEX IV
NZ	New Zealand (***)	ANNEX II	ANNEX III	ANNEX IV
US	United States	ANNEX II	ANNEX III	ANNEX IV

(*) For *in vivo* derived and *in vitro* produced embryos, the certificates to be used for imports from Switzerland are set out in Annex C to Directive 89/556/EEC, with the adaptations set out in point 2 of Chapter VI(B) of Appendix 2 of Annex 11 to the Agreement between the European Community and the Swiss Confederation on Trade in Agricultural Products as approved by Decision 2002/309/EC, Euratom of the Council, and of the Commission as regards the Agreement on Scientific and Technological Cooperation of 4 April 2002 on the conclusion of seven Agreements with the Swiss Confederation.

(**) 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.

(***) For *in vivo* derived embryos, the certificate to be used for imports from New Zealand is set out in Annex IV to Commission Decision 2003/56/EC of 24 January 2003 on health certificates for the importation of live animals and animal products from New Zealand (only for the embryos collected in New Zealand), laid down in accordance with the Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products, as approved by Council Decision 97/132/EC.

▼M3

ANNEX II

Model veterinary certificate for imports of *in vivo* derived embryos of domestic animals of the bovine species 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 Tel.			I.2. Certificate reference No	I.2.a.
			I.3. Central competent authority	
			I.4. Local competent authority	
I.5. Consignee Name Address Postal code Tel.			I.6. Person responsible for the load in EU Name Address Postal code Tel.	
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 Name Approval number Address Name Approval number Address Name Approval number Address			I.12. Place of destination Name Address Postal cod	
I.13. Place of loading			I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references			I.16. Entry BIP in EU	
			I.17.	
I.18. Description of commodity			I.19. Commodity code (HS code) **05 11 99 85**	
			I.20. Quantity	
I.21.			I.22. Number of packages	
I.23. Seal/Container No			I.24.	
I.25. Commodities certified for: Artificial reproduction ☐				
I.26. For transit through EU to third country ☐ Third country ISO code			I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Breed	Category	Donor identity	Date of collection	Date of freezing	Approval number of the team	Quantity

▼M3

COUNTRY ***In vivo* derived bovine embryos**

Part II: Certification

II. Health information	II.a. Certificate reference No	II.b.

I, the undersigned, official veterinarian of the ..... certify that:
(exporting country) (2)

II.1. The embryos to be exported:

II.1.1. were collected in the exporting country, which according to official findings:

II.1.1.1. was free from rinderpest during the 12 months immediately prior to their collection;

(1) *either* [II.1.1.2. 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) *or* [II.1.1.2. 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,

— 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.]

II.1.2. were collected by the embryo collection team (3):

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

— which carried out the collection, processing, storing and transport of the embryos 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.

II.1.3. were collected and processed on premises situated in an area of at least 10 km radius centred on them, on which 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 until dispatch to the Union, in the case of fresh embryos, or during the 30 days after collection, in the case of embryos subject to a mandatory storage for at least 30 days in accordance with point II.1.1.2.

II.1.4. from the time of collection until 30 days thereafter or, in the case of fresh embryos until the day of their dispatch to the Union, they were stored on premises situated in an area of at least 10 km radius centred on them, on which according to official findings there was no incidence of foot-and-mouth disease, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia.

II.1.5. were collected from the donor females, which:

II.1.5.1. were located, during the 30 days immediately prior to collection, on premises situated in an area of at least 10 km radius centred on them, on 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;

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

II.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 bovine 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.

II.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 third country or part thereof listed in Annex I to Commission Implementing Decision 2011/630/EU (4) or by the competent authority of a Member State.

▼M3

COUNTRY ***In vivo* derived bovine embryos**

II. Health information	II.a. Certificate reference No	II.b.

Notes

Part I:

Box I.6: *Person responsible for the load in EU*: this box is to be filled in only if it is a certificate for transit commodity.

Box I.11: Place of origin shall correspond to the embryo collection team from which the embryos are dispatched to the Union and which is listed in accordance with Article 8(2) of Directive 89/556/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm.

Box I.22: *Number of packages* shall correspond to the number of containers.

Box I.23: identification of container and seal number shall be indicated.

Box I.26: fill in according to whether it is a transit or an import certificate.

Box I.27: fill in according to whether it is a transit or an import certificate.

Box I.28: *Species*: select amongst 'Bos taurus', 'Bison bison' or 'Bubalus bubalis' as appropriate.

Category: select 'in vivo derived embryos'.

Donor identity shall correspond to the official identification of the animal.

Date of collection shall be indicated in the following format: dd.mm.yyyy.

Approval number of the team: shall correspond to the embryo collection team by which the embryos were collected, processed and stored; and listed in accordance with Article 8(2) of Directive 89/556/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm.

Part II:

([1]) Delete as appropriate.

([2]) Only third countries listed in Annex I to Decision 2006/168/EC.

([3]) Only embryo collection teams listed in accordance with Article 8(2) of Directive 89/556/EEC on Commission website: http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm.

([4]) OJ L 247, 24.9.2011, p. 32.

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

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

▼M3

ANNEX III

Model veterinary certificate for imports of *in vitro* produced embryos of domestic animals of the bovine species 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 Tel.			I.2. Certificate reference No		I.2.a.		
			I.3. Central competent authority				
			I.4. Local competent authority				
I.5. Consignee Name Address Postal code Tel.			I.6. Person responsible for the load in EU Name Address Postal code Tel.				
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 Name Address Approval number Name Address Approval number Name Address Approval number				▶(1) I.12. Place of destination ◀ Name Address Postal code			
I.13. Place of loading				I.14. Date of departure			
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references				I.16. Entry BIP in EU I.17.			
I.18. Description of commodity				I.19. Commodity code (HS code) **05 11 99 85**			
				I.20. Quantity			
I.21.				I.22. Number of packages			
I.23. Seal/Container No				I.24.			
I.25. Commodities certified for: Artificial reproduction ☐							
I.26. For transit through EU to third country ☐ Third country ISO code				I.27. For import or admission into EU ☐			

I.28. Identification of the commodities

Species (scientific name)	Breed	Category	Dam identity	Sire identity	Date of freezing	Approval number of the team	Quantity

▶(1) C1

▼M3

COUNTRY ***In vitro* produced bovine embryos**

Part II: Certification

II. Health information	II.a. Certificate reference No	II.b.

I, the undersigned, official veterinarian of ..... certify that:
(exporting country) (2)

II.1. The embryos to be exported:

II.1.1. were produced in the exporting country, which according to official findings:

II.1.1.1. was free from rinderpest during the 12 months immediately prior to their production;

(1) *either* [II.1.1.2. 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) *or* [II.1.1.2. 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,

— 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.]

II.1.2. were produced by the embryo production team (3) which:

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

— carried out the production, processing, storing and transport 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.

II.2. The oocytes used in the production of the embryos to be exported were collected on premises situated in an area of at least 10 km radius centred on them, on which 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 until their dispatch to the Union, in the case of fresh embryos, or during the 30 days after collection, in the case of embryos subject to a mandatory storage for at least 30 days in accordance with point II.1.1.2.

▶(1) II.3. From the time of collection of the oocytes until 30 days thereafter or, in the case of fresh embryos, until the day of dispatch, the embryos to be exported were stored on premises situated in an area of at least 10 km radius centred on them, on which according to official findings there was no incidence of foot-and- mouth disease, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia. ◀

II.4. The donors of oocytes used in the production of the embryos to be exported:

II.4.1. were located, during the 30 days immediately prior to collection of the oocytes, on premises situated in an area of at least 10-km radius on 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;

II.4.2. showed no clinical signs of disease on the day of collection;

II.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 bovine 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) *either* [II.4.4. were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during, collection of the oocytes.]

▶(1) C1

▼M3

COUNTRY ***In vitro* produced bovine embryos**

II. Health information	II.a. Certificate reference No	II.b.

(^{1}) *or* [II.4.4. were kept during a seasonally free period or protected from the vector 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 OIE 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* [II.4.4. underwent a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the OIE 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* [II.4.4. underwent an agent identification test, carried out in accordance with the OIE 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*.]

II.5. The embryos to be exported were conceived by *in vitro* fertilisation using semen coming from semen collection or storage centres (^{4}):

(^{1}) *either* [II.5.1. approved in accordance with Article 5(1) of Directive 88/407/EEC and located in a Member State of the European Union, and the semen complies with the requirements of Directive 88/407/EEC.]

(^{1}) *or* [II.5.1. approved in accordance with Article 9(1) of Directive 88/407/EEC and located in a third country or part thereof listed in Annex I to Commission Implementing Decision 2011/630/EU, and the semen complies with the requirements set out in Section A of Part 1 of Annex II to that Decision.]

Notes

Part I:

Box I.6: *Person responsible for the load in EU*: this box is to be filled in only if it is a certificate for transit commodity.

▶(1) Box I.11: *Place of origin* shall correspond to the embryo production team from which the embryos are dispatched to the Union and listed in accordance with Article 8(2) of Directive 89/556/EEC on the Commission website:
http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm ◀

Box I.22: *Number of packages* shall correspond to the number of containers.

Box I.23: identification of container and seal number shall be indicated.

Box I.26: fill in according to whether it is a transit or an import certificate.

Box I.27: fill in according to whether it is a transit or an import certificate.

▶(2) Box I.28: *Species*: select amongst "*Bos taurus*", "*Bison bison*" or "*Bubalus bubalis*" as appropriate.
Category: select *"in vitro-produced embryos".*
Dam identity shall correspond to the official identification of the animal.
Sire identity shall correspond to the official identification of the animal.
Date of freezing shall be indicated in the following format:
dd.mm.yyyy
Approval number of the team: shall correspond to the embryo production team by which the embryos were produced, processed and stored; and listed in accordance with Article 8(2) of Directive 89/556/EEC on the Commission website:
http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm ◀

Part II:

(^{1}) Delete as appropriate.

(^{2}) Only third countries listed in Annex I to Decision 2006/168/EC.

(^{3}) Only embryo production teams listed in accordance with Article 8(2) of Directive 89/556/EEC on Commission website: http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm

(^{4}) Only semen collection centres listed in accordance with Article 5(2) and Article 9(2) of Directive 88/407/EEC on the Commission websites:
http://ec.europa.eu/food/animal/approved_establishments/establishments_vet_field_en.htm;
http://ec.europa.eu/food/animal/semen_ova/bovine/index_en.htm.

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

▶(1) (2) C1

▼M3

COUNTRY ***In vitro* produced bovine embryos**

II. Health information	II.a. Certificate reference No	II.b.
Official veterinarian Name (in capital letters): Qualification and title: Date: Signature: Stamp:		

▼M3

ANNEX IV

Model veterinary certificate for imports of *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 Tel.			I.2. Certificate reference No		I.2.a.
			I.3. Central competent authority		
			I.4. Local competent authority		
I.5. Consignee Name Address Postal code Tel.			I.6. Person responsible for the load in EU Name Address Postal code Tel.		
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 Name Approval number Address Name Approval number Address Name Approval number Address			I.12. Place of destination Name Address Postal code		
I.13. Place of loading			I.14. Date of departure		
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references			I.16. Entry BIP in EU I.17.		
I.18. Description of commodity			I.19. Commodity code (HS code) **05 11 99 85**		
			I.20. Quantity		
I.21.			I.22. Number of packages		
I.23. Seal/Container No			I.24.		
I.25. Commodities certified for: Artificial reproduction ☐					
I.26. For transit through EU to third country ☐ Third country ISO code			I.27. For import or admission into EU ☐		

I.28. Identification of the commodities

Species (Scientific name)	Breed	Category	Dam identity	Sire identity	Date of freezing	Approval number of the team	Quantity

▼M3

COUNTRY

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

II. Health information	II.a. Certificate reference No	II.b.

Part II: Certification

I, the undersigned, official veterinarian of ..... certify that:
(exporting country) (2)

II.1. The embryos to be exported

II.1.1. were produced in the exporting country, which according to official findings:

II.1.1.1. was free from rinderpest during the 12 months immediately prior to their production;

(1) *either* [II.1.1.2. 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) *or* [II.1.1.2. 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,

— 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.]

II.1.2. were produced by the embryo production team (3) which:

— 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 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.

II.2. The oocytes used in the production of the embryos to be exported were collected on premises situated in an area of at least 10 km radius centred on them, on which 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 until their dispatch to the Union, in case of fresh embryos, or during the 30 days after collection, in case of embryos subject to a mandatory storage for at least 30 days in accordance with point II.2.2.

▶(1) II.3. From the time of collection of the oocytes until 30 days thereafter or, in the case of fresh embryos, until the day of dispatch, the embryos to be exported were stored on premises situated in an area of at least 10 km radius centred on them, on which according to official findings there was no incidence of foot-and- mouth disease, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia. ◀

II.4. The donors of oocytes used in the production of the embryos to be exported:

II.4.1. 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, vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia;

II.4.2. showed no clinical signs of disease on the day of collection;

II.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.

(1) *either* [II.4.4. were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during, collection of the oocytes.]

▼M3

COUNTRY

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

II. Health information	II.a. Certificate reference No	II.b.

([1]) *or* [II.4.4. were kept during a seasonally free period or protected from the vector 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 OIE 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* [II.4.4. underwent a serological test to detect antibodies to the bluetongue virus group, carried out in accordance with the OIE 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* [II.4.4. underwent an agent identification test, carried out in accordance with the OIE 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*.]

II.5. 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 third country or a part thereof listed in Annex I to Commission Implementing Decision 2011/630/EU ([4]) or by the competent authority of a Member State.

Notes

In accordance with Article 3(a) of Directive 89/556/EEC, the *in vitro* produced bovine embryos using semen from semen centres approved by the exporting country, imported under the conditions laid down in this certificate are excluded from intra-Union trade.

Part I:

Box I.6: *Person responsible for the load in EU*: this box is to be filled in only if it is a certificate for transit commodity.

▶[(1)] Box I.11: *Place of origin* shall correspond to the embryo production team from which the embryos are dispatched to the Union and listed in accordance with Article 8(2) of Directive 89/556/EEC on the Commission website:
http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm ◀

Box I.22: number of packages shall correspond to the number of containers.

Box I.23: identification of container and seal number shall be indicated.

Box I.26: fill in according to whether it is a transit or an import certificate.

Box I.27: fill in according to whether it is a transit or an import certificate.

▶[(2)] Box I.28: *Species:* select amongst "*Bos taurus*", "*Bison bison*" or "*Bubalus bubalis*" as appropriate.

Category: select *"in vitro*-produced embryos*"*.

Dam identity shall correspond to the official identification of the animal.

Sire identity shall correspond to the official identification of the animal.

Date of freezing shall be indicated in the following format:

dd.mm.yyyy

Approval number of the team: shall correspond to the embryo production team by which the embryos were produced, processed and stored and listed in accordance with Article 8(2) of Directive 89/556/EEC on the Commission website:

http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm ◀

Part II:

([1]) Delete as appropriate.

([2]) Only third countries listed in Annex I to Decision 2006/168/EC.

([3]) Only embryo production teams listed in accordance with Article 8(2) of Directive 89/556/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm.

([4]) Only third countries listed in Annex I to Implementing Decision 2011/630/EU.

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

▼M3

COUNTRY

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

II. Health information	II.a. Certificate reference No	II.b.
Official veterinarian Name (in capital letters): Qualification and title: Date: Signature: Stamp:		

▼B

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)	

▼B

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;

▼B

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.