DECISIONS

COMMISSION IMPLEMENTING DECISION

of 17 July 2012

amending Annexes I to IV to Decision 2006/168/EC as regards certain veterinary certification requirements for imports into the Union of bovine embryos

(notified under document C(2012) 4816)

(Text with EEA relevance)

(2012/414/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species [1], and in particular Article 7(1) and point (b) of the first subparagraph of Article 9(1) thereof,

Whereas:

(1) Commission Decision 2006/168/EC 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 [2] establishes in Annex I thereto the list of third countries from which Member States are to authorise imports of embryos of domestic animals of the bovine species ('the embryos'). It also lays down additional guarantees as regards specific animal diseases to be provided by certain third countries listed in that Annex.

(2) Decision 2006/168/EC also provides that Member States are to authorise imports of embryos that comply with the animal health requirements set out in the model veterinary certificates in Annexes II, III and IV to that Decision.

(3) The animal health requirements relating to bluetongue in the model veterinary certificates in Annexes II, III and IV to Decision 2006/168/EC are based on the recommendations of Chapter 8.3 of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE) which deals with bluetongue. That Chapter recommends a whole range of risk mitigating measures aiming at either protecting the mammalian host from exposure to the infectious vector or at inactivating the virus by antibodies.

(4) In addition, the OIE has laid down a chapter on Surveillance for arthropod vectors of animal diseases in the Terrestrial Animal Health Code. Those recommendations do not include the monitoring of ruminants for antibodies to Simbu viruses, such as the Akabane and Aino viruses of the *Bunyaviridae* family, which in the past was considered an economical method for determining the distribution of bluetongue competent vectors until more information on the spread of those diseases became available.

(5) Also, the OIE does not list Akabane and Aino diseases in the Terrestrial Animal Health Code. Consequently, the requirement for annual testing for those diseases to prove the absence of the vector should be deleted from Annex I to Decision 2006/168/EC and from the model veterinary certificates in Annexes II, III and IV thereto.

(6) In addition, bilateral agreements have been concluded between the Union and certain third countries containing specific conditions for the imports of embryos into the Union. Therefore, in the interests of consistency where those bilateral agreements contain specific conditions and model veterinary certificates for imports, those conditions and models should apply instead of the conditions and models set out in Decision 2006/168/EC.

(7) The animal health status of Switzerland is equivalent to that of the Member States. It is therefore appropriate that *in vivo* derived and *in vitro* produced embryos imported into the Union from that third country are accompanied by a veterinary certificate drawn up in accordance with the model intra-trade certificate used for trade within the Union in embryos of domestic animals of the bovine species set out in Annex C to Directive 89/556/EEC. That certificate should take account of 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 [3].

[1] OJ L 302, 19.10.1989, p. 1.
[2] OJ L 57, 28.2.2006, p. 19.
[3] OJ L 114, 30.4.2002, p. 1.

(8) On the basis of Directive 89/556/EEC, New Zealand was also recognised as a third country with an animal health status equivalent to that of Member States for imports of *in vivo* derived embryos.

(9) It is therefore appropriate that *in vivo* derived embryos collected in New Zealand and imported into the Union from that third country are accompanied by a simplified certificate drawn up in accordance with the appropriate model health certificate 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 [1] 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 [2], as approved by Council Decision 97/132/EC [3].

(10) Commission Decision 2007/240/EC [4] provides that the various veterinary, public and animal health certificates required for the imports into the Union of live animals, semen, embryo, ova and products of animal origin are to be based on the standard models for veterinary certificates set out in Annex I thereto. In the interests of consistency and simplification of Union legislation, the model veterinary certificates set out in Annexes II, III and IV to Decision 2006/168/EC should take account of Decision 2007/240/EC.

(11) Annexes I to IV to Decision 2006/168/EC should therefore be amended accordingly.

(12) To avoid any disruption of trade, the use of veterinary certificates issued in accordance with Decision 2006/168/EC in its version prior to the amendments introduced by this Decision should be authorised during a transitional period subject to certain conditions.

(13) 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 I to IV to Decision 2006/168/EC are amended in accordance with the Annex to this Decision.

Article 2

For a transitional period until 30 June 2013, Member States shall continue to authorise imports of consignments of embryos of domestic animals of the bovine species from third countries which are accompanied by a veterinary certificate issued not later than 31 May 2013 in accordance with the models set out in Annexes II, III and IV to Decision 2006/168/EC in its version prior to the amendments introduced by this Decision.

Article 3

This Decision shall apply from 1 January 2013.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 17 July 2012.

For the Commission

John DALLI

Member of the Commission

[1] OJ L 22, 25.1.2003, p. 38.
[2] OJ L 57, 26.2.1997, p. 5.
[3] OJ L 57, 26.2.1997, p. 4.
[4] OJ L 104, 21.4.2007, p. 37.

ANNEX

Annexes I to IV to Decision 2006/168/EC are replaced by the following:

'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.

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

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.

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:

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				I.12. Place of origin 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

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.

II.3. 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 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.]

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.

Box I.11: *Place of origin* shall correspond to the embryo collection team from which the embryos are dispatch 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.

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

Category: select *"in vivo derived 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 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 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.

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:		

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

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.

II.3. 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 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.]

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.

Box I.11: *Place of origin* shall correspond to the embryo collection team from which the embryos are dispatch 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.

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

Category: select "*in vivo* 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.

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:'		