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COMMISSION DECISION

of 26 August 2010

on imports of semen, ova and embryos of animals of the ovine and caprine species into the Union

(notified under document C(2010) 5780)

(Text with EEA relevance)

(2010/472/EU)

(OJ L 228, 31.8.2010, p. 74)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision 2012/411/EU of 17 July 2012	L 192	16	20.7.2012

Corrected by:

►**C1** Corrigendum, OJ L 331, 1.12.2012, p. 57 (2012/411/EU)

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COMMISSION DECISION

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(notified under document C(2010) 5780)

(Text with EEA relevance)

(2010/472/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC ([1]), and in particular Article 17(2)(b), Article 17(3), the first indent of Article 18(1), and the introductory phrase and point (b) of Article 19 thereof,

Whereas:

(1) Directive 92/65/EEC lays down the animal health conditions governing imports into the Union of semen, ova and embryos of animals of the ovine and caprine species ('the commodities'). It provides only commodities that come from a third country included on a list of third countries drawn up in accordance with that Directive and accompanied by a health certificate corresponding to a model also drawn up in accordance with that Directive, may be imported into the Union. The health certificate must certify that commodities come from approved collection and storage centres or collection and production teams offering guarantees at least equivalent to those laid down in Annex D(I) to that Directive.

(2) Commission Decision 2008/635/EC of 22 July 2008 on imports of semen, ova and embryos of the ovine and caprine species into the Community as regards lists of third countries and of semen collection centres and embryo collection teams, and certification requirements ([2]) currently sets out the list of third countries from which Member States are to authorise imports of the commodities.

(3) Directive 92/65/EEC, as amended by Council Directive 2008/73/EC ([3]), introduced a simplified procedure for the listing of semen collection and storage centres and embryo collection and production teams in third countries approved for imports of the commodities into the Union.

(4) In addition, Annex D to Directive 92/65/EEC, as amended by Commission Regulation (EU) No 176/2010 ([4]), sets out certain new requirements for the commodities which are to apply from 1 September 2010. It introduces rules concerning semen storage centres and detailed conditions for their approval and supervision.

([1]) OJ L 268, 14.9.1992, p. 54.
([2]) OJ L 206, 2.8.2008, p. 17.
([3]) OJ L 219, 14.8.2008, p. 40.
([4]) OJ L 52, 3.3.2010, p. 14.

▼B

It also sets out detailed conditions for the approval and supervision of embryo collection and production teams, for the collection and processing of *in vivo* derived embryos and the production and processing of *in vitro* fertilised embryos and micromanipulated embryos. It also amended the conditions to be applied to the donor animals of semen, ova and embryos of animals of the ovine and caprine species.

(5) Accordingly, it is necessary to establish new health certificates for imports into the Union of the commodities taking into account the amendments made to Directive 92/65/EEC by Directive 2008/73/EC and Regulation (EU) No 176/2010.

(6) In addition, it is appropriate that consignments of the commodities imported into the Union from Switzerland are accompanied by a health certificate drawn up in accordance with the models used for trade within the Union in semen, ova and embryos of animals of the ovine and caprine species set out in Commission Decision 2010/470/EU of 26 August 2010 laying down model health certificates for trade within the Union of semen, ova and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species ([1]), with the adaptations set out in point 7 of Chapter IX(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 ([2]).

(7) In the application of this Decision, account should be taken of the specific certification requirements and model health attestations which may be laid down in accordance with the Agreement between the European Community and the Government of Canada on sanitary measures to protect public and animal health in respect of trade in live animals and animal products ([3]), as approved by Council Decision 1999/201/EC ([4]).

(8) In the application of this Decision, account should also be taken of the specific certification requirements and model health attestations which may be 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 ([5]), as approved by Council Decision 97/132/EC ([6]).

(9) In the interest of clarity and consistency of Union's legislation, Decision 2008/635/EC should be repealed and replaced by this Decision.

(10) To avoid any disruption of trade, the use of health certificates issued in accordance with Decision 2008/635/EC should be authorised during a transitional period subject to certain consitions.

([1]) See page 15 of this Official Journal.
([2]) OJ L 114, 30.4.2002, p. 1.
([3]) OJ L 71, 18.3.1999, p. 3.
([4]) OJ L 71, 18.3.1999, p. 1.
([5]) OJ L 57, 26.2.1997, p. 5.
([6]) OJ L 57, 26.2.1997, p. 4.

▼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:

Article 1

Subject matter

This Decision sets out a list of third countries or parts thereof from which Members States are to authorise the importation into the Union of consignments of semen, ova and embryos of animals of the ovine and caprine species.

It also lays down certification requirements for the importation of those commodities into the Union.

Article 2

Imports of semen

Member States shall authorise imports of consignments of semen of animals of the ovine and caprine species provided that they comply with the following conditions:

(a) they come from a third country or part thereof listed in Annex I;

(b) they come from an approved semen collection or storage centre listed in accordance with Article 17(3)(b) of Directive 92/65/EEC;

(c) they are accompanied by a health certificate drawn up in accordance with the following model health certificates set out in Part 2 of Annex II, and completed in accordance with the explanatory notes set out in Part 1 of that Annex:

(i) model 1 as set out in Section A, for consignments of semen dispatched from an approved semen collection centre of origin of the semen;

(ii) model 2 as set out in Section B, for consignments of semen dispatched from an approved semen storage centre.

However, where specific certification requirements are laid down in bilateral agreements between the Union and third countries, those requirements shall apply.

(d) they comply with the requirements set out in the health certificates referred to in point (c).

Article 3

Imports of ova and embryos

Member States shall authorise imports of consignments of ova and embryos of animals of the ovine and caprine species provided that they comply with the following conditions:

(a) they come from a third country or part thereof listed in Annex III;

(b) they come from an approved embryo collection or production team listed in accordance with Article 17(3)(b) of Directive 92/65/EEC;

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(c) they are accompanied by a health certificate drawn up in accordance with the model set out in Part 2 of Annex IV, and completed in accordance with the explanatory notes set out in Part 1 of that Annex.

However, where specific certification requirements are laid down in bilateral agreements between the Union and third countries, those requirements must apply.

(d) they comply with the requirements set out in the health certificate referred to in point (c).

Article 4

General conditions concerning the transport of consignments of semen, ova and embryos to the Union

1. Consignments of semen, ova and embryos of animals of the ovine and caprine species shall not be transported in the same container as other consignments of semen, ova and embryos that:

(a) are not intended for introduction into the Union, or

(b) are of a lower health status.

2. During transport to the European Union, consignments of semen, ova and embryos shall be placed in closed and sealed containers and the seal must not be broken during the transport.

Article 5

Repeal

Decision 2008/635/EC is repealed.

Article 6

Transitional provisions

For a transitional period until 31 August 2011, Member States shall authorise imports from third countries of stocks of the following commodities:

(a) semen of animals of the ovine and caprine species which were collected, processed and stored in accordance with Directive 92/65/EEC by 31 August 2010 and which are accompanied by a health certificate issued not later than 31 May 2011 in accordance with the model set out in Annex II to Decision 2008/635/EC.

(b) ova and embryos of animals of the ovine and caprine species which were collected or produced, processed and stored in accordance with Directive 92/65/EEC by 31 August 2010 and which are accompanied by a health certificate issued not later than 31 May 2011 in accordance with the model set out in Annex VI to Decision 2008/635/EC.

Article 7

Applicability

This Decision shall apply from 1 September 2010.

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Article 8

Addressees

This Decision is addressed to the Member States.

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ANNEX I

List of third countries or parts thereof from which Member States are to authorise imports of consignments of semen of animals of the ovine and caprine species

ISO Code	Name of the third country	Remarks	
		Description of the territory (*if appropriate*)	Additional guarantees
AU	Australia		The additional guarantee as regards testing set out in point II.4.9.1 of the model health certificate set out in Section A of Part 2 of Annex II is compulsory.
CA	Canada		The additional guarantee as regards testing set out in point II.4.9.1 of the model health certificate set out in Section A of Part 2 of Annex II is compulsory.
CH	Switzerland [1]		
CL	Chile		
GL	Greenland		
HR	Croatia		
IS	Iceland		
NZ	New Zealand		
PM	Saint Pierre and Miquelon		
US	United States		The additional guarantee as regards testing set out in point II.4.9.1 of the model health certificate set out in Section A of Part 2 of Annex II is compulsory.

[1] Certificates in accordance with 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 Federation (OJ L 114, 30.4.2002, p. 1).

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ANNEX II

PART 1

Explanatory notes for the certification

(a) The health certificates shall be issued by the competent authority of the exporting third country, in accordance with the model set out in Part 2 of Annex II.

If the Member State of destination requires additional certification requirements, attestations to certify that those requirements are fulfilled shall be also incorporated in the original form of the health certificate.

(b) The original of the health certificate shall consist of a single sheet of paper, or, where more text is required, it must be in such a form that all sheets of paper required are part of an integrated whole and indivisible.

(c) Where the model health certificate states that certain statements shall be kept as appropriate, statements which are not relevant, may be crossed out and initialled and stamped by the certifying officer, or completely deleted from certificate.

(d) The health certificate shall be drawn up in at least one of the official languages of the Member State of the border inspection post of introduction of the consignment into the European Union and of the Member State of destination. However, those Member States may authorise the certificate to be drawn up in the official language of another Member State, and accompanied, if necessary, by an official translation.

(e) If for the reasons of identification of the items of the consignment (schedule in Box I.28 of the model health certificate), additional sheets of paper are attached to the health certificate, those sheets of paper shall also be considered as forming part of the original of the health certificate by application of the signature and stamp of the certifying officer, on each of the pages.

(f) When the health certificate, including additional schedules referred to in (e), comprises more than one page, each page shall be numbered (page number) of (total number of pages), at the end of the page and shall bear the certificate reference number that has been designated by the competent authority on the top of the pages.

(g) The original of the health certificate must be completed and signed by an official veterinarian the last working day prior to loading of the consignment for exportation to the European Union. The competent authorities of the exporting third country shall ensure that certification requirements equivalent to those laid down in Council Directive 96/93/EC [1] are followed.

The colour of the signature and the stamp of the official veterinarian shall be different to that of the printing on the health certificate. This requirement also applies to stamps other than those embossed or watermarks.

(h) The original of the health certificate must accompany the consignment until it reaches the border inspection post of introduction into the European Union.

(i) The certificate reference number referred to in Box I.2 and Box II.a of the model health certificate must be issued by the competent authority of the exporting third country.

[1] OJ L 13, 16.1.1997, p. 28.

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PART 2

Model health certificates for imports of consignments of semen of animal of the ovine and caprine species

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Section A

MODEL 1 — Health certificate for semen dispatched from an approved semen collection centre of origin of the semen

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	Dondor identity	Date of collection	Approval number of the centre	Quantity

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COUNTRY **Ovine and caprine semen — Section A**

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

Part II: Certification

I, the undersigned, official veterinarian, hereby certify that:

II.1. The exporting country .....
(name of exporting country) (2)

II.1.1. has been free from rinderpest, peste des petits ruminants, sheep and goat pox, contagious caprine pleuropneumonia and Rift Valley fever during the 12 months immediately prior to collection of the semen to be exported and until its date of dispatch to the Union and no vaccination against these diseases took place during that period;

II.1.2. has been free from foot-and-mouth disease during the 12 months immediately prior to collection of the semen to be exported and until its date of dispatch to the Union and no vaccination against this disease took place during that period.

II.2. The semen collection centre described in Box I.11 and at which the semen to be exported was collected and stored:

II.2.1. meets the conditions for the approval of semen collection centres laid down in Chapter I(I)(1) of Annex D to Directive 92/65/EEC;

II.2.2. is operated and supervised in accordance with the conditions applicable to semen collection centres and storage centres laid down in Chapter I(II)(1) of Annex D to Directive 92/65/EEC.

II.3. The ovine/caprine (1) animals standing at the semen collection centre:

II.3.1. prior to their stay in the quarantine accommodation described in point II.3.3,

(1)(4) either [II.3.1.1. originate from the territory described in Box I.8, which has been recognised as officially brucellosis (*B. melitensis*)-free,]

(1)or [II.3.1.1. have belonged to a holding which has obtained and maintained its officially brucellosis (*B. melitensis*)-free status in accordance with Directive 91/68/EEC,]

(1)or [II.3.1.1. originate from a holding, where in respect of brucellosis (*B. melitensis*) all susceptible animals have been free from clinical or any signs of this disease for the last 12 months, none of the ovine and caprine animals have been vaccinated against this disease, save those vaccinated with Rev. 1 vaccine more than two years ago, and all ovine and caprine animals over six months of age have been subjected to at least two tests (3), carried out with negative results on samples taken on ..... (*date*) and on ..... (*date*) at least six months apart, the latter being within 30 days of entry into the quarantine accommodation,]

and have not been kept previously in a holding of a lower status;

II.3.1.2. have been kept continuously for at least 60 days on a holding where no case of contagious epididymitis (*Brucella ovis*) has been diagnosed in the last 12 months,

(1) and [they are animals of the ovine species and have undergone during the 60 days prior to their stay in the quarantine accommodation described in point II.3.3 a complement fixation test, or any other test with an equivalent documented sensitivity and specificity, to detect contagious epididymitis with result of less than 50 ICFTU/ml;]

II.3.1.3. to the best of my knowledge do not come from holdings and have not been in contact with animals of a holding, in which, based on the official notification system and according to the written declaration made by the owner, any of the following diseases has been clinically detected within the periods referred to in (a) to (d) prior to their stay in the quarantine accommodation described in point II.3.3:

(a) contagious agalactia of sheep or goats (*Mycoplasma agalactiae, Mycoplasma capricolum, Mycoplasma mycoides var. mycoides* "large colony"), within the last six months;

(b) paratuberculosis and caseous lymphadenitis, within the last 12 months;

(c) pulmonary adenomatosis, within the last three years;

(1) either [(d) Maedi/Visna for sheep or caprine viral arthritis/encephalitis for goats, within the last three years;]

(1) or [(d) Maedi/Visna for sheep or caprine viral arthritis/encephalitis for goats, within the last 12 months, and all the infected animals were slaughtered and remaining animals subsequently reacted negatively to two tests carried out at least six months apart;]

II.3.2. have undergone the following tests carried out on a blood sample collected within the 28 days preceding the commencement of the period of quarantine specified in point II.3.3 for:

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COUNTRY **Ovine and caprine semen — Section A**

II.	Health information	II.a. Certificate reference No	II.b.
	— brucellosis (*B. melitensis*), with negative results in each case in accordance with Annex C to Directive 91/68/EEC,		
	— contagious epididymitis (*Brucella. ovis*), in the case of sheep only, with negative results in each case in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity,		
	— border disease in accordance with point 1.4 (c) of Chapter II(II) of Annex D to Directive 92/65/EEC;		
	II.3.3. have satisfied the quarantine isolation period of at least 28 days in a quarantine accommodation specifically approved for the purpose by the competent authority and during that period		
	II.3.3.1. only animals of at least the same health status were present in the quarantine accommodation;		
	II.3.3.2. the animals have undergone the following tests, carried out by the laboratory approved by the competent authority of the exporting country on samples taken not earlier than 21 days after the animals were admitted to the quarantine accommodation, for:		
	— brucellosis (*B. melitensis*) with negative results in accordance with Annex C to Directive 91/68/EEC,		
	— contagious epididymitis (*Brucella ovis*), in the case of sheep only, with negative results in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity,		
	— border disease in accordance with point 1.6 of Chapter II(II) of Annex D to Directive 92/65/EEC;		
	II.3.4. have undergone at least once a year the routine tests with negative results for:		
	— brucellosis (*B. melitensis*) in accordance with Annex C to Directive 91/68/EEC,		
	— contagious epididymitis (*Brucella ovis*) in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity; in the case of sheep only,		
	— border disease in accordance with point 5(c) of Chapter II(II) of Annex D to Directive 92/65/EEC.		
II.4.	The semen to be exported was obtained from donor rams/bucks [1] which:		
	II.4.1. were admitted to the approved semen collection centre with the express permission of the centre veterinarian;		
	II.4.2. show no clinical signs of disease on the day of admission to the approved semen collection centre and on the day the semen was collected;		
[1] either	[II.4.3. have not been vaccinated against foot-and-mouth disease during the 12 months prior to collection of the semen;]		
[1] or	[II.4.3. have been vaccinated against foot-and-mouth disease at least 30 days prior to the collection, and 5 % (with a minimum of five straws) of each collection have been submitted to a virus isolation test for foot-and-mouth disease with negative results;]		
	II.4.4. have been kept at an approved semen collection centre for a continuous period of at least 30 days immediately prior to collection of the semen, in the case of collections of fresh semen;		
	II.4.5. have not served naturally after their entry to the quarantine accommodation described in point II.3.3 and up to and including the day of semen collection;		
	II.4.6. have been kept at the approved semen collection centres:		
	II.4.6.1. which have been free from foot-and-mouth disease for at least three months prior to collection of the semen and 30 days after collection or, in the case of fresh semen, until the date of dispatch, and which are situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease for at least 30 days prior to collection of the semen;		
	II.4.6.2. which have been free, during the period commencing 30 days prior to collection and ending 30 days after collection of the semen or, in the case of fresh semen, until the date of dispatch, from brucellosis (*B. melitensis*), contagious epididymitis (*Brucella. ovis*), anthrax and rabies;		

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COUNTRY **Ovine and caprine semen — Section A**

II.	Health information		II.a. Certificate reference No	II.b.
(1) either	[II.4.7.	have remained in the exporting country for at least the past six months prior to collection of the semen to be exported;]		
(1) or	[II.4.7.	during the past six months prior to collection of the semen they satisfied the animal health conditions applying to donors of the semen which is intended for export to the Union and they have been imported into the exporting country at least 30 days prior to collection of the semen from ..... (2);]		
(1) either	[II.4.8.	were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during, collection of the semen;]		
(1) or	[II.4.8.	were kept during a bluetongue virus seasonally free period in a seasonally free zone for at least 60 days prior to, and during collection of the semen;]		
(1) or	[II.4.8.	were kept in a vector-protected establishment for at least 60 days prior to, and during collection of the semen;]		
(1) or	[II.4.8.	were subjected to 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, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment of semen;]		
(1) or	[II.4.8.	were subjected to an agent identification test for bluetongue virus, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals with negative results on blood samples taken at commencement and final collection for this consignment of semen and at least every seven days (virus isolation test) or at least every 28 days (PCR test) during collection for this consignment of semen;]		
	II.4.9.	were resident in the exporting country,		
(1)(5) either	[II.4.9.1.	which according to official findings is free from epizootic haemorrhagic disease (EHD);]		
(1) or	[II.4.9.1.	in which according to official findings the following serotypes of epizootic haemorrhagic disease (EHD) exist: ..... and were subjected with negative results in each case to:		
	(1) either	[on two occasions not more than 12 months apart in a serological test (6) carried out in an approved laboratory on samples of blood taken prior to and not less than 21 days following collection for this consignment of semen.]		
	(1) or	[a serological test (6) for the detection of antibody to the EHDV group, carried out on samples taken at intervals of not more than 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment of semen.]		
	(1) or	[an agent identification test (6) carried out in approved laboratories on blood samples collected at commencement and conclusion of, and at least every seven days (virus isolation test) or at least every 28 days (PCR test) during collection for this consignment of semen.]]		
II.5.	The semen to be exported:			
	II.5.1.	was collected after the date on which the semen collection centre was approved by the competent authority of the exporting country;		
	II.5.2.	was collected, processed, preserved, stored and transported in accordance with the requirements applicable to semen laid down in Chapter III(I) of Annex D to Directive 92/65/EEC;		
(1) either	[II.5.3.	meets the requirements of Chapter A(I) of Annex VIII to Regulation (EC) No 999/2001;]		
(1) or	[II.5.3.	meets the requirements of Chapter A(I) of Annex VIII to Regulation (EC) No 999/2001 and is destined for a Member State which benefits, for all or part of its territory, from the provisions laid down in point (b) or (c) of Chapter A(I) of Annex VIII to Regulation (EC) No 999/2001 and the donor animals comply regarding scrapie with the guarantees provided for by the national scrapie control program referred to in those points and with the guarantees (7) requested by the Member State of destination;]		
	II.5.4.	was sent to the place of loading in a sealed container in accordance with the requirements for semen to be subject to trade laid down in point 1.4 of Chapter III(I) of Annex D to Directive 92/65/EEC and bearing the number indicated in Box I.23.		
(1) either	[II.6.	No antibiotics were added to the semen.]		

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COUNTRY **Ovine and caprine semen — Section A**

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

(1) or [II.6. The following antibiotic or combination of antibiotics was added to produce a concentration in the final diluted semen of not less than (8):

.....]

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 approved semen collection centre in which the semen was collected and listed in accordance with Article 17(3)(b) of Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/ovine/index_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 "*Ovis aries*" or "*Capra hircus*" as appropriate.

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 centre shall correspond to the approval number of the semen collection centre indicated in Box I.11.

Part II:

(1) Delete as necessary.

(2) Only third countries listed in Annex I to Decision 2010/472/EU.

(3) Tests shall be carried out in accordance with Annex C to Directive 91/68/EEC.

(4) Only for the territory appearing with the entry "V" in column 6 of Part 1 of Annex I to Commission Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010, p. 1).

(5) See remarks for exporting country concerned in Annex I to Decision 2010/472/EU.

(6) Standards for EHD virus diagnostic tests are described in Chapter 2.1.3 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

(7) Additional guarantees as laid down in Article 2 of Regulation (EC) No 546/2006 (OJ L 94, 1.4.2006, p. 28).

(8) Insert names and concentrations.

Official veterinarian (*)

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

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

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Section B

MODEL 2 — Health certificate for semen dispatched from an approved semen storage centre

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. No(s) of related original certificates
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 the EU to a third country ☐ Third country / ISO code	I.27. For import or admission into the EU ☐

I.28. Identification of the commodities

Species (scientific name)	Breed	Donor identity	Date of collection	Approval number of the centre	Quantity

▼B

COUNTRY: **Ovine and caprine semen — Section A**

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

Part II: Certification

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

II.1. The centre (3) described in Box I.11 at which the semen to be exported to the European Union was stored:

(1) either [II.1.1. meets the conditions laid down in Chapter I(I)(1) of Annex D to Directive 92/65/EEC;

and II.1.2. is operated and supervised in accordance with the conditions laid down in Chapter I(II)(1) of Annex D to Directive 92/65/EEC.]

(1) or [II.1.1. meets the conditions laid down in Chapter I(I)(2) of Annex D to Directive 92/65/EEC;

and II.1.2. is operated and supervised in accordance with the conditions laid down in Chapter I(II)(2) of Annex D to Directive 92/65/EEC.]

II.2. The semen to be exported to the European Union:

II.2.1. has been collected, processed and stored for a minimum period of 30 days immediately following collection in an approved semen collection centre (4) operated and supervised in accordance with Chapter I(I)(1) and Chapter I(II)(1) of Annex D to Directive 92/65/EEC, and

(1) either [located in the exporting country;]

(1) and/or [located in ..... (5);

and has been imported to the exporting country under conditions at least as strict as for imports of semen of ovine and caprine species into the European Union in accordance with Directive 92/65/EEC;]

II.2.2. was moved to the centre described in Part I.11 under conditions at least as strict as in Section A of Part 2 of Annex II to Decision 2010/472/EU (6);]

II.2.3. was stored under conditions which satisfy the terms of Annex D to Directive 92/65/EEC;

II.2.4. was sent to the place of loading in a sealed container in accordance with point 1.4 of Chapter III(I) of Annex D to Directive 92/65/EEC and bearing the number indicated in Box I.23.

Notes

Part I:

Box I.11: place of origin shall correspond to the approved semen storage centre of dispatch of the semen.

Box I.17: shall correspond to the serial number of the individual official document(s) or health certificate(s) that accompanied the semen described above from the approved semen collection centre of its origin to the centre described in Box I.11. The original(s) of those document(s) or those certificate(s) or the officially endorsed copies of thereof must be attached to this certificate.

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.28: 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 centre shall correspond to the approval number of the approved semen collection centre in which the semen was collected.

▼B

COUNTRY: **Ovine and caprine semen — Section B**

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

Part II:

(1) Delete as necessary.

(2) Only third countries listed in Annex I to Decision 2010/472/EU.

(3) Only approved semen collection or storage centres listed in accordance with Article 17(3)(b) of Directive 92/65/EEC on the Commission website:

http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm

(4) Only approved semen collection centres listed in accordance with Article 11(4) and 17(3)(b) of Directive 92/65/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/ovine/index_en.htm

(5) Only third countries listed in Annex I to Decision 2010/472/EU and the EU Member States.

(6) The original(s) of the document(s) or the health certificate(s) or the officially endorsed copies of thereof that accompanied the semen described above from the approved semen collection centre in which the semen was collected to the approved semen storage centre of the semen dispatch described in Box I.11 must be attached to this certificate.

Official veterinarian (*)

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

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

▼**M1**

ANNEX III

List of third countries or parts thereof from which Member States are to authorise imports of consignments of ova and embryos of animals of the ovine and caprine species

ISO Code	Name of the third country	Remarks	
		Description of the territory *(if appropriate)*	Additional guarantees
AU	Australia		The additional guarantee as regards testing set out in point II.2.6.1 of the model health certificate set out in Part 2 of Annex IV is compulsory.
CA	Canada		The additional guarantee as regards testing set out in point II.2.6.1 of the model health certificate set out in Part 2 of Annex IV is compulsory.
CH	Switzerland [1]		
CL	Chile		
GL	Greenland		
HR	Croatia		
IS	Iceland		
NZ	New Zealand		
PM	Saint Pierre and Miquelon		
US	United States		The additional guarantee as regards testing set out in point II.2.6.1 of the model health certificate set out in Part 2 of Annex IV is compulsory.

[1] Certificates in accordance with the Agreement between the European Community and the Swiss Confederation on Trade in Agricultural Products as approved by Decision 2002/309/EC.

▼B

ANNEX IV

PART 1

Explanatory notes for the certification

(a) The health certificates shall be issued by the competent authority of the exporting third country, in accordance with the model set out in Part 2 of Annex IV.

If the Member State of destination requires additional certification requirements, attestations to certify that those requirements are fulfilled shall be also incorporated in the original form of the health certificate.

(b) The original of the health certificate shall consist of a single sheet of paper, or, where more text is required, it must be in such a form that all sheets of paper required are part of an integrated whole and indivisible.

(c) Where the model health certificate states that certain statements shall be kept as appropriate, statements which are not relevant, may be crossed out and initialled and stamped by the certifying officer, or completely deleted from certificate.

(d) The health certificate shall be drawn up in at least one of the official languages of the Member State of the border inspection post of introduction of the consignment into the European Union and of the Member State of destination. However, those Member States may authorise the certificate to be drawn up in the official language of another Member State, and accompanied, if necessary, by an official translation.

(e) If for the reasons of identification of the items of the consignment (schedule in Box I.28 of the model health certificate), additional sheets of paper are attached to the health certificate, those sheets of paper shall also be considered as forming part of the original of the health certificate by application of the signature and stamp of the certifying officer, on each of the pages.

(f) When the health certificate, including additional schedules referred to in (e), comprises more than one page, each page shall be numbered (page number) of (total number of pages), at the end of the page and shall bear the certificate reference number that has been designated by the competent authority on the top of the pages.

(g) The original of the health certificate must be completed and signed by an official veterinarian the last working day prior to loading of the consignment for exportation to the European Union. The competent authorities of the exporting third country shall ensure that certification requirements equivalent to those laid down in Council Directive 96/93/EC [1] are followed.

The colour of the signature and the stamp of the official veterinarian shall be different to that of the printing on the health certificate. This requirement also applies to stamps other than those embossed or watermarks.

(h) The original of the health certificate must accompany the consignment until it reaches the border inspection post of introduction into the European Union.

(i) The certificate reference number referred to in Box I.2 and Box II.a of the model health certificate must be issued by the competent authority of the exporting third country.

[1] OJ L 13, 16.1.1997, p. 28.

▼M1

PART 2

Model health certificate for imports of consignments of ova and embryos of animals of the ovine and caprine species

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	Donor identity	Date of collection	Date of freezing	Approval number of the team	Quantity

▼M1

COUNTRY **Ovine and caprine ova/embryos**

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

I, the undersigned, official veterinarian, hereby certify that:

Part II: Certification

II.1. The exporting country .....
(name of exporting country) (2)

II.1.1. has been free from rinderpest, peste des petits ruminants, sheep and goat pox, contagious caprine pleuropneumonia, and Rift Valley fever during the 12 months immediately prior to collection of the ova/embryos (1) to be exported and until their date of dispatch to the Union and no vaccination against these diseases took place during that period;

(1) either [II.1.2. has been free from foot-and-mouth disease during the 12 months immediately prior to collection of the ova/embryos (1) and did not carry out vaccination against foot-and-mouth disease during that period;]

(1) or [II.1.2. has not been free from foot-and-mouth disease during the 12 months immediately prior to collection of the ova/embryos (1) and/or carried out vaccination against foot-and-mouth disease during that period and the donor females come from holdings on which no animal was vaccinated against foot-and-mouth disease during 30 days prior to collection and no animal of susceptible species showed clinical signs of foot-and-mouth disease during the 30 days prior to, and at least 30 days after, the ova/embryos (1) were collected and the ova/embryos (1) were not subjected to penetration of *zona pellucida*;]

II.2. The ova/embryos (1) to be exported:

II.2.1. were collected/produced (1) and processed on premises within a 10-km radius of which there was no incidence of foot-and-mouth disease, vesicular stomatitis, Rift Valley fever in the 30 days immediately prior to their collection;

II.2.2. were stored at all times on approved premises within a 10-km radius of which there was no incidence of foot-and-mouth disease, vesicular stomatitis or Rift Valley fever from the time of their collection until 30 days thereafter;

II.2.3. were collected/produced (1) by the team described in Box I.11, which has been approved and supervised in accordance with the conditions for the approval and supervision of embryo collection teams and embryo production teams laid down in Chapter I(III) of Annex D to Directive 92/65/EEC;

II.2.4. meet the conditions for ova and embryos laid down in Chapter III(II) of Annex D to Directive 92/65/EEC;

II.2.5. come from the donor females of ovine/caprine (1) species which:

(1) either [II.2.5.1. were kept in a bluetongue virus-free country or zone for at least 60 days prior to, and during collection of the ova/embryos (1);]

(1) or [II.2.5.1. were kept during a bluetongue virus seasonally free period in a seasonally free zone;]

(1) or [II.2.5.1. were kept protected from the vector for at least 60 days prior to, and during the collection of the ova/embryos (1);]

(1) or [II.2.5.1. 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 of the ova/embryos (1) and giving negative results;]

(1) or [II.2.5.1. underwent an agent identification test for bluetongue virus, carried out in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on a blood sample taken on the day of the ova/embryos (1) collection or the day of slaughtering and giving negative results;]

II.2.5.2. to the best of my knowledge do not come from holdings and have not been in contact with animals of a holding, in which, based on the official notification system and according to the written declaration made by the owner, any of the following diseases has been clinically detected within the periods referred to in (a) to (d) prior to collection of the ova/embryos (1) to be exported:

(a) contagious agalactia of sheep or goats (*Mycoplasma agalactiae, Mycoplasma capricolum, Mycoplasma mycoides var. mycoides* "large colony"), within the last six months;

(b) paratuberculosis and caseous lymphadenitis, within the last 12 months;

(c) pulmonary adenomatosis, within the last three years;

(1) either [(d) Maedi/Visna for sheep or caprine viral arthritis/encephalitis for goats, within the last three years;]

(1) or [(d) Maedi/Visna for sheep or caprine viral arthritis/encephalitis for goats, within the last 12 months, and all the infected animals were slaughtered and remaining animals subsequently reacted negatively to two tests carried out at least six months apart;]

▼M1

COUNTRY **Ovine and caprine ova/embryos**

II. Health information			II.a. Certificate reference No	II.b.
	II.2.5.3.	showed no clinical signs of disease on the day of the ova/embryos (1) collection;		
(1)(4) either	[II.2.5.4	originate from the region described in Box I.8., which has been recognised as officially brucellosis *(B. melitensis)*-free, and]		
(1) or	[II.2.5.4.	have belonged to a holding which has obtained and maintained its officially brucellosis (*B. melitensis*)-free status in accordance with Directive 91/68/EEC, and]		
(1) or	[II.2.5.4.	originate from a holding, where in respect of brucellosis (*B. melitensis*) all susceptible animals have been free from any clinical or any signs of this disease for the last 12 months, none of the ovine and caprine animals have been vaccinated against this disease, save those vaccinated with Rev. 1 vaccine more than two years ago, and all ovine and caprine animals over six months of age have been subjected to at least two tests (3) , carried out with negative results on samples taken on ..... (*date*) and on ..... (*date*) at least six months apart, the latter being within 30 days prior to collection of the ova/embryos (1),]		
and		have not been kept previously in a holding of a lower status;		
(1) either	[II.2.5.5.	have remained in the exporting country for at least the past six months prior to collection of the ova/embryos (1) to be exported;]		
(1) or	[II.2.5.5	during the past six months prior to collection of the ova/embryos (1) they satisfied the animal health conditions applying to donors of the ova/embryos (1) which are intended for export to the Union and they have been imported into the exporting country at least 30 days prior to collection of the ova/embryos (1) from ..... (2);]		
	[II.2.6.	were collected/produced (1) in the exporting country,		
(1) either	[II.2.6.1.	which according to official findings is free from epizootic haemorrhagic disease (EHD);]		
▶(1) *(1)(5) or*	[II.2.6.1.	in which according to official findings the following serotypes of epizootic haemorrhagic disease (EHD) exist: ..... and the donors were subjected with negative results in each case to:		
	(1) either	[on two occasions not more than 12 months apart in a serological test (6) carried out in an approved laboratory on samples of blood taken prior to and not less than 21 days following collection for this consignment of ova/embryos (1);]		
	(1) or	[a serological test (6) for the detection of antibody to the EHDV group, carried out on samples taken at intervals of not more than 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment of ova/embryos (1);]		
	(1) or	[an agent identification test (6) carried out in approved laboratories on blood samples collected at commencement and conclusion of, and at least every seven days (virus isolation test) or at least every 28 days (PCR test) during collection for this consignment of ova/embryos (1);]]		
(1) either	[II.2.7.	meet the requirements of Chapter A(I) of Annex VIII to Regulation (EC) No 999/2001;]		
(1) or	[II.2.7.	meet the requirements of Chapter A(I) of Annex VIII to Regulation (EC) No 999/2001 and are destined for a Member State which benefits, for all or part of its territory, from the provisions laid down in point (b) or (c) of Chapter A(I) of Annex VIII to Regulation (EC) No 999/2001 and the donor animals comply regarding scrapie with the guarantees provided for by the national scrapie control program referred to in that point and with the guarantees (7) requested by the Member State of destination;]		
	II.2.8.	were collected/produced (1) after the date on which the embryo collection team was approved by the competent authority of the exporting country;		
	II.2.9.	were processed and stored under approved conditions for at least 30 days immediately after their collection/production (1) and transported under conditions for ova and embryos laid down in Chapter III(II) of Annex D to Directive 92/65/EEC;		
	II.2.10.	were sent to the place of loading in a sealed container in accordance with the requirements for the transport of embryos laid down in point 6 of Chapter III(II) of Annex D to Directive 92/65/EEC and bearing the number detailed in Box I.23;		
	(9) II.2.11.	were conceived by artificial insemination/as a result of *in vitro* fertilisation (1) using semen coming from semen collection centres.		
(1) either	[II.2.11.1.	approved in accordance with Article 11(2) of Directive 92/65/EEC and located in a Member State of the European Union, and the semen complies with the requirements of Directive 92/65/EEC.]		
(1) or	[II.2.11.1.	approved in accordance with Article 17(3)(b) of Directive 92/65/EEC and located in a third country or part thereof listed in Annex I to Decision 2010/472/EU, and the semen complies with the requirements set out in Part 2 of Annex II to that Decision.] ◀		

▼M1

COUNTRY **Ovine and caprine ova/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 approved embryo collection team or embryo production team by which the ova/embryos were collected/produced, processed and stored; and listed in accordance with Article 17(3)(b) of Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/ovine/index_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 "*Ovis aries*" or "*Capra hircus*" as appropriate.

Category: specify if *in vivo* derived embryos, *in vivo* derived ova, *in vitro* produced embryos or micromanipulated embryos.

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

Date of collection shall be indicated for *in vivo* derived embryos and in the following format: dd.mm.yyyy.

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

Approval number of the team: shall correspond to the approved embryo collection team or embryo production team by which the ova/embryos were collected/produced, processed and stored; and listed in accordance with Article 17(3)(b) of Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm

Part II:

(1) Delete as appropriate.

(2) Only third countries or parts thereof listed in Annex I to Decision 2010/472/EU.

(3) Tests shall be carried out in accordance with Annex C to Directive 91/68/EEC.

(4) Only for the territory appearing with the entry "V" in column 6 of Part 1 of Annex I to Commission Regulation (EU) No 206/2010 (OJ L 73, 20.3.2010).

(5) See remarks for exporting country or part thereof concerned in Annex III to Decision 2010/472/EU.

(6) Standards for EHD virus diagnostic tests are described in Chapter 2.1.3 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.

(7) Additional guarantees as laid down in Article 2 of Regulation (EC) No 546/2006 (OJ L 94, 1.4.2006, p. 28).

(8) Only approved semen collection centres listed in accordance with Article 11(4) and Article 17(3)(b) of Directive 92/65/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/ovine/index_en.htm

(9) Does not apply to ova.

Official veterinarian (*)

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

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