COMMISSION IMPLEMENTING DECISION

of 20 September 2013

amending Decisions 2010/470/EU and 2010/472/EU as regards the animal health requirements relating to scrapie for trade in and imports into the Union of semen, ova and embryos of animals of the ovine and caprine species

(notified under document C(2013) 5917)

(Text with EEA relevance)

(2013/470/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 the fourth indent of Article 11(2), the third indent of Article 11(3), Article 17(2)(b), the first indent of Article 18(1), and the introductory phrase and point (b) of Article 19 thereof,

Whereas:

(1) Commission Decision 2010/470/EU [2] lays down model health certificates for trade within the Union, inter alia, in consignments of semen and of ova and embryos of animals of the ovine and caprine species. Annexes III and IV to that Decision set out the relevant model health certificates.

(2) Commission Decision 2010/472/EU [3] lays down, inter alia, certification requirements for the importation into the Union of consignments of semen and of ova and embryos of animals of the ovine and caprine species. Part 2 of Annex II and Part 2 of Annex IV to that Decision set out the relevant model health certificates.

(3) Regulation (EC) No 999/2001 of the European Parliament and of the Council [4] lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine, and caprine animals. Chapter A of Annex VIII to that Regulation lays down the conditions for intra-Union trade in live animals, semen and embryos. In addition, Annex IX to that Regulation lays down the conditions for the importation of live animals, embryos, ova and products of animal origin into the Union.

(4) In the light of new scientific evidence, Regulation (EC) No 999/2001 was amended by Commission Regulation (EU) No 630/2013 [5]. The amendments to Regulation (EC) No 999/2001 lift most of the restrictions with regards to atypical scrapie. They also further align to the World Organisation for Animal Health (OIE) standards the rules relating to intra-Union trade in and imports of ovine and caprine animals and their semen and embryos to reflect a stricter approach as regards classical scrapie.

(5) The model health certificates for intra-Union trade in consignments of semen and of ova and embryos of animals of the ovine and caprine species set out in Annexes III and IV to Decision 2010/470/EU and the model health certificates for imports into the Union of consignments of semen and of ova and embryos of animals of the ovine and caprine species set out in Annexes II and IV to Decision 2010/472/EU should therefore be amended in order to reflect the requirements laid down in Regulation (EC) No 999/2001, as amended by Regulation (EU) No 630/2013.

(6) Decisions 2010/470/EU and 2010/472/EU should therefore be amended accordingly.

(7) To avoid any disruption of trade in and imports into the Union of consignments of semen and of ova and embryos of animals of the ovine and caprine species, the use of health certificates issued in accordance with Decision 2010/470/EU and Decision 2010/472/EU in their versions prior to the amendments introduced by this Decision should be authorised during a transitional period subject to certain conditions.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

[1] OJ L 268, 14.9.1992, p. 54.

[2] Commission Decision 2010/470/EU of 26 August 2010 laying down model health certificates for trade within the Union in semen, ova and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species (OJ L 228, 31.8.2010, p. 15).

[3] Commission Decision 2010/472/EU of 26 August 2010 on imports of semen, ova and embryos of animals of the ovine and caprine species into the Union (OJ L 228, 31.8.2010, p. 74).

[4] Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

[5] Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 179, 29.6.2013, p. 60).

HAS ADOPTED THIS DECISION:

Article 1

Annexes III and IV to Decision 2010/470/EU are amended in accordance with Annex I to this Decision.

Article 2

Annexes II and IV to Decision 2010/472/EU are amended in accordance with Annex II to this Decision.

Article 3

1. For a transitional period until 31 December 2014, Member States shall authorise trade within the Union in consignments of:

(a) semen of animals of the ovine and caprine species which was collected, processed and stored in accordance with Directive 92/65/EEC until 31 December 2013 and which are accompanied by a health certificate issued not later than 31 December 2014 in accordance with the model health certificate set out in Part A of Annex III to Decision 2010/470/EU in its version prior to the amendments introduced by this Decision;

(b) ova and embryos of animals of the ovine and caprine species which were collected, processed and stored in accordance with Directive 92/65/EEC until 31 December 2013 and which are accompanied by a health certificate issued not later than 31 December 2014 in accordance with the model health certificate set out in Part A of Annex IV to Decision 2010/470/EU in its version prior to the amendments introduced by this Decision.

2. For a transitional period until 31 December 2014, Member States shall authorise imports into the Union of consignments of:

(a) semen of animals of the ovine and caprine species which was collected, processed and stored in accordance with Directive 92/65/EEC until 31 December 2013 and which are accompanied by a health certificate issued not later than 31 December 2014 in accordance with the model health certificate set out in Section A of Part 2 of Annex II to Decision 2010/472/EU in its version prior to the amendments introduced by this Decision;

(b) ova and embryos of animals of the ovine and caprine species which were collected, processed and stored in accordance with Directive 92/65/EEC until 31 December 2013 and which are accompanied by a health certificate issued not later than 31 December 2014 in accordance with the model health certificate set out in Part 2 of Annex IV to Decision 2010/472/EU in its version prior to the amendments introduced by this Decision.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 20 September 2013.

For the Commission

Tonio BORG

Member of the Commission

ANNEX I

Annexes III and IV to Decision 2010/470/EU are amended as follows:

(1) in Annex III, Part A is replaced by the following:

'PART A

Model health certificate IIIA for trade within the Union in consignments of semen of animals of the ovine and caprine species collected in accordance with Council Directive 92/65/EEC after 31 August 2010 and dispatched from an approved semen collection centre of origin of the semen

EUROPEAN UNION **Intra trade certificate**

Part I: Details of consignment presented

I.1. Consignor Name Address Postal code	I.2. Certificate reference No	I.2.a. Local reference No
	I.3. Central competent authority	
	I.4. Local competent authority	
I.5. Consignee Name Address Postal code	I.6.	
	I.7.	
I.8. Country of origin ISO code I.9. Region of origin Code	I.10. Country of destination ISO code I.11. Region of destination Code	
I.12. Place of origin Semen centre ☐ Name Approval number Address Postal code	I.13. Place of destination Semen centre ☐ Holding ☐ Name Approval number Address Postal code	
I.14.	I.15.	
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification	I.17.	
I.18. Description of commodity	I.19. Commodity code (CN code) **05 11 99 85**	
	I.20. Quantity	
I.21. Temperature of products Ambient ☐ Chilled ☐ Frozen ☐	I.22. Number of packages	
I.23. Seal/Container No	I.24. Type of packaging	
I.25. Commodities certified for: Artificial reproduction ☐		
I.26. Transit through third country ☐ Third country ISO code Exit point Code Entry point BIP No	I.27. Transit through Member States ☐ Member State ISO code Member State ISO code Member State ISO code	
I.28. Export ☐ Third country ISO code Exit point Code	I.29.	
I.30.		

I.31. Identification of the commodities

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

EUROPEAN UNION **Ovine and caprine semen — Part 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 semen described above:

II.1.1. was collected, processed and stored in a semen collection centre ([2]) approved and supervised by the competent authority in accordance with Chapter I(I)(1) and Chapter I(II)(1) of Annex D to Directive 92/65/EEC;

II.1.2. comes from donor animals which meet the requirements of Chapter II(II) of Annex D to Directive 92/65/EEC;

II.1.3. was collected, processed, stored and transported under conditions which comply with the requirements of Chapters II(II) and III(I) of Annex D to Directive 92/65/EEC;

([1]) either [II.1.4. was collected from animals which have been kept continuously since birth on a holding or holdings recognised as having a negligible or controlled risk of classical scrapie according to point 1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.]

([1]) or [II.1.4. was collected from animals which have been kept continuously for the last three years before the collection on a holding or holdings which has/have complied for the last three years before the collection with the requirements laid down in points 1.3(a) to (f) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.]

([1]) or [II.1.4. was collected from animals which have been kept continuously since birth in a Member State or zone of a Member State with a negligible risk status for classical scrapie approved in accordance with point 2.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.]

([1]) or [II.1.4. was collected from ovine animals of the ARR/ARR prion protein genotype;]

II.1.5. 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 detailed in Box I.23.

([1]) either [II.2. No antibiotics or no mixture of antibiotics were added to the semen.]

([1]) or [II.2. The following antibiotic or combination of antibiotics was added to produce a concentration in the final diluted semen of not less than ([3]):

.....]

Notes

Part I:

Box I.12.: *Place of origin* shall correspond to the semen collection centre of origin of the semen.

Box I.13.: *Place of destination* shall correspond to the semen collection or storage centre or to the holding of semen destination.

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

Box I.31.: *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 centre indicated in Box I.12 where the semen was collected.

Part II:

([1]) Delete as appropriate.

([2]) Only approved semen collection centres listed in accordance with Article 11(4) of Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/approved_establishments/establishments_vet_field_en.htm

([3]) Insert names and concentrations.

— The colour of the stamp and signature must be different from that of the other particulars in the certificate.

EUROPEAN UNION **Ovine and caprine semen — Part A**

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

Official veterinarian or official inspector

Name (in capital letters): Qualification and title:

Local veterinary unit: LVU No:

Date: Signature:

Stamp:'

(2) in Annex IV, Part A is replaced by the following:

'PART A

Model health certificate IVA for trade within the Union in consignments of ova and embryos of animals of the ovine and caprine species collected or produced in accordance with Council Directive 92/65/EEC after 31 August 2010 and dispatched by an approved embryo collection or production team of origin of the ova or embryos

EUROPEAN UNION **Intra trade certificate**

Part I: Details of consignment presented

I.1. Consignor
Name
Address
Postal code

I.2. Certificate reference No | I.2.a. Local reference No

I.3. Central competent authority

I.4. Local competent authority

I.5. Consignee
Name
Address
Postal code

I.6.

I.7.

I.8. Country of origin ISO code | I.9. Region of origin Code

I.10. Country of destination ISO code | I.11. Region of destination Code

I.12. Place of origin
Embryo team ☐
Name Approval number
Address
Postal code

I.13. Place of destination
Holding ☐ Embryo team ☐
Name Approval number
Address
Postal code

I.14.

I.15.

I.16. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification

I.17.

I.18. Description of commodity

I.19. Commodity code (CN code)
05 11 99 85

I.20. Quantity

I.21. Temperature of products
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Seal/Container No

I.24. Type of packaging

I.25. Commodities certified for:
Artificial reproduction ☐

I.26. Transit through third country ☐
Third country ISO code
Exit point Code
Entry point BIP No

I.27. Transit through Member States ☐
Member State ISO code
Member State ISO code
Member State ISO code

I.28. Export ☐
Third country ISO code
Exit point Code

I.29.

I.30.

I.31. Identification of the commodities

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

EUROPEAN UNION **Ovine and caprine ova/embryos — Part A**

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

Part II: Certification

I, the undersigned official veterinarian, hereby certify that:

(1) either [II.1. the *in vivo* derived embryos (1)/*in vivo* derived ova (1) described above were collected, processed and stored by an embryo *collection* team (2) approved and supervised in accordance with Chapter I(III)(1) of Annex D to Directive 92/65/EEC;]

(1) or [II.1. the *in vitro* produced embryos (1)/micromanipulated embryos (1) described above were produced, processed and stored by an embryo production team (2) approved and supervised in accordance with Chapter I(III)(1) and (2) of Annex D to Directive 92/65/EEC;]

(1) either [II.2. the *in vivo* derived embryos described above meet the requirements of Chapter III(II)(1) of Annex D to Directive 92/65/EEC;]

(1) or [II.2. the *in vivo* derived ova described above meet the requirements of Chapter III(II)(2) of Annex D to Directive 92/65/EEC;]

(1) or [II.2. the *in vitro* produced embryos described above meet the requirements of Chapter III(II)(3) of Annex D to Directive 92/65/EEC;]

(1) or [II.2. the micromanipulated embryos described above meet the requirements of Chapter III(II)(4) of Annex D to Directive 92/65/EEC;]

(1) [II.3. the consignment consists of embryos of the ovine or caprine species which:

(1) either [were collected from animals which have been kept continuously since birth on a holding or holdings recognised as having a negligible or controlled risk of classical scrapie according to point 1 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]]

(1) or [were collected from animals which have been kept continuously for the last three years before the collection on a holding or holdings which have complied for the last three years before collection with the requirements laid down in point 1.3(a) to (f) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]]

(1) or [were collected from animals which have been kept continuously since birth in a Member State or zone of a Member State with a negligible risk status for classical scrapie approved in accordance with point 2.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]]

(1) or [were collected from ovine animals of the ARR/ARR prion protein genotype;]]

II.4. the ova or embryos described above come from female donors of the ovine (1)/caprine species (1) which meet the requirements of Chapter IV(3) of Annex D to Directive 92/65/EEC;

(1) either [II.5. the embryos described above were conceived as a result of artificial insemination of the donor females with semen which was collected, processed, stored and transported under conditions which comply with the requirements of Chapters I(I), II(I) and III(I) of Annex D to Directive 92/65/EEC;]

(1) or [II.5. the embryos described above were conceived as a result of *in vitro* fertilisation of ova complying with the conditions in Chapter III(II)(2) of Annex D to Directive 92/65/EEC with semen which was collected, processed, stored and transported under conditions which comply with the requirements of Chapters I(I), II(I) and III(I) of Annex D to Directive 92/65/EEC;]

(1) or [II.5. the ova have not been in contact with semen of the ovine and caprine species;]

II.6. the ova or embryos described above were sent to the place of loading in a sealed container in accordance with point 6 of Chapter III(II) of Annex D to Directive 92/65/EEC and bearing the number detailed in Box I.23.

Notes

Part I:

Box I.12.: *Place of origin* shall correspond to the embryo collection team or embryo production team of embryos collection/production.

Box I.13.: *Place of destination* shall correspond to the embryo collection team, embryo production team or to the holding of ova/embryos destination.

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

EUROPEAN UNION **Ovine and caprine ova/embryos — Part A**

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

Box I.31.: *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 in the following format: dd/mm/yyyy.

Approval number of the team shall correspond to the embryo collection team or embryo production team of ova/embryos collection/production.

Part II:

(1) Delete as appropriate.

(2) Only approved embryo collection or production teams listed in accordance with Article 11(4) of Directive 92/65/EEC on the Commission website: http://ec.europa.eu/food/animal/approved_establishments/establishments_vet_field_en.htm

— The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian or official inspector

Name (in capital letters): Qualification and title:

Local veterinary unit: LVU No:

Date: Signature:

Stamp:'

ANNEX II

Annexes II and IV to Decision 2010/472/EU are amended as follows:

(1) in Part 2 of Annex II, Section A is replaced by the following:

'**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	Donor identity	Date of collection	Approval number of the centre	Quantity

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 (1)/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 before 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 points (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:

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 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 1.6 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 for:

— 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 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 ([1])/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 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;

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 last six months prior to collection of the semen they complied with 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 for the detection of antibody to the bluetongue virus group, carried out in accordance with the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, with negative results, on blood samples taken 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;]		
(1)(5) either	[II.4.9.	were resident in the exporting country which according to official findings is free from epizootic haemorrhagic disease (EHD);]		
(1) or	[II.4.9.	were resident in the exporting country 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	[a serological test (6) for the detection of antibody to the EHDV group carried out in an approved laboratory on samples of blood taken on two occasions not more than 12 months apart prior to and not less than 21 days after the final collection for this consignment of semen.]]		
	(1) or	[a serological test (6) for the detection of antibody to the EHDV group, carried out in an approved laboratory on samples of blood 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 an approved laboratory on samples of blood taken 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.4.10.	have been kept continuously since birth in a country where the following conditions are fulfilled:		
	II.4.10.1.	classical scrapie is compulsorily notifiable;		
	II.4.10.2.	an awareness, surveillance and monitoring system is in place;		
	II.4.10.3.	ovine and caprine animals affected with classical scrapie are killed and completely destroyed;		
	II.4.10.4.	the feeding to ovine and caprine animals of meat-and-bone meal, or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period of at least the last seven years;		
(1) either	[II.4.11.	have been kept continuously for the last three years before the collection of the semen to be exported in a holding or holdings which has/have been complying for the last three years before the collection of the semen to be exported with the requirements laid down in points 1.3(a) to (f) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]		
(1) or	[II.4.11.	are ovine animals of ARR/ARR prion protein genotype.]		

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

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

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;

II.5.3. 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]) other [II.6. No antibiotics were added to the semen.]

([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 ([7]):

.....]

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]) Insert names and concentrations.

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

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

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

(2) in Annex IV, Part 2 is replaced by the following:

'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

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 (1)/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 (1)/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 (1)/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 (1)/embryos (1) were collected and the ova (1)/embryos (1) were not subjected to penetration of *zona pellucida*;]

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

II.2.1. were collected (1)/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 (1)/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 (1)/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 (1)/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 (1)/embryos (1);]

(1) or [II.2.5.1. underwent a serological test to detect antibody 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 (1)/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 (1)/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 points (a) to (d) prior to collection of the ova (1)/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;]

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 (1)/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 (1)/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 (1)/embryos (1) to be exported;]		
(1) or	[II.2.5.5.	during the past six months prior to collection of the ova (1)/embryos (1) they complied with the animal health conditions applying to donors of the ova (1)/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 (1)/embryos (1) from ..... (2);]		
	II.2.5.6.	have been kept continuously since birth in a country where the following conditions are fulfilled:		
	II.2.5.6.1.	classical scrapie is compulsorily notifiable;		
	II.2.5.6.2.	an awareness, surveillance and monitoring system is in place;		
	II.2.5.6.3.	ovine and caprine animals affected with classical scrapie are killed and completely destroyed;		
	II.2.5.6.4.	the feeding to ovine and caprine animals of meat-and-bone meal, or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period of at least the last seven years;		
(1) either	[II.2.5.7.	have been kept continuously for the last three years before the collection of the embryos to be exported in a holding or holdings which has/have been complying for the last three years before the collection of the embryos to be exported with the requirements laid down in points 1.3(a) to (f) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001;]		
(1) or	[II.2.5.7.	are ovine animals and the embryos of the ARR/ARR prion protein genotype;]		
	[II.2.6.	were collected (1)/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)(5) or	[II.2.6.1.	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	[a serological test (6) for the detection of antibody to the EHDV group carried out in an approved laboratory on samples of blood taken on two occasions not more than 12 months apart prior to and not less than 21 days following collection for this consignment of ova (1)/embryos (1);]]		
	(1) or	[a serological test (6) for the detection of antibody to the EHDV group, carried out on samples of blood 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 (1) /embryos (1);]]		
	(1) or	[an agent identification test (6) carried out in approved laboratories on samples of blood 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 (1)/embryos (1);]]		
	II.2.7.	were collected (1)/produced (1) after the date on which the embryo collection team was approved by the competent authority of the exporting country;		
	II.2.8.	were processed and stored under approved conditions for at least 30 days immediately after their collection (1)/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.2.9.	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.		

COUNTRY **Ovine and caprine ova/embryos**

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

([1]) [II.2.10. the consignment consists of embryos of the ovine or caprine species which were conceived by artificial insemination ([1])/as a result of *in vitro* fertilisation ([1]) using semen coming from semen collection centres approved ([7]) in accordance with:

([1]) either [II.2.10.1. 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.2.10.1. 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.]]

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, p. 1).

([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]) 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

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

COUNTRY **Ovine and caprine ova/embryos**

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