# Commission Decision 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 (notified under document number C(2008) 3625) (Text with EEA relevance) (2008/635/EC)

## COMMISSION DECISION

## 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

(notified under document number C(2008) 3625)

(Text with EEA relevance)

(2008/635/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to the animal health requirements laid down in the specific Community acts referred to therein. It also provides for the establishment of a list of those third countries or parts of third countries, able to provide guarantees equivalent to those provided for in Chapter II therein, from which Member States may import semen, ova and embryos of the ovine and caprine species.

(2) Directive 92/65/EEC also provides for the establishment of a list of semen and embryo collection centres in third countries, for which those third countries are able to give the guarantees referred to in Article 11 of that Directive.

(3) However, as regards collection centres for ova and embryos of the ovine and caprine species, for the sake of consistency of Community legislation, and taking into account international nomenclature, it is more appropriate to use the term ‘embryo collection teams’ instead of ‘collection centres’ in that case.

(4) Directive 92/65/EEC provides that semen, ova and embryos of the ovine and caprine species to be imported into the Community are to be accompanied by health certificates, models of which are to be established in accordance with that Directive.

(5) Directive 92/65/EEC also provides for the establishment of the specific animal health requirements or guarantees equivalent to those provided for in that Directive, for imports into the Community of semen, ova and embryos of the ovine and caprine species.

(6) Commission Decision 94/63/EC of 31 January 1994 drawing up a list of third countries from which Member States authorise imports of semen, ova and embryos of the ovine and caprine species and ova and embryos of the porcine species[(2)] provides that Member States are to authorise imports of semen, ova and embryos of the ovine and caprine species from the third countries appearing in the list in the Annex to Council Decision 79/542/EEC[(3)], from which imports of live animals of the ovine and caprine species are authorised.

(7) Decision 94/63/EC has now been repealed by Commission Decision 2008/636/EC[(4)].

(8) Accordingly, a list of third countries from which Member States are to authorise imports of semen, ova and embryos of the ovine and caprine species should be established by this Decision.

(9) The lists of semen collection centres and embryo collection teams from which Member States are to authorise imports of semen, ova and embryos of the ovine and caprine species, originating in third countries, should also be established by this Decision.

(10) Article 17(3) of Directive 92/65/EEC provides for the procedure of amendments to the lists of semen collection centres and embryo collection teams from which Member States are to authorise the imports of semen, ova and embryos of the ovine and caprine species. The amended lists are to be published on the website of the Commission[(5)].

(11) In the interests of consistency of Community legislation, the requirements governing intra-Community trade in ovine and caprine animals for breeding, and the specific test regimes for those animals, set out in Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals[(6)], should be taken into account in the model health certificate for imports of semen of the ovine and caprine species set out in this Decision.

(12) The animal health conditions for the importation into the Community of animals of the ovine and caprine species intended for breeding are laid down in Decision 79/542/EEC. Those requirements should also be taken into account in the model health certificate for imports of semen of the ovine and caprine species set out in this Decision.

(13) Certain infectious diseases of animals of the ovine and caprine species are transmissible via semen. Therefore, particular animal health tests identifying such diseases must be carried out according to specific test programmes reflecting the movements of the donors prior to, and during, the period of semen collection. Those tests and test programmes should be in line with international standards and therefore indicated in

the model health certificate for imports of semen of the ovine and caprine species set out in this Decision.

(14) Account should also be taken of the provisions of 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[7] and of Commission Regulation (EC) No 546/2006 of 31 March 2006 implementing Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards national scrapie control programmes and additional guarantees and derogating from certain requirements of Decision 2003/100/EC and repealing Regulation (EC) No 1874/2003[8].

(15) Sanitary conditions for the collection, processing, storage and transport of ova and embryos and the health conditions applied to donor females are laid down in Chapters III and IV of Annex D to Directive 92/65/EEC. However, it is necessary to provide for additional guarantees, in particular as regards the official veterinary supervision of embryo collection teams in this Decision.

(16) In the interests of clarity of Community legislation, it is appropriate to set out in this Decision a list of third countries and approved semen collection centres from which Member States are to authorise imports into the Community of semen of the ovine and caprine species, a list of third countries and approved embryo collection teams from which Member States are to authorise imports into the Community of ova and embryos of those species, and the certification requirements relating to such imports in order to gather all these requirements under a single act.

(17) In the application of the present Decision, account should be taken of the specific certification requirements provided for in point 7(b) 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[9], 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[10]. Therefore, for consignments of semen, ova or embryos of ovine or caprine species from Switzerland to the Community, the certificates provided for in Commission Decision 95/388/EC of 19 September 1995 determining the specimen certificate for intra-Community trade in semen, ova and embryos of the ovine and caprine species[11] should apply, as adopted in accordance with that Decision.

(18) In application of the present 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[12], as approved by Council Decision 1999/201/EC[13].

(19) In application of the present 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[14], as approved by Council Decision 97/132/EC[15].

(20) 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*

**Imports of semen**

The Member States shall authorise imports of semen of the ovine and caprine species, collected in a third country and in an approved semen collection centre, listed in Annex I, and complying with the animal health requirements set out in the model health certificate in Annex II.

*Article 2*

**Imports of ova and embryos**

The Member States shall authorise imports of ova and embryos of the ovine and caprine species, collected in a third country and by an approved embryo collection team, listed in Annex III, and complying with the animal health requirements set out in the model health certificate in Annex IV.

*Article 3*

**Applicability**

This Decision shall apply from 1 September 2008.

*Article 4*

**Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 22 July 2008.

*For the Commission*

Androulla VASSILIOU

*Member of the Commission*

# ANNEX I

## LIST OF THIRD COUNTRIES AND APPROVED SEMEN COLLECTION CENTRES FROM WHICH MEMBER STATES ARE TO AUTHORISE IMPORTS OF SEMEN OF THE OVINE AND CAPRINE SPECIES

| **ISO code** | **Name of the third country** | **Approval number of the centre** | **Name of the centre** | **Address of the centre** | **Date of approval of the centre** | **Remarks** | |
|---|---|---|---|---|---|---|---|
| | | | | | | **Description of the territory(if appropriate)** | **Additional guarantees** |
| AU | Australia | | | | | | The additional guarantees as regards testing set out in points II.4.8 and II.4.9 of the certificate in Annex II are compulsory. |
| CA | Canada | | | | | Territory as described in Part 1 of Annex I to Decision 79/542/ EEC (as last amended). | The additional guarantee as regards testing set out in point II.4.8 of the certificate in Annex II is compulsory. |
| CH | Switzerland | | | | | | |
| 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.4.8 of the certificate in Annex II is compulsory. |

Notes

(a) Health certificates shall be produced by the exporting country, based on the model appearing in Annex II. They shall contain, in the numbered order that appears in the model, the attestations that are required for any third country and, as the case may be, those supplementary guarantees that are required for the exporting third country as indicated in Annex I.
If so requested by the EU Member State of destination, the additional certification requirements shall be also incorporated in the original form of the health certificate.

(b) The original of each certificate shall consist of a single page, both sides, or, where more text is required; it shall be in such a form that all pages needed are part of an integrated whole and indivisible.

(c) It shall be drawn up in at least one of the official languages of the EU Member State in which the inspection at the border post shall be carried out and of the EU Member State of destination. However, these Member States may allow another Community language instead of their own, accompanied, if necessary, by an official translation.

(d) If for reasons of identification of the items of the consignment (schedule in point I.28 of the model of certificate), additional pages are attached to the certificate, these pages shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying official veterinarian, on each of the pages.

(e) When the certificate, including additional schedules referred to in (d), comprises more than one page, each page shall be numbered — (*page number*) of (*total number of pages*) — on its bottom and shall bear the code number of the certificate that has been designated by the competent authority on its top.

(f) The original of the certificate must be completed and signed by an official veterinarian the last working day prior to loading of the consignment for exportation to the Community. In doing so, the competent authorities of the exporting country shall ensure that principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.
The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermarked.

(g) The original of the certificate must accompany the consignment until it reaches the EU border inspection post.

(h) The certificate shall be valid for 10 days from the date of issuing. In the case of transport by ship the time of validity is prolonged by the time of the trip in the ship.

(i) Semen and ova/embryos shall not be transported in the same container together with other semen and ova/embryos that, either is/are not destined for the European Community, or is/are of a lower health status.

(j) During its transport to the European Community, the container shall remain closed and the seal shall not be broken.

(k) The certificate reference number referred to in Boxes I.2 and II.a. must be issued by the competent authority.

# ANNEX II

## Model health certificate for import of semen of the ovine and caprine species

**COUNTRY** **Veterinary certificate to EU**

**Part I: Details of dispatched consignment**

| | | | |
|---|---|---|---|
| I.1. Consignor<br>Name<br>Address<br>Tel. | | I.2. Certificate reference number | I.2.a |
| | | I.3. Central Competent Authority | |
| | | I.4. Local Competent Authority | |
| I.5. Consignee<br>Name<br>Address<br>Postal code<br>Tel. | | I.6. Person responsible for the load in EU<br>Name<br>Address<br>Postal code<br>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<br>Name Approval number<br>Address<br>Name Approval number<br>Address<br>Name Approval number<br>Address | | I.12. Place of destination<br>Name<br>Address<br>Postal code | |
| I.13. Place of loading | | I.14. Date of departure | |
| I.15. Means of transport<br>Aeroplane ☐ Ship ☐ Railway wagon ☐<br>Road vehicle ☐ Other ☐<br>Identification:<br>Documentary references: | | I.16. Entry BIP in EU | |
| | | I.17. | |
| I.18. Description of commodity | | I.19. Commodity code (HS code)<br>**05 11 99 90** | |
| | | I.20. Quantity | |
| I.21. | | I.22. Number of packages | |
| I.23. Identification of container/Seal number | | I.24. | |
| I.25. Commodities certified for:<br>Artificial reproduction ☐ | | | |
| I.26. For transit through EU to third Country ☐<br>Third country ISO code | | I.27. For import or admission into EU ☐ | |

I.28. Identification of the commodities

| Species (Scientific name) | Identification mark | Approval number of the centre | Quantity |
|---|---|---|---|
| | | | |

**COUNTRY** **Ovine and caprine semen**

**Part II: Certification**

| II. Health information | II.a. Certificate reference number | II.b. |
|---|---|---|
| | | |

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 up until its date of dispatch 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 up until its date of dispatch and no vaccination against this disease took place during that period;

II.2. the centre at which the semen to be exported was collected and stored:

II.2.1. meets the conditions laid down in Chapter I(I) of Annex D to Directive 92/65/EEC;

II.2.2. is operated and supervised in accordance with the conditions laid down in Chapter I(II) 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.3.2,

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

*(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, and]

*(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* [and ovine animals have undergone during the 60 days prior to their stay in the quarantine accommodation described in point II.3.2 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 IU/ml;]

II.3.1.3. to the best of my knowledge and according to the written declaration made by the owner do not come from holdings, and have not been in contact with animals of a holding, in which any of the following diseases have been clinically detected within the stated periods prior to their stay in the quarantine accommodation described in point II.3.2:

(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; and

*(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.3.1.4. are included in an official system for notification of diseases mentioned in point II.3.1.3;

II.3.2. have satisfied the quarantine isolation period of at least 28 days and within that period, and at least 21 days after being admitted to the quarantine accommodation, have undergone with negative results the tests, carried out by the laboratory approved by the competent authority of the exporting country, for:

— brucellosis (*B. melitensis*) in accordance with Annex C to Directive 91/68/EEC,

— ovine epididymitis (*Brucella ovis*), in the case of sheep only, in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity,

— Border disease virus;

II.3.3. 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,

— ovine 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;

II.4. the semen to be exported was obtained from donor rams/bucks ([1]) which:

II.4.1. show no clinical signs of disease on the day the semen was collected;

*([1]) either* [II.4.2. have not been vaccinated against foot-and-mouth disease during the 12 months prior to collection of the semen;]

*([1]) or* [II.4.2. have been vaccinated against foot-and-mouth disease between 7 and 12 months prior to 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.4.3. 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.4.4. have not served naturally after their entry to the quarantine accommodation described in point II.3.2 and up to and including the day of semen collection;

II.4.5. have been kept at the approved semen collection centres:

II.4.5.1. 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.4.5.2. 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 (*B. ovis*), anthrax and rabies;

*([1]) either* [II.4.6. have remained in the exporting country for at least the last six months prior to collection of the semen to be exported;]

*([1]) or* [II.4.6. have remained in the exporting country for at least 30 days prior to collection of the semen since entry and they were imported from ..... ([2]) during the period of less than six months prior to collection of the semen and satisfied the animal health conditions applying to donors of the semen which is intended for export to the Community;]

*([1]) either* [II.4.7. 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.4.7. 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.4.7. were kept protected from the bluetongue virus competent vector *Culicoides* for at least 60 days prior to, and during collection of the semen;]

*([1]) or* [II.4.7. 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 with negative results on samples taken between 21 and 60 days after collection of the semen;]

*([1]) or* [II.4.7. underwent 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 on the day of semen collection and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during the semen collection and have been protected from the bluetongue virus competent vector *Culicoides* during collection of the semen;]

*(1) either* [II.4.8. were resident in the exporting country (5) which according to official findings is free from epizootic haemorrhagic disease (EHD);]

*(1) or* [II.4.8. were resident in the exporting country (5) in which according to official findings the following serotypes of epizootic haemorrhagic disease (EHD) exist: ..... and were tested on two occasions in an agar-gel immuno-diffusion test or competitive enzyme-linked immunosorbent assay (6) and in a virus neutralisation test for all above listed serotypes of EHD, carried out with negative results in an approved laboratory on samples of blood taken not more than 12 months apart prior to and not less than 21 days following collection of the semen;]

*(1) either* [II.4.9. were resident in the exporting country (5) which according to official findings is free from Akabane disease and Aino disease;]

*(1) or* [II.4.9. were resident in the exporting country (5) and were tested on two occasions in an agar-gel immuno-diffusion test and in a serum neutralisation test for Akabane virus and Aino virus carried out with negative results in an approved laboratory on samples of blood taken not more than 12 months apart prior to and not less than 21 days following collection of the semen;]

II.5. the semen to be exported

II.5.1. was collected after the date on which the centre was approved by the competent authority of the exporting country;

II.5.2. was processed, stored and transported under conditions which satisfy the terms laid down in Chapter III 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 States 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 programmes referred to in that point and with the guarantees (7) requested by the EU Member States of destination.]

**Notes**

**Part I**

— Box reference I.8: Provide the code of territory as appearing in Annex I to Decision 2008/635/EC.

— Box reference I.11: place of origin shall correspond to the semen collection centre of the semen origin listed in the Annex I to Decision 2008/635/EC.

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

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

— Box reference I.28: *Species:* select amongst '*Ovis aries*' and '*Capra hircus*' as appropriate.

Identification mark shall correspond to the identification of the donor animals and the date of collection.

Approval number of centre: shall correspond to the semen collection centre of the semen origin listed in the Annex I to Decision 2008/635/EC.

**Part II**

(1) Delete as necessary.

(2) Countries listed in Annex I to Decision 2008/635/EC.

(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 Council Decision 79/542/EEC [OJ L 146, 14.6.1979, p. 15] as last amended.

(5) See remarks for exporting country concerned in Annex I to Decision 2008/635/EC.

(6) Standards for EHD virus diagnostic tests are described in the Bluetongue Chapter of the 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].

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

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp

# ANNEX III

## LIST OF THIRD COUNTRIES AND APPROVED EMBRYO COLLECTION TEAMS FROM WHICH MEMBER STATES ARE TO AUTHORISE IMPORTS OF OVA AND EMBRYOS OF THE OVINE AND CAPRINE SPECIES

| **ISO code** | **Name of the third country** | **Approval number of the team** | **Name of the team** | **Address of the team** | **Date of approval of the team** | **Remarks** | |
|---|---|---|---|---|---|---|---|
| | | | | | | **Description of the territory(if appropriate)** | **Additional guarantees** |
| AU | Australia | | | | | | The additional guarantees as regards testing set out in points II.5.1 and II.5.2 of the certificate in Annex IV are compulsory. |
| CA | Canada | | | | | Territory as described in Part 1 of Annex I to Decision 79/542/ EEC | The additional guarantee as regards testing set out in point II.5.2 of the certificate in Annex IV is compulsory. |
| CH | Switzerland | | | | | | |
| 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.5.2 of the certificate in Annex IV is compulsory. |

Notes

(a) Health certificates shall be produced by the exporting country, based on the model appearing in Annex IV. They shall contain, in the numbered order that appears in the model, the attestations that are required for any third country and, as the case may be, those supplementary guarantees that are required for the exporting third country as indicated in Annex III.
If so requested by the EU Member State of destination, the additional certification requirements shall be also incorporated in the original form of the health certificate.

(b) The original of each certificate shall consist of a single page, both sides, or, where more text is required; it shall be in such a form that all pages needed are part of an integrated whole and indivisible.

(c) It shall be drawn up in at least one of the official languages of the EU Member State in which the inspection at the border post shall be carried out and of the EU Member State of destination. However, these Member States may allow another Community language instead of their own, accompanied, if necessary, by an official translation.

(d) If for reasons of identification of the items of the consignment (schedule in point I.28 of the model of certificate), additional pages are attached to the certificate, these pages shall also be considered as forming part of the original of the certificate by the application of the signature and stamp of the certifying official veterinarian, on each of the pages.

(e) When the certificate, including additional schedules referred to in (d), comprises more than one page, each page shall be numbered — (*page number*) of (*total number of pages*) — on its bottom and shall bear the code number of the certificate that has been designated by the competent authority on its top.

(f) The original of the certificate must be completed and signed by an official veterinarian the last working day prior to loading of the consignment for exportation to the Community. In doing so, the competent authorities of the exporting country shall ensure that principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed.
The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermarked.

(g) The original of the certificate must accompany the consignment until it reaches the EU border inspection post.

(h) The certificate shall be valid for 10 days from the date of issuing. In the case of transport by ship the time of validity is prolonged by the time of the trip in the ship.

(i) Ova/embryos and semen shall not be transported together in the same container with other ova/embryos and semen that, either are/is not destined for the European Community, or are/is of a lower health status.

(j) During its transport to the European Community, the container shall remain closed and the seal shall not be broken.

(k) The certificate reference number referred to in Boxes I.2 and II.a must be issued by the competent authority.

# ANNEX IV

## Model health certificate for import of ova and embryos of the ovine and caprine species

**COUNTRY** **Veterinary certificate to EU**

**Part I: Details of dispatched consignment**

| | | | |
|---|---|---|---|
| I.1. Consignor<br>Name<br>Address<br>Tel. | | I.2. Certificate reference number | I.2.a |
| | | I.3. Central Competent Authority | |
| | | I.4. Local Competent Authority | |
| I.5. Consignee<br>Name<br>Address<br>Postal code<br>Tel. | | I.6. Person responsible for the load in EU<br>Name<br>Address<br>Postal code<br>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<br>Name Approval number<br>Address<br>Name Approval number<br>Address<br>Name Approval number<br>Address | | I.12. Place of destination<br>Name<br>Address<br>Postal code | |
| I.13. Place of loading | | I.14. Date of departure | |
| I.15. Means of transport<br>Aeroplane ☐ Ship ☐ Railway wagon ☐<br>Road vehicle ☐ Other ☐<br>Identification:<br>Documentary references: | | I.16. Entry BIP in EU | |
| | | I.17. | |
| I.18. Description of commodity | | I.19. Commodity code (HS code)<br>**05 11 99 90** | |
| | | I.20. Quantity | |
| I.21. | | I.22. Number of packages | |
| I.23. Identification of container/Seal number | | I.24. | |
| I.25. Commodities certified for:<br>Artificial reproduction ☐ | | | |
| I.26. For transit through EU to third country ☐<br>Third country ISO code | | I.27. For import or admission into EU ☐ | |

I.28. Identification of the commodities

| Species (Scientific name) | Category | Identification mark | Approval number of the team | Quantity |
|---|---|---|---|---|
| | | | | |

**COUNTRY** **Ovine and caprine ova/embryos**

**Part II: Certification**

| II. Health information | II.a. Certificate reference number | II.b. |
|---|---|---|
| | | |

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 ova/embryos (1) to be exported and up until its date of dispatch 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 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.3. the embryo collection team described under point I.11:

II.3.1. has been approved by the competent authority for export of ova/embryos (1) of the ovine and caprine species to the European Community;

II.3.2. carried out collection, processing, storing and transport of the ova/embryos (1) to be exported in accordance with Chapter III of Annex D to Directive 92/65/EEC;

II.3.3. is subject to inspection by an official veterinarian at least twice a year;

II.4. the donor females:

*(1) either* [II.4.1. 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.4.1. were kept during a bluetongue virus seasonally free period in a seasonally free zone;]

*(1) or* [II.4.1. were kept protected from the bluetongue virus competent vector *Culicoides* for at least 60 days prior to, and during the collection of the ova/embryos (1);]

*(1) or* [II.4.1. 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.4.1. 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.4.2. to the best of my knowledge and according to the written declaration made by the owner, do not come from holdings, and have not been in contact with animals of a holding, in which any of the following diseases have been clinically detected within the stated periods 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; and

*(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.4.3. are included in an official system for notification of diseases mentioned in point II.4.2;

II.4.4. showed no clinical signs of disease on the day of the ova/embryos (1) collection;

*(1) (4) either* [II.4.5. originate from the territory described under point I.8, which has been recognised as officially brucellosis (*B. melitensis*)-free, and]

*(1) or* [II.4.5. 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.4.5. 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 prior to collection of the ova/embryos (1), and]

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

*(1) either* [II.4.6. have remained in the exporting country for at least the last six months prior to collection of the ova/embryos (1) to be exported;]

*(1) or* [II.4.6. have remained in the exporting country for at least 30 days prior to collection of the ova/embryos (1) since entry into which they were imported from ..... (2) during the period of less than six months prior to collection of the ova/embryos (1) and satisfied the animal health conditions applying to donors of the ova/embryos (1) which are intended for export to the Community;]

II.5. The ova/embryos (1) to be exported:

*(1) either* [II.5.1. were collected in the exporting country (5), which according to official findings is free from Akabane disease and Aino disease;]

*(1) or* [II.5.1. were collected in the exporting country (5) and were not subjected to penetration of the *zona pellucida*, and the donor females underwent a serum neutralisation test for Akabane virus and Aino virus carried out on a blood sample taken not less than 21 days following their collection and giving negative results;]

*(1) either* [II.5.2. were collected in the exporting country (5), which according to official findings is free from epizootic haemorrhagic disease (EHD);]

*(1) or* [II.5.2. were collected in the exporting country (5) in which according to official findings the following serotypes of epizootic haemorrhagic disease (EHD) exist: ..... and were tested negative on two occasions not more than 12 months apart in an agar-gel immuno-diffusion test or competitive enzyme-linked immunosorbent assay (6) and a virus neutralisation test for all above-listed serotypes of EHD, carried out in approved laboratory on samples of blood taken prior to and not less than 21 days following collection of the ova/embryos (1);]

*(1) either* [II.5.3. meet the requirements of Chapter A(I) of Annex VIII to Regulation (EC) No 999/2001;]

*(1) or* [II.5.3. meet the requirements of Chapter A(I) of Annex VIII to Regulation (EC) No 999/2001and are destined for a Member States which benefits, for all or part of its territory, from the provisions laid down in points (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 programmes referred to in that point and with the guarantees (7) requested by the EU Member States of destination;]

II.6. The ova/embryos (1) to be exported

II.6.1. were collected after the date on which the embryo collection team was approved by the competent authority of the exporting country;

II.6.2. were processed and stored under approved conditions for at least 30 days immediately after their collection and transported under conditions which satisfy the terms laid down in Chapter III of Annex D to Directive 92/65/EEC;

II.7. The embryos were conceived by artificial insemination using semen coming from semen collection centres approved in accordance with Articles 11(2) and 17(3) respectively of Directive 92/65/EEC and located in a Member State of the European Community or in a third country listed in Annex I to Decision 2008/635/EC (8).

**Notes**

**Part I**

— Box reference I.8: Provide the code of territory as appearing in Annex III to Decision 2008/635/EC.

— Box reference I.11: place of origin shall correspond to the embryo collection team by which the ova/embryos were collected, processed and stored and listed in Annex III to Decision 2008/635/EC.

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

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

— Box reference I.28: Species: select amongst *'Ovis aries'* and *'Capra hircus'* as appropriate.

Category: specify if (a) penetration or (b) non penetration of *zona pellucida*.

Identification mark shall correspond to the identification of the donor animals and the date of collection.

Approval number of the team: shall correspond to the embryo collection team of the ova/embryos origin listed in the Annex III to Decision 2008/635/EC.

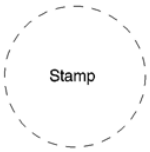
**Part II**

(1) Delete as appropriate.
(2) Countries listed in Annex I to Decision 2008/635/EC.
(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 Decision 79/542/EEC as last amended.
(5) See remarks for exporting country concerned in Annex III to Decision 2008/635/EC.
(6) Standards for EHD virus diagnostic tests are described in the Bluetongue Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.
(7) Additional guarantees as laid down in Article 2 of Regulation (EC) No 546/2006.
(8) Semen collection centres approved in accordance with EC legislation are listed on the Commission website: http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html
— The signature and the stamp must be in a different colour to that of the printing.

Official veterinarian

Name (in capital letters): Qualification and title:

Date: Signature:



(**1**) OJ L 268, 14.9.1992, p. 54. Directive as last amended by Commission Decision 2007/265/EC (OJ L 114, 1.5.2007, p. 17).

(**2**) OJ L 28, 2.2.1994, p. 47. Decision as last amended by Decision 2004/211/EC (OJ L 73, 11.3.2004, p. 1).

(**3**) OJ L 146, 14.6.1979, p. 15. Decision as last amended by Commission Decision 2008/61/EC (OJ L 15, 18.1.2008, p. 33).

(**4**) See page 32 of this Official Journal.

(**5**) http://circa.europa.eu/irc/sanco/vets/info/data/semen/semen.html

(**6**) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).

(**7**) OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 571/2008 (OJ L 161, 20.6.2008, p. 4).

(**8**) OJ L 94, 1.4.2006, p. 28.

(**9**) OJ L 114, 30.4.2002, p. 132.

(**10**) OJ L 114, 30.4.2002, p. 1.

(**11**) OJ L 234, 3.10.1995, p. 30. Decision as amended by Decision 2005/43/EC (OJ L 20, 22.1.2005, p. 34).

(**12**) OJ L 71, 18.3.1999, p. 3.

(**13**) OJ L 71, 18.3.1999, p. 1.

(**14**) OJ L 57, 26.2.1997, p. 5.

(**15**) OJ L 57, 26.2.1997, p. 4. Decision as amended by Decision 1999/837/EC (OJ L 332, 23.12.1999, p. 1).

**Changes to legislation:**
Commission Decision 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 (notified under document number C(2008) 3625) (Text with EEA relevance) (2008/635/EC) is up to date with all changes known to be in force on or before 23 October 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

**Changes and effects yet to be applied to :**

– Decision repeal by EUDN 2010/472 Decision