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

[F1 ANNEX A

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1398/2003 of 5 August 2003 amending Annex A to Council Directive 92/65/EEC to include the small hive beetle (Aethina tumida), the Tropilaelaps mite (Tropilaelaps spp.), Ebola and monkey pox (Text with EEA relevance).

NOTIFIABLE DISEASES IN THE CONTEXT OF THIS DIRECTIVE

Disease	**Order/family/species primarily concerned**
African horse sickness	*Equidae*
African swine fever	*Suidae* and *Tayassuidae*
Avian influenza	*Aves*
American foulbrood	*Apis*
Anthrax	*Bovidae, Camelidae, Cervidae, Elephantidae, Equidae* and *Hippopotamidae*
Bluetongue	*Antilocapridae, Bovidae, Cervidae, Giraffidae*, and *Rhinocerotidae*
Brucella abortus	*Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae* and *Tragulidae*
Brucella melitensis	*Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae* and *Tragulidae*
Brucella ovis	*Camelidae, Tragulidae, Cervidae, Giraffidae, Bovidae* and *Antilocapridae*
Brucella suis	*Cervidae, Leporidae, Ovibos moschatus, Suidae* and *Tayassuidae*
Classical swine fever	*Suidae* and *Tayassuidae*
Contagious bovine pleuropneumonia	Bovines (including zebu, buffalo, bison and yak)
Ebola	Non-human primates
Foot-and-mouth disease	*Artiodactyla* and Asian elephants
Infectious haematopoeitic necrosis	*Salmonidae*
Lumpy skin disease	*Bovidae* and *Giraffidae*
Monkey pox	*Rodentia* and non-human primates
Mycobacterium bovis	*Mammalia*, in particular *Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae*, and *Tragulidae*

Newcastle disease	*Aves*
Peste des petits ruminants	*Bovidae* and *Suidae*
Porcine enterovirus encephalomyelitis	*Suidae*
Psitacosis	*Psittaciformes*
Rabies	*Carnivora* and *Chiroptera*
Rift valley fever	*Bovidae, Camelus* species and *Rhinocerotidae*
Rinderpest	*Artiodactyla*
Small hive beetle *(Aethina tumida)*	*Apis* and *Bombus*
Sheep and goat pox	*Bovidae*
Swine vesicular disease	*Suidae* and *Tayassuidae*
Tropilaelaps mite (*Tropilaelaps* spp).	*Apis*
Vesicular stomatitis	*Artiodactyla* and *Equidae*
TSE	*Bovidae, Cervidae, Felidae* and *Mustelidae***]**

ANNEX B

LIST OF DISEASES FOR WHICH NATIONAL PROGRAMMES MAY BE RECOGNIZED UNDER THIS DIRECTIVE

Mink	Viral enteritis Aleutian disease
Bees	European foulbrood varroasis and acariasis
Apes and felids	Tuberculosis
Ruminants	Tuberculosis
Lagomorphs	Myxomatosis Viral haemorrhagic disease Tularaemia

[F2ANNEX C

CONDITIONS GOVERNING APPROVAL OF BODIES, INSTITUTES OR CENTRES

Textual Amendments

F2 Substituted by Commission Regulation (EC) No 1282/2002 of 15 July 2002 amending Annexes to Council Directive 92/65/EEC 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(1) to Directive 90/425/EEC (Text with EEA relevance).

1. In order to be granted official approval under Article 13(2) of this Directive, a body, institute or centre as defined in Article 2(1)(c) must:

(a) be clearly demarcated and separated from its surroundings or the animals confined and located so as not to pose a health risk to agricultural holdings whose health status might be jeopardised;

(b) have adequate means for catching, confining and isolating animals and, have available adequate quarantine facilities and approved procedures for animals coming from non-approved sources;

(c) be free of the diseases listed in Annex A and the diseases listed in Annex B where the country concerned has a programme pursuant to Article 14. In order that a body, institute or centre is declared free from these diseases, the competent authority shall assess the records on the animal health status kept for at least the previous three years and the results of the clinical and laboratory tests carried out on the animals in the body, institute or centre. However, by way of derogation from this requirement new establishments shall be approved if the animals forming the collection are derived from approved establishments;

(d) keep up to date records indicating:

(i) the number and identity (age, sex, species and individual identification where practical) of the animals of each species present in the establishment;

(ii) the number and identity (age, sex, species and individual identification where practical) of animals arriving in the establishment or leaving it, together with information on their origin or destination, the transport from or to the establishment and the animals health status;

(iii) the results of blood tests or any other diagnostic procedures;

(iv) cases of disease and, where appropriate, the treatment administered;

(v) the results of the post-mortem examinations on animals that have died in the establishment, including still-born animals;

(vi) observations made during any isolation or quarantine period;

(e) either have an arrangement with a competent laboratory to perform post-mortem examinations, or have one or more appropriate premises where these examinations may be performed by a competent person under the authority of the approved veterinarian;

(f) either have suitable arrangements or on-site facilities for the appropriate disposal of the bodies of animals which die of a disease or are euthanised;

(g) secure, by contract or legal instrument, the services of a veterinarian approved by and under the control of the competent authority, who:

(i) shall comply *mutatis mutandis* with the requirements referred to in Article 14(3)(B) of Directive 64/432/EEC,

(ii) shall ensure that appropriate disease surveillance and control measures in relation to the disease situation of the country concerned are approved by the competent authority and applied in the body, institute or centre. Such measures shall include:

— an annual disease surveillance plan including appropriate zoonoses control of the animals,

— clinical, laboratory and post-mortem testing of animals suspected to be affected by transmissible diseases,

— vaccination of susceptible animals against infectious diseases as appropriate, only in conformity with Community legislation;

(iii) shall ensure that any suspect deaths or the presence of any other symptom suggesting that animals have contracted one or more of the diseases referred to in Annexes A and B is notified without delay to the competent authority, if that particular disease is notifiable in the Member State concerned;

(iv) shall ensure that incoming animals have been isolated as necessary, and in accordance with the requirements of this Directive and the instructions, if any, given by the competent authority;

(v) shall be responsible for the day to day compliance with the animal health requirements of this Directive and of Community legislation on welfare of animals during transport and disposal of animal waste;

(h) if it keeps animals intended for laboratories carrying out experiments, in conformity with the provisions of Article 5 of Directive 86/609/EEC.

2. Approval shall be maintained where the following requirements are met:

(a) the premises are under the control of an official veterinarian from the competent authority, who:

(i) shall visit the premises of the body, institute or centre at least once per year;

(ii) shall audit the activity of the approved veterinarian and the implementation of the annual disease surveillance plan;

(iii) shall ensure that the provisions of this Directive are met;

(b) only animals coming from another approved body, institute or centre, are introduced into the establishment, in accordance with the provisions of this Directive;

(c) the official veterinarian verifies that:

— the provisions of this Directive are fulfilled,

— the results of the clinical, post-mortem and laboratory tests on the animals have revealed no occurrence of the diseases referred to in Annexes A and B;

(d) the body, institute or centre keeps the records referred to in point 1(d) after approval, for a period of at least ten years.

3. By way of derogation from Article 5(1) of this Directive and point 2(b) of this Annex, animals including apes (*simiae* and *prosimiae*) having an origin other than an approved body, institute or centre may be introduced in an approved body, institute or centre, provided that these animals undergo a quarantine under official control and in accordance with the instructions given by the competent authority before being added to the collection.

For apes (*simiae and prosimiae*) the quarantine requirements laid down in the OIE International Health Code (Chapter 2.10.1 and Appendix 3.5.1) shall be respected.

For other animals undergoing quarantine in accordance with point 2(b) of this Annex, the quarantine period must be at least 30 days with respect to the diseases listed in Annex A.

4. Animals held in an approved body, institute or centre, shall only leave this establishment if destined to another approved body, institute or centre, in that Member State or another Member State; however, if not destined to an approved body, institute or centre, shall only leave in accordance with the requirements of the competent authority to ensure no risk of possible spread of disease.

5. Where a Member State benefits from additional guarantees under Community legislation it may request appropriate additional requirements and certification for the susceptible species to be added to the approved body, institute or centre.

6. The procedures for partly or completely suspending, withdrawing or restoring approval are the following:

(a) where the competent authority finds that the requirements of point 2 have not been fulfilled or there has been a change of usage which is no longer covered by Article 2 of this Directive the approval shall be suspended or withdrawn;

(b) where notification is given of the suspicion of one of the diseases listed in Annex A or B, the competent authority shall suspend approval of the body, institute or centre, until the suspicion has been officially ruled out. Depending on the disease involved and the risk of disease transmission, the suspension may relate to the establishment as a whole or only to certain categories of animals susceptible to the disease in question. The competent authority shall ensure that the measures necessary to confirm or rule out the suspicion and to avoid any spread of disease are taken, in accordance with Community legislation governing measures to be taken against the disease in question and on trade in animals;

(c) where the suspected disease is confirmed, the body, institute or centre shall again be approved only when, after eradication of the disease and source of infection in the premises, including suitable cleaning and disinfection, the conditions laid down in point 1 of this Annex, with the exception of point 1(c), are again fulfilled;

(d) the competent authority shall inform the Commission of the suspension, withdrawal or restoration of approval of a body, institute or centre.**]**

[F3ANNEX D

Textual Amendments

F3 Substituted by Commission Regulation (EU) No 176/2010 of 2 March 2010 amending Annex D to Council Directive 92/65/EEC as regards semen collection and storage centres, embryo collection and production teams, and conditions for donor animals of the equine, ovine and caprine species and for handling semen, ova and embryos of those species (Text with EEA relevance).

CHAPTER I

Conditions applicable to semen collection centres, semen storage centres, embryo collection teams and embryo production teams

I. *Conditions for the approval of semen collection and storage centres*

1. In order to be given approval and the veterinary registration number referred to in Article 11(4) each semen collection centre shall:

1.1. **[**F4be placed under the supervision of a centre veterinarian authorised by the competent authority;**]**

1.2. have at least:

(a) lockable animal accommodation and if required for equidae an exercise area which is physically separated from the collection facilities, the processing and storage rooms;

(b) isolation facilities which have no direct communication with the normal animal accommodation;

(c) semen collection facilities, that may be open air protected from adverse weather effects, with slip-proof flooring which protects from dramatic injury in case of fall, at and around the place of semen collection, without prejudice to the requirements in point 1.4;

(d) a separate room for the cleansing and disinfection or sterilisation of equipment;

(e) a semen processing room separated from the collection facilities and the room for cleansing equipment referred to in point (d) which need not necessarily be on the same site;

(f) a semen storage room which need not necessarily be on the same site;

1.3. be so constructed or isolated that contact with outside livestock is prevented;

1.4. be so constructed that the entire semen collection centre except the office rooms and, in the case of equidae the exercise area, can be readily cleansed and disinfected.

Textual Amendments

F4 Substituted by Commission Implementing Regulation (EU) No 846/2014 of 4 August 2014 amending Annex D to Council Directive 92/65/EEC as regards the conditions for donor animals of the equine species (Text with EEA relevance).

2. In order to be given approval each semen storage centre shall:

(a) in the case the storage is not limited to semen of a single species collected at semen collection centres approved in accordance with this Directive, or embryos are stored at the centre in compliance with this Directive, be given distinct veterinary registration numbers referred to in Article 11(4) for each of the species the semen of which is stored at the centre;

(b) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;

(c) have a semen storage room furnished with the necessary installation to store the semen and/or the embryos, which is so constructed that it protects those products and the installation from adverse weather and environment effects;

(d) be so constructed that contact with outside livestock or other animals is prevented;

(e) be so constructed that the entire centre except the office rooms and, in the case of equidae the exercise area, can be readily cleansed and disinfected;

(f) be so constructed that unauthorised access of people is effectively prevented.

II. *Conditions for the supervision of semen collection and storage centres*

1. Semen collection centres shall:

1.1. be supervised to ensure that:

(a) they contain only animals of the species whose semen is to be collected;

Other domestic animals may none the less also be admitted, provided that they present no risk of infection to those species whose semen is to be collected, and that they comply with the conditions laid down by the centre veterinarian.

If in the case of equidae the semen collection centre shares a site with an artificial insemination or service centre, then female equidae (mares) and uncastrated male equidae (stallions) for teasing or natural service shall be admitted provided that they meet the requirements of points 1.1, 1.2, 1.3 and 1.4 of Section I of Chapter II;

(b) the entry of unauthorised persons is prevented and that authorised visitors are required to comply with the conditions laid down by the centre veterinarian;

(c) only competent staff is employed who have received adequate training on disinfection and hygiene techniques to prevent the spread of disease;

1.2. be monitored to ensure that:

(a) records are kept which show:

(i) the species, breed, date of birth and identification of each animal present in the centre;

(ii) any movement of animals entering or leaving the centre;

(iii) the health history and all diagnostic tests and the results thereof, treatments and vaccinations carried out on animals kept;

(iv) the date of collecting and processing semen;

(v) the destination of semen;

(vi) the storage of semen;

(b) none of the animals kept in the centre is used for natural breeding at least 30 days prior to the date of the first semen collection and during the collection period;

(c) the collection, processing and storage of semen is carried out only in premises set aside for these purposes;

(d) all instruments which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilised prior to use, except for instruments which are new, disposable and discarded after use (single-use instruments);

Where, in the case of equidae, the collection centre shares a site with an artificial insemination centre or a service centre, there shall be a strict separation between the semen and instruments and equipment for artificial insemination or natural service and instruments and equipment coming into contact with donor animals or other animals kept in the collection centre;

(e) products of animal origin used in the processing of semen, including diluents, additives or extenders, are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;

(f) cryogenic agents used for the preservation or storage of semen have not been previously used for other products of animal origin;

(g) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for containers which are new, disposable and discarded after use (single-use containers);

(h) each individual dose of semen or each ejaculate of fresh semen intended for further processing is clearly marked in such a way that the date of collection of the semen, the species, the breed and identification of the donor animal and the approval number of the semen collection centre can be readily established;

1.3. be inspected by an official veterinarian during the breeding season at least once every calendar year in the case of animals with seasonal breeding and twice every calendar year in the case of a non-seasonal reproduction in order to consider and verify, where necessary on the base of records, standard operating procedures and internal audits, all matters relating to the conditions of approval, supervision and monitoring.

2. Semen storage centres shall:

2.1. be supervised to ensure that:

(a) the status of the donor animals whose semen is stored at the centre complies with the requirements of this Directive;

(b) the requirements laid down in points 1.1(b) and (c) are complied with;

(c) records are kept of all movement of semen entering and leaving the storage centre;

2.2. be monitored that:

(a) only semen collected in and coming from approved semen collection or storage centres and transported in conditions offering every possible health guarantee, having had no contact with semen not complying with this Directive, is brought into an approved semen storage centre;

(b) storage of semen takes place only on the premises set aside for the purpose and under strict conditions of hygiene;

(c) all instruments which come into contact with the semen are properly disinfected or sterilised prior to use, except for single-use instruments;

(d) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;

(e) cryogenic agents used for preservation or storage of semen have not been previously used for other products of animal origin;

(f) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the species, the breed and identification of the donor animal, the approval number of the semen collection centre can be readily established; each Member State shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory;

2.3. by way of derogation from point 2.2(a), the storage of embryos in the approved semen storage centre is authorised provided they meet the requirements of this Directive and are stored in separate storage containers;

2.4. be inspected by an official veterinarian at least twice every calendar year in order to consider and verify, where necessary based on records, standard operating procedures and internal audits, all matters relating to the conditions of approval, supervision and monitoring.

III. *Conditions for the approval and the supervision of embryo collection teams and embryo production teams*

1. In order to be given approval each embryo collection team shall comply with the following requirements:

1.1. the collection, processing and storage of embryos shall be carried out either by a team veterinarian or under his responsibility by one or more technicians who are competent and trained by the team veterinarian in methods and techniques of hygiene and in techniques and principles of disease control;

1.2. the team veterinarian shall be responsible for all team operations, including amongst others:

(a) verification of the identity and health status of the donor animal;

(b) sanitary handling and surgery of donor animals;

(c) disinfection and hygienic procedures;

(d) keeping records which shows:

(i) the species, breed, date of birth and identification of each donor animal;

(ii) the health history and all diagnostic tests and the results thereof, treatments and vaccinations carried out on donor animals;

(iii) the place and date of collecting, processing and storing of oocytes, ova and embryos;

(iv) the identification of embryos and details of their destination if known;

1.3. the team shall be placed under the general supervision of the official veterinarian, who shall inspect it at least once every calendar year to ensure, where necessary based on records, standard operating procedures and internal audits, compliance with the sanitary conditions regarding collection, processing and storage of embryos and to verify all matters relating to the conditions of approval and supervision;

1.4. the team shall have at its disposal a permanently sited laboratory or a mobile laboratory where embryos can be examined, processed and packed, consisting of at least a work surface, an optical or stereo microscope and cryogenic equipment where necessary;

1.5. in the case of a permanently sited laboratory, it shall have:

(a) a room where embryos can be processed which is physically separate from the area used to handle the donor animals during collection;

(b) a room or area for cleansing and sterilising instruments, except when using only single-use equipment;

(c) a room for storing embryos;

1.6. in the case of a mobile laboratory, it shall:

(a) have a specially equipped part of the vehicle consisting of two separate sections:

(i) one for the examination and processing of embryos which shall be a clean section; and

(ii) the other for accommodating equipment and materials used in contact with the donor animals;

(b) use only single-use equipment, unless the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and processing of embryos can be ensured by the contact with a permanently sited laboratory;

1.7. the design and layout of buildings and laboratories shall be laid out and team operations carried out so as to ensure that cross-contaminations of embryos are prevented;

1.8. the team shall have at its disposal storage premises which shall:

(a) comprise at least one lockable room for the storage of ova and embryos;

(b) be easy to cleanse and disinfect;

(c) have permanent records of all incoming and outgoing ova or embryos;

(d) have storage containers for ova and embryos which are stored in a place which is under the control of the team veterinarian and which is subject to regular inspections by an official veterinarian;

1.9. the competent authority may authorise storage of semen in storage premises referred to in point 1.8 provided that the semen:

(a) meets the requirements of this Directive for either ovine and caprine species or equine species, or of Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species[(1)] for porcine species;

(b) is stored for the operation of the team in separate storage containers in the premises for storing approved embryos.

2. In order to be given approval each embryo production team shall also comply with the following additional requirements:

2.1. the team members have received adequate training on disease control and laboratory techniques, particularly in procedures for working in sterile conditions;

2.2. the team shall have at its disposal a permanently sited laboratory which shall:

(a) have adequate equipment and facilities, including separate rooms for:
— recovering oocytes from ovaries,
— processing oocytes, ova and embryos,
— storing embryos;

(b) have a laminar-flow or other suitable facilities where all technical operations associated with specific sterile conditions (processing of ova, embryos and semen) are conducted.

However, the centrifugation of semen may be carried out outside the laminar-flow facility or other facility, as long as full hygienic precautions are taken;

2.3. where ova and other tissues are to be collected in a slaughterhouse, it shall have at its disposal suitable equipment for the collection and transport of the ovaries and other tissues to the processing laboratory in a hygienic and safe manner.

CHAPTER II

Conditions applicable to donor animals

I. *Conditions applicable to donor stallions*

1. In order to be used for the collection of semen, the donor stallion shall, to the satisfaction of the centre veterinarian, meet the following requirements:

1.1. it shall not show any clinical sign of an infectious or contagious disease at the time of admission and on the day the semen is collected;

1.2. it shall come from the territory or, in the case of regionalisation, from the part of the territory of a Member State or a third country and from a holding under veterinary supervision each of which satisfy the requirements of Directive 90/426/EEC;

1.3. it shall be kept for 30 days prior to the date of semen collection in holdings where no equine has shown any clinical sign of equine viral arteritis or contagious equine metritis during that period;

1.4. it shall not be used for natural mating during the 30 days prior to the first semen collection and during the collection period;

1.5. **[**[F4]it shall be subjected to the following tests, carried out and certified in a laboratory which is recognised by the competent authority and has the tests referred to hereinafter included in its accreditation in accordance with Article 12 of Regulation (EC) No 882/2004 of the European Parliament and of the Council[(2)], according to the programme provided for in point 1.6:

(a) an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia with negative result;

(b) a test for the isolation of the equine arteritis virus or the detection of its genome by polymerase chain reaction (PCR) or real-time PCR carried out with negative result on an aliquot of the entire semen of the donor stallion, unless the donor stallion has reacted with negative result at a serum dilution of one in four in a serum neutralisation test for equine viral arteritis;

(c) an agent identification test for contagious equine metritis, carried out with negative result in each case on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than seven days, and in no case earlier than seven days (systemic treatment) or 21 days (local treatment) after possible antimicrobial treatment of the donor stallion, from at least the following sites:

— the penile sheath (prepuce),
— the urethra,
— the fossa glandis.

The specimens shall be placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.

The specimens shall be subjected to at least one of the following tests:

(i) culture under microaerophilic conditions for at least 7 days for the isolation of *Taylorella equigenitalis*, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport; or

(ii) polymerase chain reaction (PCR) or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within 48 hours after taking the specimens from the donor animal.**]**

1.6. it shall be subjected to one of the following testing programmes:

(a) [F4if the donor stallion is continuously resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, and no equidae on the semen collection centre come into direct contact with equidae of lower health status than the donor stallion, the tests required in point 1.5 shall be carried out on samples taken from the donor stallion at least once a year at the beginning of the breeding season or prior to the first collection of semen intended for trade in fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection;

(b) if the donor stallion is resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, but may leave the centre occasionally under the responsibility of the centre veterinarian for a continuous period of less than 14 days, and/or other equidae on the collection centre come into direct contact with equidae of lower health status, the tests required in point 1.5 shall be carried out as follows:

(i) at least once a year on samples taken from the donor stallion at the beginning of the breeding season or prior to the first collection of semen intended for trade in fresh, chilled or frozen semen and not less than 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection; and

(ii) during the period of collection of semen intended for trade in fresh, chilled or frozen semen as follows:

— the test required in point 1.5(a) on samples taken not more than 90 days prior to the collection of semen for trade,

— the test required in point 1.5(b) on samples taken not more than 30 days prior to the collection of semen for trade, unless the non-shedder state of a donor stallion is confirmed by virus isolation test, PCR or real-time PCR carried out on samples of an aliquot of the entire semen taken not more than 6 months prior to the collection of semen for trade and the donor stallion has reacted with positive result at a serum dilution of at least one in four in a serum neutralisation test for equine viral arteritis,

— the test required in point 1.5(c) on samples taken not more than 60 days prior to the collection of semen for trade, which in the case of PCR or real-time PCR may be carried out on three specimens (swabs) taken on a single occasion;

(c) if the donor stallion does not meet the conditions in points (a) and (b) and the semen is collected for trade in frozen semen, the tests required in point 1.5 shall be carried out on samples collected from the donor stallion as follows:

(i) at least once a year at the beginning of the breeding season;

(ii) during the storage period provided for in point 1.3(b) of Section I of Chapter III and before the semen is removed from the centre or used, on samples taken not earlier than 14 days and not later than 90 days following the date of collection of the semen.

By way of derogation from point (ii) of the first subparagraph, post-collection sampling and testing for equine viral arteritis as described in 1.5(b) is not required in case the non-shedder state of a seropositive donor stallion is confirmed by virus isolation test, PCR or real-time PCR carried out with negative result on samples of an aliquot of the entire semen of the donor stallion taken twice a year at an interval of at least four months and the donor stallion has reacted with positive result at a serum dilution of at least one in four in a serum neutralisation test for equine viral arteritis.**]**

1.7. if any of the tests provided for in point 1.5 is positive, the donor stallion shall be isolated, and the semen collected from it since the date of the last negative test shall not be subject for trade with the exception, for equine viral arteritis, of semen from every ejaculate which has undergone the equine arteritis virus isolation test with negative result.

Semen collected from all other stallions at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests provided for in point 1.5. shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 1.5;

1.8. semen collected from stallions at a semen collection centre subject to a prohibition order in accordance with Article 4 or 5 of Directive 90/426/EEC shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored by the official veterinarian in accordance with Directive 90/426/EEC and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex A to Directive 90/426/EEC.

II. *Conditions applicable to male ovine and caprine donor animals*

1. For all ovine and caprine animals admitted to a semen collection centre the following requirements shall apply:

1.1. they have been kept in quarantine for a period of at least 28 days in accommodation specifically approved for the purpose by the competent authority, and where only animals having at least the same health status are present (quarantine accommodation);

1.2. prior to their stay in the quarantine accommodation, they have belonged to an officially brucellosis-free ovine or caprine holding pursuant to Article 2 of Directive 91/68/EEC and they shall not be previously kept in a holding of a lower health status as regards brucellosis;

1.3. they come from a holding where during the 60 days prior to their stay in the quarantine accommodation they have undergone a serological test for contagious epidydimitis (*B. ovis*) carried out in accordance with Annex D to Directive 91/68/EEC or any other test with an equivalent documented sensitivity and specificity;

1.4. they 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 1.1, with negative results in each case, except for the test for Border disease referred to in point (c)(ii):

(a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

(b) for contagious epididymitis (*B. ovis*), a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

(c) for Border disease:

(i) a virus isolation test or a test for virus antigen; and

(ii) a serological test to determine the presence or absence of antibodies (antibody test).

The competent authority may authorise that the tests referred to in this point are carried out on samples collected in the quarantine accommodation. If such authorisation is granted, the period of quarantine referred to in point 1.1 shall not commence before the date of sampling. However, if any of the tests referred to in this point prove positive, the animal concerned shall be immediately removed from the quarantine accommodation. In the event of group isolation, the quarantine period referred to in point 1.1 shall not commence for the remaining animals until the animal which tested positive has been removed;

1.5. they have undergone the following tests carried out on samples taken during the period of quarantine specified in point 1.1, and at least 21 days after being admitted to the quarantine accommodation, with negative results:

(a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

(b) for contagious epididymitis (*B. ovis*), a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

1.6. they have undergone the tests for Border disease referred in points 1.4(c)(i) and (ii) carried out on the blood samples taken during the period of quarantine specified in point 1.1, and at least 21 days after being admitted to the quarantine accommodation.

Any animal (seronegative or seropositive) shall only be allowed entry to the semen collection centre if no sero-conversion occurs in animals which tested seronegative before the day of entry into the quarantine accommodation.

If sero-conversion occurs, all animals that remain seronegative shall be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three weeks from the day the sero-conversion occurred.

Serologically positive animals shall be allowed entry into the semen collection centre subject to a negative result in a test referred in point 1.4(c)(i).

2. Animals shall only be admitted to the semen collection centre with the express permission of the centre veterinarian. All movements into and out of the semen collection centre shall be recorded.

3. No animals admitted to the semen collection centre shall show any clinical sign of disease on the date of admission.

All animals shall, without prejudice to point 4, have come from quarantine accommodation, which on the day of dispatch of the animals to the semen collection centre complies with the following conditions:

(a) it is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius;

(b) it has for the past three months been free from foot-and-mouth disease and brucellosis;

(c) it has for the past 30 days been free from compulsory notifiable diseases as defined in Article 2(b)(6) of Directive 91/68/EEC.

4. Provided, that the conditions set out in point 3 are complied with and the routine tests referred to in point 5 have been carried out during 12 months prior to the movement of the animals, animals may be moved from one approved semen collection centre to another of equal health status, without isolation or testing if the transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used shall be disinfected before use. If an animal is moved from one semen collection centre to a semen collection centre in another Member State that movement shall be carried out in accordance with Directive 91/68/EEC.

5. All ovine and caprine animals kept at an approved semen collection centre shall be subjected at least once every calendar year to the following tests, with negative results:

(a) for brucellosis (*B. melitensis*), a serological test carried out in accordance with Annex C to Directive 91/68/EEC;

(b) for contagious epidydimitis (*B. ovis*) a serological test carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

(c) for Border disease, the antibody test referred to in point 1.4(c)(ii) which is applied only to seronegative animals.

6. All tests referred to in this section shall be carried out by an approved laboratory.

7. If any of the tests described in point 5 is positive, the animal shall be isolated and the semen collected from it since the date of the last negative test shall not be subject for trade.

The animal referred to in the first paragraph shall be removed from the centre, except in the case of Border disease, in which case the animal shall be subjected with negative result to a test referred in point 1.4(c)(i).

Semen collected from all other animals at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests described in point 5 shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 5.

8. Semen shall be obtained from animals which:

(a) show no clinical signs of disease on the date the semen was collected;

(b) during the 12 months prior to the date of the collection of the semen:

(i) either have not been vaccinated against foot-and-mouth disease; or

(ii) have been vaccinated against foot-and-mouth disease at least 30 days prior to the collection, in which case 5 % (with a minimum of five straws) of each semen collection shall be submitted to a virus isolation test for foot-and-mouth disease with negative results;

(c) have been kept at an approved semen collection centre for a continuous period of at least 30 days prior to the date of collection of the semen, in the case of collection of fresh semen;

(d) meet the requirements laid down in Articles 4, 5 and 6 of Directive 91/68/EEC;

(e) if kept on holdings referred to in the first indent of Article 11(2), had undergone with negative results during the 30 days prior to the date of collection of the semen:

(i) a serological test for brucellosis (*B. melitensis*) carried out in accordance with Annex C to Directive 91/68/EEC;

(ii) a serological test for contagious epididymitis (*B. ovis*) carried out in accordance with Annex D to Directive 91/68/EEC, or any other test with an equivalent documented sensitivity and specificity;

(iii) a test for the Border disease virus;

(f) shall not be used for natural breeding during at least 30 days prior to the date of first semen collection and between the date of the first sample referred to in points 1.5 and 1.6 or in point (e) and until the end of the collection period.

9. Semen collected from male ovine and caprine donor animals at a semen collection centre or holding referred to in first indent of Article 11(2) subject to a prohibition on animal health grounds in accordance with Article 4 of Directive 91/68/EEC shall be kept in separate storage and shall not be subject for trade until the health status of the semen collection centre or the holding has been restored by the official veterinarian in accordance with Directive 91/68/EEC and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex B(I) to Directive 91/68/EEC.

CHAPTER III

Requirements applicable to semen, ova and embryos

I. *Conditions for the collection, processing, preservation, storage and transport of semen*

1.1. Where, without prejudice to Directive 2001/82/EC of the European Parliament and of the Council[(3)], antibiotics or a mixture of antibiotics are added with a bactericidal activity at least equivalent to that of the following mixtures in each ml of semen: gentamicin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg); penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg); or amikacin (75 µg), divekacin (25 µg), the names of the antibiotics added and their concentration shall be stated in the health certificate referred to in the fourth indent of Article 11(2).

1.2. All instruments used for the collection, processing, preservation or freezing of semen shall be either disinfected or sterilised as appropriate before use, except for single-use instruments.

1.3. Frozen semen shall:

(a) be placed and stored in storage containers:

(i) which have been cleansed and disinfected or sterilised before use, or are single-use containers;

(ii) with a cryogenic agent; which shall not be previously used for other products of animal origin;

(b) prior to dispatch or use, be stored in approved conditions for a minimum period of 30 days from the date of collection.

1.4. Semen to be subject for trade shall:

(a) be transported to the Member State of destination in transport containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved semen collection or storage centres;

(b) be marked in such a way that the number on the straws or other packages coincides with the number on the health certificate referred to in the fourth indent of Article 11(2) and with the container in which they are stored and transported.

II. *Conditions for ova and embryos*

1. Collection and processing of *in vivo* derived embryos

In vivo derived embryos shall be conceived as a result of artificial insemination with semen meeting the requirements of this Directive and shall be collected, processed and preserved in accordance with the following:

1.1. Embryos shall be collected and processed by an approved embryo collection team, without coming into contact with any other batch of embryos not complying with the requirements of this Directive.

1.2. Embryos shall be collected in a place, which is separated from other parts of the premises or holding where the embryo is collected and which shall be in good repair and constructed with materials which permit its effective and easy cleansing and disinfection.

1.3. Embryos shall be processed (examined, washed, treated and placed in identified and sterile straws, ampoules or other packages) in either a permanently sited laboratory or a mobile laboratory, which, as regards susceptible species, is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius.

1.4. All equipment used to collect, handle, wash, freeze and store embryos shall either be sterilised or properly cleansed and disinfected prior to use according to the IETS Manual[(4)], or be single-use equipment.

1.5. Any biological product of animal origin used in the media and solutions for collection, processing, washing or storage of embryos shall be free of pathogenic micro-

organisms. Media and solutions used in the collection, freezing and storage of embryos shall be sterilised by approved methods according to the IETS Manual and handled in such a manner as to ensure that sterility is maintained. Antibiotics might be added, when appropriate, to collection, processing, washing and storage media according to the IETS Manual.

1.6. The cryogenic agents used for preservation or storage of embryos shall not be previously used for other products of animal origin.

1.7. Each embryo straw, ampoule or other package shall be clearly identified by labels according to the standardised system according to the IETS Manual.

1.8. **[**[F4]The embryos shall be washed and have an intact *zona pellucida*, or the embryonic capsule in case of equine embryos, before and immediately after washing. In accordance with the IETS Manual, the standard washing procedure shall be modified to include additional washes with the enzyme trypsin where recommended for the inactivation or removal of certain pathogens.**]**

1.9. Embryos from different donor animals shall not be washed together.

1.10. **[**[F4]The *zona pellucida* of each embryo, or the embryonic capsule in case of equine embryos, shall be examined over its entire surface area at not less than 50 × magnification and certified to be intact and free of adherent material.**]**

1.11. Embryos of a batch that has successfully undergone the examination set out in point 1.10 shall be placed in a sterile straw, ampoule or other package marked in accordance with point 1.7 which shall be sealed immediately.

1.12. Each embryo shall, where appropriate, be frozen as soon as possible and stored in a place which is under the control of the team veterinarian.

1.13. Each embryo collection team shall submit for official examination for bacterial and viral contamination routine samples of non-viable embryos or ova, flushing fluids or washing fluids resulting from its activities according to the IETS Manual.

1.14. Each embryo collection team shall keep a record of its activities in respect of embryo collection for a period of two years after the embryos have been the subject of trade or import, including:

(a) the breed, age and individual identification of the donor animals concerned;

(b) the place of collection, processing and storage of embryos collected by the team;

(c) the identification of the embryos together with details of the consignee of the shipment.

2. Collection and processing of ova, ovaries and other tissues, with the aim of producing *in vitro* derived embryos

The conditions set out in points 1.1 to 1.14 shall apply *mutatis mutandis* to the collection and processing of ova, ovaries and other tissues for use in *in vitro* fertilisation and/or *in vitro* culture. In addition, the following shall apply:

2.1. The competent authority shall have knowledge of, and authority over, the holding(s) of origin of the donor animals.

2.2. When ovaries and other tissues are collected at a slaughterhouse, either from individual animals or from batches of donors (batch collection), the slaughterhouse shall be officially approved in accordance with Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[(5)] and under the supervision of a veterinarian whose responsibility it is to ensure that *ante-mortem* and *post-mortem* inspections of potential donor animals are carried out and to certify them to be free of signs of the relevant contagious diseases transmissible to animals. The slaughterhouse shall, as regards susceptible species, be situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius.

2.3. Batches of ovaries shall not be brought into the processing laboratory until *post-mortem* inspection of donor animals is completed.

2.4. Equipment for removal and transport of ovaries and other tissues shall be cleansed and disinfected or sterilised before use and exclusively used for these purposes.

3. Processing of *in vitro* derived embryos

The conditions laid down in points 1.1 to 1.14 shall apply *mutatis mutandis* to the processing of *in vitro* derived embryos. In addition, the following shall apply:

3.1. *In vitro* derived embryos shall be conceived as a result of *in vitro* fertilisation with semen meeting the requirements of this Directive.

3.2. After the *in vitro* culture period is completed but prior to freezing, storage and transport of the embryos, they shall be washed and undergo the treatments referred to in points 1.8, 1.10 and 1.11.

3.3. Embryos from different donor animals, in the case of individual animal recovery, or from different batch collections shall not be washed together.

3.4. Embryos from different donor animals, in the case of individual animal recovery, or from different batch collections shall not be stored in the same straw, ampoule or other package.

4. Processing of micromanipulated embryos

Prior to any micromanipulation which compromises the integrity of the *zona pellucida*, all embryos or ova shall be collected and processed according to the sanitary conditions set out in points 1, 2 and 3. In addition, the following conditions shall apply:

4.1. Where micromanipulation of the embryo which involves penetration of the *zona pellucida* is carried out, this shall be done in suitable laboratory facilities under supervision of an approved team veterinarian.

4.2. Each embryo collection team shall keep records of its activities according to point 1.14, including details of micromanipulation techniques which involve penetration of the *zona pellucida* and which have been performed on the embryos. In the case of embryos derived by *in vitro* fertilisation, the identification of the embryos may be done on the basis of a batch, but shall contain details of the date and place of collection of ovaries and/or ova. It shall also be possible to identify the holding of origin of the donor animals.

5. Storage of embryos

5.1. Each embryo collection and production teams shall ensure that the embryos are stored at suitable temperatures in storage premises referred to in point 1.8 of Section III of Chapter I.

5.2. Frozen embryos shall, prior to dispatch, be stored in approved conditions for a minimum period of 30 days from the date of their collection or production.

6. Transport of embryos

6.1. Embryos to be subject for trade shall be transported to the Member State of destination in containers which have been cleansed and disinfected or sterilised before use, or are single-use containers, and which have been sealed and numbered prior to dispatch from the approved storage premises.

6.2. The straws, ampoules or other packages shall be marked in such a way that the number on the straws, ampoules or other packages coincides with the number on the health certificate referred to in the third indent of Article 11(3) and with the container in which they are stored and transported.

CHAPTER IV

Requirements applicable to donor females

1. Donor females shall only be used for the collection of embryos or ova if they and the holdings from which they originate meet, to the satisfaction of the official veterinarian, the requirements of the relevant Directives on intra-Union trade in live animals for breeding and production for the species concerned.

2. In addition to the requirements laid down in Directive 64/432/EEC, donor females of porcine species shall, except *in vivo* derived embryos subject to a trypsin treatment, comply with the requirements for Aujeszky's disease laid down in accordance with Article 9 or 10 of that Directive.

3. The provisions of Directive 91/68/EEC shall apply to donor females of ovine and caprine species.

[[F4]4. In addition to the requirements laid down in Directive 90/426/EEC, donor mares shall:

4.1. not be used for natural breeding during at least 30 days prior to the date of collection of ova or embryos and between the date of the first sample referred to in points 4.2 and 4.3 and the date of the collection of ova and embryos;

4.2. be subjected with negative result to an agar-gel immuno-diffusion test (Coggins test) or an ELISA for equine infectious anaemia carried out on a blood sample taken not less than 14 days following the date of the commencement of the period of at least 30 days referred to in point 4.1 and not more than 90 days prior to the collection of ova or embryos for trade;

4.3. be subjected to an agent identification test for contagious equine metritis, carried out with negative result in each case in a laboratory referred to in point 1.5 of Chapter (II)(I) on at least two specimens (swabs) taken from the donor mare in no case earlier than seven days (systemic treatment) or 21 days (local treatment) after possible antimicrobial treatment of the donor mare, from at least the following sites:

— the mucosal surfaces of the clitoral fossa,

— the clitoral sinuses.

The specimens shall be taken during the period referred to in point 4.1 on two occasions with an interval of not less than seven days in the case of the test referred to in point (i), or on one occasion in the case of the test referred to in point (ii).

The specimens shall be placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.

The specimens shall be subjected to at least one of the following tests:

(i) culture under microaerophilic conditions for at least seven days for the isolation of *Taylorella equigenitalis*, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport; or

(ii) polymerase chain reaction (PCR) or real-time PCR for the detection of genome of *Taylorella equigenitalis*, carried out within 48 hours after taking the specimens from the donor animal.**]]**

[[F5]ANNEX E

Textual Amendments

F5 Substituted by Commission Decision of 26 April 2007 amending Annex E to Council Directive 92/65/EEC to include additional health measures for the trade in live bees, and to update the health certificates models (notified under document number C(2007) 1811) (Text with EEA relevance) (2007/265/EC).

[F6Part 1 – Health Certificate for trade in animals from holdings (ungulates, birds vaccinated against avian influenza, lagomorphs, dogs, cats and ferrets) 92/65 EI]

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. No(s) of related original certificates	No(s) of accompanying documents
		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 Holding ☐ Name Approval/registration number Address Postal code		I.13. Place of destination Holding ☐ Establishment ☐ Approved body ☐ Name Approval number Address Postal code	
I.14. Place of loading Postal code		I.15. Date and time of departure	
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification		I.17. Transporter Name Approval number Address Postal code	
I.18. Description of commodity			I.19. Commodity code (CN code) I.20. Quantity

I.21.	I.22. Number of packages
I.23. Seal/Container No	I.24.

I.25. Commodities certified for:

Breeding ☐ Production ☐ Artificial reproduction ☐ Slaughter ☐ Pets ☐ Approved body ☐

I.26. Transit through third country ☐	I.27. Transit through Member States ☐
Third country ISO code	Member State ISO code
Exit point Code	Member State ISO code
Entry point BIP No	Member State ISO code
I.28. Export ☐	I.29. Estimated journey time
Third country ISO code	
Exit point Code	

I.30. Route plan

Yes ☐ No ☐

I.31. Identification of the commodities

Species (Scientific name)	Identification system	Identification number	Passport number	Sex	Age	Quantity

EUROPEAN UNION **92/65 EI** **Animals from holdings (ungulates, birds (2), lagomorphs, dogs, cats and ferrets)**

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

Part II: Certification

I, the undersigned official veterinarian (1)/veterinarian responsible for the holding of origin and approved by the competent authority (1) certify that:

II.1. the animals described in Box I.31 comply with the conditions of Article 4 of Council Directive 92/65/EEC and at the time of inspection were fit to be transported for the intended journey in accordance with the provisions of Council Regulation (EC) No 1/2005.

(1) *either* [II.2. the ruminant(s) (1)/*suidae* (1) other than that/those covered by Council Directive 64/432/EEC (1) or Council Directive 91/68/EEC (1)

(a) belong(s) to the species .....;

(b) at the time of examination, do(does) not show any clinical sign of any disease to which it/they is/are susceptible;

(c) come(s) from an officially tuberculosis-free (1)/officially brucellosis-free (1) or brucellosis-free (1) herd (1)/holding (1) not subject to swine fever restrictions or from a holding where it/they was/were subjected with negative results to the tests laid down in Article 6(2)(b) (1)/the test laid down in Article 6(3)(d) (1) of Council Directive 92/65/EEC.]

(1) (2) *or* [II.2. the birds other than those referred to in Council Directive 2009/158/EC

(a) at the time of examination do not show any clinical sign of any disease to which they are susceptible;

(b) satisfy the requirements of Article 7 of Council Directive 92/65/EEC;

(c) conform to Commission Decision 2007/598/EC and were vaccinated against avian influenza on ..... (*date*) with vaccine ..... (*name*) and come from a holding on which vaccination against avian influenza was carried out during the past 12 months.]

(1) *or* [II.2. the lagomorphs

(a) at the time of examination do not show any clinical signs of disease to which they are susceptible;

(b) satisfy the requirements of Article 9 of Council Directive 92/65/EEC.]

(1) *or* [II.2. the dogs

(a) at the time of examination by a veterinarian authorised by the competent authority within 48 hours prior to the time of dispatch, showed no signs of diseases;

(b) are marked in accordance with Article 17(1) of Regulation (EU) No 576/2013 of the European Parliament and of the Council;

(1) *either* [(c) were at least 12 weeks old at the time of vaccination against rabies and at least 21 days have elapsed since the completion of the primary anti-rabies vaccination carried out in accordance with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council, and any subsequent revaccination was carried out within the period of validity of the preceding vaccination];

(1) *or* [(c) are less than 12 weeks old and have not received an anti-rabies vaccination, or are between 12 and 16 weeks old and have received an anti-rabies vaccination, but 21 days at least have not elapsed since the completion of the primary vaccination against rabies carried out in accordance with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council, and

(i) the Member State of destination has informed the public in accordance with point (b) of Article 37(2) of Regulation (EU) No 576/2013 of the European Parliament and of the Council that it authorises the movement of such animals into its territory; and they are accompanied by

EUROPEAN UNION **92/65 EI** **Animals from holdings (ungulates, birds (2), lagomorphs, dogs, cats and ferrets)**

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

(1) *either* [(ii) a declaration of the owner (3), attached to this certificate, stating that from birth until the time of dispatch the animals have had no contact with wild animals of species susceptible to rabies];

(1) *or* [(ii) their mother, on whom they still depend, and from the passport of their mother, it can be established that the mother received before their birth an anti-rabies vaccination which complied with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council];

(d) are accompanied by a passport drawn up in accordance with Commission Implementing Regulation (EU) No 577/2013;

(1) *and* [(e) due to their scheduled destination (4) indicated in Box I.10, or in Box I.11 where regionalisation is applied, have been treated against *Echinococcus multilocularis* in accordance with Commission Delegated Regulation (EU) 2018/772]];

(1) *or* [II.2. the cats (1)/ferrets (1)

(a) at the time of examination by a veterinarian authorised by the competent authority within 48 hours prior to the time of dispatch, showed no signs of diseases;

(b) are marked in accordance with Article 17(1) of Regulation (EU) No 576/2013 of the European Parliament and of the Council;

(1) *either* [(c) were at least 12 weeks old at the time of vaccination against rabies and at least 21 days have elapsed since the completion of the primary anti-rabies vaccination carried out in accordance with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council, and any subsequent revaccination was carried out within the period of validity of the preceding vaccination];

(1) *or* [(c) are less than 12 weeks old and have not received an anti-rabies vaccination, or are between 12 and 16 weeks old and have received an anti-rabies vaccination, but 21 days at least have not elapsed since the completion of the primary vaccination against rabies carried out in accordance with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council, and

(i) the Member State of destination has informed the public in accordance with point (b) of Article 37(2) of Regulation (EU) No 576/2013 of the European Parliament and of the Council that it authorises the movement of such animals into its territory; and they are accompanied by

(1) *either* [(ii) a declaration of the owner (3), attached to this certificate, stating that from birth until the time of dispatch the animals have had no contact with wild animals of species susceptible to rabies];

(1) *or* [(ii) their mother, on whom they still depend, and from the passport of their mother, it can be established that the mother received before their birth an anti-rabies vaccination which complied with the validity requirements set out in Annex III to Regulation (EU) No 576/2013 of the European Parliament and of the Council];

(d) are accompanied by a passport drawn up in accordance with Commission Implementing Regulation (EU) No 577/2013.]

(1) *or* [II.2. the dogs (1)/cats (1)/ferrets (1) are destined for a body, institute or centre described in Box I.13 and approved in accordance with Annex C to Council Directive 92/65/EEC, and

(a) at the time of examination by a veterinarian authorised by the competent authority within 48 hours prior to the time of dispatch, showed no signs of diseases;

(b) are marked in accordance with Article 17(1) of Regulation (EU) No 576/2013 of the European Parliament and of the Council;

EUROPEAN UNION **92/65 EI** **Animals from holdings (ungulates, birds (2), lagomorphs, dogs, cats and ferrets)**

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

(c) are accompanied by a passport drawn up in accordance with Commission Implementing Regulation (EU) No 577/2013.]

II.3. The additional guarantees regarding diseases listed in Annex B (5) to Council Directive 92/65/EEC are as follows (1):

Disease	Decision
Disease	Decision
Disease	Decision

Notes

Part I:

Box I.6: No(s) of accompanying documents: CITES, if applicable.

Box I.19: Use the appropriate CN code: 01.06.19, 01.06.31, 01.06.32, 01.06.39.

Box I.31: *Identification system*: individual identification must be used wherever possible but in the case of small animals, batch identification may be used. In the case of dogs, cats and ferrets, select passport.

Identification number: in the case of dogs, cats and ferrets, indicate the alphanumeric code of the tattoo or transponder.

Passport number: in the case of dogs, cats and ferrets, indicate the unique alphanumeric code of the passport.

Part II:

(1) Delete as necessary.

(2) Certification requirements only apply to birds that have been vaccinated against avian influenza under a preventive vaccination plan approved by Commission Decision 2007/598/EC.

(3) The declaration referred to in point II.2 to be attached to the certificate shall be drawn up in accordance with Annex I to Commission Implementing Regulation (EU) No 577/2013.

(4) Member States or parts thereof listed in the Annex to Commission Implementing Regulation (EU) 2018/878.

(5) As requested by a Member State benefiting from additional guarantees under Union legislation.

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

This certificate is valid for 10 days from the date of signature of the official veterinarian or of the veterinarian responsible for the holding of origin and approved by the competent authority.

Official veterinarian

Name (in capital letters):	Qualification and title:
Local veterinary unit:	LVU No:
Date:	Signature:
Stamp:	

Textual Amendments

F6 Substituted by Commission Implementing Decision (EU) 2019/1206 of 12 July 2019 amending Part 1 of Annex E to Council Directive 92/65/EEC as regards the animal health certificate for trade in dogs, cats and ferrets (notified under document C(2019) 5210) (Text with EEA relevance).

[[F7]Part 2 —

Health certificate for trade in bees and bumble bees

92/65 EII**]**

EUROPEAN UNION **Intra trade certificate**

Part I: Details ▶[5] of consignment ◀ presented

I.1. Consignor
Name
Address
Postal code

I.2. Certificate reference number | I.2.a. Local reference number:

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.

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

I.12. Place of origin/Place of harvest
Holding ☐ Other ☐
Name Approval number
Address
Postal code

I.13. Place of origin/Place of harvest
Holding ☐ Other ☐
Name Approval number
Address
Postal code

I.14. Place of loading
Postal code

I.15. Date and time of departure

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

I.17.

I.18. Animal species/product

I.19. Commodity code (CN code)
01.06.90

I.20. Number/quantity

I.21.

I.22. Number of packages

I.23. Identification of container/seal number

I.24.

I.25. Animals certified as/products certified for:
Breeding ☐ Transhumance ☐ ▶[6] Production (pollination) ☐ ◀

I.26. Transit through third country ☐
Third country ISO code
Exit point Code
Entry point BIP unit 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 animals

Species (Scientific name)	Quantity	Batch number	▶[6] Nature of commodity queens, packages of bees, nucleus colonies, colonies ◀

COUNTRY **92/65 EII Bees** *(Apis mellifera)* and bumble bees (*Bombus* spp.)

Part II: Certification

II. **Health information**	II.a. Certificate reference number	II.b.

I, the undersigned certify that:

II.1

either (2) [(a) the bees/bumble bees (2) come from an area which is not subject of the prohibition order associated with an occurrence of American foulbrood (the period of prohibition has been continued for at least 30 days following the last recorded case and the date of which all hives within a radius of three kilometres have been checked by the competent authority and all infected hives burned or treated and inspected to the satisfaction of the said competent authority);]

or (2) [(a) the bumble bees come from an environmentally isolated structure recognised by and under the supervision of the competent authority of the Member State which is free of American foulbrood and was inspected immediately prior to dispatch and all bumble bees and breeding stock show no clinical signs or suspicion of the disease;]

and (b) the bees/bumble bees (2) come from an area of at least 100 km radius which is not the subject of any restrictions associated with the suspicion or confirmed occurrence of the small hive beetle (*Aethina tumida*) or the Tropilaelaps mite (*Tropilaelaps* spp.), and where these infestations are absent;

▶(1) *or*

(b) the consignment consists only of cages of queen bees each containing one single queen with a maximum of 20 accompanying attendants and comes from an area of at least 100 km radius which is not the subject of any restrictions associated with the suspicion or confirmed occurrence of the Tropilaelaps mite (*Tropilaelaps* spp.) and from an establishment that fulfils all the following requirements:

— it is situated at least 30 km distance from the limits of a protection zone of at least 20 km in radius around confirmed occurrence(s) of the small hive beetle, and

— it is situated outside of a zone restricted by protective measures established by the Union due to the occurrence of small hive beetle, and

— it is situated in an area where annual surveillance for the detection of small hive beetle by the competent authority is ongoing to provide a confidence level of at least 95 % of detecting small hive beetle if at least 2 % of the apiaries were infested, and

— it is inspected every month by the competent authority with negative results to provide a confidence level of at least 95 % of detecting small hive beetle if at least 2 % of the hives were infested, and

— where each cage or the whole consignment is covered by a fine mesh of maximum 2 mm pore size immediately after the visual examination for the health certification;

or

(b) the bumble bees come from an environmentally isolated structure recognised by and under the supervision of the competent authority, which is free of small hive beetle; ◀

and (c) the bees/bumble bees (2) as well as their packaging have undergone a visual examination to detect the occurrence of the small hive beetle (*Aethina tumida*) or their eggs and larvae, or other infestations, in particular the Tropilaelaps mite (*Tropilaelaps spp.*), affecting bees.

II.2 the additional guarantees regarding diseases listed in Annex B (1) to Directive 92/65/EEC are as follows (2):

Disease	Decision
Disease	Decision
Disease	Decision

Notes

Part I:

— Box reference I.31: Species: introduce *Apis mellifera* or *Bombus* spp.
Quantity: provide the number of colonies.
Batch number: provide the number of seals where applicable.

Part II:

(1) As requested by a Member State benefiting from additional guarantees under Union legislation.
(2) Delete as necessary.

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

Approved veterinarian or approved official

Name (in capital letters): Qualification and title:

Date: Signature:

Stamp:

Textual Amendments

F7 Substituted by Commission Decision of 6 May 2010 amending Parts 1 and 2 of Annex E to Council Directive 92/65/EEC as regards the model health certificates for animals from holdings and for bees and bumble bees (notified under document C(2010) 2624) (Text with EEA relevance) (2010/270/EU).

[F8Part 3 —

Health certificate for trade in animals, semen, ova and embryos from approved bodies, institutes or centres 92/65 EIII]]

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. No(s) of related original certificates	No(s) of accompanying documents
		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 Approved body ☐ Name Approval number Address Postal code		I.13. Place of destination Approved body ☐ Name Approval number Address Postal code	
I.14. Place of loading Postal code		I.15. Date and time of departure	
I.16. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification		I.17. Transporter Name Approval number Address Postal code	
I.18. Description of commodity		I.19. Commodity code (CN code)	
		I.20. Quantity	
I.21.		I.22. Number of packages	
I.23. Seal/Container No		I.24.	
I.25. Commodities certified for: Approved body ☐			
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. Estimated journey time	
I.30. Route plan Yes ☐ No ☐			
I.31. Identification of the commodities Species (scientific name) Identification system Identification number Sex Age Quantity			

EUROPEAN UNION **92/65 EIII Animals from approved bodies, institutes or centres**

Part II: Certification

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

I, the undersigned official veterinarian (1)/veterinarian responsible for the establishment of origin and approved by the competent authority (1) certify that:

II.1. The body, institute or centre of origin is approved in accordance with Annex C to Council Directive 92/65/EEC for the purpose of trade in the animals, semen, ova or embryos described in Box I.18.

II.2. The animals (1)/donor animals (1) described in this certificate have been examined today (1)/on the day of collection (1) and found to be healthy and free of clinical signs of infectious diseases including those listed in Annex A to Directive 92/65/EEC and are not subject to any official restrictions and remained in this body, institute or centre either since birth or for the following time ..... *(months or years)*.

II.3. At the time of inspection, the above animals were fit to be transported on the intended journey in accordance with the provisions of Council Regulation (EC) No 1/2005 and IATA requirements and/or CITES guidelines for transport, where applicable.

II.4. The additional guarantees regarding diseases listed in Annex B (2) to Council Directive 92/65/EEC are as follows: (1)

Disease	Decision
Disease	Decision
Disease	Decision

[II.5. Birds conforming to Decision 2007/598/EC were vaccinated against avian influenza on ..... (date) with vaccine ..... (name) and come from an approved body, institute or centre of origin on which vaccination against avian influenza was carried out during the past 12 months.] (1)

Notes

Part I:

— Box reference I.6: No(s) of accompanying documents: CITES, if applicable.

— Box reference I.19: Use the appropriate HS code: 01.06.11, 01.06.19, 01.06.31, 01.06.32, 01.06.39, 05.11.99.85.

— Box reference I.31: *Identification system*: individual identification must be used wherever possible but in the case of small animals, batch identification may be used.

In the case of semen, ova and embryos it shall correspond to the *donor identity* and the *date of collection* and shall be indicated in the following format: official identification of the animal/dd/mm/yyyy.

Age and *sex*: to be completed only in the case of live animals, if appropriate.

Quantity: in the case of semen, ova and embryos the number of straws, ampoules or other packaging express as units should be indicated.

Part II:

(1) Delete as necessary.
(2) As requested by a Member State benefiting from additional guarantees under Union legislation.
— 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:	

Textual Amendments

F8 Substituted by Commission Implementing Decision of 17 February 2012 amending Annex E to Council Directive 92/65/EEC as regards the model health certificates for animals from holdings and animals,

semen, ova and embryos from approved bodies, institutes or centres (notified under document C(2012) 860) (Text with EEA relevance) (2012/112/EU).

[F9[X1ANNEX F

Editorial Information

X1 Substituted by Corrigendum to Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC (Official Journal of the European Union L 139 of 30 April 2004).

Textual Amendments

F9 Inserted by Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC (Text with EEA relevance).

Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine

Council Directive 88/407/EEC of 14 June 1988 laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species

Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species

Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of Equidae

Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species

Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs

Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products

Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals

Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC.**]]**

(1) **[**[F3]OJ L 224, 18.8.1990, p. 62.**]**

(2) **[**[F3]**[**[F4]Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).**]]**

(3) **[**[F3]OJ L 311, 28.11.2001, p. 1.**]**

(4) **[**[F3]Manual of the International Embryo Transfer Society — A procedural guide and general information for the use of embryo transfer technology emphasising sanitary procedures, published by the International Embryo Transfer Society, 1111 North Dunlap Avenue, Savoy, Illinois 61874 USA (http://www.iets.org/).**]**

(5) **[**[F3]OJ L 139, 30.4.2004, p. 206.**]**

Textual Amendments

F3 Substituted by Commission Regulation (EU) No 176/2010 of 2 March 2010 amending Annex D to Council Directive 92/65/EEC as regards semen collection and storage centres, embryo collection and production teams, and conditions for donor animals of the equine, ovine and caprine species and for handling semen, ova and embryos of those species (Text with EEA relevance).

F4 Substituted by Commission Implementing Regulation (EU) No 846/2014 of 4 August 2014 amending Annex D to Council Directive 92/65/EEC as regards the conditions for donor animals of the equine species (Text with EEA relevance).